Telix Pharmaceuticals Limited
ACN 616 620 369
55 Flemington Road
North Melbourne,
Victoria, 3051
Australia

ASX ANNOUNCEMENT

Results Announcement for the Year Ended 31 December 2025

Melbourne (Australia) and Indianapolis, IN (U.S.A.) — 20 February 2026. Telix Pharmaceuticals Limited (ASX: TLX, Nasdaq: TLX, Telix, the Company) announces its financial results for the year ended 31 December 2025.

As approved by the Board of Telix, and in accordance with ASX Listing Rule 4.3A, please find attached the following for immediate release to the market:

- Appendix 4E; and
- Annual Report.

Annual General Meeting

Telix's Annual General Meeting (AGM) will be held on Thursday, 21 May 2026 at 10am (Melbourne time). Full details of the agenda and instructions to participate in the AGM will be provided to shareholders when the Notice of Meeting is released.

In accordance with Telix's Constitution, the closing date for Director candidate nominations is Thursday, 9 April 2026, being at least 30 business days before the AGM.

Authorized for lodgement by:

Genevieve Ryan
Company Secretary

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55 Flemington Road
North Melbourne,
Victoria, 3051
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Appendix 4E

Financial year ended

31 December 2025

Results announcement to the market

Current Reporting Period:	**year ended 31 December 2025**
Previous Reporting Period:	year ended 31 December 2024

This page and the following pages comprise the year end information given to the ASX under Listing Rule 4.3A.

The results are prepared in accordance with International Financial Reporting Standards (IFRS), and also comply with Australian Accounting Standards. Amounts are presented in US dollars (US$).

Revenue and net profit/(loss)

	2025 Result	Change	Change	Change	2024 Result
	US$'000		US$'000	%	US$'000
Revenue from contracts with customers	803,794	Up	287,243	56	516,551
(Loss)/profit after income tax for the year attributable to members	(7,125)	Down	(40,810)	(121)	33,685
Total comprehensive (loss)/income for the year attributable to members	(14,124)	Down	(50,090)	(139)	35,966

Dividends

No dividend was proposed or paid. Should any dividends be paid in the future, no assurances can be given as to the level of franking credits attaching to such dividends.

	2025	2024
	Cents	Cents
(Loss)/profit per share	(2.11)	10.17
Net tangible assets per share	(100.00)	16.00
Dividend per share	-	-

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Brief explanation of results

Telix recorded an operating profit for the year of $29,776,000 (2024: profit of $55,177,000), primarily driven by continued strong growth in U.S. sales of Illuccix and the launch of Gozellix. The Company generated total revenue of $803,794,000 (2024: $516,551,000). Operating expenditure in the year totalled $408,397,000 (2024: $285,871,000). Included within operating expenditure was $171,249,000[1] (2024: $127,930,000) related to R&D activities for the Company's assets and development programs. Income tax expense for the year was $1,859,000 (2024: $4,230,000).

For further commentary on the Company's results and other information required by Listing Rule 4.3A, please refer to the Company's investor releases and Annual Report, including the Operating and financial review and Financial report lodged with the ASX today.

This Appendix 4E should be read in conjunction with the Annual Report, including on Form 20-F, which includes:

- Item 18 Financial statements; and

- Other sections, comprising the Directors' report, as tabled below.

Australian Disclosure Requirements	Form 20-F Reference
Principal activities	Item 4.B Business Overview See subheading "Principal Activities of the Company in the year under review"
Review of operations and activities	Item 4.B Business Overview Item 5.A Operating Results
Business strategies and prospects for future years	Item 4.B Business Overview Item 5.A Operating Results
Business risks	Item 3.D Risk Factors
Significant changes in the state of affairs	Item 5.E Critical Accounting Estimates See subheading - "State of Affairs"
Events subsequent to the end of the financial year	Item 5.E Critical Accounting Estimates See subheading - "Events subsequent to the end of the financial year"
Review of operations, likely developments and expected results; Business strategies and prospects for future years	Item 4.B Business Overview See subheadings - "Review of operations, likely developments and expected results; Business Strategies and prospects for future years"
Environmental regulation and compliance	Item 4.B Business Overview See subheadings - "Environmental regulation and compliance; Sustainability report"
Dividends	Item 8.A Consolidated Statements and Other Financial Information See subheading - "Dividends"
Information on directors	Item 6.A Directors and Senior Management See subheading - "Directors and Key Management Personnel" Item 6.C Board Practices See subheadings - "Meetings and attendance" "Directors' interests in the securities of Telix"; and "Shares issued for acquisitions, on exercise of rights or options and lapse of options"
Remuneration report	The Remuneration report starts at Item 6 and ends part way through Item 6.B as indicated
Indemnification of officers	Item 6.C Board Practices See subheading - "Indemnification of officers"
Indemnification of auditors	Item 6.C Board Practices See subheading - "Indemnification of auditors"

[1] Includes $14.1 million of inventory for TLX250-Px (Zircaix®) commercial launch expensed to R&D. This expense arises from commercial inventory produced in anticipation of Zircaix approval and will be reversed upon FDA approval if received.

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Australian Disclosure Requirements	Form 20-F Reference
Rounding	Item 6.C Board Practices See subheading - "Rounding"
Corporate governance	Item 6.C Board Practices See subheading - "Corporate governance"
Non-audit Services	Item 6.C Board Practices See subheading "Auditor independence and non-audit services"
Auditor's independence declaration	Exhibit 99.2
Directors' Resolution	Item 6.B Compensation See subheading - "Directors' resolution"

Audit report

This Appendix 4E is based on the audited Financial report for the year ended 31 December 2025, contained in the attached Annual Report.

The Appendix 4E and Annual Report have been approved for release by the Board of Directors.

Genevieve Ryan
Company Secretary

20 February 2026

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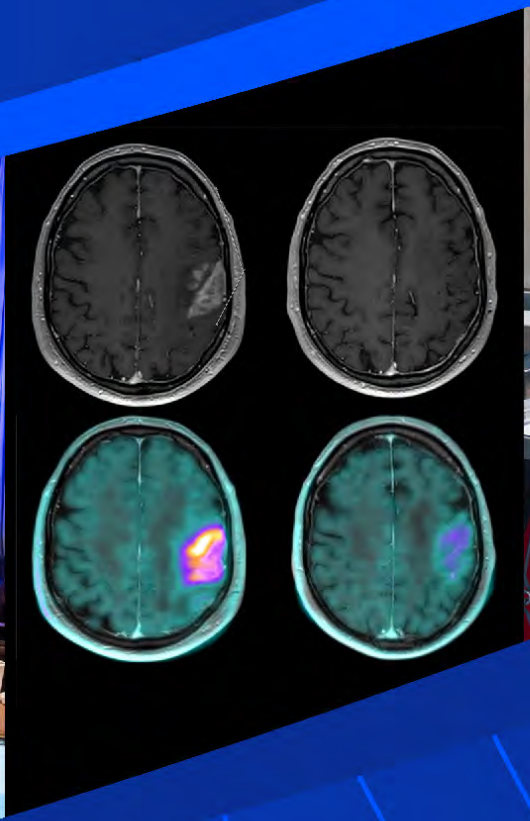
Telix



2025

Telix Pharmaceuticals
Annual Report

Legal notice. This report is intended for global use.

This 2025 Annual Report is a summary of Telix Pharmaceuticals Limited (Telix) operations and activities for the year ended December 31, 2025 and its financial position as at December 31, 2025.

This report covers Telix's global operations, including subsidiaries, unless otherwise noted. A reference to Telix, Telix Group, we, us and our and similar expressions refer collectively to Telix Pharmaceuticals Limited and its related bodies corporate. The information contained in this report is not intended to be an offer for subscription, invitation or recommendation with respect to securities of Telix in any jurisdiction, including the United States (U.S.). The information and opinions contained in this report are subject to change without notification. To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to update or revise any information or opinions contained in this report, including any forward- looking statements (as referred to below), whether as a result of new information, future developments, a change in expectations or assumptions, or otherwise. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained or opinions expressed in the course of this report.

Telix products are currently investigational use only unless indicated and are subject to future regulatory developments and product approvals. Illuccix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved in multiple markets globally. Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection) has been approved by the U.S. FDA. Telix's osteomyelitis (bone infection) imaging agent, technetium-99m (^{99m}Tc) besilesomab, marketed under the brand name Scintimun®, is approved in 32 European countries and Mexico. Telix's miniaturized surgical gamma probe, SENSEI®, for minimally invasive and robotic-assisted surgery, is registered with the FDA for use in the U.S. and has attained a Conformité Européenne (CE) Mark for use in the European Economic Area. No other Telix product has received a marketing authorization in any jurisdiction. Any other Telix drug or device that is discussed in this report, including Zircaix and Pixclara, is investigational or under development and not approved by any regulatory authority. The efficacy or safety profile of any unapproved drug or device has not been determined by any regulatory authority. In addition, Zircaix and Pixclara brand names and launch are subject to final regulatory approval. Registrations vary from country to country. Some statements about products, registered product indications or procedures may differ in certain countries. Therefore, always consult the country specific product information, package leaflets or instructions for use. Any content relating to third party products is based on publicly available data and is accurate at the date of publication.

Forward-looking statements

This report contains forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as "may", "expect", "intend", "plan", "estimate", "anticipate", "believe", "outlook", "forecast" and "guidance", or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on Telix's good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect Telix's business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix's business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress and results of Telix's preclinical and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix's product candidates, including the planned NDA resubmission for TLX101-Px and the planned BLA resubmission for TLX250-Px, manufacturing activities and product marketing activities; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialization of Telix's product candidates, if or when they have been approved; Telix's ability to obtain an adequate supply of raw materials at reasonable costs for its products and product candidates; estimates of Telix's expenses, future revenues and capital requirements; Telix's financial performance; developments relating to Telix's competitors and industry; the anticipated impact of U.S. and foreign tariffs and other macroeconomic conditions on Telix's business; and the pricing and reimbursement of Telix's product candidates, if and after they have been approved. Telix's actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements.

This report also contains estimates and other statistical data made by independent parties and by Telix relating to market size and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of Telix's future performance and the future performance of the markets in which it operates are necessarily subject to a high degree of uncertainty and risk.

Readers should read this report together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX) and U.S. Securities and Exchange Commission (SEC) or on our website. Readers are cautioned not to place undue reliance on forward-looking statements. Except as required by applicable laws or regulations, Telix does not undertake to publicly update or review any forward-looking statements. Past performance cannot be relied on as a guide to future performance.

Non-IFRS financial measures

Telix's results are reported under International Financial Reporting Standards (IFRS). This report includes various non-IFRS financial information to reflect its underlying performance, which has not been subject to audit or review. These non-IFRS measures include Adjusted EBITDA, which represents net earnings attributable to the Group excluding finance costs, income tax expense, depreciation and amortization, remeasurement of provisions, other income and expenses. As required by SEC rules, we have provided reconciliations of these non-IFRS financial measures to the most directly comparable IFRS measures, which for Adjusted EBITDA, is Profit/(loss) before income tax. The Group believes that these non-IFRS measures, which are not considered to be a substitute for or superior to IFRS measures, provide stakeholders with additional useful information on the underlying trends, performance and position of the Group and are consistent with how business performance is measured internally. The non-IFRS measures are not defined by IFRS and therefore may not be directly comparable with other companies' alternative performance measures.

Trademarks and Trade Names

All trademarks and trade names referenced in this report are the property of Telix or, where applicable, the property of their respective owners. For convenience, trademarks and trade names may appear without the ® or ™ symbols. Such omissions are not intended to indicate any waiver of rights by Telix or the respective owners. Trademark registration status may vary from country to country. Telix does not intend the use or display of any third-party trademarks or trade names to imply any affiliation with, endorsement by, or sponsorship from those third parties.

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Front cover images left to right: Telix Advanced Training Summit, New York (NY), December 2025; Case report published in EJNMMI describing a near complete response in glioblastoma following treatment with TLX101-Tx, Credit A. T. Braat, UMC Utrecht - patient representative example, individual results may vary; RLS employee inspecting patient doses.

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Australian disclosure requirements

The Directors' report (including Remuneration report) as required primarily by sections 298-300A and 307C of the Australian Corporations Act 2001 (Cth) is presented on pages 8 to 18 and the Australian disclosure requirements in the following sections within the Form 20-F:

- Item 3.D - Risk factors
- Item 4.B - Business overview
- Item 5 - Operating and financial review and prospects
- Item 6 - Directors and senior management; Compensation; Board practices
- Item 8.A - Consolidated statements and other financial information
- Exhibit 15.2 - Auditor's independence declaration

The Operating and financial review as required by section 299A of the Australian Corporations Act 2001 (Cth) is presented on pages 4 to 18 and the following sections within the Form 20-F:

- Item 3.D - Risk factors
- Item 4.B - Business overview
- Item 5 - Operating and financial review and prospects

Refer to the Appendix 4E lodged with this Annual Report for a detailed cross-reference of the sections within the Form 20-F that correspond to specific Australian disclosure requirements.

Message from the Chair (Interim)

"Telix is now a global radiopharmaceutical company with a specialist commercial organization and fully integrated radiopharma company, assisted by our acquisition of RLS Radiopharmacies."

Dear Shareholders,

I am pleased to share our results and operating review for the year ended December 31, 2025 on behalf of your Board. I will also take this as an opportunity to reflect on what I believe makes Telix such a dynamic and innovative company and the drivers behind its substantial growth and continued performance.

Leading a new frontier of therapeutic innovation

At our core, we exist to create products that seek to improve the quality of life for people living with cancer and rare diseases. Telix is now a global radiopharmaceutical company with a specialist commercial organization and fully integrated radiopharma company, assisted by our acquisition of RLS Radiopharmacies during the year. Our broad pipeline is enabling us to build depth in our focus areas of urologic oncology, neurologic oncology and other cancer types to maximize the full potential of targeted radionuclide therapy across various stages of disease burden.

Commercial performance provides a strong foundation

Telix has clearly demonstrated its ability to commercialize and gain meaningful market share in the competitive prostate cancer imaging market. Importantly this success has provided the foundation to advance and launch future precision medicine and therapeutic products globally and provides the Company with a growing revenue stream.

During the 2025 financial year we secured U.S. Food and Drug Administration ("FDA") approval and reimbursement for Gozellix®, launched new clinical programs, and delivered clinical data across multiple therapeutic programs. There have been several significant challenges, specifically the Complete Response Letters received for TLX250-Px (Zircaix®[1]) and TLX101-Px (Pixclara®[1]). These events should be expected in the complex environment of drug development, and reflect the vanguard nature of the products we are developing. We remain focused on remediation with the expectation that we will ultimately obtain the marketing authorizations for both of these imaging candidates.

Our intention is to continue to reinvest earnings to see our first therapeutic products through to commercialization. Ultimately, we believe that this will deliver a significant impact to patients and pave the way for value creation for shareholders.

Investing in manufacturing infrastructure to support long-term growth

To be clinically and commercially successful, particularly in a field with such complexity and time sensitivity as radiopharmaceuticals, we must have in place the infrastructure and capabilities to evolve manufacturing and deliver doses to patients globally. The strategic investments we have made over the past 24 months across manufacturing, research and development ("R&D") and pipeline expansion support our long-term growth strategy as a vertically integrated radiopharmaceutical company. Our manufacturing and supply chain has continued to mature and today we are executing at scale, delivering more than 2.9 million commercial and clinical doses on an annual basis across the Group.

Our commitment to governance and sustainability

Your Board has continued to focus on upholding good governance and effective risk management. We are pleased to present the Company's first Sustainability report aligned to AASB S2[2] principles and compliant with Australian regulations. This follows the completion of our first Double Materiality Assessment, which identified the key sustainability factors that are material to Telix. We have also transitioned to an integrated Annual Report to meet both Australian and U.S. reporting requirements as a dual Australian Securities Exchange ("ASX") and Nasdaq-listed company.

[1] Brand name subject to final regulatory approval.
[2] Australian Accounting Standards Board, Standard 2: *Climate-related Disclosures* – based on IFRS S2 *Climate-related Disclosures*.

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Board composition

Over the past 12 months, the Board has undergone several changes. Our longstanding and original chairman Kevin McCann AO retired in May 2025 and was succeeded as Chair by Tiffany Olson. In February 2026, Tiffany in turn resigned and was replaced by myself in an orderly fashion. Your Board was also pleased to welcome Marie McDonald in March 2025 as a Non-Executive Director and Chair of our People Committee. We will continue our process of Board renewal with further appointments in due course to appropriately direct Telix's business, including the Company's dual-listed status.

I extend my gratitude to all Telix employees for their dedication to serve our purpose. I would also like to thank my hardworking fellow Directors for their ongoing commitment to Telix's success.

Finally, on behalf of the Board, I thank all of our shareholders for their support of Telix. The Company continues to strive to make lives of patients living with cancer and rare diseases better.

Yours sincerely

Mark Nelson

Independent Non-Executive Chair (Interim)

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Message from the CEO

"Telix remains strongly positioned for long-term growth, driven by scientific excellence and an unwavering commitment to improving patient outcomes worldwide."

Dear Shareholders,

2025 was a year of meaningful progress and growth for Telix. While the external pressures of a dynamic operating environment and regulatory hurdles created challenges, they also underscore the resilience of our business. Telix has continued to deliver against its strategic priorities and reinforce our differentiated position as a leader in precision oncology.

Our strategy remains clear: Deliver our late-stage pipeline, grow our precision medicine business, build the next generation of products, and expand our global infrastructure. We have deployed our financial resources and talent effectively to deliver on this strategy. Amid the inherent complexity of pioneering new molecular imaging and therapeutic pathways, we continue to build deep expertise across clinical development, manufacturing, and commercial delivery - laying the foundation for long-term growth.

An established track record in commercial delivery

Telix achieved record revenue of US$803.8M, a 56% increase year-over-year. This is significantly driven by the acquisition of RLS, continued success of Illuccix® and the FDA approval and CMS reimbursement of Gozellix®, our next generation PSMA-PET[1] imaging agent. Together, these products position us uniquely in the growing prostate cancer imaging market, offering clinicians choice based on workflow and reimbursement needs.

Illuccix is now also available across global markets, including Australia, Brazil, Canada, Europe, and the United Kingdom, with a new drug application filed and accepted for review in China. Building a global presence is part of our long-term strategy, differentiates us from many of our peers and is aligned with our patient-centric values.

Innovation remains central to Telix, and our investment in lifecycle management and platforms such as AIFluor™ is creating new opportunities to grow the market and increase our share. In 2025, we launched BiPASS™[2], a first-of-its-kind registrational trial combining MRI[3] with Illuccix and Gozellix PET[4] imaging for prostate cancer diagnosis. This initiative could add 800,000 scans annually to the addressable market, significantly advancing early disease detection.

Following receipt of FDA Complete Response Letters for TLX250-Px (Zircaix®[5]) and TLX101-Px (Pixclara®[5]), our teams acted swiftly to engage with regulators and determine a pathway for resubmission. These experiences underscore the complexity of pioneering novel therapies; progress is rarely linear, but the lessons learned will enable resubmission and strengthen future regulatory filings.

Advancing our pipeline

We now have three active therapeutic pivotal trials in prostate, kidney, and brain cancer. The progress made this year sets the stage for the delivery of future clinical milestones and inflection points to realize the value in our theranostic pipeline and firmly position Telix as a therapeutics company.

In prostate cancer, recruitment into Part 2 of the ProstACT Global[6] Phase 3 study of TLX591-Tx is underway across Australia, New Zealand, and Canada. The study is also approved to commence in China, Japan[7], Singapore, South Korea, Türkiye and the United Kingdom, with U.S. and European expansion pending regulatory clearance. Our prostate cancer portfolio exemplifies our approach to building clinical and commercial depth in our focus areas. Alongside TLX591-Tx, our lead therapy candidate, we are advancing TLX592-Tx (alpha therapy) and TLX090-Tx an investigational treatment for pain from bone metastases, which includes but is not limited to prostate cancer. These therapeutic candidates are complemented by our commercial precision diagnostics. This deep commitment to urologic oncology is enhancing our reputation as a leading innovator and creates additional opportunities to impact patients and create value.

[1] Imaging of prostate-specific membrane antigen with positron emission tomography.
[2] ClinicalTrials.gov ID: NCT07052214.
[3] Magnetic resonance imaging.
[4] Positron emission tomography.
[5] Brand name subject to final regulatory approval.
[6] ClinicalTrials.gov ID: NCT06520345.
[7] Japanese regulator Pharmaceuticals and Medical Devices Agency ("PMDA") has granted approval for a Japan-specific Part 1 in nine patients, prior to commencing Part 2.

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As the field of radiopharmaceuticals evolves we believe that we need to go beyond a one-size-fits-all approach to maximize the full potential of theranostics. This is reflected in our current pipeline but is also central to our R&D strategy. Our specialist R&D capability spans biologics for optimized targeting, next generation alpha therapies, and enabling technologies such as AI-driven dosimetry for personalized treatment. Combined with our vertically integrated approach, Telix has a unique set of end-to-end capabilities.

Building global manufacturing scale

Our ability to deliver at scale is anchored in strategic investment and execution. The acquisition of RLS Radiopharmacies has significantly expanded our U.S. footprint. Integration has progressed rapidly, unlocking commercial synergies and enabling us to accelerate capital investment toward delivering the next generation of zirconium-89 and gallium-68 based products, and establishing a radiometal production network for the U.S. market.

We achieved Good Manufacturing Practice ("GMP") accreditation for Telix Manufacturing Solutions ("TMS") Brussels South and advanced new facilities in Yokohama and North Melbourne, reinforcing TMS as a global growth platform. Together with our IsoTherapeutics facilities and ARTMS production technology, we are building a differentiated manufacturing capability, one that positions Telix to meet global demand and deliver innovation at scale.

Leadership and talent

Our operating structure of three core business segments - Therapeutics ("Tx"), Precision Medicine ("Px"), and TMS - provides focus and alignment of resources. This framework has strengthened accountability and enabled a strategic pivot toward a more U.S.-centric executive leadership team, reflecting both our growth trajectory and the increasing concentration of operations in this key market. The Telix team is deeply aligned with our purpose and energized by the Company's long-term vision. This culture of commitment enables us to attract and retain exceptional talent in an increasingly competitive market, ensuring we have the expertise to deliver on our ambitious goals.

Conclusion

Telix remains strongly positioned for long-term growth, driven by scientific excellence and an unwavering commitment to improving patient outcomes worldwide. None of this would be possible without the dedication of our employees and the guidance of our Board. Together, we are shaping the future of cancer care.

Thank you for your continued support.

Dr. Christian (Chris) Behrenbruch

Managing Director and Group CEO

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Our performance and strategy

Telix has demonstrated strong performance against our four strategic pillars over the course of 2025. Key achievements are listed below. Further detail on our performance and strategy can be found in Form 20-F Item 4.B (Business Overview).

Deliver our late-stage therapeutic pipeline

- **TLX591-Tx (lutetium (Lu177) rosopatamab tetraxetan):** Completed Part 1 of ProstACT Global Phase 3 trial in advanced metastatic castration-resistant prostate cancer ("mCRPC"). First patients dosed in Part 2 (randomized treatment expansion) in Australia with the study also approved to open in Canada, China, Japan[1], New Zealand, Singapore, South Korea, Türkiye and the United Kingdom.
- **TLX250-Tx (^{177}Lu-DOTA-girentuximab):** Received regulatory approval to commence LUTEON[2], a global Phase 2/3 trial of TLX250-Tx as a monotherapy in advanced metastatic clear cell renal cell carcinoma ("ccRCC"), initiating sites. First patients dosed in the STARLITE-1[3] Phase 1b/2 investigator-initiated trial exploring TLX250-Tx in combination with cabozantinib and nivolumab in ccRCC[4].
- **TLX101-Tx (iodofalan ^{131}I):** Received regulatory approval in Australia and the European Union to commence the IPAX BrIGHT[5] pivotal trial of TLX101-Tx in recurrent glioblastoma ("GBM") with sites open for enrollment. The IPAX-Linz[6] Phase 2 investigator-initiated trial ("IIT") reported encouraging preliminary efficacy in recurrent GBM[7].
- **TLX66-Tx (^{90}Y-DTPA-besilesomab):** First patients dosed in the Phase 2 IIT in pediatric high-risk leukemia[8].

Build the next generation of radiopharmaceuticals

- **TLX592-Tx (^{225}Ac-PSMA-RADmAb):** Received regulatory approval to commence AlphaPRO, a Phase 1, first-in-human ("FIH") study of Telix's targeted alpha therapy ("TAT") candidate in advanced mCRPC.
- **TLX400-Tx (^{177}Lu-DOTAGA.Glu.(FAPi)$_2$):** Acquired a suite of clinically validated Fibroblast Activation Protein ("FAP")- targeting theranostic candidates. Results demonstrating encouraging clinical anti-tumor activity and safety profile for the lead therapeutic candidate TLX400-Tx were published in the Journal of Nuclear Medicine[9] and in Thyroid[10], the official journal of the American Thyroid Association.
- **TLX300-Px (^{89}Zr-olaratumab):** First patients dosed in the ZOLAR[11] Phase 1, FIH imaging study for patients with advanced, metastatic soft tissue sarcoma ("STS") and other platelet derived growth factor receptor alpha ("PDGFRα") positive tumors, aiming to demonstrate proof of concept for therapy.
- **TLX252-Tx (^{225}Ac-DOTA-girentuximab):** Received regulatory approval to commence ALPHIX, a Phase 1, FIH study of Telix's TAT candidate for the treatment of patients with advanced metastatic kidney cancer and other carbonic anhydrase IX ("CAIX") expressing cancers.
- **TLX102-Tx (^{211}At astato-L-phenylalanine, or ^{211}At-APA):** Granted Orphan Drug Designation ("ODD") by the U.S. FDA for the treatment of malignant glioma (brain cancer). Preparing for FIH studies in GBM and leptomeningeal disease ("LMD").

[1] Japanese regulator Pharmaceuticals and Medical Devices Agency ("PMDA") has granted approval for a Japan-specific Part 1 in nine patients, prior to commencing Part 2.
[2] ClinicalTrials.gov ID: NCT07197580.
[3] ClinicalTrials.gov ID: NCT05663710.
[4] Telix ASX disclosure October 14, 2025.
[5] ClinicalTrials.gov ID: NCT07100730.
[6] EudraCT Number: 2021-006426-43.
[7] Telix ASX disclosure April 16, 2025
[8] ClinicalTrials.gov ID: NCT04856215.
[9] Ballal et al. *J Nucl Med.* 2025.
[10] Ballal et al. *Thyroid.* 2025.
[11] Telix media release April 2, 2025. ClinicalTrials.gov ID: NCT06537596.

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- **TLX090-Tx (^{153}Sm-DOTMP):** First U.S. patients dosed[1] in SOLACE[2], a Phase 1 study evaluating safety, dosimetry, patient-reported outcomes, and potential opioid-sparing effects of TLX090-Tx in patients with metastatic bone pain.

- Acquired a pipeline of next generation therapeutic candidates, proprietary novel biologics technology platform, and protein engineering and discovery research facility from antibody engineering company ImaginAb, Inc.[3]

Grow our industry-leading precision medicine business

- **Gozellix®:** Launched in the U.S. following FDA approval and reimbursement by Centers for Medicare and Medicaid Services (CMS), via a Level II HCPCS code[4] and transitional pass through (TPT) payment status effective 1 October 2025[5]. Telix is the only company with two FDA-approved PSMA imaging products.

- **Illuccix®:** Granted marketing authorization in all 19 markets in Telix's European submission, along with Brazil and the United Kingdom. Completed enrollment[6] in the Phase 3 registration study in China[7], reported preliminary data[8] and submitted a new drug application ("NDA"), which was accepted for review[9]. Dosed the first patient[9] in the Phase 3 registration study in Japan[10]. Prior Approval Supplement ("PAS") received to update U.S. Prescribing Information to include patient selection for PSMA-directed therapy in the pre-taxane setting[11].

- **BiPASS™**: First patients dosed in Australia[12] and the U.S.[13] in the BiPASS™ Phase 3 registration-enabling study to evaluate magnetic resonance imaging ("MRI") combined with Illuccix® and Gozellix® PET imaging for prostate cancer diagnosis.

- **Varian collaboration:** Announced a strategic collaboration with Varian to develop novel clinical applications that combine Telix's theranostic products and external beam radiation therapy ("EBRT")[14].

- **AlFluor™:** Announced a novel PET radiochemistry solution based on fluorine-18 (^{18}F)-aluminum fluoride ("AlF") as part of product lifecycle management[15]. Strategic agreement with University Hospital Ghent and Ghent University for [^{18}F]AlF-PSMA-11, including extensive clinical data to enable a U.S. registration trial.

- **Zircaix® (TLX250-Px, ^{89}Zr-DFO-girentuximab):** Participated in two Type A meetings with the FDA to address deficiencies identified in the CRL received in August 2025 for Telix's ccRCC PET imaging candidate[16]. Following these meetings, Telix believes it has alignment with the Agency on key resubmission aspects and is now focused on completing the required deliverables. TLX250-Px was included in leading international guidelines for renal imaging[17]. ZIRCON-X study data[18] showed almost half of all patients imaged with TLX250-Px would undergo a change in clinical management when compared with standard of care ("SOC") imaging.

- **Pixclara® (TLX101-Px, floretyrosine F18):** Participated in a Type A meeting with the FDA to address deficiencies identified in the CRL received in April 2025 for Telix's PET imaging candidate for glioma. Following this meeting, Telix believes it has aligned on a pathway to refiling in the U.S. and is currently finalizing the resubmission package. In February 2026, Telix submitted a marketing authorization application for TLX101-Px in Europe. In June 2025, TLX101-Px was included in updated NCCN Guidelines® for Central Nervous System Cancers for PET imaging of gliomas[19].

Expand our global infrastructure for product delivery

- In January 2025, Telix completed the acquisition of RLS Radiopharmacies[20], America's only joint Commission-accredited radiopharmacy network, distributing PET, SPECT, and therapeutic radiopharmaceuticals. The acquisition of over 30 radiopharmacies significantly expands Telix's U.S. presence. The process to install cyclotrons at select RLS sites is underway in line with Telix's stated vision to build a radiometal production network for U.S.-based manufacturing.

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[1] Telix media release October 23, 2025.
[2] ClinicalTrials.gov ID: NCT07197645.
[3] Telix ASX disclosure January 31, 2025.
[4] Telix ASX disclosure July 9, 2025.
[5] Telix ASX disclosure September 23, 2025.
[6] Telix media release May 13, 2025.
[7] ClinicalTrials.gov ID: NCT05847348.
[8] Telix ASX disclosure December 22, 2025.
[9] Telix ASX disclosure January 20, 2026.
[10] Japan Registry of Clinical Trials identifier: JRCT2031250473.
[11] Telix ASX disclosure October 14, 2025.
[12] Telix media release September 10, 2025.
[13] Telix media release January 16, 2026.
[14] Telix media release December 10, 2025.
[15] Telix media release June 20, 2025.
[16] Telix ASX disclosure August 28, 2025.
[17] Telix media release October 23,2025.
[18] Telix media release November 20, 2025.
[19] National Comprehensive Cancer Network® ("NCCN") Clinical Practice Guidelines in Oncology ("NCCN Guidelines®") for Central Nervous System Cancers V1.2025.
[20] Telix ASX disclosure January 28, 2025.

- TMS Brussels South in Seneffe, Belgium, received its GMP accreditation for Illuccix and began production of GMP commercial radiopharmaceutical doses[1].
- Opened a GMP manufacturing facility in Yokohama, Japan[2]. This is Telix's first cyclotron facility in the Asia Pacific region and will serve as a hub for commercial and clinical drug product supply, and future R&D.
- Received radiation licenses for the TMS North Melbourne, Australia, and TMS Yokohama facilities for a broad range of clinically and commercially important medical isotopes[3]. TMS North Melbourne is in the final stages of fit-out and preparing for operational readiness.
- ARTMS' drug master file ("DMF") for gallium-68 (^{68}Ga) production using its QUANTM Irradiation System® (QIS®) cyclotron technology was referenced with an FDA-approved product for the first time with Gozellix[4] in March 2025, and subsequently with Illuccix in January 2026.
- Established a joint venture with R2PHARMA to commercialize and distribute our therapeutic and diagnostic radiopharmaceutical products in Brazil[5]. This builds on our existing partnership established in 2019.
- Developed and validated a breakthrough generator technology for the production of the alpha-emitting isotope, lead-212 (^{212}Pb) and successfully completed production runs[6].

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[1] Telix media release June 25, 2025.
[2] Telix media release November 21, 2025.
[3] Telix ASX disclosure October 14, 2025.
[4] ARTMS media release April 1, 2025.
[5] Telix ASX disclosure March 18, 2025.
[6] Telix media release March 13, 2025.

Our commercial and clinical focus

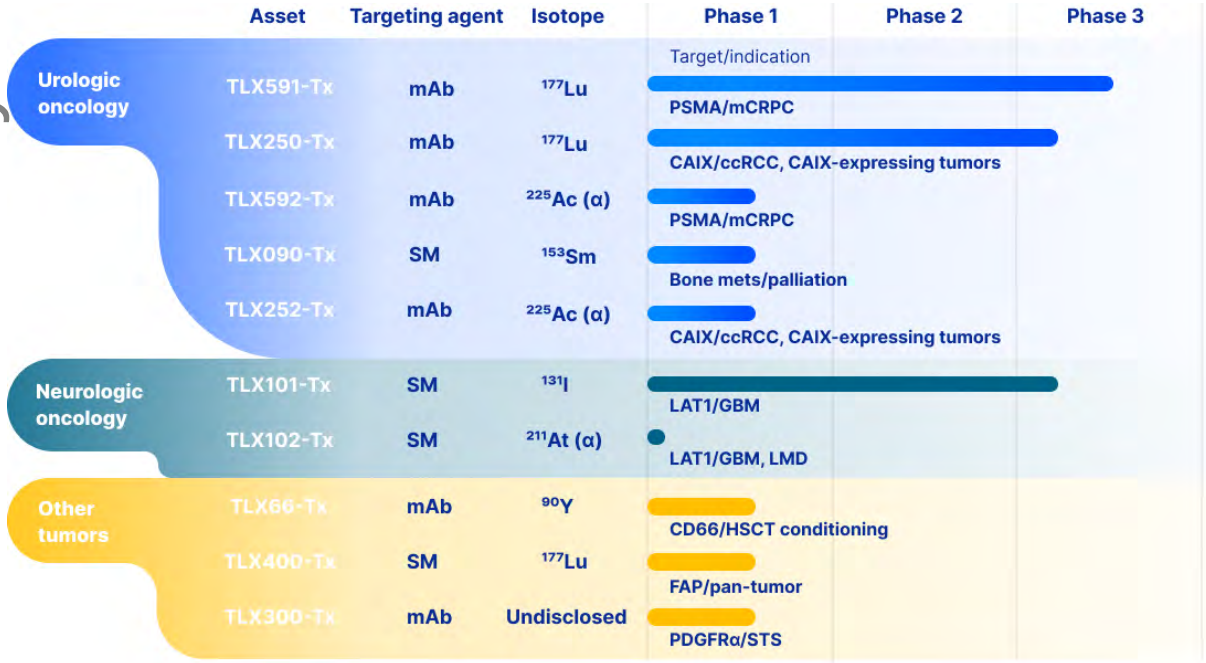
Our focus areas

Our theranostic approach combines therapeutics with diagnostics, focusing on urologic oncology (prostate and kidney), neurologic oncology (glioma), as well as other solid tumors and hematologic malignancies. These areas represent markets with significant unmet patient needs, and clear opportunities for improved treatment approaches and potential first-mover advantage.

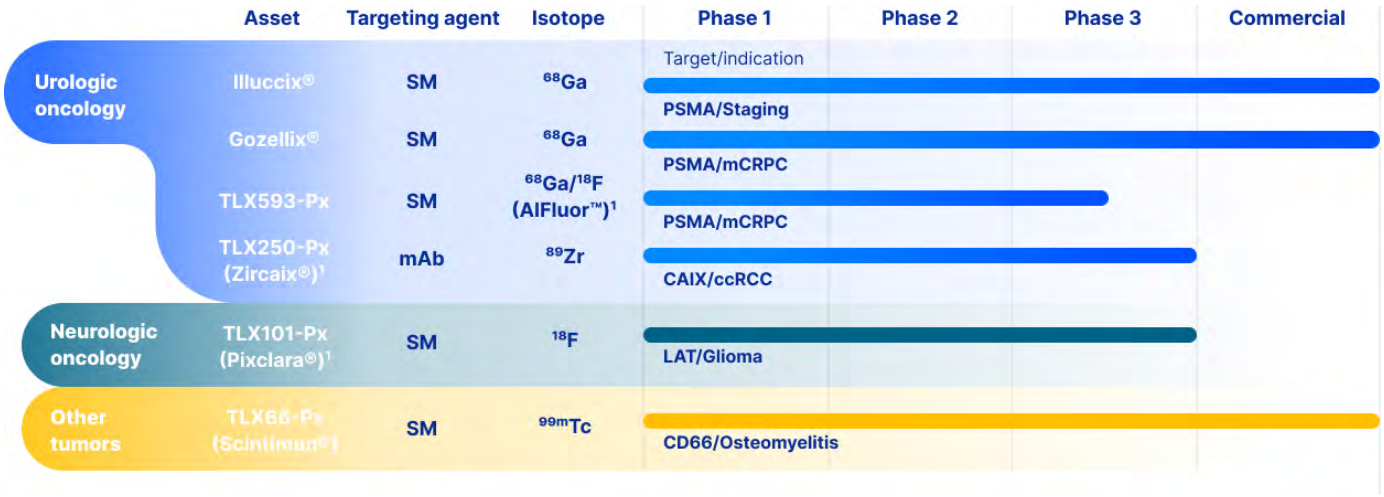
Pipeline

Therapeutic pipeline

Further detail on our product pipeline and development programs can be found in Form 20-F Item 4.B (Business Overview).



Precision medicine portfolio



[1] Brand name subject to final regulatory approval.

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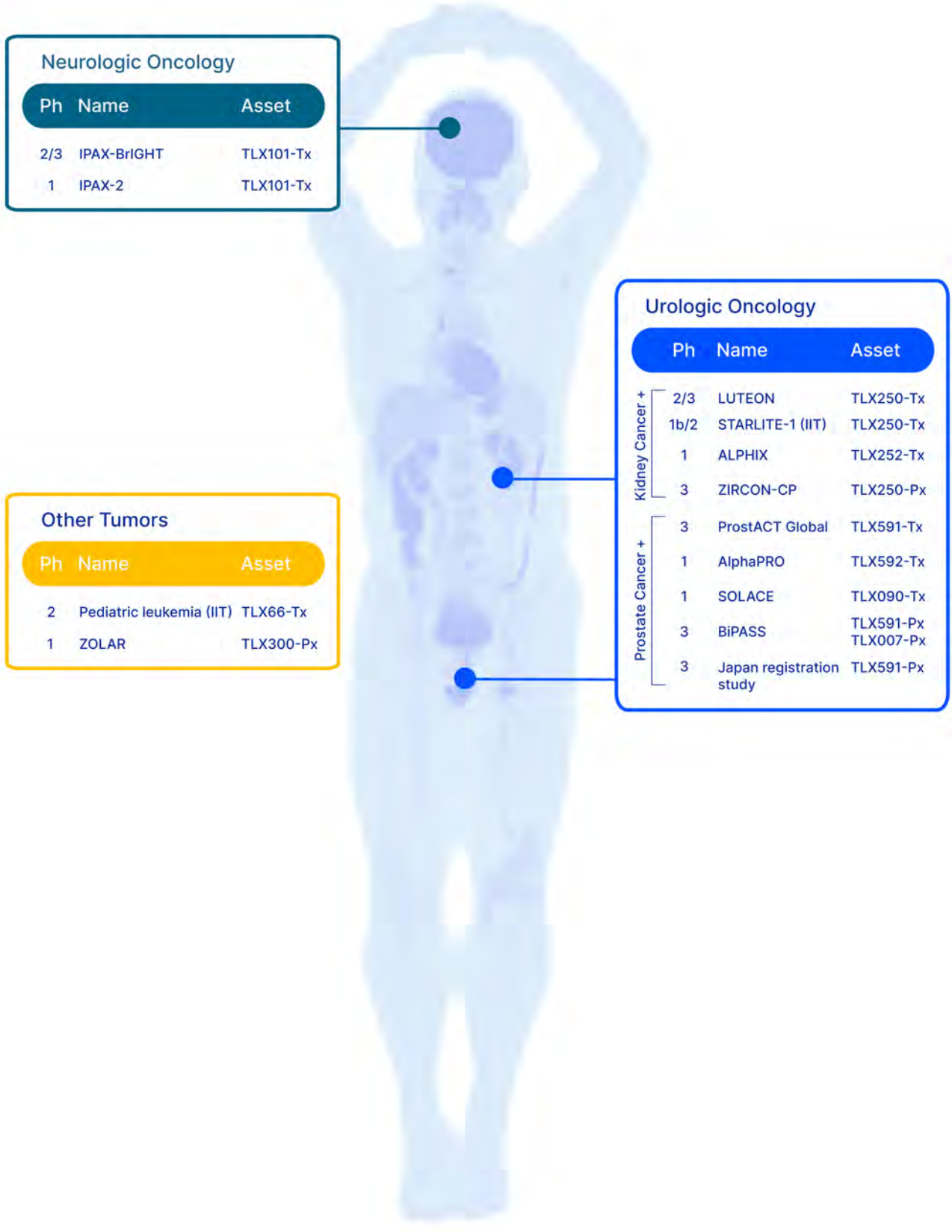
Our clinical trials

Telix is at the forefront of theranostic drug development, dedicated to enhancing the quality of life for people affected by cancer. We put patients first in everything we do and currently have 33 clinical trials active worldwide, including partnered IITs, across various diseases. Refer to the graphic below for Telix-sponsored trials and select IITs.

To learn more about our active and completed clinical trials visit: ClinicalTrials.gov



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Financial review

$803.8M
Total Group revenue
Up $287.2M from 2024

53%
Gross margin
Reflects product mix shift to include RLS third-party sales, dose preparation, pharmacy and delivery costs

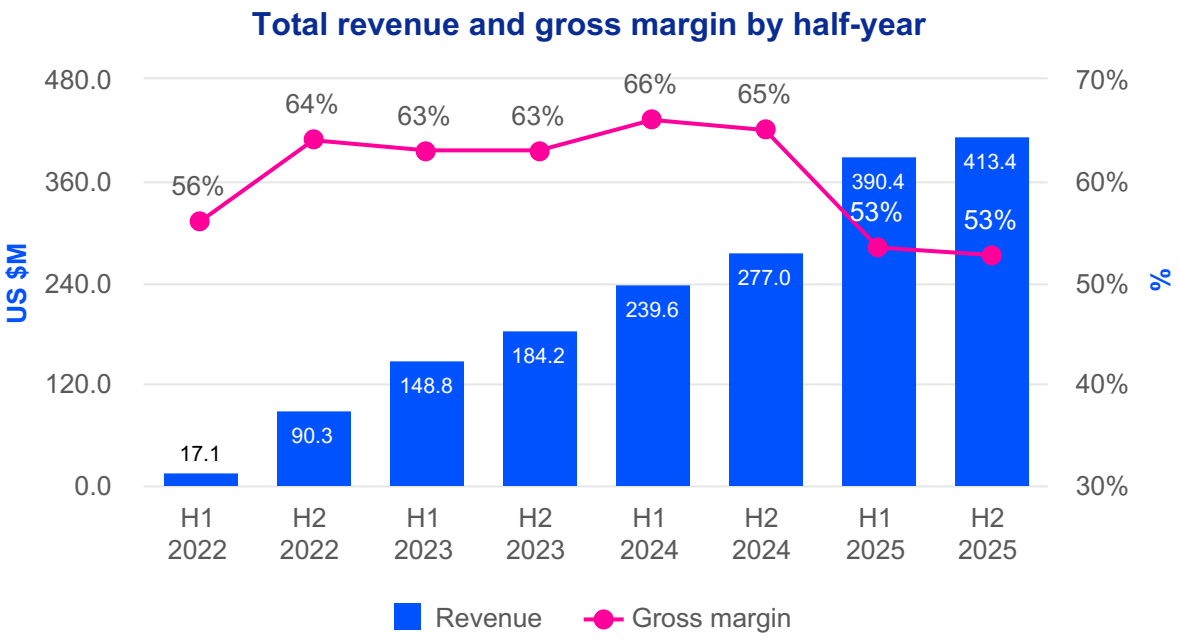
$7.1M
Net loss after tax
Includes $22.5M in non-cash interest unwind (convertible bonds)

$39.5M
Adjusted EBITDA
Down $27.4M from $66.9M in 2024

Revenue and gross margin

Revenue increased to $803.8 million for the full year ended December 31, 2025, up by $287.2 million, or 56% compared to $516.6 million in the prior period. Revenue from our Precision Medicine business was $621.9 million, and the Group generated a further $170.1 million in sales of third-party products and services by RLS Radiopharmacies.

Gross margin was 53% for the year ended December 31, 2025 (compared to 65% in 2024). The Group's gross margin reflects changes in the product mix following the acquisition of RLS and its sales of lower-margin SPECT imaging products. RLS cost of sales includes both direct and indirect manufacturing and distribution costs associated with dose preparation and delivery to customers.



Research and development (R&D)

Investment for the year increased to $171.2 million[1] (2024: $127.9 million) enabled by the Company's higher revenue. Expenditure predominantly focused on advancing clinical trials for late-stage therapeutic assets and on scaling up manufacturing and inventory for the commercial launch of precision medicine assets.

R&D investment also included progressing the Zircaix® (TLX250-Px, ^{89}Zr-DFO-girentuximab) Biologics License Application ("BLA"), progressing towards resubmitting the New Drug Application ("NDA") for Pixclara® (TLX101-Px, floretyrosine F18), and completing target enrollment in Part 1 of the ProstACT Global Phase 3 trial.

[1]Includes 14.1 million of inventory for TLX250-Px (Zircaix®) commercial launch that is expensed to R&D. This expense arises from commercial inventory produced in anticipation of Zircaix approval and will be reversed upon FDA approval.

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Group financial performance

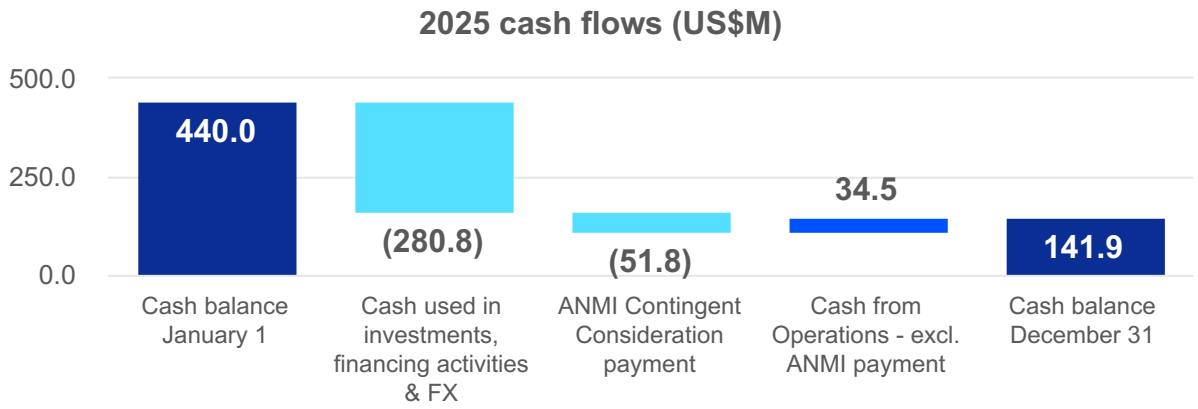
Telix continues to deliver strong revenue growth while investing in its supply chain and progressing its pipeline of therapeutic candidates. These investments have transformed the Company, positioning it for sustainable, long-term growth, while its diversified business provides multiple opportunities for geographic and product expansion.

2025 represents a transitional period that reflects expanded business operations, incremental investment to support the launch of new products and into new markets, and a planned increase in R&D investment as we accelerate the development of late-stage therapeutic assets.

Reported loss after tax attributable to Telix shareholders was $7.1 million, compared to a profit of $33.7 million in 2024. The net loss reflects the impact of scale up manufacturing and inventory for the commercial launch of precision medicine assets, finance costs on convertible bonds issued in July 2024 and increased investment in the Phase 3 ProstACT Global trial. Adjusted EBITDA was $39.5 million, representing a decrease of $27.4 million or 41% when compared to $66.9 million in the prior comparable period, also reflecting the increased R&D and manufacturing investments.

Cash balance and activities

Cash and cash equivalents were $141.9 million as at December 31, 2025 (December 31, 2024: $440.0 million), with positive net operating cash flow excluding the final ANMI contingent consideration payment.



Operating activities

Net cash used in operating activities was $17.3 million (2024: $27.5 million generated from operating activities). The primary sources of cash from operating activities were collections from Precision Medicine sales and RLS collections from sales of SPECT and third-party PET products of $774.2 million (2024: $467.7 million). The improved customer receipts reflect sales growth from the Precision Medicine business and the newly acquired RLS third-party product sales.

The primary uses of cash in operating activities were payments to suppliers and employees of $710.6 million (2024: $418.3 million), including manufacturing and R&D expenditures to progress our late-stage assets and new product applications, final ANMI contingent consideration payment of $51.8 million, selling and marketing efforts, interest paid of $13.7 million (2024: $3.1 million), and income taxes paid (primarily in the U.S. and Belgium) of $21.3 million (2024: $2.0 million).

Investing activities

Net cash used in investing activities of $285.9 million (2024: $86.7 million) mainly comprised payments for:

- $220.7 million for the acquisition of RLS, net of acquired cash.
- $18.1 million for the asset acquisitions of ImaginAb and the suite of FAP targeting candidates.
- $25.7 million (2024: $9.1 million) for the expanded investment at Telix Manufacturing Solutions ("TMS") sites across RLS Radiopharmacies, the IsoTherapeutics site in Angleton, Texas (U.S.), the sites in Brussels South (Seneffe) and North Melbourne.

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Remuneration report

Letter from the Chair of the People Committee

Dear fellow Shareholder,

On behalf of the Board of Directors, I am pleased to present Telix's Remuneration disclosures for the year ended December 31, 2025. This report contains details of Telix's Key Management Personnel ("KMP") for 2025 and their remuneration, and cross refers to information provided in Item 6 ("Directors, Senior Management and employees") of the Form 20-F. Section references in this letter are to Item 6 of the report.

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Telix 2025 performance aligned to our long-term growth strategy

Under the leadership of the MD & CEO and Executive team, Telix has delivered significant growth and strategic progress, supported by the continued strengthening of governance and risk frameworks befitting a maturing, global organization.

Telix delivered annual revenue of US$803.8 million, representing 56% growth year-over-year, reflecting our strong commercial execution and global presence. This performance has enabled disciplined investment of US$171.2 million in research and development across our Precision Medicine and Therapeutic pipeline, which we believe positions the Company to drive future revenue growth and long-term value creation.

The acquisition of RLS Radiopharmacies significantly expanded our workforce and U.S. presence, further strengthening our global manufacturing footprint. The successful integration of RLS and other acquisitions is strengthening Telix's competitive advantage and positioning the Company for future growth.

Amid a period of rapid transformation, including operating as a dual-listed company, Telix has continued to demonstrate a strong commitment to governance and risk management. In 2025, the Company made substantial progress toward Sarbanes-Oxley ("SOX") compliance, reflecting the governance standards required of U.S.-listed companies. 2025 also saw strong workplace health and safety ("WHS") performance and outcomes across the business, notably achieving 100% compliance in environmental permitting and radiation dose to workers, zero fines, and zero official notices of violation within the WHS remit.

While 2025 delivered significant achievements the year also presented challenges, as outlined in the Chair and CEO letters, particularly relating to the regulatory filings for TLX250-Px and TLX101-Px, which impacted near-term revenue expansion. The Board has taken these factors into account in remuneration outcomes for 2025 and in setting remuneration for 2026.

Telix 2025 remuneration

Outcomes

In summary, Executive KMP and Non-Executive Director remuneration is disclosed as follows:

- Statutory remuneration in sections 3.5 and 5.3.
- Short Term Variable Remuneration ("STVR") outcomes between 60 and 65% of target in section 3.3.1, reflecting corporate performance in 2025.
- Long Term Variable Remuneration ("LTVR") outcome of 125% of target for 2023 PSARs with vesting in March 2026 in section 3.3.2, reflecting strong performance over the longer term.

MD & CEO remuneration, which incorporated fixed remuneration of base salary, superannuation and leave accruals was US$556,718 for the 2025 year. An STVR outcome of US$339,874was awarded to the MD & CEO for the 2025 outcomes based on performance detailed in section 3.3.1, of which 50% will be deferred to equity and will be presented to shareholders for approval at the 2026 Annual General Meeting.

No Board adjustment applied

As detailed in section 3.3.1, the STVR is calculated based upon the achievement against the Corporate Objectives (100% for MD & CEO and 50% for Executive KMP) and Business Unit objectives (50% for Executive KMP excluding the MD & CEO). The Board considers application of a Values Modifier up or down, however in 2025 the Board exercised no discretion to modify the STVR outcomes for any Executive KMP.

No Board discretion was applied to the 2023 LTVR PSAR vesting outcome. Commentary is provided on each measure in section 3.3.2, with the Board endorsing the results as they were realized, with no positive or negative discretion applied.

Remuneration changes in 2025

Each year we engage with numerous stakeholders to ensure our Remuneration Framework is appropriate for the needs of Telix and aligned to long-term shareholder interests.

Executive KMP remuneration changes adopted in 2025 were aligned with remuneration recommendations prepared by Mercer Consulting (Australia) Pty Ltd ("Mercer") (under section 9B of the Australian Corporations Act 2001 (Cth)) in 2023. These changes were disclosed in the 2024 Remuneration report, and are detailed in section 3.

Non-Executive Director ("NED") equity plans were also introduced in 2025. These were disclosed in the 2024 Remuneration report and 2025 Notice of Meeting, and are detailed in section 5.2.

The introduction of the Employee Stock Purchase Plan ("ESPP") in the U.S. and an Australian ESPP, allow employees (including Executive KMP, but excluding the CEO) to purchase Telix shares (Australian employees) or American Depository Shares (U.S. employees). Details were provided in the 2025 Notice of Meeting and in sections 6.3 and 6.4.

KMP changes in 2025

As mentioned in the Message from the Chair, there were three KMP changes in 2025: the retirement of Mr. Kevin McCann AO, the appointment of Ms. Tiffany Olson to the Chair of the Board[1], and my appointment as Non-Executive Director and Chair of the People Committee. There were no changes to Executive KMP.

Telix 2026 remuneration

Benchmarking and updates

During 2025, the Board engaged Mercer to provide updated market benchmarking for all KMP (Executives and Non-Executive Directors). This benchmarking review was timely due to Telix's significant growth since the 2023 remuneration benchmarking exercise. Unlike 2023, Mercer was not requested to make a recommendation, but instead provided market data for Board consideration. A global peer group of 40 companies was established with Telix positioned near the median for metrics such as market capitalization and revenue, based on six month average data to June 30, 2025. For NEDs, ASX peer groups were also considered. Given the changes in Telix's share price during the year, updated data as to Telix's positioning in the peer groups, as at end of October 2025, was also obtained.

The June 30 data indicated that current executive KMP remuneration was significantly below the benchmark median. The October data also confirmed that remuneration remained below Telix's then position in the global peer group.

Having regard to the shareholder experience in 2025, the Board decided not to make any material changes to all KMP (Executives and NEDs) remuneration opportunity for 2026 (other than those mentioned below). Further details regarding the insights and changes to KMP remuneration for 2026 as a result of the 2025 review are provided in sections 4 and 5.4.

[1] Ms. Olson resigned from the Board effective February 3, 2026.

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Executive KMP remuneration

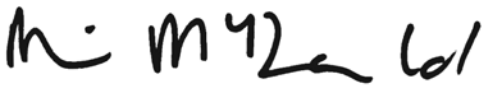
The Board determined to apply a 3.5% increase to base remuneration for Executive KMP (including the MD & CEO) in 2026, consistent with the average increase for the Telix workforce. An exception was for Dr. Patti, who received a 15% uplift in recognition of the significant increase in the position scope of his Group COO role to include radiopharmacy site and distribution network management as a result of the RLS acquisition.

To promote alignment across the organization in 2026 we are returning to having the same set of measures for STVR for all GET members, consisting of corporate financial objectives (40%) and shared business unit objectives (60%).

Non-Executive Director remuneration

The benchmarking data indicated that Board and Committee fees were generally below benchmark, in some cases significantly so. However, having regard to the shareholder experience in 2025, the Board does not presently propose to increase fees in 2026. For more information, please refer to section 5.4.

I invite you to read the Remuneration report which will be presented for approval at Telix's 2026 AGM.



Marie McDonald
Chair, People Committee

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Sustainability report

About the report

This Sustainability report presents information about how Telix identifies, manages, and responds to sustainability risks and opportunities, specifically highlighting climate-related considerations as a core part of our sustainability strategy.This report is designed to provide investors, regulators, and other stakeholders insights into our progress integrating sustainability into our business practices and operations.

Our approach reflects Telix's commitment to creating long-term value through responsible practices that advance patient health, protect the environment, and strengthen our communities. This report also demonstrates how we actively integrate sustainability - including climate-related disclosures - into our governance, risk management, and strategic planning processes.

Basis of preparation

This report has been prepared in accordance with the Australian Sustainability Reporting Standard ("ASRS") AASB S2 – Climate-related Disclosures and the Australian Corporations Act 2001 (Cth). This section and the following section, titled "Climate-related financial risks and opportunities", provides the required statutory disclosures. Subsequent sections focusing on Employees and Patients, include voluntary disclosures aimed at helping investors gain insights into these crucial aspects of our business. 2025 is Telix's first year of reporting under AASB S2.

The Sustainability report covers the year ended December 31, 2025 and should be read in conjunction with the Group's Consolidated Financial Statements.

The Group defines time horizons based on the periods during which sustainability-related risks and opportunities could reasonably be expected to arise. As at the end of the reporting period, the following time horizons have been identified, consistent with the timelines used for strategic decision-making: Short-term (0 to 12 months), medium-term (one to five years), and long-term (beyond five years).

All amounts presented in this report are presented in US$ and are rounded to the nearest thousand unless otherwise stated.

First-time adoption of ASRS and transition reliefs

AASB S2 provides transition reliefs for the first annual reporting period in which an entity applies the standards. The Group has applied the following transition reliefs:

Citation in Standard	Details
AASB S2 (Appendix C, para C3)	An entity is not required to disclose comparative information in the first annual reporting period in which it applies this Standard.
AASB S2 (Appendix C, para C4(b))	An entity is not required to disclose its Scope 3 greenhouse gas emissions in the first annual reporting period in which it applies this Standard.

Scope and boundary

The report covers Telix Pharmaceuticals Limited and its controlled subsidiaries, in Australia, the U.S., Europe, and Asia.

Greenhouse gas ("GHG") emissions data have been compiled using the operational control approach of the GHG Protocol (2004). 2025 serves as Telix's baseline year for Scope 1 and 2 emissions; prior-year data are not presented as they were not assured.

Telix believes the operational control approach is the most appropriate method for measuring GHG emissions, given there are several assets that the Group does not own but it controls operationally.

Forward-looking statements

This report includes forward-looking statements regarding sustainability targets and initiatives. These statements are based on current expectations and assumptions and are subject to risks and uncertainties. Actual outcomes may differ due to changes in regulatory requirements, market conditions, or technological developments.

Our approach

Telix's sustainability journey has evolved alongside the Company's growth and increasing global footprint. In recent years, we have strengthened our approach to sustainability governance, risk management, and disclosure to ensure alignment with leading global standards and stakeholder expectations.

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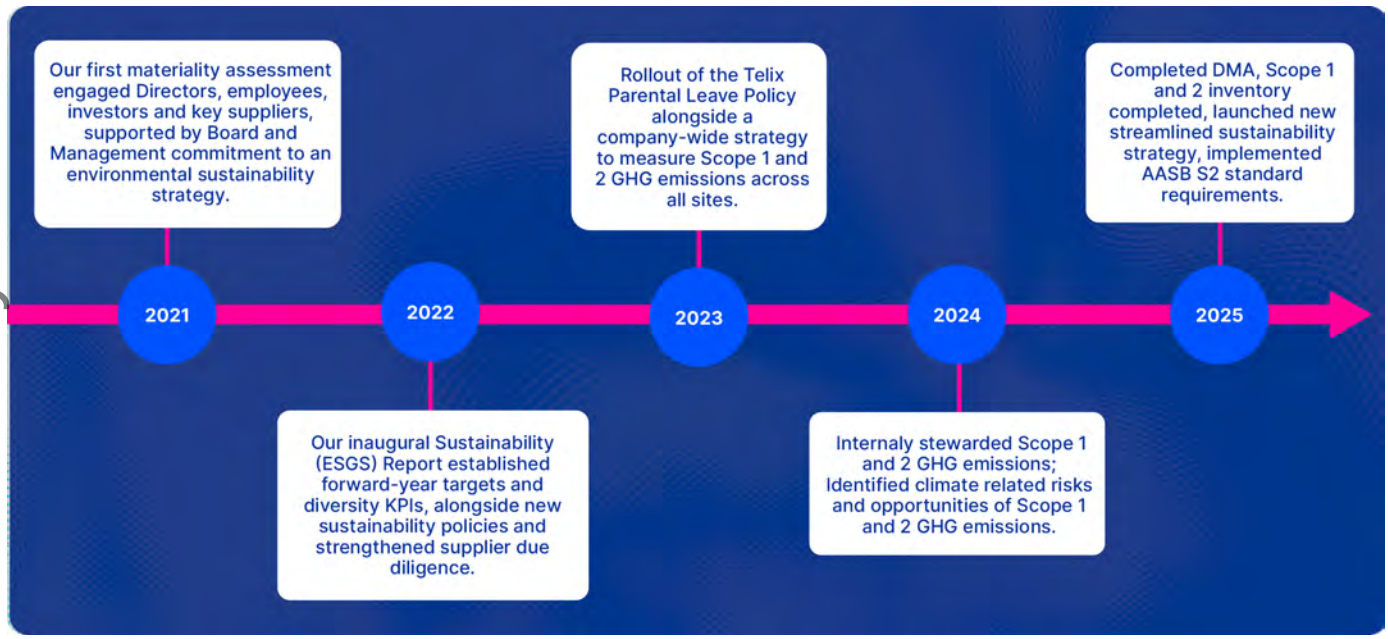
During the reporting period, Telix undertook its first Double Materiality Assessment ("DMA") to systematically evaluate sustainability-related impacts, risks, and opportunities across the value chain. The insights from this assessment provided a clearer understanding of the sustainability topics most relevant to Telix's business model, operating context, and long-term strategy.

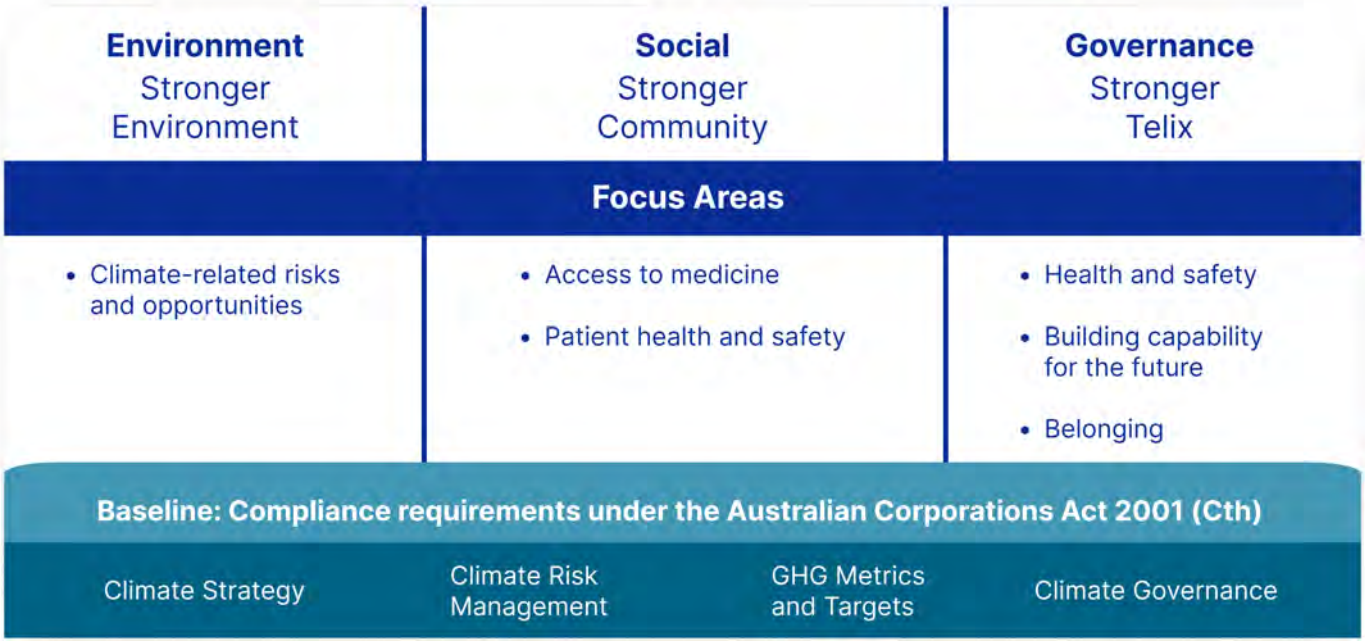
As a result, Telix transitioned from a broad five-pillar sustainability framework to a more focused three-pillar strategy, enhancing clarity and strategic alignment. This evolution reflects a shift toward a more targeted, evidence-based approach to managing sustainability risks and opportunities, while strengthening accountability and transparency.

The refined sustainability strategy was approved by the Board in August 2025, marking an important milestone in Telix's Environmental, Social and Governance ("ESG") journey and reinforcing sustainability as an integral component of enterprise governance and decision-making.



Building on this evolution, Telix's sustainability strategy is structured around three interconnected pillars that define our strategic priorities and guide the disclosures that follow.

Sustainability



The three-pillar strategy provides the overarching framework for this report. Climate-related financial risks and opportunities, addressed under the Stronger Environment pillar, are disclosed in accordance with AASB S2 in the mandatory section that follows. Broader sustainability risks and opportunities related to Stronger Communities and Stronger Telix are addressed in the voluntary sustainability disclosures later in this report.

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This report distinguishes between mandatory climate-related financial disclosures, prepared in accordance with AASB S2, and voluntary sustainability disclosures informed by Telix's broader sustainability assessment processes. Together, these sections provide a comprehensive view of how Telix identifies, manages, and responds to sustainability-related risks and opportunities.

Stronger environment

Climate-related financial risks and opportunities

Identification and assessment process

Telix identifies climate-related risks and opportunities through a structured process aligned with AASB S2, focusing on matters that could reasonably be expected to affect the Group's financial position, financial performance, cash flows, or access to capital over the short-, medium-, and long-term.

Identification of climate-related risks and opportunities

The identification process draws on two complementary inputs:

1. TCFD baseline assessment and executive workshops

In October 2024, Telix commenced a Task Force on Climate-Related Financial Disclosures ("TCFD") baseline assessment, including a structured review of existing disclosures and peer benchmarks. This assessment was supplemented by two executive-level workshops to identify potential climate-related risks and opportunities across multiple time horizons. These sessions considered transition risks and opportunities - including evolving regulatory requirements, carbon pricing, market dynamics, and supply chain exposures - as well as physical climate-related risks arising from acute and chronic weather-related events. Climate-related opportunities associated with innovation, energy efficiency improvements, and strategic positioning in a lower-carbon economy were also identified.

2. Financial materiality determination

All identified climate-related risks and opportunities were assessed solely on the basis of financial materiality, consistent with AASB S2. The financial materiality determination drew on the DMA methodology, which provided a structured, evidence-based assessment of the likelihood and magnitude of potential financial effects across Telix's value chain. The assessment considered:

- the likelihood of occurrence, and
- the magnitude of potential financial effects on revenue, operating costs, capital expenditure, asset values, cash flows, and access to capital.

Risks and opportunities were classified as materially affecting enterprise value where their assessed likelihood and financial magnitude exceeded defined financial materiality thresholds. Assessments were conducted on a gross basis, without taking into account existing mitigation or adaptation measures, to provide transparency regarding inherent financial exposures.

In assessing likelihood and financial magnitude, Telix applied a combination of quantitative and qualitative inputs. These included company-specific information on operations, geographic footprint, value chains, asset base, and product development activities, together with external data reflecting climate-related policy, market, and physical risk drivers relevant to the jurisdictions in which the Group operates. Judgments and assumptions were based on management's best estimates as of the reporting date, informed by observable market trends, regulatory developments, and relevant climate-related scenario variables.

Climate-related scenario analysis was applied to validate and deepen the assessment of financial materiality for the risks and opportunities identified through the TCFD workshops and financial materiality determination, but it was not used to identify new risks or opportunities.

Outcomes and integration

The process resulted in a prioritized list of climate-related risks and opportunities reflecting those with the greatest potential financial relevance to Telix. These outcomes inform the Group's enterprise risk management activities, strategic planning, and the climate-related disclosures presented in this report.

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Financially material climate-related risks identified

Topic	Placement in value chain	Time-horizon	Description
Physical: Acute and chronic climate hazards	Telix's own operations	Long-term	Telix is exposed to acute physical climate risks due to its operations, which rely on highly time-sensitive, temperature-controlled delivery of radiopharmaceuticals with short half-lives. Unlike many industries that can stockpile inventory or tolerate short delays, Telix's products must be produced, shipped, and delivered to hospitals within tightly defined windows. Its expanding footprint, including a large U.S. radiopharmacy network and key manufacturing assets in Belgium, Japan and Australia, creates multi-regional exposure to storms, flooding, heatwaves, and power outages. Extreme weather events can disrupt production cycles, impede last-mile delivery, and jeopardize product viability.
Transition: Energy	Telix's own operations	Medium-term	Telix's operations depend on continued electricity supply to power cyclotrons, cold-chain logistics, radiopharmacy production, and laboratory environments. As jurisdictions introduce carbon pricing or as wholesale markets shift during the low-carbon transition, Telix faces the risk of rising energy costs, particularly in Belgium, Australia, Japan, and the United States where it has major facilities. As radiopharmaceutical manufacturing cannot easily reduce energy demand, Telix has less flexibility to adapt quickly to energy-transition pressures than companies with more discretionary energy loads.

Financially material climate opportunities identified

Although Telix has not identified any material climate-related opportunities at this time, proactive mitigation of the climate risks described above may create potential opportunities in the future. As sustainability expectations increase across the healthcare sector, early improvements in emissions performance, renewable-energy adoption, and transparent climate reporting could position Telix to differentiate itself as a preferred low-carbon partner, strengthening future customer relationships and opening sustainability-driven market segments. Likewise, Telix's energy-intensive radiopharmacy and manufacturing operations present a longer-term opportunity to enhance margins through efficiency upgrades, equipment modernization, logistics optimization, and fleet electrification, interventions that may become financially advantageous as energy markets evolve and regulatory incentives emerge. Telix will continue to monitor all potential climate-related opportunities and assess their materiality over time.

Risk management

Risk management of climate-related risks and opportunities

Telix manages climate-related risks and opportunities through its Enterprise Risk Management Framework ("ERMF"), which is aligned with ISO 31000:2018 and applied across the Group. The ERMF provides the governance, processes and controls through which financially material climate-related risks and opportunities identified in accordance with AASB S2 are assessed, prioritized, monitored and integrated into strategic and operational decision-making.

Integration with identification and materiality assessment

The identification and financial materiality assessment of climate-related risks and opportunities is described in the section "Identification of climate-related risks and opportunities." Only climate-related risks and opportunities assessed as financially material through that process are managed and monitored under the ERMF for the purposes of mandatory AASB S2 disclosures.

Assessment, prioritization and scenario analysis

Financially material climate-related risks are incorporated into Telix's enterprise risk management processes rather than managed through a standalone framework. Climate-related risks are assessed within the Group's strategic risk profile under the "Environment" risk category and evaluated alongside other strategic and operational risks.

Assessment uses the same methodology applied across the ERMF, including qualitative evaluation of the nature of the risk (transition or physical), likelihood of occurrence, and potential magnitude of financial impact. Climate-related risks are prioritized relative to other enterprise risks using established risk appetite, tolerance thresholds and escalation criteria.

While Telix's climate-related risks were initially identified through the TCFD climate-risk workshop and the financial materiality results of the DMA, climate-related scenario analysis is used to validate and deepen the assessment of those risks. Scenario analysis helps Telix understand how the identified transition and physical risks could evolve under different climate pathways (for example, 1.5°C versus 2.5+°C+), quantify potential short-, medium-, and long-term financial effects, and confirm whether the risks are reasonably expected to affect Telix's prospects. As a result, scenario analysis informs Telix's overall evaluation and prioritization of climate-related risks within the ERMF, even though the risks themselves were identified through separate processes.

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Monitoring and governance

Monitoring of financially material climate-related risks and opportunities occurs through Telix's existing risk management processes, including enterprise and business unit risk registers and regular management review. The Audit and Risk Committee ("ARC") reviews material strategic risks quarterly as part of its oversight of the ERMF, with significant matters escalated to the Board as required.

Climate-related opportunities assessed as financially material are managed through the same ERMF processes and considered in strategic planning and operational resilience discussions.

Changes compared with prior reporting periods

FY 2025 represents an enhancement in Telix's approach to climate-related risk and opportunity management, reflecting the formalization of climate-related processes for AASB S2 reporting and the establishment of FY 2025 as the baseline year. Compared with prior periods, climate-related considerations are more explicitly integrated into enterprise risk registers, scenario-based assessment processes, and Board and executive oversight arrangements.

Governance

Board oversight

The Board has ultimate responsibility for the oversight of Telix's sustainability strategy, which includes the identification, assessment and management of climate-related risks and opportunities. Responsibilities for climate-related risks and opportunities are formally embedded in existing governance instruments. Under the Board Charter, the Board oversees Telix's sustainability strategy and associated market disclosures, including matters related to climate change, as part of its broader responsibility for risk management and strategic oversight.

Further, the ARC, operating under its Charter, supports the Board by overseeing Telix's ERMF and sustainability strategy and reporting framework, including in relation to material environmental and social risks such as climate change. Climate-related risks and opportunities are considered within the Company's broader sustainability and enterprise risk governance arrangements, consistent with the approach described in the Risk management section of the Sustainability report.

In exercising oversight, the Board and ARC evaluate the trade-offs associated with enterprise level strategic risks, as part of ERMF decision-making, risk-appetite setting, and capital allocation. These deliberations are informed by management reporting under the ERMF, which assesses risks based on likelihood, consequence, and potential financial impacts across short-, medium- and long-term horizons. The ARC Chair reports material matters to the full Board through standard Board reporting processes quarterly, ensuring the Board remains informed of key climate-related developments consistent with its oversight responsibilities.

Skills and capacity building

The Board ensures it has the skills and competencies to oversee climate-related risks and opportunities through a combination of relevant director experience in risk and compliance and targeted capability-building. During the year, Directors received a deep-dive briefing on sustainability-related risks and opportunities, including outputs from the DMA. The Board and ARC also draw on Telix's internal subject-matter experts from Operations, Finance, Risk and Sustainability for technical climate-related insights. These mechanisms enable the Board to maintain the oversight capability necessary to respond to climate-related risks.

Management roles and delegation

Responsibility for implementing Telix's sustainability strategy, including the management of climate-related risks and opportunities, is delegated by the Board to the Group Executive Team ("GET"), which integrates climate-related considerations into business planning and operations, via the enterprise risk management processes. At the operational level, climate-related risks are managed through Telix's ERMF in accordance with the Enterprise Risk Management Policy and Procedure. These risks are captured within the "Environment" strategic risk category and are identified, assessed, escalated, and monitored through business unit risk registers, management controls, and formal reporting processes. This work is supported by the cross-functional Sustainability Working Group ("SWG"), which coordinates sustainability initiatives, supports risk identification, and ensures alignment with reporting and assurance requirements.

Management responsibility for climate-related risks is delegated through the enterprise leadership structure. The Senior Vice President (SVP), Risk, Sustainability, and Environmental Affairs is accountable for the enterprise-wide risk program and coordinates inputs from functional subject-matter experts across Operations, Finance, Risk and Sustainability. The Director of Global Sustainability prepares climate-related materials for ARC review, with oversight from the CFO, SVP Risk, Sustainability, and Environmental Affairs and the Company Secretary as part of established Board-paper governance processes. Climate-related risks are reviewed with operational and finance leadership through existing management forums and escalated to the ARC in line with the ERMF; the MD & CEO, receives these updates concurrently.

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Targets, monitoring and remuneration

While Telix has not yet set climate-related targets, the ARC has commenced oversight of their development. In 2025, the ARC reviewed the Company's first full-year GHG emissions baseline and requested a GHG reduction roadmap and cross-functional implementation plans to inform future target-setting. Executive remuneration for 2025 does not include climate-related performance metrics. Following the establishment of climate-related targets, Telix will consider the incorporation of relevant climate-related KPIs into short- and long-term incentive arrangements to align executive accountability with the Company's decarbonization strategy.

Ethics and transparency

Telix's governance model prioritizes integrity and transparency in all its reporting. The Company follows its Code of Conduct, Whistleblower Protection Policy, and Anti-Bribery and Anti-Corruption Policy.

Climate-related risks - Analysis

Scenario framework

Telix conducted the climate scenario analysis in 2025. To ensure consistency across all climate-related risk assessments in this report, Telix applied a single, common set of climate-related scenarios to evaluate both transition and physical risks. Two internationally recognized pathways were used for all analyses: a ~1.5°C lower-warming scenario aligned with the Intergovernmental Panel on Climate Change (IPCC) AR6 SSP1-1.19 pathway, which reflects rapid global decarbonization consistent with the temperature-stabilization objective of the Paris Agreement; and a ~2.5+°C higher-warming scenario aligned with the IPCC AR6 SSP2-4.5 pathway, representing delayed global policy action, continued dependence on fossil fuels, and significantly heightened physical-hazard intensification. These scenarios draw on widely used global reference frameworks, including IPCC assessments and comparable datasets used in regulatory and financial-sector scenario analysis. Together, they bracket a plausible range of future climate conditions through 2050 and provide a consistent basis for assessing Telix's resilience, anticipated financial effects, and adaptive capacity across all identified climate-related risks.

For the purposes of anticipated financial impacts, Telix applies a business-as-usual ("BAU") operating scenario, reflecting current regulatory settings, observed historical disruption patterns, and management's forward view of expected operating conditions across the short-, medium- and long-term. This BAU scenario represents Telix's best estimate of expected conditions absent accelerated global climate-policy change and is therefore separate from, aligned with IPCC AR6 SSP5-8.5.

Extreme climate events (acute physical risk)

Telix's exposure has increased following expansion of its owned manufacturing and distribution footprint, including the U.S. radiopharmacy network. Intensified rainfall or flooding could damage infrastructure or render transport routes impassable, while storms or heatwaves could cause power outages affecting temperature-controlled storage. Such events may lead to production delays, emergency logistics costs, and potential lost revenue if Telix is unable to supply hospitals and patients on time.

Scope and boundary

Operations included:

- Site-level modelling for U.S. radiopharmacies, including last-mile distribution.
- Belgium manufacturing and Japan operations are qualitatively assessed using the same hazard framework. Revenue and operating data was unavailable for these sites as they were still being commissioned for Telix's manufacturing.

Across Telix's footprint, a conservative approach was used for the analysis considering 100% of manufacturing and distribution sites exposure to extreme-weather-related disruption risk under the physical-hazard scenarios assessed. Manufacturing sites represent approximately 65% of Telix's operational footprint, with the remainder comprising R&D facilities and office locations, which also face varying degrees of exposure to climate-related hazards, which could result in potential indirect enterprise financial impacts.

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Approach, assumptions and uncertainties

Topic	Description
Methodology	• Analysis draws on observed historical disruption data from U.S. radiopharmacy sites, supplemented with regional physical-climate hazard drivers (including extreme precipitation, storm patterns, and days exceeding 95°F). • Intensity and duration multipliers are applied to historical disruption effects, and sensitivity banding is used to bracket outcomes under intensity-dominant and frequency-dominant futures.
Key assumptions	• Analysis is performed on a gross (pre-mitigation) basis, without reflecting planned resilience measures, to provide a transparent view of inherent physical-risk exposure. • Historical disruption data are assumed to be an appropriate indicator of operational sensitivity, with conservative imputation applied where observed disruption is incomplete or where historical data set is limited.
Principal uncertainties	• Event frequency and clustering can vary materially by geography and year, which could influence the effective factors in the medium- to long-term. • Insurance, market capacity and pricing trends may amplify or moderate cost outcomes that are not fully captured by historical ratios. • Local infrastructure resilience and regulatory responses may alter disruption duration and cost structures.

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Current effects

No material asset impairments occurred in 2025. Observed effects were short-duration operational disruptions and localized expense volatility in the U.S. radiopharmacy network. Based on historical data the aggregated annual loss of revenue due to extreme weather events is approximately 0.35-0.4% of total enterprise revenue. Similarly the aggregated annual impact on manufacturing and distribution costs is approximately 1.3-1.4%.

Anticipated effects under BAU

Impact type	Short-term	Medium-term	Long-term
Expected conditions	Continue to expect similar weather patterns and financial effects as 2025.	Frequency and scale of events expected to rise gradually.	Increased risk of logistical delays and power interruptions expected. Greater volatility due to hazard intensification.
Revenue	0.35-0.4% of total enterprise revenue.	0.4-0.5% of total enterprise revenue.	0.5-0.6% of total enterprise revenue.
Manufacturing and distribution costs	1.3-1.4% of manufacturing and distribution costs.	1.4-1.5% of manufacturing and distribution costs. Costs attributed to increase in extreme weather events and increase in capital expenditure for resilience upgrades.	1.8-1.9% of manufacturing and distribution costs with greater volatility in costs and additional resilience needs and redundancy expenses.
Insurance/financing	Slight increase in insurance premiums or deductibles could be expected.	Possible tightening of coverage terms.	In addition to the short- and medium-term effects, insurance providers available in extreme weather regions will potentially reduce.
Impact on business strategy and business model	Physical climate risks are expected to continue causing localized, short-duration operational disruptions, primarily in the U.S. radiopharmacy network, with no material impact on assets or fundamental business model. Telix may increase focus on emergency logistics and short-cycle operational adjustments.	As Belgian and Japanese operations scale, heatwaves, storms, and extreme precipitation may introduce incremental operating expenditure (e.g., cooling-energy loads, temporary logistics delays). These effects remain modest but begin influencing capital allocation priorities, including targeted resilience upgrades (e.g., improved temperature control, drainage improvements).	Intensifying hazards may drive progressive integration of climate resilience into manufacturing design and supply-chain planning, potentially requiring additional redundancy, hardened infrastructure, and backup-power solutions. While the core business model remains intact, resilience needs increasingly shape how Telix designs, invests in, and operates its global network.

As non-U.S. operations are still building out manufacturing and distribution capacity, quantification is not available in this cycle. A qualitative assessment based on publicly available regional data indicates that physical climate risks such as heatwaves, storms and extreme precipitation may cause short-duration disruptions in Belgium and Japan. While no material asset impairments are expected, Telix anticipates potential increases in operating expenditure (e.g., higher cooling-energy loads, temporary logistics delays) and possible rises in business-interruption costs over the medium- to

long-term. These impacts are expected to remain modest but may lead to incremental resilience-related capital expenses over time (e.g., temperature control system upgrades, backup power, logistics redundancy).

Climate scenario analysis

Scenario	Short-term	Medium-term	Long-term
~1.5°C lower-warming scenario, aligned with the temperature-stabilization objective of the Paris Agreement	0.35-0.4% of total enterprise revenue. 1.3-1.4% of manufacturing and distribution costs.	0.25-0.3% of total enterprise revenue. 1-1.2% of manufacturing and distribution costs.	0.3-0.35% of total enterprise revenue. 1-1.2% of manufacturing and distribution costs.
~2.5+°C higher-warming scenario, reflecting delayed global policy action and greater physical-hazard intensification	0.35-0.4% of total enterprise revenue. 1.3-1.4% of manufacturing and distribution costs.	0.3-0.35% of total enterprise revenue. 1-1.2% of manufacturing and distribution costs.	0.3-0.35% of total enterprise revenue. 1.2-1.5% of manufacturing and distribution costs.
Impact on business strategy and business model	Limited, manageable operational adjustments: localized resilience measures, short-cycle cost controls, and adjustments to logistics and workforce planning.	Strategic shifts begin: capital allocation influenced by energy-cost exposure; increased adoption of lower-emission assets; resilience and supply-chain continuity planning incorporated into the operating model.	Structural business-model evolution: manufacturing footprint and logistics redesigned for energy cost stability; investment in zero-carbon energy, automation, and climate-resilient infrastructure; fleet fully transitioned to low- or no-emission technologies.

Strategy, actions and resourcing

The Group's response emphasizes operational resilience and disciplined capital allocation. Current actions include emergency-logistics playbooks, redundant inventory to buffer supply disruptions, protection of critical IT, and carrier diversification with route flexibility. Anticipated actions include phased facility hardening (for example, drainage improvements and elevation of critical equipment) at higher-risk sites. Inventory and service-level adjustments will be calibrated to regulatory and shelf-life constraints. An ongoing focused business resiliency review has identified exposure points where extreme events can give rise to financial effects (e.g., isotope supply timing, packaging integrity, temperature-controlled carriers, regional hubs and hospital delivery windows). These insights were used to inform risk identification.

Activities are resourced through operating budgets, targeted resilience investments are expected to be considered within capital plans. Execution is expected to be supported by operating cash flow; insurance recoveries may apply where relevant; no material disposals are currently committed.

Climate resilience and capacity to adapt

Telix's resilience to climate-related physical and transition risks is supported by the Group's financial flexibility, the adaptability of its asset base, and current and planned resilience measures.

Financial resources and flexibility

Short-term: Telix maintains sufficient liquidity to absorb short-duration cost volatility associated with acute weather disruptions or changes in electricity and natural-gas prices. Cash and cash equivalents and positive net working capital enable Telix to fund temporary spikes in logistics, operating expenses, or facility repairs without material changes to strategy.

Medium-term: As manufacturing capacity scales in Belgium and Japan and as multiple cyclotrons are commissioned, energy-price exposure will increase. Telix's financial resources allow the Group to fund targeted upgrades such as backup-power enhancements and efficiency measures to manage increased energy intake and cost volatility under both the ~1.5°C and ~2.5+°C scenarios.

Long-term: Over extended horizons, intensifying physical hazards and transitioning energy systems may require continued modernization of facilities and expansion of resilience measures. Telix expects to meet these needs primarily through operating cash flows, with financing flexibility available as required. Even under higher-volatility scenarios, the Group's capital structure provides adequate capacity to continue adapting its operations.

Ability to repurpose/upgrade/decommission assets

Short-term: Radiopharmacy sites are modular and can be upgraded with limited disruption, enabling quick implementation of measures such as elevating critical equipment, improving drainage, or adding backup-power capability.

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Medium term: The staged construction and cyclotron replacement program at the Belgium manufacturing facility demonstrates the Group's capability to modify complex assets as operational risk profiles evolve. As non-U.S. manufacturing capacity scales, Telix can incorporate additional reliability, ventilation, and temperature-control enhancements where needed.

Long term: The decentralized operating model provides strategic flexibility. Over longer horizons, Telix retains the optionality to repurpose, expand, or relocate selected sites if physical-risk thresholds or energy-system changes warrant adjustments to the global footprint.

Effect of mitigation/adaptation investments

Telix does not currently operate dedicated resilience or climate-adaptation investment programs; however, several operational measures are already in place, such as facility inventory redundancy and emergency generators, which provide a stabilizing effect by reducing disruption duration and maintaining service continuity during acute weather events. Planned investments, including phased facility hardening at higher-exposure sites (e.g., drainage improvements, elevation of critical equipment, and backup-power enhancements), are expected to moderate event-period operating expense spikes and reduce long-term interruption risks as physical hazards intensify. These measures collectively improve Telix's ability to absorb short-duration shocks and manage operational volatility across the medium- to long-term.

Energy dependency (transition risk)

Energy dependency represents a climate-related transition risk for the Group arising from reliance on electricity and natural gas in the context of evolving climate policy, decarbonization of energy systems, and energy-market volatility. Energy is a critical input to manufacturing activities, radiopharmaceutical production, cold-chain logistics, and office operations. Changes in energy prices, supply conditions, and policy settings may affect operating costs, cost volatility, and service continuity.

Scope and boundary

The assessment covers all Telix-operated facilities, including radiopharmacies, manufacturing and distribution facilities (including those still undergoing capacity expansion), offices, and R&D locations.

Energy dependency includes exposure associated with electricity use and natural-gas consumption across the Group's global operating footprint. Where energy is directly metered or billed, actual usage data are applied. For smaller or co-located facilities where monthly rental charges include utilities and metered data are not available, energy consumption is estimated based on facility characteristics, including floor area, facility use type, jurisdiction-appropriate energy-intensity factors, and operating hours. This approach ensures consistent coverage of all sites while reflecting data availability across the portfolio.

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Approach, assumptions and uncertainties

Topic	Description
Methodology	• The Group conducted a structured assessment of energy dependency across all operated facilities, evaluating exposure to electricity and natural-gas markets across the short-, medium- and long-term. • Analysis incorporated site-level 2025 baselines, including electricity and natural-gas use and related cost shares. • Facility-level BAU trajectories and scenario-based cost projections were modeled using regional wholesale/retail price pathways, carbon-policy drivers, and country-specific energy-market assumptions, with uplift factors applied consistently across buildings and fleet-fuel use.
Key assumptions	• Energy prices reflect regional market dynamics, national decarbonization policies and embedded carbon-pricing mechanisms. • Electricity and fuel costs under the scenarios evaluated are assumed to increase at differentiated rates corresponding to orderly versus disorderly transition pathways. • Facility energy consumption was assumed to grow in line with operational expansion, particularly cyclotron operation and increased radiopharmacy activity, while per-unit consumption efficiency remains stable absent specific mitigation actions. • BAU costs were projected using consistent 2025 $US/kWh normalization across all modeled years. • Consumption volumes were held constant for scenario modelling, with cost variances driven solely by projected price changes.
Principal uncertainties	• Uncertainty arises from the timing, scale and design of future climate-policy changes, shifts in energy-market structure, national carbon-pricing mechanisms, and the speed of energy-system transformation. • Additional uncertainty relates to wholesale price volatility in regions critical to Telix (Belgium, Australia, U.S., Japan), potential divergence between regulated tariffs and market prices, and unforeseen changes in fuel-supply conditions. • Facility-level uncertainty includes operational variability as the manufacturing footprint expands and site-specific energy intensity evolves.

Current effects

Energy costs represented approximately 6% of total manufacturing and distribution costs in 2025. Vehicle fuel represented an additional approximately 2% of total manufacturing and distribution costs in the same year. No jurisdictions in Telix's operating footprint currently impose additional standalone carbon taxes on purchased electricity or fuels beyond those already reflected in market prices.

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Anticipated effects under BAU

Impact type	Short-term	Medium-term	Long-term
Expected conditions	Near-term installation of cyclotrons, which will increase energy intake. Continue to expect similar fuel prices as FY2025. No carbon taxes or fees expected in this period.	Continued capacity building will increase energy intake. Additionally, cost of electricity expected to rise at key sites, especially in Belgium, Australia and Japan.	Bringing manufacturing and distribution capacity in-house will support long-term corporate strategy, but will continue to impact energy consumption in the form of increases, and thus impact energy costs. Costs of conventional energy predicted to rise globally, however renewable sources expected to reach economic scale.
Facilities energy consumption	10-15% of manufacturing and distribution costs.	35-40% of manufacturing and distribution costs.	45-50% of manufacturing and distribution costs.
Vehicle fuel consumption	2-2.5% of manufacturing and distribution costs.	2.5-3% of manufacturing and distribution costs.	3-3.35% of manufacturing and distribution costs.
Impact on business strategy and business model	Rising energy intake due to cyclotron installation and radiopharmacy expansion increases cost exposure but does not alter strategy materially. Telix focuses on energy-efficiency measures, facility-level reliability enhancements, and fleet optimization to manage near-term volatility.	Continued expansion of manufacturing capacity and rising electricity prices at key sites (Belgium, Australia, Japan) increase reliance on cost-management, procurement flexibility, and energy-reliability planning.	Increasing global energy prices and higher electricity demand shape strategic planning for facility design, long-term energy sourcing, and reliability. While BAU assumes no new standalone carbon taxes, energy-system trends may drive greater emphasis on efficiency upgrades, backup systems, and strategic procurement frameworks, influencing how Telix optimizes its global footprint.

Across Telix's global operations, carbon-pricing mechanisms, where they exist, are embedded within electricity and fuel prices rather than applied as separate charges. In the medium- and long-term, the primary sources of carbon-related cost exposure arise from national or regional emissions-trading schemes that influence wholesale energy markets.

In the European Union (EU), electricity prices incorporate costs from the EU Emissions Trading System ("ETS"), and from 2027 the new EU ETS2 will apply to natural gas and other heating fuels through upstream fuel suppliers, affecting end-user fuel prices. Japan will introduce a mandatory Green Transformation-ETS from FY 2026 and a fossil-fuel levy from FY 2028, with associated costs reflected in electricity and fuel markets. Australia operates the Safeguard Mechanism for large emitters; any associated carbon-compliance costs are incorporated into facility operations and electricity market pricing. In Canada, the federal consumer fuel charge has been set to zero as of April 2025, with the Output-Based Pricing System remaining in place for large industrial facilities; compliance obligations apply only to covered emitters and do not create separate carbon costs on electricity or fuels.

Overall, Telix's Scope 1 and Scope 2 emissions-related cost exposure is driven by these embedded carbon costs within electricity and fuel prices, alongside facility-specific compliance obligations where industrial carbon-pricing systems apply.

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Climate scenario analysis

Scenario	Short-term	Medium-term	Long-term
~1.5°C lower-warming scenario, aligned with the temperature-stabilization objective of the Paris Agreement	Facilities energy consumption 10-15% of manufacturing and distribution costs. Vehicle fuel consumption 2-2.5% of manufacturing and distribution costs.	Facilities energy consumption approximately 20% of manufacturing and distribution costs. Vehicle fuel consumption 2-2.5% of manufacturing and distribution costs.	Facilities energy consumption approximately 20% of manufacturing and distribution costs. Vehicle fuel consumption 2-2.5% of manufacturing and distribution costs.
~2.5+°C higher-warming scenario, reflecting delayed global policy action and greater physical-hazard intensification	Facilities energy consumption 10-15% of manufacturing and distribution costs. Vehicle fuel consumption 2-2.5% of manufacturing and distribution costs.	Facilities energy consumption approximately 20-25% of manufacturing and distribution costs. Vehicle fuel consumption 2.5-3% of manufacturing and distribution costs.	Facilities energy consumption approximately 30% of manufacturing and distribution costs. Vehicle fuel consumption 3-3.5% of manufacturing and distribution costs.
Impact on business strategy and business model	Limited near-term adjustments: focus on energy-efficiency measures and fleet optimization.	Strategic shifts begin: capital allocation influenced by energy-cost exposure; increased adoption of lower-emission assets; resilience and supply-chain continuity planning incorporated into the operating model.	Structural business-model evolution: manufacturing footprint and logistics redesigned for energy cost stability; investment in climate-resilient infrastructure; fleet fully transitioned to low- or no-emission technologies.

Strategy, actions and resourcing

Telix's response to energy-transition risk emphasizes operational resilience, cost discipline, and procurement flexibility. The Group integrates operating-cost and energy-reliability considerations into its facility-management processes, including planning for the increased electricity and natural-gas consumption associated with expanding manufacturing capacity, cyclotron installations, and temperature-controlled logistics.

The Group does not operate a separate, dedicated energy-transition investment program; however, energy-related risks are increasingly considered within business planning cycles. Site-level improvements—such as backup-power enhancements and temperature-controlled systems are evaluated for implementation through normal operating budgets or incorporated into broader capital-planning processes. Resourcing will be supported by operating cash flows, liquidity reserves, and existing financing arrangements. These resources enable Telix to absorb near-term energy-price volatility and invest in incremental efficiency or resilience upgrades where these provide long-term cost stability or support operational continuity.

Climate resilience and capacity to adapt

Telix's capacity to adapt to transition-related energy risks reflects the availability of financial resources, the flexibility of its asset base, and both current and planned mitigation measures.

Financial resources and flexibility:

Short-term: Telix maintains adequate liquidity to manage near-term volatility in electricity and natural-gas prices. Cash reserves and positive net working capital allow the Group to absorb cost increases associated with the commissioning of new cyclotrons and expanding radiopharmacy operations without structural changes to its business model.

Medium-term: As energy consumption increases with the expansion of manufacturing capacity in Belgium and Japan, Telix's financial resources support investment in site-level efficiency improvements and reliability measures such as temperature-control modernization, backup-power upgrades, and energy-management improvements to mitigate rising exposure under both the ~1.5°C and ~2.5+°C climate-policy scenarios.

Long-term: Over longer horizons, transition-policy developments and structural changes in global electricity markets may require continued adaptation. Telix's balance sheet and financing capacity provide flexibility to respond to higher energy-price volatility, invest in resilience technologies, and support diversification of energy sourcing where feasible.

Ability to repurpose/upgrade/decommission assets:

Short-term: Radiopharmacy sites and key logistics hubs are modular, enabling targeted upgrades to improve energy efficiency and reliability such as improved insulation, HVAC optimization, and enhanced power-backup capabilities without major operational disruption.

Medium-term: The Belgium facility, including phased cyclotron installation and replacement, demonstrates Telix's ability to modify complex energy-intensive assets as operating needs evolve. As additional manufacturing capacity comes

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online, facilities can incorporate improved energy-monitoring systems, heat-management solutions, and redundancy to respond to changing energy-system conditions.

Long-term: If long-term electricity-market conditions or transition policies materially alter operating cost profiles in specific geographies, Telix retains the ability to repurpose, expand, or relocate specific facilities to maintain competitiveness. The decentralized network model provides strategic flexibility to rebalance the operating footprint as needed.

Effect of mitigation/adaptation investments:

Although Telix does not operate a dedicated climate-adaptation capital program, several operational measures already provide a stabilizing effect on energy-related risk exposure by maintaining service continuity and moderating operational volatility. Scenario modelling shows Telix is more resilient under an orderly ~1.5°C transition pathway, where energy-price escalation is gradual and volatility is relatively contained. Under a ~2.5+°C higher-warming scenario, energy-market volatility increases due to policy uncertainty and physical-system stress, amplifying operating-cost exposure. Even under this higher-warming pathway, Telix's combination of financial flexibility, procurement optionality, and scalable site-level adaptation measures positions the Group to maintain operational continuity and manage energy-transition risks across short-, medium-, and long-term horizons.

Conclusion

Climate-related transition plan

Telix does not have a climate-related transition plan. Accordingly, no transition-plan assumptions, dependencies, or decarbonization pathways are included beyond those inherent in the scenario analysis. Telix continues to integrate climate-risk considerations into business-planning cycles and will evaluate whether a formal transition plan becomes necessary as manufacturing expansion progresses.

Assessment of potential material adjustments to asset and liability values

Based on the climate-related risk assessments and scenario analysis undertaken, including modelling of acute physical hazards and transition-related energy impacts, Telix has not identified any climate-related risks that are expected to result in material adjustments to the carrying amounts of assets or liabilities within the next annual reporting period.

Metrics and targets

Overview

2025 marks Telix's first full year of comprehensive greenhouse gas (GHG) measurement under a high-integrity sustainability framework. The Company quantified Scope 1 and Scope 2 emissions across its global footprint of more than 50 leased and owned office and laboratory sites, applying the GHG Protocol's Operational Control approach to ensure all material emissions sources are captured.

Scope 1 and 2 GHG emissions

Metric	2025 (t CO_2-e)	Coverage / Boundary	Methodology reference
Scope 1 – Direct Emissions	3,750.32	Fuel use from company vehicles, onsite combustion and refrigeration fugitive emissions	GHG Protocol (2004); Operational Control Approach
Scope 2 – Indirect Emissions (location-based)	3,405.14	Purchased electricity across owned and leased sites	GHG Protocol (2004); Operational Control Approach, National Grid Factors
Total Scope 1 + 2 Emissions (Baseline)	**7,155.46**	**Global operations (Australia, U.S., Europe, Asia)**	

Note: As 2025 represents Telix's first baseline year for GHG reporting, prior periods are not presented because emissions were not quantified or subject to assurance in previous years.

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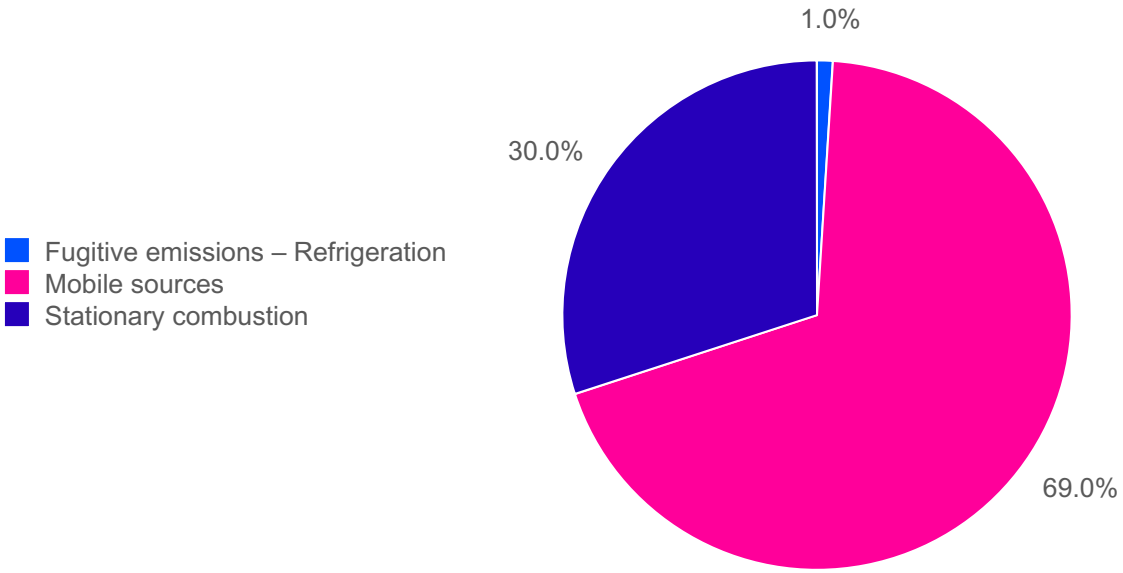
Scope 1 Contributions by Source



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Measurement approach

Telix quantifies Scope 1 and Scope 2 greenhouse gas emissions in accordance with the GHG Protocol using an Operational Control boundary. Under this approach, Telix accounts for 100% of emissions from facilities where it has operational control, including more than 50 owned or leased offices and laboratories across Australia, Europe, Asia, and the U.S. All GHG emissions-related data is managed using a third party emissions management tool called Workiva Carbon.

Emissions are calculated from four primary source categories:

Scope 1:

- Stationary combustion (natural gas)
- Mobile combustion (gasoline/petrol)
- Fugitive emissions (refrigerants)

Scope 2:

- Purchased electricity (location-based) as the primary contributor

Where actual activity data is available such as, electricity invoices, natural gas invoices, or vehicle fuel spend, the Company uses this data directly. Where actual data is unavailable, Telix applies structured estimation methodologies developed within the Workiva Carbon platform, including the 2025 Building Estimation Tool and the Refrigerant Leakage Estimator. These tools allow Telix to estimate consumption, leakage, refrigerant type and capacities. They do so by selecting energy intensity factors, sourced from a variety of location-specific databases, based on facility-specific factors such as area, location, climate zone, operating days, and equipment quantities. For mobile combustion, where fuel-volume data is unavailable, Telix estimates gasoline consumption by converting fleet fuel spend into gallons using historic U.S. average gasoline prices sourced from the U.S. Energy Information Administration ("EIA").

Emission factor sources

Database / Organization	Region / Application	Used For
U.S. Environmental Protection Agency (EPA) – GHG Factors (2024)	U.S.	Stationary combustion (natural gas), electricity and mobile combustion
EPA eGRID (2022)	U.S.	Electricity
International Energy Agency (IEA) (2023)	Global	Electricity
Australian National Greenhouse Accounts (NGA) (2023)	Australia	Natural gas; electricity
Department for Business, Energy, and Industrial Strategy (DBEIS) - GHG Conversion Factors (2023)	UK	Natural gas; electricity
U.S. EIA	U.S.	Mobile sources (gasoline prices)
California Air Resources Board (CARB)	U.S. California	Refrigerants
The Climate Registry (TCR) (2022)	North America	Refrigerants
Honeywell® & 3M® Technical Refrigerant Sources (2022)	Global	Refrigerant GWP and leakage assumptions

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Inputs and assumptions

The calculation of Telix's Scope 1 and Scope 2 emissions relies on a consistent set of inputs and assumptions that support transparency, completeness, and auditability as required under the GHG Protocol and AASB S2. These inputs define how activity data, estimation models, and emission factors are applied across Telix's global operations.

Data inputs: Actual versus estimated activity data

Telix uses a hierarchical data approach:

- Primary input: Actual activity data (utility invoices, metered consumption, fleet fuel spend, and recorded asset usage) wherever available.
- Secondary input: Estimated activity data when actual data is unavailable, incomplete, or cannot be obtained due to the constraints of leased facilities.
- In 2025, 26% of electricity and 55% of natural gas activity data were estimated; 100% of refrigerant data was estimated.

Key assumptions underpinning estimation models

When estimation is required, calculation tools embedded in Workiva Carbon apply a set of standardized assumptions designed to approximate consumption, leakage refrigerant type and capacities reasonably, conservatively, and consistently:

Facility Operational assumptions:

- Operating days and operating months determine the proportion of annual consumption attributable to a site.
- Assumptions reflect actual operating patterns, not calendar averages.

Building characteristics:

- Facility area (square footage/meters) is used as the scaling variable for estimating electricity, natural gas, and refrigerant capacity.
- Building type (office vs. laboratory) is assumed to determine relative intensity because laboratories have higher HVAC and equipment loads.

Equipment and refrigerant assumptions:

- Refrigerant charges and leakage rates are derived from typical equipment profiles, not Telix-specific asset-level data.
- Assumptions incorporate typical annual leakage rates, equipment counts, and refrigerant capacity per area, aligned with the Workiva 2025 Refrigerant Leakage Estimator.

These assumptions reflect industry norms and are documented to support assurance.

Intensity and conversion assumptions:

Where actual consumption data is missing, Telix uses region-appropriate intensity factors, which embed assumptions related to:

- Climate zone.
- Local heating/cooling load profiles.
- Energy mix characteristics.
- Typical consumption levels for similar building types in the region.

These factors are sourced from reliable national datasets listed in the Emissions factors source table. The assumption is that similarly sized buildings in similar climate conditions exhibit comparable electricity and natural gas demand.

Spend-based assumptions (mobile combustion):

For fleet emissions, Telix assumes:

- All recorded fuel spend corresponds to standard gasoline/petrol purchased for fleet vehicles.
- Fuel spend can be converted to gallons using U.S. average gasoline prices from the U.S. Energy Information Administration.
- No adjustments are made for variations in fuel grade or regional price deviations.

Emission factor and GWP assumptions:

- Published regional factors (e.g., NGA, DBEIS, EPA) accurately represent emissions per unit of consumption in those regions.
- Refrigerant factors from CARB, TCR, 3M, and Honeywell reflect valid GWP and leakage characteristics.
- Where regional emission factors are already expressed in CO_2-e and not by gas type, Telix assumes the factor reflects the appropriate underlying GWP basis and uses the factor as published.

Additional metrics

Climate targets and roadmap

Telix recognizes the importance of setting credible, science-aligned climate targets. In 2025, Telix completed its first full GHG inventory across Scope 1 and Scope 2 categories, supported by independent data assurance. This inaugural inventory establishes a robust baseline that will serve as the foundation for future target-setting.

At this stage, Telix has not set quantitative emissions reduction targets. This decision reflects our commitment to accuracy and integrity: targets will be informed by a complete year of verified data and a comprehensive understanding of our emissions profile. Using this benchmark, we will develop a GHG reduction roadmap in 2026, aligned with science-based methodologies and international frameworks such as the Science Based Targets initiative ("SBTi").

Our roadmap will:

- Define short-, medium-, and long-term decarbonization pathways.
- Prioritize operational efficiency, renewable energy sourcing, and value-chain engagement.
- Include interim milestones and governance oversight to ensure accountability.

We believe this phased approach - benchmarking first, then target-setting - ensures that our commitments are credible, achievable, and aligned with stakeholder expectations and regulatory requirements.

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Amount and percentages exposed to climate-related risks and opportunities

Metric	Amount (US$'000)	Percentage	Judgments
Assets or business activities vulnerable to climate-related physical risks	332,125	62 %	Telix operated manufacturing and distribution, which are most impacted by physical risks, are currently at U.S. assets. Non-current assets used as indicator of exposure.
Assets or business activities vulnerable to climate-related transition risks	206,146	38 %	Transition policy most advanced in non-U.S. jurisdictions with Telix operations. Non-current assets used as indicator of exposure.
Assets or business activities aligned with climate-related opportunities	—	—	As Telix is at the early stages of climate-related mitigations, it currently does not have assets that can provide an advantage or opportunity from this perspective. Looking forward, this is expected to change as mitigations and proactive actions are enacted.
Amount of capital expenditure, financing or investment deployed towards climate-related risks and opportunities	—	—	2025 was the first year Telix has identified and stewarded financially material climate-related risks and opportunities. These risks and opportunities will drive capital planning and investments in the future.

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Carbon credits

Telix did not use carbon credits or offsets to offset 2025 emissions data. Our priority is to reduce emissions through operational improvements and value-chain engagement. Once targets are established, we will evaluate the role of high-quality carbon credits within a broader decarbonization strategy, ensuring any future use adheres to recognized standards for quality, permanence, and transparency.

By deferring offset use until targets are set, Telix ensures that future commitments are grounded in accurate data and credible reduction strategies rather than relying on offsets as a substitute for operational improvements.

Internal carbon pricing

Telix does not currently apply an internal carbon price. During 2026, the Company will evaluate the adoption of an internal cost of carbon to support capital allocation, scenario analysis, and assessment of climate-related financial risks and opportunities.

Any future adoption of an internal carbon price will be disclosed in accordance with AASB S2.

Directors' declaration

The directors of Telix Pharmaceuticals Limited declare that, in their opinion, Telix Pharmaceuticals Limited has taken reasonable steps to ensure that the substantive provisions of Telix Pharmaceuticals Limited's Sustainability report for the year ended December 31, 2025 set out on pages 19 to 37 are in accordance with the Corporations Act 2001 (Cth) ("the Act") including section 296C of the Act (compliance with applicable sustainability standards such as the Australian Sustainability Reporting Standard AASB S2 Climate-related Disclosures) and section 296D of the Act (climate statement disclosures).

This declaration is made on February 20, 2026 in accordance with a resolution of the board of directors of Telix Pharmaceuticals Limited, and is signed for and on behalf of the board of directors by:

Mark Nelson	Christian Behrenbruch
Interim Chair	Managing Director and Group CEO
February 20, 2026	February 20, 2026

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Independent Auditor's Review Report on specified Sustainability Disclosures

To the Members of Telix Pharmaceuticals Limited

Review Conclusion

We have conducted a review of the following specified Sustainability Disclosures in the Sustainability Report of Telix Pharmaceuticals Limited (the Company) and its controlled entities (together, the Group) for the year ended December 31, 2025, as required by Australian Standard on Sustainability Assurance ASSA 5010 *Timeline for Audits and Reviews of Information in Sustainability Reports under the Corporations Act 2001* issued by the Auditing and Assurance Standards Board (AUASB):

Sustainability Disclosures	**Reporting requirement of Australian Sustainability Reporting Standard AASB S2 *Climate-related Disclosures* (AASB S2) (including related general disclosures required by Appendix D)**	**Location in Sustainability Report[1]**
Governance	Paragraph 6	'Governance' section on pages 24 to 25
Strategy (risks and opportunities)	Subparagraphs 9(a), 10(a) and 10(b)	'Climate-related financial risks and opportunities' section on pages 22 to 23.
Scope 1 and 2 emissions	Subparagraphs 29(a)(i)(1) to (2) and 29(a)(ii) to (v)	'Metrics and targets' section on pages 32 to 35

The requirements of AASB S2 identified in the table above form the criteria relevant to the specified Sustainability Disclosures and apply under Division 1 of Part 2M.3 of the *Corporations Act 2001* (the Act).

We have not become aware of any matter in the course of our review that makes us believe that the Sustainability Disclosures specified in the table above do not comply with Division 1 of Part 2M.3 of the *Corporations Act 2001*.

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Basis for Conclusion

Our review has been conducted in accordance with Australian Standard on Sustainability Assurance ASSA 5000 *General Requirements for Sustainability Assurance Engagements* (ASSA 5000) issued by the AUASB. Our review includes obtaining limited assurance about whether the specified Sustainability Disclosures are free from material misstatement.

In applying the relevant criteria, we note that subsection 296C(1) of the Act includes a requirement to comply with AASB S2.

Our conclusion is based on the procedures we have performed and the evidence we have obtained in accordance with ASSA 5000. The procedures in a review vary in nature and timing from, and are less in extent than for, an audit. Consequently, the level of assurance obtained in a review is substantially lower than the assurance that would have been obtained had an audit been performed. See the 'Summary of the Work Performed' section of our report below.

Our responsibilities under ASSA 5000 are further described in the Auditor's Responsibilities section of this report.

We are independent of the Company in accordance with the applicable ethical requirements of APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* issued by the Accounting Professional & Ethical Standards Board Limited (November 2018 incorporating all amendments to June 2024) (the Code), together with the ethical requirements in the Act, that are relevant to our review of the specified Sustainability Disclosures. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Our firm applies Australian Standard on Quality Management ASQM 1 *Quality Management for Firms that Perform Audits or Reviews of Financial Reports and Other Financial Information, or Other Assurance or Related Services Engagements*, which requires the firm to design, implement and operate a system of quality management, including policies and procedures regarding compliance with ethical requirements, professional standards, and applicable legal and regulatory requirements.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our conclusion.

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Other Information

The directors of the Company are responsible for the other information. The other information comprises the information included in the Group's Sustainability Report for the year ended December 31, 2025, but does not include the specified Sustainability Disclosures and our auditor's report thereon.

Our conclusion on the specified Sustainability Disclosures does not cover the other information and we do not express any form of assurance conclusion thereon. We have issued a separate opinion on the Financial Report including the Remuneration Report included in the Annual Report.

In connection with our review of the specified Sustainability Disclosures, our responsibility is to read the other information identified above and, in doing so, consider whether the other information is materially inconsistent with the specified Sustainability Disclosures, or our knowledge obtained when conducting the review, or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities for the specified Sustainability Disclosures

The directors of the Company are responsible for:

- The preparation of the specified Sustainability Disclosures in accordance with the Act; and
- Designing, implementing and maintaining such internal control necessary to enable the preparation of the specified Sustainability Disclosures, in accordance with the Act that are free from material misstatement, whether due to fraud or error.

Inherent Limitations in preparing the specified Sustainability Disclosures

Sustainability information may be subject to more inherent limitations than financial information, given both its nature and the methods used for determining, calculating, and estimating such information. Different acceptable methods have varying precision and can affect the comparability of sustainability information across entities and over time.

In addition, greenhouse gas emissions quantification is subject to inherent uncertainty, which arises because of incomplete scientific knowledge used to determine emissions factors and the values needed to combine emissions of different gases.

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The specified Sustainability Disclosures in relation to Strategy (risks and opportunities) have been prepared using assumptions about future events, and management's actions, that may not occur.

Auditor's Responsibilities

Our objectives are to plan and perform the review to obtain limited assurance about whether the specified Sustainability Disclosures are free from material misstatement, whether due to fraud or error, and to issue a review report that includes our conclusion. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence decisions of users taken on the basis of the specified Sustainability Disclosures.

As part of a review in accordance with ASSA 5000, we exercise professional judgement and maintain professional scepticism throughout the engagement. We also:

- Perform risk assessment procedures, including obtaining an understanding of internal control relevant to the engagement, to identify and assess the risks of material misstatements, whether due to fraud or error, at the disclosure level but not for the purpose of providing a conclusion on the effectiveness of the entity's internal control.

- Design and perform procedures responsive to assessed risks of material misstatement at the disclosure level. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

Summary of the Work Performed

A review is a limited assurance engagement and involves performing procedures to obtain evidence about the specified Sustainability Disclosures. The nature, timing and extent of procedures selected depend on professional judgement, including the assessed risks of material misstatement at the disclosure level, whether due to fraud or error. In conducting our review, we:

- Inspected the specified Sustainability Disclosures and assessed the completeness and accuracy of these disclosures against the relevant disclosure requirements of AASB S2 and with reference to the knowledge and evidence obtained during the assurance engagement;

- Performed enquiries of management regarding the methodologies, processes and controls for capturing, collating, calculating and reporting the specified Sustainability Disclosures and assessed their alignment with AASB S2 and applicable method and measurement approaches;

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- Inspected and assessed, on a sample basis, charters, policies, minutes of meetings regarding the monitoring, management and oversight of climate-related matters, and other underlying evidence supporting the climate-related financial disclosures on governance;
- Performed enquiries of management regarding the approach taken by the Group to:
    - Identify climate-related risks and opportunities;
    - Identify material information for disclosure with regards to the Strategy (risks and opportunities) disclosures;
- Performed enquiries of management and examined underlying evidence to assess the completeness and accuracy of the establishment of the organisational boundary, and sources of emissions, in the context of the specified Sustainability Disclosures.
- Performed enquiries of management regarding the estimates, assumptions, conversion factors and greenhouse gas emission factors applied within the calculations of the Scope 1 and 2 emissions;
- Applied analytical procedures to evaluate the Scope 1 and 2 emissions and the underlying activity data;
- Performed testing over the calculations of the Scope 1 emissions, including testing the activity data utilised within the calculations to third-party records, information captured by onsite measurement devices at the facilities within the organisational boundary and other relevant underlying information, on a sample basis and;
- Performed testing over the calculations of the Scope 2 emissions, including testing the activity data utilised within the calculations to third-party records, and other relevant underlying information, on a sample basis.

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PricewaterhouseCoopers

Scott Thompson
Partner

Melbourne
February 20, 2026

Auditor's Independence Declaration

As lead auditor of Telix Pharmaceuticals Limited's financial report for the year ended December 31, 2025, and lead auditor of Telix Pharmaceuticals Limited's sustainability report for the year ended December 31, 2025, respectively, we each declare that, having regard to our responsibilities in relation to the respective audit of the financial report and audit of the sustainability report, to the best of our knowledge and belief, there have been:

a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the respective audit of the financial report or the review of the sustainability report; and

b) no contraventions of any applicable code of professional conduct in relation to the respective audit of the financial report or the review of the sustainability report.

Brad Peake	Scott Thompson	Melbourne
Lead auditor (financial report)	Lead auditor (sustainability report)	February 20, 2026
Partner	Partner	
PricewaterhouseCoopers	PricewaterhouseCoopers	

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Voluntary disclosures

In addition to the mandatory climate-related disclosures prepared in accordance with AASB S2, Telix voluntarily identifies and assesses a broader set of sustainability-related risks and opportunities to inform strategic decision-making, risk management, and long-term value creation. This voluntary disclosure is intended to provide stakeholders with greater transparency on sustainability matters beyond climate that may influence Telix's operating context, stakeholder relationships, and long-term resilience.

Double materiality assessment

Purpose and scope

In 2025, Telix completed its inaugural DMA to systematically identify sustainability-related risks and opportunities across sustainability topics. The DMA provides a structured and evidence-based foundation for Telix's sustainability strategy, enterprise risk management, and voluntary disclosures, supporting long-term value creation and resilience.

This assessment considers both how Telix's activities may impact people and the environment and how sustainability-related matters may, over time, influence the Company's business model, operating context, and enterprise value.

Climate-related risks and opportunities assessed as financially material are disclosed separately in the section titled "Climate-related financial risks and opportunities", prepared in accordance with AASB S2. The DMA does not determine materiality for mandatory AASB S2 disclosures.

Methodology

The DMA was conducted using a science-based methodology developed in collaboration with sustainability adviser Upright. The methodology integrates peer-reviewed scientific research and large-scale benchmarking across more than 50,000 companies, supplemented by Telix-specific operational, financial, and geographic data.

The assessment evaluates sustainability topics across two distinct but complementary dimensions:

- Impact materiality: the nature and significance of Telix's positive and negative impacts on the environment and society.
- Financial materiality: the potential for sustainability-related risks and opportunities, including dependencies on natural, human, and social capital, to affect enterprise value through impacts on revenue, costs, capital expenditure, cash flows, asset values, or access to capital.

To ensure a comprehensive assessment, sustainability topics were evaluated through four analytical perspectives:

- Product-based assessment: reflecting impacts and dependencies associated with Telix's products and services and their value chains.
- Industry-based assessment: capturing sector-wide sustainability patterns and risks.
- Geographic assessment: considering the locations of Telix's operations, suppliers, and customers.
- Data point-based assessment: incorporating company-specific sustainability indicators where relevant.

Each topic was assessed using defined criteria for scale, scope, irremediability (for negative impacts only), and likelihood, and then positioned along axes of impact and financial materiality.

Scoring, thresholds and governance

Sustainability topics were quantified using Upright's established scoring methodology:

- Impact materiality is determined by multiplying scale, scope, irremediability, and likelihood, with individual impacts considered material where scores meet or exceed defined thresholds.
- Financial risks and opportunities are assessed based on the likelihood and magnitude of potential financial effects, with explicit thresholds applied to identify financially relevant risks and opportunities.

All assessments were conducted on a gross basis, without considering existing mitigation measures, to provide a transparent view of inherent impacts and exposures.

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The DMA was carried out over a six-month period and included interviews and workshops with stakeholders across eight functional areas, including People & Culture, Legal, Environment, Health & Safety, Finance, and Risk. Results were independently calibrated using Upright's data model and validated by Telix's SWG, with findings reviewed by members of the ARC. Telix intends to refresh the DMA every three years to reflect changes in operations, regulation, and stakeholder expectations.

Stakeholder engagement

Stakeholder input was incorporated to enhance the relevance and robustness of the assessment. Engagement activities included:

- Internal stakeholders: interviews and surveys across key functional areas to capture operational insights and emerging risks.
- External stakeholders: engagement with institutional investors, suppliers, and B2B customers to understand perspectives on sustainability-related risks, governance expectations, and value-chain considerations.

Stakeholder views were used to validate and, where necessary, challenge the science-based results, ensuring that the DMA reflects both objective evidence and real-world business context.

Key findings

The DMA assessed 30 sustainability topics and mapped them across dimensions of impact and financial materiality. Topics positioned higher on the matrix indicate greater societal or environmental impact, while those further to the right reflect stronger relevance to enterprise value.

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Financial materiality

Impact materiality	Low	Medium	High
High		Building capacity for the future (own workforce) Access to medicine	Opportunities: Patient health and safety Health and safety (own workforce) Climate-related risks (climate change mitigation, acute and chronic climate hazards, energy) Resource outflows and waste Pollution of air
Medium	Ecosystem services Non-discrimination (of consumers and end-users) Access to (quality) information (consumers and end-users) Pollution (in context of biodiversity) Responsible marketing practices (of consumers and end-users) Pollution of water and soil Ecosystems and species Gender equality and equal pay for work of equal value (workers in the value chain) Freedom of association, the existence of works councils and the information, consultation and participation rights of workers (own workforce) Working time (workers in the value chain) Work-life balance (workers in the value chain)	Health and safety (workers in the value chain)	Belonging Resource inflows, including resource use Political engagement Water and sanitation (affected communities) Animal welfare Water withdrawals and consumption Privacy (of consumers and end-users) Substances of very high concern Corruption and bribery
Low	60 matters with low or no materiality		Opportunities: Climate-related opportunities (climate change mitigation, energy) Health and safety (own workforce)

This analysis provides a perspective on the intersection of sustainability priorities with business risks and opportunities, helping guide strategic focus and resource allocation. All impacts, risks, and opportunities were evaluated on a gross basis, without considering existing mitigation measures, to ensure a transparent understanding of their inherent significance. These results informed the prioritization of actions disclosed in the Climate-related financial risks and opportunities section of this report.

Integration with governance and strategy

The outcomes of the DMA are used to support Telix's governance and risk management processes by providing a structured view of sustainability-related risks and opportunities across the enterprise. These insights inform management discussions, policy development, and future strategic initiatives, and help ensure alignment with evolving regulatory requirements and stakeholder expectations in multiple jurisdictions.

While this voluntary disclosure reflects Telix's broader sustainability risk and opportunity landscape, it does not replace or alter the determination of materially significant climate-related risks and opportunities disclosed under AASB S2.

Unless otherwise stated, the sustainability-related risks and opportunities disclosed in this section are not assessed as financially material for the purposes of AASB S2 but are disclosed voluntarily to provide broader transparency on Telix's sustainability context and strategic priorities.

These pillars are clearly defined concepts, rooted in our DMA findings, which identified the issues most critical to our stakeholders and overall enterprise value.

Value-creation linkages

The DMA findings show that Telix's activities positively influence patient health outcomes and drive innovation, while also acknowledging moderate environmental dependencies, particularly related to electricity and water consumption.

By incorporating both impact and financial materiality perspectives, Telix ensures sustainability considerations inform decision-making across research and development, manufacturing, and logistics.

Stronger Telix - our employees

Focus areas:

- *Health and safety (own workforce)*
- *Building capability for the future*
- *Belonging*

Health and safety (own workforce)

Our success begins with our people. We are dedicated to providing a safe, healthy and inclusive workplace for our employees and contractors and have a comprehensive Environment, Health and Safety (EHS) program and wellbeing strategy.

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We report both leading and lagging EHS and wellbeing statistics to the GET, People Committee, and Board. These statistics include incidents, accidents, near misses, training participation, wellbeing surveys, utilization of the Employee Assistance Program, anonymous reports, and practices that may pose hazards to the work environment and employee wellbeing.

Our wellbeing program aims to foster conversations on psychosocial health and support employees when they need it. Through the Employee Assistance Program, employees and their families can access early intervention and clinical resources, including free, independent, and confidential support from trained professionals as well as self-assessment tools across a range of wellness areas.

We actively monitor and address employee wellbeing through regular surveys and initiatives designed to promote wellness, encourage work-life balance, and provide direct support. Additionally, we offer employees up to four paid wellness days each calendar year, in addition to statutory leave requirements.

Creating a safe workplace and a culture that promotes belonging and wellbeing is crucial for cultivating a healthy, innovative and high-performing workforce, which ultimately helps us retain top talent. Our programs and practices include:

- Hybrid work and flexible working.
- A global paid parental leave policy and entitlement.
- Mandatory Code of Conduct training, addressing anti-bullying, harassment, sexual harassment, and discrimination for all employees
- Mental health awareness resources, surveys and initiatives.
- Employee engagement surveys.

In 2025, we launched an initiative to promote a 'speak up' culture. The campaign is based on three pillars designed to encourage daily actions that foster a culture of courage, connection, and accountability. These are:

- Speak with intent
- Listen to learn
- See it through

Building capability for the future

Our core priority is to develop strong, capable leaders at every level. The Rise Leadership Series is at the heart of our leadership development initiatives, featuring three tiered programs that support leaders as they navigate increasing complexity, influence, and impact in their roles.

Basecamp equips new and aspiring leaders with the foundational confidence and competence needed to lead effectively from day one. This program primarily consists of self-directed study and e-learning, supplemented by internally facilitated workshops.

Ascend is a nine-month program for manager to director level leaders. It focuses on cultivating a growth mindset, enhancing communication and collaboration in a global environment, navigating matrix structures, building informal influence, and sustaining resilience.

Summit, our senior leadership program, is intended to help VP-level and other senior leaders refine their strategic vision, translate strategy into action, inspire high performance, and lead through complexity. The inaugural program ran from February to June 2025, and future cohorts will be selected based on performance, potential, and commitment to growth.

In 2025, Telix graduated 36 leaders across the Ascend and Summit programs, fostering connections and strengthening capabilities among participants from different functions and regions.

In addition to the Rise Leadership Series, all Telix employees are encouraged and supported to pursue both internal and external professional development opportunities. Internally, employees can access lunch-and-learn sessions with subject matter experts, peer-learning networks, and a large collection of self-paced learning modules through Nucleus, our learning management system. Building deep domain expertise is essential at Telix, and employees are committed to continuous learning in areas such as radiochemistry, radiopharmaceutical science, oncology, imaging, and related technical disciplines.

Externally, Telix allocates an annual budget to support participation in specialized programs, including project management, agile methodology, regulatory pathways, transparency reporting, communication, negotiation, and people leadership.

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Professional development is a cornerstone of our success. Over the past year, we hosted numerous learning sessions featuring both internal and external experts in oncology, radiology, and other relevant fields. By providing our workforce with regular access to industry leaders and current best practices, we ensure our employees remain at the forefront of their respective disciplines.

In summary, professional development is essential to Telix's success, enabling our people to grow, innovate, and lead in a rapidly evolving global environment.

Belonging at Telix

We are dedicated to creating a workplace where every employee feels a sense of belonging, is treated with respect, and can thrive. Since we serve patients from diverse communities, it is essential that our workforce reflects a wide range of perspectives, experiences, and skills to meet their needs with empathy and excellence. A sense of belonging empowers our team to contribute their best to this mission.

We believe every employee has the right to fair treatment, equal access to opportunity, and employment opportunities based on merit. This principle forms the foundation of our approach to recruitment, development, performance, evaluation and advancement. By basing roles, promotions, and learning opportunities on capability, contribution, and potential, we foster an environment where individuals can grow confidently, knowing their achievements and aspirations are recognized fairly and consistently.

For more information see Telix's 2025 Corporate Governance Statement, available at: https://ir.telixpharma.com/governance/documents-charters

Stronger communities: patient support

Focus areas:

- *Patient health and safety*
- *Access to medicine*

Patient health and safety

Patients are the reason we strive for excellence. Our commitment to patient care goes beyond product development to include comprehensive engagement and support programs. We actively collaborate with patients and advocacy groups throughout our product lifecycle, ensuring their voices shape our research, development, and accessibility initiatives.

In 2025, Telix strengthened global patient engagement through advisory boards, educational partnerships, and advocacy collaborations. Our Patient Advisory Boards at American Society of Clinical Oncology ("ASCO") with our kidney and prostate cancer partners, and at ASCO with our brain cancer partners, provided critical insights that influenced the design of key clinical studies, including ProstACT Global (TLX591-Tx), TLX250-Px and TLX101-Px and Tx programs. These forums emphasized patient priorities such as diagnostic clarity, treatment convenience, and messaging that resonates with diverse communities.

We promoted disease awareness and access barriers to treatment through initiatives like the Kidney Cancer Community Engagement at the American Urological Association annual meeting, overcoming health inequity at numerous Prostate Health Education Network ("PHEN") clinical trial and disparity rallies, End Brain Cancer Initiative "Know Your Treatments" webinar, and Brain Tumour Alliance Australia's powerful advocacy meeting, "Head to the Hill" in Canberra, ensuring patients and caregivers have access to accurate, actionable information. Telix also partnered with advocacy groups to co-create educational materials and recruitment campaigns for clinical trials, including videos and digital resources tailored for the prostate and brain cancer communities.

Brain Tumour Alliance Australia's "Head to the Hill" meeting in Canberra, October 2025.

Prostate Health Education Network Disparity Rally at Little Rock AME Zion Church in Charlotte (NC), January 2025.

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Our support extends to Early Access Programs, enabling compassionate use of TLX250-Px and TLX101-Px, as well as grants that empower patient organizations to deliver vital education and support services. Employees demonstrated personal commitment through participation in fundraising events such as the Long Run for Prostate Cancer Foundation Australia, ZERO Prostate Cancer Run/Walks and Go Gray in May, complemented by corporate matching donations.

Access to medicine

Telix's patient-centric approach is grounded in addressing global disparities in healthcare access. Through collaboration with industry, government, and advocacy partners, we champion policies that enable equitable and sustainable access to nuclear medicine.

In 2025, Telix partnered with leading Australian organizations to launch Nuclear Medicines Australia, an industry coalition advocating for sovereign manufacturing capability, streamlined regulatory and reimbursement processes, and national workforce development. This initiative culminated in the first National Nuclear Medicine Roundtable, held at Parliament House in Canberra, bringing together expert stakeholders from across the healthcare, research and policy sectors.

This followed the publication of Telix's first nuclear medicine report, "Radiopharmaceuticals Empowering Australia's Future", that outlined five key recommendations to strengthen Australia's leadership in radiopharmaceutical innovation. the report generated significant national media attention and informed ongoing engagement with policymakers.

Telix also advanced global advocacy efforts in 2025, hosting government and industry delegates at our facilities in Australia, Europe Japan and the U.S., and contributing to legislative initiatives such as the BRAIN Act in the U.S. and PET infrastructure development in Canada.

Our commitment to access extends beyond advocacy, encompassing compassionate use programs, support for clinical trial recruitment, and initiatives to eliminate systemic barriers to treatment. These efforts reflect Telix's broader strategy to make advanced cancer care more accessible to patients worldwide.

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Glioblastoma Awareness Day on Capital Hill (Washington) with the National Brain Tumor Society (NBTS), July 2025. Left to right: Ashley Brennan, Chief Development Officer (NBTS), Elizabeth Leff, Patient Advocacy Lead, Americas (Telix), Gary Heimberg, JD, Chief Policy and Advocacy Officer, Counsel (NBTS), David F. Arons, JD, President & Chief Executive Officer (NBTS), Bruce Carroll, Director, Public Affairs - U.S. (Telix).

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report: _____

Commission file number 001-42128

Telix Pharmaceuticals Limited

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

Australia

(Jurisdiction of incorporation or organization)

55 Flemington Road

North Melbourne, Victoria 3051, Australia

(Address of principal executive offices)

Christian Behrenbruch

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North Melbourne, Victoria 3051, Australia

Tel: +61 3 9093 3855

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American depositary shares, each representing one ordinary share, no par value Ordinary shares, no par value*	**TLX**	**The Nasdaq Global Select Market**

- Listed not for trading, but only in connection with the listing of the American Depositary Shares, pursuant to the requirements of the Securities & Exchange Commission

Securities registered or to be registered pursuant to Section 12(g) of the Act: *None.*

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: *None.*

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: The number of ordinary shares outstanding as of December 31, 2025 was 338,777,049.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐	Emerging growth company	☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐
International Financial Reporting Standards as issued by the International Accounting Standards Board ☒
Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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INTRODUCTION

Telix Pharmaceuticals Limited was incorporated under the laws of Australia in January 2017. Our ordinary shares have been listed on the Australian Securities Exchange ("ASX") since November 2017, and since November 2024, have been listed on the Nasdaq Global Select Market in the form of American depositary shares ("ADSs"), with each ADS representing one of our ordinary shares. JP Morgan Chase Bank, N.A., acts as depositary for the ADSs. Throughout this annual report, all references to “ADRs” mean the American depositary receipts that evidence the ADSs.

As of January 1, 2025, our reporting currency is the United States Dollar ("US$"). All amounts presented in this Annual Report on Form 20-F ("Annual Report") are presented in US$ unless otherwise indicated. Prior to January 1, 2025, our presentation currency was the Australian Dollar. The change in presentation currency has been applied retrospectively to all comparative periods presented See Note 2.3.1 to our audited consolidated financial statements included elsewhere in this Annual Report.

The consolidated financial statements and related notes included elsewhere in this Annual Report have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board, (“IFRS Accounting Standards”), which differ in certain significant respects from generally accepted accounting principles in the United States ("U.S. GAAP").

We also maintain a website at www.telixpharma.com. The information contained on our website or available through our website is not incorporated by reference into and should not be considered a part of this Annual Report, and any references to our website throughout this Annual Report are inactive textual references only.

Unless otherwise stated or the context indicates otherwise, all references herein to “Telix,” “Telix Pharmaceuticals,” "the Company," "the Group," “our company,” “we,” “us,” “our” and similar references refer to Telix Pharmaceuticals Limited and its consolidated subsidiaries, taken as a whole.

Australian Disclosure Requirements

Our ordinary shares are primarily quoted on the ASX in addition to our listing of our ADSs on the Nasdaq Global Select Market. As part of our ASX listing, we are required to comply with various disclosure requirements as set out under the Australian Corporations Act 2001 (Cth) and the ASX Listing Rules. Information furnished under the sub-heading “Australian Disclosure Requirements” is intended to comply with ASX listing and Australian Corporations Act 2001 (Cth) disclosure requirements and is not intended to fulfill information required by this Annual Report.

INDUSTRY AND MARKET DATA

This Annual Report contains estimates and information concerning our industry and our business, including estimated market size and projected growth rates of the markets for our product candidates. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources.

This information involves a number of assumptions and is based on limited available information. Although we are responsible for all of the disclosure contained in this Annual Report and we believe the third-party market position, market opportunity and market size data included in this Annual Report are reliable, we have not independently verified the accuracy or completeness of this third-party data. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Item 3. Key Information — D. Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

TRADEMARKS AND SERVICE MARKS

Telix Pharmaceuticals, the Telix logo and other trademarks or service marks of Telix appearing in this Annual Report are the property of Telix or its subsidiaries. Solely for convenience, the trademarks, service marks and trade names referred to in this Annual Report are listed without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their right thereto. All other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. Any use or display of any third-party trademarks, trade names or service marks is not intended to imply a relationship with, endorsement or sponsorship of or by the respective owners.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations, financial condition, business strategy, prospective products, product approvals, research and development costs, future revenue and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would,” or the negative of these words or other similar terms or expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of known and unknown risks, uncertainties, other factors and assumptions, including the risks described in “Item 3. Key Information — D. Risk Factors” and elsewhere in this Annual Report, regarding, among other things:

- the ongoing commercialization of our Commercial Products and our preparation for the commercialization of our product candidates, if they are approved;
- the timing and review of submissions for regulatory approval of our product candidates, including review of our resubmissions for Pixclara® (TLX101-Px) and Zircaix® (TLX250-Px), and our ability to obtain and maintain such regulatory approvals;
- the initiation, timing, progress and results of our ongoing and planned clinical trials, including the timing of dosing of patients, enrollment and completion of these trials, including multi-national trials, and the anticipated results from these trials;
- our sales, marketing and distribution capabilities and strategies, including for the commercialization and manufacturing of our Commercial Products and any future products;
- our ability to obtain and maintain an adequate supply at reasonable costs of raw materials we may incorporate into our products and product candidates;
- our ability to address the fulfillment and logistical challenges posed by the time-limited stabilization of our products and product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy, including the timing and costs of expanding our manufacturing capabilities;
- the rate and degree of market acceptance and clinical utility of our products and product candidates, if they are approved;
- the pricing and reimbursement of our products and product candidates, if and after they have been approved;
- estimates of our expenses, future revenues and capital requirements;
- our financial performance;
- developments relating to our competitors and industry;
- the success of our collaborations and partnerships with third parties;
- our ability to maintain, expand, protect and enforce our regulatory exclusivity and intellectual property ("IP") portfolio;
- our expectations regarding our ability to obtain and maintain regulatory exclusivity and intellectual property protection for our products and product candidates;
- our ability to successfully integrate the businesses that we have acquired or may acquire in the future;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- changes to law, policy and regulation in the U.S., Australia and other jurisdictions;
- disruptions caused by the current U.S. presidential administration or as a result of legislative or judicial action or lack thereof, including at the FDA and other government agencies;
- our ability to remain compliant with the respective listing rules and standards of the ASX, the Singapore Exchange Securities Trading Limited ("SGX"), and the Nasdaq Global Select Market ("Nasdaq");

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- our ability to attract and retain key scientific or management personnel;
- the success of competing therapies that are or may become available;
- the volatility of currency exchange rates;
- the impact of and changes in governmental regulations or the enforcement thereof, tax laws and rates, accounting guidance and similar matters in regions in which we operate or will operate in the future;
- any changes in laws, rules or regulations, including the imposition of tariffs or other trade restrictions, affecting our ability to manufacture, test, develop, or commercialize our Commercial Products and product candidates;
- changes to staffing, process, or policy at government agencies, including, but not limited to, the FDA; and
- changes in U.S. and international trade policies, including the imposition of tariffs on raw materials and finished products; and
- other risks and uncertainties, including those listed under “Item 3. Key Information — D. Risk Factors.”

These risks are not exhaustive. Other sections of this Annual Report may include additional factors that could harm our business and financial performance. New risk factors may emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We undertake no obligation to update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date of this Annual Report or to reflect new information or the occurrence of unanticipated events, except as required by law.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject.

These statements are based on information available to us as of the date of this Annual Report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

You should read this Annual Report and the documents that we reference and have filed as exhibits to the Annual Report with the understanding that our actual future results, performance and achievements may be different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and Senior Management

Not applicable.

B. Advisers

Not applicable.

C. Auditors

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

A. Offer Statistics

Not applicable.

B. Method and Expected Timetable

Not applicable.

ITEM 3. KEY INFORMATION

A. Reserved

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Investing in our securities involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this Annual Report, including our consolidated financial statements and related notes included elsewhere in this Annual Report, before making an investment decision. If any of the following risks actually occur, it could harm our business, prospects, results of operations and financial condition. In such event, the trading price of our ordinary shares and the ADSs could decline, and you might lose all or part of your investment.

Risk Factors Summary

- We have a history of significant net losses, our operating expenses may increase in the future, and we may not be able to maintain profitability in future periods.
- We may need to raise capital to achieve our business objectives if we are unable to fund our operations with our cash flows from the sale of our products. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs and/or commercialization efforts.
- We may not be able to effectively integrate the businesses that we have acquired and/or may acquire in the future.
- Our business is substantially dependent on the commercial success of our Commercial Products and our product candidates, if approved. If we are unable to successfully commercialize our Commercial Products as currently

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approved or to successfully commercialize our product candidates, if approved, our business, financial condition and results of operations will be materially harmed.

- Clinical development is a lengthy and expensive process, with uncertain timelines and outcomes. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates, if approved.

- The results of previous clinical trials may not be predictive of future trial results, and preliminary, interim or top-line data may be subject to change or qualification based on the complete analyses of data and, therefore, may not be predictive of the final results of a trial.

- We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

- Due to their radioactive nature, our Commercial Products and our product candidates have time-limited stability, and as a result, we may encounter difficulties with fulfillment and logistics.

- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

- The commercial success of our Commercial Products and our product candidates, if approved, will depend upon public perception of radiopharmaceuticals and the degree of their market acceptance by physicians, patients, healthcare payors and others in the medical community.

- We may be unable to generate and/or obtain a sufficient supply of radioisotopes to support clinical development or manufacturing at commercial scale.

- Even if we are able to effectively commercialize our Commercial Products or any product candidates for which we obtain approval, the products may not receive coverage or may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, all of which would harm our business.

- We depend on collaborations with third parties for certain aspects of the development, marketing and/or commercialization of our Commercial Products and our product candidates. If those collaborations are not successful, or if we are not able to maintain our existing collaborations or establish additional collaborations, we may have to alter our development and commercialization plans and may not be able to capitalize on the market potential of our Commercial Products or our product candidates, if approved.

- If we are unable to obtain and/or maintain commercially valuable regulatory exclusivity and intellectual property, or to protect our patents, trademarks, know-how and trade secrets, our ability to successfully commercialize our Commercial Products and product candidates, if approved, would be adversely impacted.

- We may experience sustainability risks, including: physical climate-related risks such as extreme weather events that could disrupt internal operations, suppliers, and logistics, and increase operational costs; resource and energy risks such as increasing energy prices, regulatory actions and increased resource efficiency standards that may increase operating expenses and capital expenditure for facility upgrades; and, non-compliance with increased social and governance regulations that could lead to fines, reputational damage, and increased compliance costs.

- An active and liquid market for our securities may not continue to be developed or sustained, which could harm the market price of the ADSs.

- As a foreign private issuer, we are permitted to follow certain home country corporate governance practices in lieu of certain Nasdaq requirements applicable to domestic issuers.

- We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our ADSs.

Risks Related to Our Financial Position and Capital Requirements

We have a history of significant net losses, our operating expenses may increase in the future, and we may not be able to maintain profitability in future periods.

Until 2023, we incurred significant operating losses. Our loss after tax was $7.1 million for the year ended December 31, 2025. Our net operating cash flow was $17.3 million (outflow) for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $154.5 million. Although we launched Illuccix in April 2022 and Gozellix in June 2025 and have recognized profits in recent periods, we cannot be certain that we will sustain profitability or positive cash flows from operations in future periods.

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We have invested most of our resources in developing our technology and product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We continue to incur significant research and development ("R&D"), and other expenses related to ongoing operations and may incur losses in the future.

Investment in biotechnology product development, as well as medical device development, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will be unable to demonstrate effectiveness or an acceptable safety profile, gain regulatory approval, gain competitive pricing or reimbursement and become commercially viable.

Illuccix has been approved by the FDA, the Australian Therapeutic Goods Administration ("TGA"), by Health Canada, by the Brazilian Health Regulatory Agency ("ANVISA"), by the United Kingdom Medicines and Healthcare Products Regulatory Agency ("MHRA") and by health regulators in 19 European Economic Area member states. Gozellix was approved by the FDA in March 2025. Throughout this Annual Report, “Commercial Products” is used to refer to Illuccix and Gozellix collectively.

We have historically financed our operations principally through product sales, private and institutional placements of our ordinary shares, proceeds from our initial public offering of ordinary shares on the ASX, proceeds from our issuance of convertible bonds, loan agreements with financial institutions and cash generated from our business development activities. Substantially all of our operating losses in previous periods have resulted from costs incurred in connection with our research and development programs, the pursuit of regulatory approvals within and outside of the U.S., and the commercialization of our Commercial Products. We expect to continue to incur significant expenses as we continue to commercialize our Commercial Products in the jurisdictions in which we have received marketing authorization, and other jurisdictions, if approved, and engage in activities to prepare for the potential approval and commercialization of our product candidates. The profits or losses we incur may fluctuate significantly from quarter to quarter and year to year.

While we began to generate revenue from the sales of Illuccix in April 2022 and from Gozellix in June 2025, there can be no assurance as to the amount or timing of future product or license and other revenues, and we may not be able to maintain profitability in future periods. Our ability to remain profitable depends significantly on our success in many areas, including:

- effectively commercializing Illuccix, Gozellix or any future products either on our own or with a collaborator, including by maintaining a full commercial organization required to market, sell and distribute our products, and achieving an adequate level of market acceptance;
- the impact of current or future competing products on product sales of Illuccix, Gozellix or any future products;
- obtaining sufficient pricing, coverage and reimbursement, under U.S. federal healthcare programs, such as Medicare and Medicaid, and from private payors, for Illuccix, Gozellix and any future products from private and government payors and the impact of any pricing changes;
- initiating and successfully completing clinical trials required to file for, obtain and maintain regulatory approval for our product candidates;
- obtaining and maintaining regulatory approvals, and the timing of such approvals;
- manufacturing at commercial scale;
- establishing and managing any collaborations for the development, marketing and/or commercialization of our products and product candidates, if approved, including the level of success of any such collaborators’ efforts and the timing and amount of any milestone or royalty payments we may receive; and
- obtaining, maintaining and protecting our intellectual property rights.

We anticipate that our operating expenses will continue to be significant and increase as we continue to:

- commercialize Illuccix and Gozellix in the U.S., and Illuccix in Australia, New Zealand, Brazil, Canada, Europe and other jurisdictions following regulatory approval, including maintaining our commercial infrastructure;
- obtain and/or maintain regulatory approval for Illuccix, Gozellix and our product candidates, including completing any required post-marketing requirements to the satisfaction of the FDA or other regulatory agencies;
- expand our research and development programs, identify additional product candidates and initiate and conduct clinical trials, including clinical trials required by the FDA or other regulatory agencies in addition to those that have been or are currently expected to be conducted;
- maintain, expand and protect our intellectual property portfolio;
- manufacture Illuccix, Gozellix and our product candidates;

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- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future radiopharmaceutical commercialization efforts;
- operate as a publicly listed company in the U.S. and Australia; and
- acquire or in-license other products, product candidates or technologies.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of our revenue and expenses or if we will be able to maintain profitability. We cannot be certain that our revenue from sales of Illuccix and Gozellix, in the currently approved indications, will be sufficient for us to remain profitable in future periods. We may not generate revenues that are significant or large enough to sustain or increase profitability on an annual basis. Our failure to remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development and commercialization efforts, expand our business and/or continue our operations. This could result in a material adverse effect on the value of our company and could cause our shareholders and ADS holders to lose all or part of their investment.

We may need to raise additional capital to achieve our business objectives if we are unable to fund our operations with our cash flows from the sale of our products. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs and/or commercialization efforts.

Discovering, developing and commercializing products involve time-consuming, expensive and uncertain processes that take years to complete. We have used substantial funds to develop Illuccix and Gozellix and expect our operating expenses to continue to increase as we continue to commercialize Illuccix, Gozellix or any future approved products, conduct further research and development of our product candidates, seek approval and prepare for commercialization of TLX250-Px and TLX101-Px and continue to conduct clinical trials for our other product candidates.

Furthermore, we will continue to incur additional costs associated with operating as a public company, hiring additional personnel and expanding our geographical reach. Although currently Illuccix is commercially available in multiple jurisdictions worldwide and Gozellix is commercially available in the U.S., we cannot be certain that our revenue from product sales of Illuccix and Gozellix will be sufficient for us to remain profitable on an annual basis. Accordingly, we may need to continue to rely on additional financing to achieve our business objectives.

As of December 31, 2025, we had $141.9 million in cash and cash equivalents. The amount and timing of our future capital requirements will depend on many factors, including, but not limited to:

- the scope, progress, results, timing and costs of our current and planned development efforts and regulatory review of our product candidates;
- the amount and timing of revenues from sales of Illuccix, Gozellix or any product candidate for which we receive regulatory approval;
- the cost of, and our ability to expand and maintain, the commercial infrastructure required to support the commercialization of Illuccix, Gozellix and any other product for which we receive regulatory approval, including medical affairs, manufacturing, marketing and distribution functions;
- our ability to establish and maintain collaboration, partnership, licensing, marketing, distribution or other arrangements on favorable terms and the level and timing of success of these arrangements;
- the extent to which we acquire or in-license other products, product candidates and technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

In addition, the terms of any financing may adversely affect the holdings or the rights of our shareholders and ADS holders. If we raise funds by issuing equity securities, dilution to our existing shareholders and ADS holders will result, and this may also have an impact on the market price of our ordinary shares and ADSs. In addition, as a condition to providing additional funding to us, future investors may demand, and may be granted, rights superior to those of existing shareholders. Moreover, any debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities and, in the event of insolvency, would be paid before holders of equity securities received any distribution of corporate assets. Our ability to satisfy and meet any future debt service obligations will depend upon our future performance, which will be subject to financial, business and other factors affecting our operations, many of which are beyond our control.

Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations. Any future fundraising efforts could divert our management's attention away from their day-to-day activities. Further, adequate additional financing may not be available to us on acceptable terms, or at all. In addition, raising funds in the current economic environment may present additional

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challenges. For example, any sustained disruption in the capital markets from adverse macroeconomic conditions, such as the disruption and uncertainty caused by rising inflation, increasing interest rates and slower economic growth or recession, could negatively impact our ability to raise capital and we cannot predict the extent or duration of such macro-economic disruptions. If adequate funds are not available to us on a timely basis or on attractive terms, we may be required to delay, reduce or eliminate our research and development programs or any current or future commercialization efforts for one or more of our products or product candidates, any of which could have a material adverse effect on our business, operating results and prospects.

Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause the trading price of our ordinary shares and the ADSs to fluctuate or decline.

We expect our operating results to be subject to fluctuations. Our profit or loss and other operating results will be affected by numerous factors, including:

- timing and variations in the level of expense related to the current or future development of our programs;
- timing and status of enrollment for our clinical trials;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- timing of any milestone payments or other payment obligations to be paid by us pursuant to existing supply agreements, licenses or collaborations;
- timing of any milestone payments or other payments to be received by us pursuant to our license agreement;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, or other post-grant proceeding or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any product candidate we may develop receives regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidate;
- the timing and cost to establish a sales, marketing and distribution infrastructure to commercialize any products or product candidates for which we may obtain regulatory approval and intend to commercialize on our own or jointly with current or future collaborators;
- regulatory developments affecting our Commercial Products or any other of our product candidates or those of our competitors, including disruptions at FDA or other government agencies; and
- changes in general market and economic conditions, including as a result tariffs, trade restrictions, conflicts or other geopolitical risks that may arise.

If our operating results fall below the expectations of investors or securities analysts, the price of our ordinary shares and ADSs could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our ordinary shares and ADSs to fluctuate substantially. We believe that comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our Loan Agreements with BNP Paribas and IMBC Group contain various covenants and other provisions, which, if violated, could result in the acceleration of payments due under such agreement, as well as affect the buildout of our Brussels South manufacturing facility.

In March 2022, one of our subsidiaries, Telix Pharmaceuticals (Belgium) SPRL (now "Telix Pharmaceuticals (Belgium) SRL"), entered into Loan Agreements ("the Loan Agreements") with BNP Paribas and IMBC Group. The borrowings under these Loan Agreements were used to fund in part the construction of our Brussels South manufacturing facility. Pursuant to the Loan Agreements, Telix Pharmaceuticals (Belgium) SRL is required to comply with various covenants relating to the conduct of its business. The Loan Agreements also include customary events of default upon the occurrence of enumerated events, including non-payment of required repayments, failure to perform certain covenants and the occurrence of insolvency proceedings, specified judgments, specified cross-defaults or specified revocations. Upon the occurrence of an event of default and in the event of a change of control, BNP Paribas and IMBC Group may accelerate payments due under the Loan Agreements or terminate the Loan Agreements, which would have an adverse impact on our business.

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Future issuances of equity or convertible debt securities may cause dilution to our shareholders and ADS holders, restrict our operations or require us to relinquish rights to our product candidates.

We expect to finance our cash needs through a combination of revenues from product sales, equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our shareholders and ADS holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of ordinary shareholders and ADS holders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through further collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our research and product development or current or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our indebtedness could limit cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under our indebtedness.

On July 30, 2024, we issued $426.1 million (A$650.0 million) principal amount of 2.375% unsecured convertible bonds due 2029 ("the Convertible Bonds") on the SGX. Additionally, as of December 31, 2025, we had $10.3 million of other indebtedness. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a portion of our cash flow from operations to service our indebtedness, which would reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing shareholders as a result of issuing ordinary shares upon conversion of the Convertible Bonds; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our ability to pay the principal of or interest on the Convertible Bonds or to make cash payments in connection with any conversion of the Convertible Bonds depends on our future performance, which is subject, in part, to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service the Convertible Bonds or other future indebtedness and make necessary capital expenditures.

If we are unable to redeem the Convertible Bonds for cash when required, or repay the Convertible Bonds when due at maturity, we may need to seek alternative financing arrangements, which could impose restrictions on our operations and business.

On July 30, 2024, we completed our issuance of the Convertible Bonds to institutional and professional investors on the SGX outside of the U.S. The Convertible Bonds mature on July 30, 2029, unless redeemed, repurchased, or converted in accordance with their terms.

Subject to the satisfaction of conditions in the trust deed, we have the right at our option to redeem all of the bonds on or after August 13, 2027 if (i) the closing price of our ordinary shares on the ASX exceeds 130% of the then-applicable conversion price for at least 20 trading days, whether consecutive or not, during any consecutive 30 trading day period or (ii) conversion rights have been exercised in respect of 85% or more in principal amount of the Convertible Bonds.

We may be required to redeem the Convertible Bonds prior to the maturity date in certain circumstances. Upon the occurrence of an event constituting a change of control or the delisting of our ordinary shares on the ASX, each bondholder will have the right under the trust deed governing the Convertible Bonds to require us to redeem all or some of such bondholder's Convertible Bonds at their principal amount, together with accrued but unpaid interest. We are also required under the trust deed to redeem the Convertible Bonds on July 30, 2027 at the option of each holder at their principal amount, together with accrued but unpaid interest.

We may not be able to redeem all or any of such Convertible Bonds or pay all or any amounts due upon conversions thereof if we do not have sufficient funds to do so. Non-payment of any principal or interest payable with respect to the

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Convertible Bonds would constitute an event of default under the trust deed governing the Convertible Bonds. Upon the occurrence of an event of default, the full principal amount, together with accrued but unpaid interest, of the Convertible Bonds then outstanding will become due and payable. A default under the trust deed could also lead to a default under agreements governing any of our indebtedness outstanding at the time. If we are unable to redeem the Convertible Bonds at maturity or upon the occurrence of certain events specified by the trust deed governing the Convertible Bonds, we may need to seek alternative financing arrangements, which could impose restrictions on our operations and business. We cannot assure you that such alternative financing will be available to us on acceptable terms, if at all.

Servicing the Convertible Bonds will require a significant amount of cash, and we may not have sufficient cash flow from our business to make payments on the Convertible Bonds.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance the Convertible Bonds depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate sufficient cash flow from operations in the future to service the Convertible Bonds. If we are unable to generate sufficient cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional share capital on terms that may be unfavorable to us or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at the time we seek to refinance such indebtedness. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We have engaged and plan to engage in various acquisitions and strategic partnerships in the future. If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders and ADS holders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We have engaged and plan to continue to engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities which would result in dilution to our shareholders and ADS holders;
- assimilation of operations, intellectual property, products and product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

RLS may have liabilities that are not known to us and the indemnities in the purchase agreement may not offer adequate protection.

As part of the acquisition, we have agreed to assume certain liabilities of RLS. In addition, there may be liabilities that we failed or were unable to discover in the course of performing due diligence investigations, including with respect to decommissioning and decontamination ("D&D"), requirements with respect to the closing of facilities that use and produce radioactive materials. Also, we may not have correctly assessed the significance of certain liabilities and assets identified in the course of our due diligence. Any such liabilities, individually or in the aggregate, could have a material adverse effect on our business, financial condition and results of operations. As we integrate RLS into our operations, we may learn additional information about the entity, such as unknown or contingent liabilities and issues relating to compliance with applicable laws, that could potentially have an adverse effect on our business, financial condition and results of operations.

We may not be able to effectively integrate the businesses that we have acquired and/or may acquire in the future.

Our ability to realize the anticipated benefits of acquisitions we have completed and/or may complete in the future, including the completed acquisitions of RLS (USA) Inc. ("RLS"), QSAM Biosciences, Inc. ("QSAM"), ARTMS Inc. ("ARTMS"), IsoTherapeutics Group, LLC, ("IsoTherapeutics"), and certain assets of ImaginAb, Inc., ("ImaginAb") will depend on our ability to integrate those businesses with our own. The combination of multiple independent businesses is a complex, costly and time-consuming process and there can be no assurance that we will be able to successfully integrate businesses into our business, or if such integration is successfully accomplished, that such integration will not be costlier

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or take longer than presently contemplated. If we cannot successfully integrate and manage the businesses within a reasonable time, such difficulties or delays could result in the loss of key employees from the acquired businesses, the disruption of the acquired businesses, inefficiencies, or inconsistencies in standards, controls, information technology systems, procedures and policies, and we may not be able to realize the potential and anticipated benefits of such acquisitions, which could have a material adverse effect on our business, financial position, and results of operations. We face numerous risks relating to the integrated of acquired businesses, including:

- the inability to integrate effectively the operations, products, technologies and personnel of the acquired companies (some of which are in diverse geographic regions) and achieve expected synergies;
- the potential disruption of existing business and diversion of management's attention from day-to-day operations;
- the inability to maintain uniform standards, controls, procedures and policies;
- the need or obligation to divest portions of the acquired companies to satisfy regulatory requirements;
- the potential failure to identify material problems and liabilities during due diligence review of acquisition targets;
- the potential failure to obtain sufficient indemnification rights to fully offset possible liabilities associated with acquired businesses; and
- the challenges associated with operating in new product segments and/or geographic regions.

The failure to maintain our licenses and realize their benefits may harm our business.

We have acquired and in-licensed certain of our technologies from third parties. We may in the future acquire, in-license or invest in additional technology that we believe would be beneficial to our business. We are subject to a number of risks associated with our acquisition, in-license or investment in technology, including the following:

- diversion of financial and managerial resources from existing operations;
- successfully negotiating a proposed acquisition, in-license or investment in a timely manner and at a price or on terms and conditions favorable to us;
- successfully combining and integrating a potential acquisition into our existing business to fully realize the benefits of such acquisition;
- the impact of regulatory reviews on a proposed acquisition, in-license or investment; and
- the outcome of any legal proceedings that may be instituted with respect to the proposed acquisition, in-license or investment.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new R&D programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction, we might incur costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities.

Risks Related to Commercialization and Product Development

Our business is substantially dependent on the commercial success of our Commercial Products and our product candidates, if approved. If we are unable to successfully commercialize our Commercial Products as currently approved or to successfully obtain regulatory approvals to commercialize our other product candidates, our business, financial condition and results of operations will be materially harmed.

Our business and our ability to generate product revenue from the sales of diagnostic imaging agents and therapies that treat cancer and other diseases depend on continued commercialization of our Commercial Products in the jurisdictions in which they have received marketing authorization. We are also developing our Commercial Products for additional indications. We are currently pursuing marketing authorizations for our Commercial Products, either directly or in collaboration with regional commercial partners, in a number of additional jurisdictions. We believe that obtaining these additional regulatory approvals and successfully developing our Commercial Products for additional potential indication will be important to reach the full potential utilization of our Commercial Products and failure to do so could have a material adverse effect on our business.

Our long-term prospects also depend on our ability to obtain regulatory approval for additional imaging and therapeutic product candidates. Regulatory approvals are subject to changing standards from time to time and the timing to obtain the required regulatory approvals is subject to many factors, some of which may be outside our control. For example, regulatory agencies may face resource constraints, causing delays in the review process, and there is no guarantee that the regulators are bound by any product development or regulatory advice offered earlier in the review process. In May 2024, we completed our submission of a biologics license application ("BLA"), to the FDA for TLX250-Px for the

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characterization of renal masses as clear cell renal cell carcinoma ("ccRCC"). In July 2024, the FDA declined to review the BLA and issued a Refuse to File ("RTF"), determination. A RTF determination is a response from the FDA following its preliminary review, communicating the FDA's determination that the application does not include all pertinent information and data. The denial of acceptance for filing was based on a filing concern related to demonstrating adequate sterility assurance during dispensing of TLX250-Px in the radiopharmacy production environment. In December 2024 we resubmitted our BLA to the FDA for TLX250-Px, and the FDA accepted our application in February 2025. In August 2025, the FDA issued a Complete Response Letter ("CRL"), citing deficiencies relating to the Chemistry, Manufacturing, and Controls ("CMC") package. The FDA requested additional data to establish comparability between the drug product used in the ZIRCON Phase 3 clinical trial and the scaled-up manufacturing process intended for commercial use. Additionally, the FDA documented notices of deficiency (Form 483) issued to two third-party manufacturing and supply chain partners that required remediation prior to resubmission. In December 2025 we participated in a Type A meeting with the FDA to align on plans to address CMC deficiencies cited, and in January 2026 we participated in an additional Type A meeting to align on plans to address comparability between the clinical drug product and that intended for commercial use. Following these meetings, Telix believes it has alignment with the Agency on key resubmission aspects. While we believe that the planned remediation of the BLA for TLX250-Px will meet FDA requirements, there can be no assurance that, once re-submitted, the FDA will accept our BLA for review, or approve TLX250-Px.

In August 2024, we submitted a NDA for TLX101-Px for the characterization of progressive or recurrent glioma from treatment related changes in both adult and pediatric patients. In October 2024, the FDA accepted the New Drug Application ("NDA"), and granted priority review and assigned a Prescription Drug User Fee Act ("PDUFA"), goal date of April 26, 2025. In April 2025, the FDA issued a CRL, stating that additional confirmatory clinical evidence was required to progress the application. Following engagement with the FDA, including a successful Type A meeting, in September 2025 we reached agreement with the FDA regarding our NDA and are finalizing our resubmission package. There can be no assurance that the FDA will accept our resubmitted NDA for review, or approve TLX101-Px.

In February 2026, we submitted a Marketing Authorization Application ("MAA") for TLX101-Px in Europe, with France acting as the Reference Member State ("RMS"). The French National Agency for Medicines and Health Products Safety ("ANSM") in its capacity as RMS is responsible for coordinating and leading the scientific evaluation of the dossier, in collaboration with the Concerned Member States, nominated by Telix and representing the major European markets for Telix's brain cancer imaging product. There can be no assurance that the MAA will be validated, or that marketing authorizations for TLX101-Px will ultimately be granted.

Any adverse action by the FDA with respect to the BLA or NDAs, could delay our planned commercial development timelines or could prevent us from commercializing these product candidates. If the FDA determines that our submissions and the data supporting the submissions are not sufficient to support approval in these indications, we may be required to conduct an additional clinical trial or trials, which would increase our costs and delay the program. Any such delay or other adverse impact could have a material adverse effect on our business.

We have not submitted any applications for regulatory approval or obtained regulatory approval for any of our therapeutic product candidates. Our most advanced therapeutic candidate, TLX591-Tx (lutetium (Lu177) rosopatamab tetraxetan), is a lutetium-labeled radio antibody-drug conjugate ("rADC"), which we are evaluating in a two-part Phase 3 clinical trial in patients with advanced prostate cancer, called ProstACT Global. We dosed the first patient in this clinical trial in November 2023 in Australia. We received authorization to conduct Part 1 of the trial in the U.S. in April 2024 and completed target enrollment of 30 patients in August 2025. We dosed the first patient in ProstACT Global Part 2 (randomized treatment expansion) in Australia in December 2025. We cannot be certain that TLX591-Tx, or any of our clinical trials of our other therapeutic product candidates, will generate safety and efficacy data sufficient for regulatory approval in any jurisdiction.

The commercial success of our Commercial Products and our product candidates, if approved, is dependent on many factors, some of which are beyond our control, including clinical development, the regulatory submission and approval process, market access or reimbursement frameworks, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts. If we are unable to continue to commercialize our Commercial Products or to develop, receive regulatory approval for and successfully commercialize our product candidates, or experience delays as a result of any of these factors or otherwise, our business and results of operations could be substantially harmed.

Clinical development is a lengthy and expensive process, with uncertain timelines and outcomes. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates, if approved.

Our long-term success depends in large part on our ability to continue to successfully develop additional product candidates in imaging and therapeutic indications. Clinical testing is expensive, time consuming, difficult to design and implement, and is inherently uncertain as to outcome. Clinical failure can occur at any stage of the clinical development process and, therefore, the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later stage clinical trials. Furthermore, the failure of any product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our company or our products and/or cause the FDA or other regulatory authorities to require additional testing before any of our product candidates are approved.

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We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval of our product candidates, including, but not limited to, the following:

- delays or failure to reach agreement with regulatory authorities on a trial design or the receipt of feedback requiring us to modify the design of our clinical trials, perform additional or unanticipated clinical trials to obtain approval or alter our regulatory strategy;
- clinical trials of our product candidates may produce negative or inconclusive results or other patient safety concerns, including undesirable adverse events or other unexpected characteristics, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials, suspend ongoing clinical trials or abandon product development programs, including as a result of a finding that the participants are being exposed to unacceptable health risks;
- enrollment in our clinical trials may be slower than we anticipate or we may not be able to enroll the number of patients that we expect, including as a result of competition with other ongoing clinical trials for the same indications as our product candidates or because the patient population may be limited for orphan indications;
- regulators may revise the requirements for approving our product candidates, even after providing a positive opinion on or otherwise reviewing and providing comments on a clinical trial protocol, or such requirements may not be as we anticipate;
- delays or failure in obtaining the necessary authorization from regulatory authorities or institutional review boards to permit us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or the suspension or termination of a clinical trial once commenced;
- delays or failure to reach agreement on acceptable terms with prospective clinical trial sites or contract research organizations ("CROs");
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including manufacturers or CROs, may fail to comply with regulatory requirements, perform effectively, or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might be found to be non-compliant with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- regulators or institutional review boards/ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- imposition of a temporary or permanent clinical hold by regulatory authorities for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment, as a result of a new safety finding that presents unreasonable risk to clinical trial participants, or a negative finding from an inspection of our clinical trial operations or study sites;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in trial of the same class of agents conducted by other companies;
- any partners or collaborators that help us conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us; and
- negative impacts resulting from infectious disease epidemics or pandemics, including impacts to healthcare systems and our trial sites' ability to conduct trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate or are unable to successfully complete clinical trials of our product candidates or other testing, on

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a timely basis or at all, and/or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining, or not obtain at all, regulatory approval for the indication or product candidate;
- obtain regulatory approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining regulatory approval.

Further, we do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our products, allow our competitors to bring products to market before we do or impair our ability to successfully commercialize our products, which would harm our business and results of operations. In addition, many of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of regulatory approval of our product candidates.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.

We may not be able to initiate or continue our ongoing or planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other applicable foreign regulator. In addition, some of our competitors may have planned or ongoing clinical trials or expanded access programs for approved and/or investigational products that would treat the same patients as our therapeutic product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in our competitors' clinical trials or expanded access programs. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- the incidence and prevalence of our target indications;
- clinicians' and patients' awareness of, and perceptions as to the potential advantages and risks of our product candidates in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- invasive procedures required to enroll patients and to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the ability of our companion diagnostics to identify patients;
- the size of the patient population required for analysis of the trial's primary endpoints;
- efforts to facilitate timely enrollment in clinical trials;
- whether we are subject to a partial or full clinical hold on any of our clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll and retain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in

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increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Serious adverse events related to our Commercial Products or our product candidates may delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials or abandon further development, limit the commercial value of approved indications or result in significant negative financial consequences following any regulatory approval.

If our Commercial Products or any of our product candidates are associated with undesirable adverse events or have characteristics that are unexpected in clinical trials or following approval and/or commercialization, we may need to abandon or limit their development or limit marketing to certain uses or subpopulations in which the undesirable adverse events or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Adverse events in our clinical trials to date have been generally predictable and typically manageable, with frequency and severity for adverse events applicable to imaging less than for therapy product candidates. The most common adverse events for Illuccix in clinical trials were nausea, diarrhea, and dizziness. The most common adverse events arising in the Phase 3 ZIRCON clinical trial of 300 patients dosed with TLX250-Px were mild and non-serious, including nausea, procedural pain and headache. The most common severe adverse events were post-procedural hemorrhage (six events), urinary retention (three events), hypertension (three events), pyelonephritis (two events), anemia (two events), and syncope (two events). For TLX101-Px there have been two events reported to date in an ongoing clinical trial, which are injection site reaction and nausea, both mild and non-serious.

With respect to our therapeutic product candidates, our most clinically advanced therapeutic, TLX591-Tx, has been evaluated in 242 patients across eight Phase 1 and 2 trials, including the Phase 1 ProstACT SELECT trial. In Cohort 2 of ProstACT SELECT (25 participants), treatment emergent adverse events ("TEAE") rates were: Grade 3 thrombocytopenia (16%, 4/25), grade 3 neutropenia (28%, 7/25), grade 4 thrombocytopenia (20%, 5/25) and grade 4 neutropenia (4%, 1/25). Six patients received intervention in the form of platelet or red blood cell transfusion(s), or both. Early-stage trial results should be interpreted with caution and efficacy outcomes should be evaluated for statistical and clinical significance in a larger Phase 3 randomized controlled trial. TLX591-Tx is presently being investigated in Telix's Phase 3 ProstACT Global trial.

The occurrence of adverse events in either our clinical trials or following regulatory approval could result in a more restrictive label for any product candidates approved for marketing or could result in the delay or denial of approval to market any product candidates by the FDA or comparable foreign regulatory authorities, which could prevent us from generating sufficient revenue from product sales or maintaining profitability. Treatment-related adverse effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, result in potential product liability claims or cause patients and/or healthcare providers to elect alternative courses of treatment. In addition, these adverse events may not be appropriately recognized or managed by the treating medical staff. Inadequate training or education of healthcare professionals to recognize or manage the potential adverse events following treatment with our Commercial Products or our product candidates, if approved, could result in increased treatment-emergent adverse events and cause patients to discontinue treatment. Any of these occurrences may harm our business, financial condition and prospects significantly.

Results of our trials could reveal an unacceptably high severity and prevalence of adverse events. In such an event, our trials could be suspended or terminated by us or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications.

Adverse events in the results of trials conducted by our competitors could also cause the FDA or comparable foreign regulatory authorities to raise concerns regarding our trials and product candidates, and/or impose additional safety and tolerance procedures on us, which may be costly. Many compounds that initially showed promise in early-stage trials for treating cancer or other diseases have later been found to cause adverse events that prevented further development of the compound. If such an event occurs after any of our product candidates are approved and/or commercialized, a number of potentially significant negative consequences may result, including:

- regulatory authorities may withdraw the approval of such product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning, precaution or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or impose distribution or use restrictions;
- patients and/or healthcare providers may elect to utilize other treatment options that have or are perceived to have more tolerable adverse events;
- regulatory authorities may require one or more post-marketing studies;
- we may be required to implement a Risk Evaluation and Mitigation Strategy ("REMS"), or create a medication guide outlining the risks of such adverse events for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;

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- we could be sued and held liable for harm caused to patients;
- the product could become less competitive; and
- our reputation may suffer.

Further, we and our clinical trial investigators currently determine if serious adverse events are product-related in accordance with scientific practice and current knowledge. The FDA or foreign regulatory authorities may disagree with our or our clinical trial investigators' interpretation of data from clinical trials and the conclusion by us or our clinical trial investigators that a serious adverse event was not product-related. The FDA or foreign regulatory authorities may require more information related to the safety profile of our Commercial Products or our product candidates, including additional preclinical or clinical data to support approval, which may cause us to incur additional expenses, delay or prevent the approval of one of our product candidates, and/or delay or cause us to change our commercialization plans, or we may decide to abandon the development of the product candidate altogether.

Any of these events could prevent the affected product candidate, if approved, from achieving or maintaining market acceptance, or could substantially increase costs and expenses of development or commercialization, which could delay or prevent us from generating sufficient revenue from the sale of our Commercial Products or any other approved product and harm our business and results of operations.

The results of previous clinical trials may not be predictive of future trial results, and preliminary, interim or top-line data may be subject to change or qualification based on the complete analyses of data and, therefore, may not be predictive of the final results of a trial.

Clinical failure can occur at any stage of the clinical development process and, therefore, the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later stage clinical trials. For example, preliminary, interim or top-line data may be based on unaudited data provided by our clinical trial investigators.

Finalization and cleaning of this data may change the conclusions drawn from this unaudited data provided by our clinical trial investigators indicating less promising results than we currently anticipate. Further, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the dropout rate among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety data sufficient to obtain regulatory approval to market our product candidates, if approved. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks.

We may publicly disclose preliminary, interim or top-line data from our clinical trials. Disclosures are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as further patient data become available and following a more comprehensive review of the data related to the particular study or trial. For any study that we report preliminary, interim or top-line data, we make assumptions, estimations, calculations and conclusions as part of our analyses of data. We may not have received or had the opportunity to fully and carefully evaluate all data, or our conclusions may differ from those of the FDA or other regulatory authorities.

Consequently, the preliminary, interim or top-line data results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or based on differing views from regulatory agencies. Preliminary, interim or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, these early data points should be viewed with caution until the final data are available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Furthermore, we may report interim analyses of only certain endpoints rather than all endpoints. Investors may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business.

If the preliminary, interim or top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, if approved, may be harmed, which could harm our business, operating results, prospects, or financial condition.

Our approach to the discovery and development of therapeutic product candidates represents a novel approach to radiation therapy, which creates significant and potentially unpredictable challenges for us.

Our success depends on the successful development of our therapeutic product candidates, which are designed to treat solid tumors using a novel approach to radiation therapy. There are currently few approved radiopharmaceutical

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therapeutic products. In addition, there has been limited historical clinical trial experience, generally, for the development of radiopharmaceutical therapeutics. As a result, the design and conduct of clinical trials for these drugs is uncertain and subject to increased risk.

While the use of external beam radiation as a therapy for cancers has existed for decades, the use of systemic delivery of targeted radiopharmaceuticals in general is relatively new, including for both beta- and alpha-emitting therapies. It is difficult to accurately predict the challenges we may incur for our therapeutic product candidates as they proceed through clinical trials. In addition, assessments of the long-term safety of targeted beta- and alpha-emitting isotope therapies have been limited, and there may be long-term effects from treatment with our therapeutic product candidates that we cannot predict at this time.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our ongoing or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Before we can initiate clinical trials for any future product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing required for authorization to proceed with clinical development. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory filing, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing or planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs.

We do not know whether our planned and ongoing trials will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards ("IRBs");
- IRBs or ethics committees refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- delays in identifying, recruiting and training suitable clinical investigators;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of our product candidates for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials due to movement restrictions, health reasons or otherwise resulting from ongoing or future public health or geopolitical concerns;
- subjects choosing alternative treatments for the indications for which we are developing our therapeutic product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial or incurring greater costs than we anticipate;
- subjects experiencing severe or serious unexpected treatment-emergent adverse events;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;

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- failure of a facility manufacturing our product candidates or any of their components to produce clinical trial materials in accordance with current good manufacturing practice requirements("cGMP"), regulations (and similar foreign requirements) or other applicable requirements;

- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations (and similar foreign requirements) or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;

- any transfer of manufacturing processes to alternate facilities or any other changes to our manufacturing process that may be necessary or desired;

- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice ("GCP"), requirements or other regulatory requirements;

- third-party contractors not performing data collection or analysis in a timely or accurate manner; or

- third-party clinical investigators or becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such clinical investigators or contractors in support of our marketing applications.

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We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, failure to demonstrate a benefit from using a drug or diagnostic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates, if approved, will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues if the product candidate is approved. Such delays could also shorten any period during which we may have the exclusive right to commercialize our product candidates, if approved, and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Subject enrollment is affected by many factors including the size and nature of the patient population, the severity of the disease under investigation, the availability and efficacy of approved drugs and diagnostics for the disease under investigation, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, patient referral practices of physicians, the ability to monitor patients adequately during and after treatment, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development.

We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. The potential patient populations for our clinical trials may be narrow, and we may experience difficulties in identifying and enrolling a sufficient number of patients in our clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities.

Other pharmaceutical or biotechnology companies targeting the same diseases and intended uses as our product candidates are recruiting for their clinical trials from these patient populations, which may make it more difficult to fully enroll our clinical trials. Our inability to enroll a sufficient number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, the process of finding eligible subjects may prove costly.

Moreover, we rely on CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance. We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Due to their radioactive nature, our Commercial Products and our product candidates have time-limited stability, and as a result, we may encounter difficulties with fulfillment and logistics.

The radioactive components of our Commercial Products and our product candidates have short shelf lives due to their half lives, which refers to the time it takes for the radioactivity to decrease by 50%. Post addition of the radioactive isotope, radioactivity decay reduces the shelf life of our Commercial Products and our product candidates, which requires us to manufacture and deliver our Commercial Products and our product candidates for use in clinical trials to patients in a timely manner.

Our products and product candidates are commonly manufactured as a cold-kit, namely our Commercial Products, enabling longer shelf storage of between 12-24 months prior to radiolabeling for specific patient administration on an as-needed basis. As such, our Commercial Products and our product candidates must be radiolabeled on an as-needed basis, and shipped almost immediately thereafter. Because of this, specific radiolabeled patient doses of our Commercial Products or our product candidates cannot be "stock-piled" and stored for even a small number of days ahead of shipment, we or any third-party pharmacy network or hospital must be able to radiolabel them on an as-needed rolling basis. Any delay, even if seemingly insignificant, could result in an immediate and substantial impact on our ability to deliver our Commercial Products or product candidates to patients. Any significant delays in delivering our Commercial Products or our product candidates to patients could damage our reputation and result in deviations from our clinical trial protocols, which in turn could affect our ability to advance the clinical development of our current and future product candidates on a timely basis, or at all. In addition, we currently substantially rely on our third-party radiopharmacy partners for the production of our Commercial Products for commercial supply in the U.S. We cannot be sure that these manufacturers will be able to meet our demand for our Commercial Products on a timely basis.

With respect to our product candidates, as we continue to scale our operations and enroll larger clinical trials, and prepare for potential commercialization, if marketing authorization is obtained, we will need to scale our shipping abilities. Labor disputes, government restrictions, work stoppages, pandemics, derailments, damage or loss events, adverse weather conditions, other events beyond our control could interrupt or delay transportation, which could result in the loss or damage of our Commercial Products or any product candidates with similar stabilization restrictions. We have insurance which covers material loss or damage to Illuccix and/or Gozellix while in partner control or during transit, subject to customary insurance limitations and restrictions. Our insurance may not cover all instances worldwide.

If we or our manufacturers are unable to meet the challenges posed by the time-limitations inherent in the composition of our Commercial Products or any of our product candidates, it would adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to identify or discover additional product candidates or our decisions to prioritize the development of certain product candidates over others may later prove wrong.

Part of our strategy involves identifying and developing product candidates to build a pipeline of product candidates. Our diagnostic and therapeutic discovery or development efforts may not be successful in identifying compounds that are useful in diagnosing or treating cancer or other diseases. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- potential product candidates may, on further study, be shown to have harmful adverse events or other characteristics that indicate that they are unlikely to be products that will receive regulatory approval and/or achieve market acceptance; or
- potential product candidates may not be effective in treating their targeted diseases or yield clinically significant outcomes.

We are currently advancing multiple imaging and therapeutic product candidates in clinical development, which may create a strain on our limited human and financial resources. As a result, we may not be able to provide sufficient resources to any single product candidate to permit the successful development and commercialization of such product candidate, if approved, which could result in material harm to our business. Further, we have limited financial and

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managerial resources, and we can only focus our research programs on developing product candidates for certain indications.

As a result, we may forego or delay pursuit of opportunities with other product candidates or the same product candidate for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our strategy involves pairing our diagnostic imaging product or product candidates with a complementary therapeutic product candidate, and we may not be successful in developing both the diagnostic and therapeutic product candidates that are designed to be paired, which could impact the successful development of both.

In connection with certain targets for which we are developing drug or biological candidates for treatment use, we are developing diagnostic imaging agents to help inform whether a particular patient's disease condition is appropriate for treatment with our drug or biological candidate. For example, we are using Illuccix as the paired diagnostic to our therapeutic product candidate, TLX591-Tx (in addition to Illuccix being previously studied and used in the VISION trial as a diagnostic for Novartis' Pluvicto radioligand therapy) and we are developing TLX300-Px as the paired diagnostic to evaluate the potential utility of TLX300-Tx, and similarly we are developing paired diagnostics for our other therapeutic product candidate development programs. We may not be successful in developing an appropriate diagnostic imaging agent or its development may cause a delay or result in expenditure of more funds than we currently anticipate. In addition, the development of a diagnostic imaging agent will be subject to FDA review and approval, which may be delayed or not obtained, or require additional development and testing than currently planned. If the FDA considers the diagnostic imaging agent to be required for the use of the therapeutic product candidate, the FDA may require the approval of the diagnostic imaging agent before it can approve the therapeutic product candidate. Equivalent foreign regulatory review and approval would also be required before the product could be supplied for use in patient treatment. Failure to successfully develop and obtain regulatory approval for a diagnostic imaging agent may delay FDA or foreign regulatory approval of a drug or biological candidate intended for therapeutic use and delay or adversely affect commercialization of that drug or biological candidate, if approved, or require us to engineer or identify alternative solutions to select patients who are most likely to benefit from our drug or biological candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The discovery, development and commercialization of new diagnostics and therapies is highly competitive, particularly in the cancer field. We face competition with respect to our Commercial Products and will face competition with respect to any product candidates that we are developing and may seek to commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, academic institutions and governmental agencies as well as public and private research institutions worldwide, many of which have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

There are a number of major pharmaceutical, specialty pharmaceutical and biotechnology companies that currently market and sell diagnostics and therapies and/or are pursuing the development of diagnostics and therapies for the treatment of cancer and the other disease indications for which we are developing our products and product candidates.

With respect to Illuccix and Gozellix, our main competitors in the U.S. include companies with approved PSMA-PET diagnostics, including Novartis AG, Lantheus Holdings, Inc. and The Bracco Group (through its Blue Earth Diagnostics affiliate). Certain academic institutions, like University of California, Los Angeles and University of California, San Francisco, also hold a license for a commercial PSMA-PET diagnostic. Our main competitors also include companies developing PSMA imaging agents, including Curium Holding France S.A.S., Clarity Pharmaceuticals Limited, ABX advanced biochemical compounds GmbH, Isotopia Molecular Imaging Ltd., Itel Group, ITM Isotope Technologies Munich SE, Five Eleven Pharma Inc., FutureChem Co. Ltd., Radiomedix, Inc., CellBion Co., Ltd., Norroy Biosciences Co. Ltd., HTA, and Jiangsu Hengrui Pharmaceuticals Company Ltd. Our competitors will also include companies developing other modalities to localize prostate cancer.

In the kidney and brain cancer imaging fields, there are no approved agents for molecular imaging for ccRCC or glioma. Our main future competitors in these fields are companies developing agents, including ITM Isotope Technologies Munich SE, Philogen S.p.A., Precision Molecular, Inc., Norroy Biosciences Co. Ltd., PeptiDream Inc., Five Eleven Pharma Inc., Novartis AG, The Bracco Group (through its Blue Earth Diagnostics Ltd. Subsidiary), RadioPharm Theranostics Limited, Curasight A/S, Molecular Targeting Technologies, Inc. ("MTTI"), and BoomRay Pharmaceuticals Co., Ltd.

With respect to our therapeutic product candidates, we consider our most direct competitors to be companies developing targeted radiopharmaceuticals for the treatment of cancer. There are several companies with approved beta-based radiopharmaceuticals, including Novartis AG, Sirtex Medical Limited, Boston Scientific Corporation, Acrotech Biopharma LLC, and Q BioMed Inc. and other companies developing beta-based radiopharmaceuticals, including Lantheus Holdings, Inc., Eli Lilly and Company Ltd, ITM Isotope Technologies Munich SE, Debiopharm SA, Curium Holding

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France S.A.S, Clarity Pharmaceuticals Limited, The Bracco Group (through its Blue Earth Therapeutics Ltd. subsidiary), and Y-mAbs Therapeutics, Inc. The beta emitting isotopes used by these companies include Iodine-131, Lutetium-177, Strontium-89, Copper-67, and Yttrium-90. A recently approved beta particle-based radiopharmaceutical is Pluvicto, which was developed by Novartis AG and approved by the FDA in 2022 for the treatment of patients with metastatic prostate cancer.

There are also several companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer, including Bayer AG, Novartis AG, Johnson & Johnson, Abdera Therapeutics Inc., Actinium Pharmaceuticals, Inc., Aktis Oncology, Inc., Convergent Therapeutics, Inc., AstraZeneca PLC, ITM Isotope Technologies Munich SE, Perspective Therapeutics, Inc., Eli Lilly & Company Ltd, RadioMedix, Inc., Bristol Myers Squibb Company, and Y-mAbs Therapeutics, Inc. These companies are targeting a wide range of solid and hematologic malignancies using various alpha-emitting isotopes, including Radium-223, Lead-212, and Actinium-225. The first and only approved alpha particle-based therapy is Xofigo (Radium-223), which was developed by Bayer AG and approved in 2013 for the treatment of prostate cancer with symptomatic bone metastases.

With respect to TLX591-Tx (lutetium (Lu177) rosopatamab tetraxetan), our main competitors include Novartis AG, with Pluvicto as the only currently approved PSMA-targeted therapy. Our main competitors also include companies developing PSMA-targeted therapies, including AstraZeneca PLC, Convergent Therapeutics, Inc., Eli Lilly & Company Ltd., Lantheus Holdings, Inc., Curium Holding SAS, ArtBio, Inc., The Bracco Group (through its Blue Earth Therapeutics Ltd. Subsidiary), Clarity Pharmaceuticals Ltd., Bayer AG, Orano Med SAS, Isotopia Molecular Imaging Ltd., ITM Isotope Technologies Munich SE, Johnson & Johnson, AdvanCell Isotopes Pty Ltd., Alpha-9 Theranostics Inc., Cancer Targeted Technology LLC, FutureChem Co Ltd., Beijing Sinotau Intl. Pharmaceutical Technology Co., Ltd., Norroy Biosciences Co. Ltd., RadioPharm Theranostics Limited, Precision Molecular, Inc., CellBion Co., Ltd., StarPharma Holdings Limited, Amgen Inc., Crescendo Biologics Limited, Poseida Therapeutics, Inc., Regeneron Pharmaceuticals Inc., BioXcel Therapeutics, Inc., Lava Therapeutics NV, Janux Therapeutics, Inc., Vir Therapeutics, Inc., Bivision Pharmaceuticals, Inc., GlyTherix Ltd, Jiangsu Hengrui Pharmaceuticals Co., Ltd., and Full-Life Technologies Limited. Our competitors also include companies developing other modalities to treat patients in metastatic castration-resistant prostate cancer ("mCRPC").

For TLX400-Tx (^{177}Lu-DOTAGA.Glu.$(FAPi)_2$), our main competitors are companies developing FAP-targeting radiotherapeutics or diagnostics, including Novartis AG, Eli Lilly and Company Ltd, 3BP Pharmaceuticals GmbH, Ratio Therapeutics Inc., Akiram Therapeutics, BoomRay Pharmaceuticals Co., Ltd., Philogen SPA, Precirix NV, Ratio Therapeutics Inc., Spago Nanomedical AB, Yantai LNC, ITM Isotope Technologies Munich SE, Lantheus Holdings, Inc, Perspective Therapeutics, Inc., Precision Molecular Inc., Sofie Biosciences, Inc., and GE Healthcare.

For TLX300-Tx (-olaratumab), our main competitors include companies with licensed soft-tissue sarcoma treatments including Novartis AG, Adaptimmune Therapeutics plc, Agilent Technologies Inc., Boehringer Ingelheim GmbH, Esai Co., Ltd., , Mark, PharmaMar SA, Johnson & Johnson, Taiho Pharmaceuticals as well as other companies commercializing chemotherapy regimens approved in soft-tissue sarcoma. Our competitors also include companies developing therapies in the field of sarcoma including Ratio Therapeutics Inc., PTC Therapeutics, Polaris Pharmaceuticals, BioAtla. Eli Lilly and Company Ltd, Advenchen Laboratories LLC, Intensity Therapeutics Inc, Sun Pharmaceutical Industries Ltd, Exelixis Inc, Y-mAbs Therapeutics Inc, QBiotics Group Limited, Apollomics Inc, Pyxis Oncology, AADi Bioscience Inc, Moleculin Biotech Inc, Cornerstone Pharmaceuticals Inc, Shasqi Inc, Noxopharm Limited, NANO MRNA Co Ltd, Avacta Group plc, Iovance Biotherapeutics Inc, Foghorn Therapeutics Inc., OncoTherapy Science Inc. and Syena.

For TLX250-Tx (^{177}Lu-DOTA-girentuximab), our main competitors include ITM Isotope Technologies Munich SE, Precision Molecular, Inc., Norroy Biosciences Co. Ltd., PeptiDream Inc, Bristol Myers Squibb Company and Bayer AG. Our competitors will also include companies developing other modalities to image renal cell carcinoma and carbonic anhydrase IX.

For TLX101-Tx (iodofalan ^{131}I), our main competitors include ITM Isotope Technologies Munich SE, Molecular Targeting Technologies, Inc. ("MTTI"), Novartis AG, Radiopharm Theranostics Limited, Plus Therapeutics, Inc., Ariceum Therapeutics GmbH, Boston Scientific Corporation, and Cellectar Biosciences, Inc. Our competitors will also include companies developing other modalities to treat brain cancer.

For TLX090-Tx (^{153}Sm-DOTMP), our main competitors include commercially available compounds that relieve pain from osteoblastic bone metastases, including Novartis AG, Bayer AG, Pfizer Inc., Purdue Pharma L.P., Roxane Laboratories, Inc., Johnson & Johnson, Mallinckrodt Inc., Endo Pharmaceuticals Holdings Inc., Mylan Laboratories Inc., Noven Pharmaceuticals, Inc., Aveva Group PLC, Sandoz Group AG, Ranbaxy Laboratories Ltd., Amneal Pharmaceuticals LLC, Hoffmann-La Roche AG, Apotex Inc, Orchid Healthcare LTD, Grünenthal GmbH, as well as other companies commercializing or developing other palliative agents for osteoblastic bone metastases.

We are currently focused on developing and commercializing our Commercial Products and our product candidates for the diagnosis and treatment of cancer and there are a variety of commercially available imaging and therapeutic products marketed for cancer. In many cases, cancer imaging products and therapeutics are administered in combination to enhance efficacy. Some of these products are branded and subject to patent protection, and others are available on a generic basis or prepared under the practice of pharmacy or pharmacy compounding exemptions in certain jurisdictions.

Many of these products are well-established and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic diagnostics and therapeutics. Our Commercial Products are, and any candidate for which we obtain marketing authorization will likely be, priced at a

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significant premium over competitive generic products, also known as “home-brew” or “compounded” non-cGMP products, which may make it difficult for us to achieve our business strategy of using our products in combination with existing products or replacing existing products with our products, particularly if clinical differentiation or innovation contribution is more limited compared to currently available products.

Further, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are or are perceived to be more effective, safer, more tolerable, more convenient and/or less costly than any of our currently approved products or product candidates which receive marketing authorization or that would render our products obsolete or non-competitive. Our competitors may also obtain regulatory approval from the FDA or other regulatory authorities for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a stronger market position before we are able to enter the market or preventing us from entering into a particular indication at all.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, engaging clinical trial sites and enrolling patients in clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

If we are not able to compete effectively against current or potential competitors, our business may be materially harmed and our financial condition and results of operations will be adversely affected.

We may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, of our Commercial Products and any product candidates for which we obtain regulatory approval, including Illuccix and Gozellix, in which case we may not generate significant revenues or remain profitable.

We may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success of our Commercial Products and any product candidates for which we obtain regulatory approval. Oncologists may be reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their oncologists recommend switching products or they are required to switch therapies due to lack of coverage and reimbursement for existing therapies.

Efforts to drive adoption within the medical community and third-party payors based on the benefits of our products and product candidates require significant resources and may not be successful. The success of our Commercial Products and our current or future product candidates, if approved, whether alone or in collaboration with third parties, including achieving and maintaining an adequate level of market adoption, depends on several factors, including:

- our ability to successfully launch and achieve broad adoption of our Commercial Products or any other product for which we obtain approval, or any future indications for which our Commercial Products may be approved;
- the competitive landscape for our Commercial Products and our product candidates, including the timing of new competing products entering the market and the level and speed at which these products achieve market acceptance;
- actual or perceived advantages or disadvantages of our Commercial Products or any product candidates for which we obtain approval as compared to alternative treatments, including their respective safety, tolerability and efficacy profiles, the potential convenience and ease of administration, access or cost effectiveness;
- the effectiveness of our sales, marketing, manufacturing and distribution strategies and operations;
- the consistency of any new data we collect and analyses we conduct with prior results; whether they support a favorable safety, efficacy and effectiveness profile of our Commercial Products; and any potential impact on our FDA or any foreign regulatory approvals and/or labeling for our Commercial Products;
- our ability to comply with the FDA’s and comparable foreign regulatory authorities’ post-marketing requirements and commitments, including through successfully conducting, on a timely basis, additional studies that confirm clinical efficacy, effectiveness and safety of our Commercial Products (or any product candidates for which we obtain approval and are required to conduct such studies) and acceptance of the same by the FDA or similar foreign regulatory authorities;
- acceptance of current indications of our Commercial Products and future indications of our Commercial Products and other product candidates, if approved, by patients, the medical community and third-party payors;
- obtaining and maintaining coverage, adequate pricing and reimbursement by third-party payors, including government payors, for our Commercial Products and our product candidates, if approved;

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- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or as co-pay amounts under third-party coverage;
- our ability to enforce intellectual property rights in and to our products to prohibit a third-party from marketing a competing product and our ability to avoid third-party post-grant patent proceeding or intellectual property infringement claims;
- current and future restrictions or limitations on our approved or future indications and patient populations or other adverse regulatory actions;
- the performance of our manufacturers, license partners, distributors, providers and other business partners, over which we have limited control;
- any significant mis-estimations of the size of the market and market potential for any of our Commercial Products or our product candidates;
- establishing and maintaining commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, based, in part, on their perception of our clinical trial data and/or the actual or perceived safety, tolerability and effectiveness profile;
- maintaining an acceptable safety and tolerability profile of our Commercial Products or any of our product candidates for which we obtain approval, including the prevalence and severity of any adverse events;
- the ability to offer our Commercial Products or any product candidates for which we obtain approval for sale at competitive prices;
- adverse publicity about our Commercial Products or favorable publicity about competitive products; and
- our ability to maintain compliance with existing and new health care laws and regulations, including government pricing, price reporting and other disclosure requirements related to such laws and regulations, and the potential impact of such laws and regulations on physician prescribing practices and payor coverage.

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our Commercial Products or our product candidates, if approved, which would materially harm our business.

If we are unable to maintain or expand our sales, marketing and distribution capabilities, we may not be successful in commercializing our Commercial Products or any of our product candidates, if approved.

We have built a commercial infrastructure in Australia, New Zealand, the U.S., Brazil, Canada and Europe for our Commercial Products. Prior to building this infrastructure, we did not previously have any experience in the sales, marketing or distribution of pharmaceutical products. If any of our product candidates are approved, we may need to evolve our sales, marketing and distribution capabilities and we may not be able to do so successfully or on a timely basis. In the future, we may choose to expand our sales, marketing and distribution infrastructure to market or co-promote one or more of our product candidates, if and when they are approved, or enter into collaborations with respect to the sale, marketing and distribution of our product candidates. We are working with existing and may in the future work with additional partners to develop the commercial infrastructure to support the sale of our Commercial Products in other jurisdictions.

There are risks involved with establishing and maintaining our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any commercial launch of a product candidate or negatively impact ongoing commercialization efforts for our approved products.

Further, we may underestimate the size of the sales force required for a successful product launch and we may need to expand our sales force earlier and at a higher cost than we anticipated. If the commercial launch of any of our product candidates is delayed or does not occur for any reason, including if we do not receive regulatory approval in the timeframe we expect, we may have prematurely or unnecessarily incurred commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to successfully commercialize our Commercial Products or any of our product candidates, if approved, on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, market access, market analytics, operations and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe current or future products;

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- the lack of complementary products, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales, marketing and distribution organization;
- our inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies;
- our ability to supply, manufacture and deliver sufficient inventory of our products for commercial sale on a timely basis; and
- existing or new competitors taking share from our Commercial Products or any other product candidate for which we obtain approval in the future, or preventing our Commercial Products or any such product from gaining share in its approved indications.

The commercial success of our Commercial Products and our product candidates, if approved, will depend upon public perception of radiopharmaceuticals and the degree of their market acceptance by physicians, key opinion leaders, patients, healthcare payors and others in the medical community.

Adverse events in clinical trials of our product candidates, or in clinical trials or other studies conducted by others involving similar products, which may include the same radioisotopes as our Commercial Products and/or our product candidates, and the resulting negative publicity, as well as any other adverse events in the field of radiopharmaceuticals that may occur in the future, could result in a decrease in demand for our Commercial Products or any future product candidates that we may develop and for which we obtain regulatory approval. If public perception is influenced by claims that radiopharmaceuticals or specific therapies within radiopharmaceuticals are unsafe, our Commercial Products or any product candidates for which we obtain regulatory approval may not be accepted by the general public or the medical community.

In particular, the commercial success of our Commercial Products and our product candidates, if approved, will depend upon, among other things, these products gaining and maintaining acceptance by physicians, key opinion leaders, patients, third-party payors, and other members of the medical community as efficacious and cost-effective alternatives to competing products and treatments. If our Commercial Products or any of our product candidates, once approved, do not achieve and maintain an adequate level of acceptance, we may not generate material sales of that product or be able to successfully commercialize it. The degree of market acceptance of our Commercial Products or our product candidates, if approved, will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any adverse events in general, and differentiation relative to other treatments;
- limitations or warnings contained in the labeling approved by the FDA;
- the size of the target patient population;
- advertising concerning our products or competing products and treatments;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the ability to offer our products for sale at competitive prices;
- the relative convenience and ease of administration of our Commercial Products and product candidates, if approved, which may require coordination amongst multiple physicians across disciplines for administration;
- the willingness of the target patient population to try new products and of physicians to prescribe these products;
- strength of marketing and distribution support;
- publicity for our Commercial Products and competing products and treatments;
- the existence of distribution and/or use restrictions, such as through a REMS;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups;
- any restrictions on the use of our products together with other medications; and

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- the sufficiency of coverage or reimbursement by third parties.

Manufacturing of radiopharmaceuticals is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our Commercial Products or any of our product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.

Manufacturing of radiopharmaceuticals is complex, highly regulated and must comply with cGMPs and similar foreign requirements. While we have manufacturing capabilities of our own, we also rely on third parties, such as contract manufacturing organizations ("CMOs"), for the manufacture of our Commercial Products and our product candidates. If we are unable to obtain or maintain arrangements with CMOs, or to do so on commercially reasonable terms, we may not be able to commercialize our Commercial Products or develop our product candidates successfully. Our third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs on a timely basis or at all, and may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third-party's proprietary process, and a third-party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, either of which could significantly increase the cost of and significantly delay the manufacture of our Commercial Products or any of our product candidates.

Additionally, as we expect the market for our Commercial Products and PSMA-PET imaging to expand and our product candidates to progress through preclinical studies and clinical trials towards potential approval and commercialization, it is possible that various aspects of manufacturing will be altered in an effort to optimize processes and results. Such changes may require new submissions to and approval from regulators, which may further delay the timeframes under which modified manufacturing processes can be used for our Commercial Products or any of our product candidates, and additional bridging studies or trials may be required. Any such delay could harm our business, financial condition, results of operations and prospects.

We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMPs or similar foreign requirements. Despite our efforts to audit and verify regulatory compliance, we or one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMPs or similar foreign regulations. This may result in shutdown of our facility or that of the third-party vendor or invalidation of product lots or processes, which could adversely affect our business, financial condition, results of operations and prospects. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our products and could be costly and result in reputational damage.

We may be unable to generate and/or obtain a sufficient supply of radioisotopes to support clinical development or manufacturing at commercial scale.

As a radiopharmaceutical company, our Commercial Products and our product candidates are prepared for patient administration using radioisotopes. Gallium-68 (^{68}Ga) is a necessary component isotope for radiopharmacies to radiolabel our Commercial Products for patient administration and is sourced by a radiopharmacy directly. Other important isotopes applicable to our current pipeline of diagnostic and therapeutic product candidates include zirconium-89 (^{89}Zr), lutetium-177 (^{177}Lu), yttrium-90 (^{90}Y), fluorine-18 (^{18}F), iodine-131 (^{131}I), technetium-99m or (^{99m}Tc), actinium-225 (^{225}Ac), astatine-211 (^{211}At), and Samarium-153 (^{153}Sm). We procure these isotopes from suppliers based predominantly in Canada or Europe. Global isotope supply chains, including obtaining precursor or raw materials necessary to produce many of the synthetic radioisotopes used in nuclear medicine, are commonly sourced from countries such as Russia, Brazil, South Africa and Türkiye that may, from time-to-time, be subject to instability, unrest, protests, intergovernmental conflicts and various international trade or monetary sanctions. Where isotopes or raw materials are procured under various medical or humanitarian exemptions, including countries that may, from time-to-time, be subject to instability, unrest, protests, intergovernmental conflicts and various international trade or monetary sanctions, those exemptions may be repealed or altered in a way that is detrimental to our ability to operate our business.

We aim to maintain multiple supply agreements with isotope suppliers and stockpiles to ensure adequate quantities to meet our current pipeline development needs. However, there is a limited supply of some radioisotopes due to the limited supply of starting radioactive raw materials to create the radioisotope or the complexity required to manufacture isotopes to the required quality and purity standards for effective radiolabeling. We aim to maintain supply relationships with all major current suppliers and for certain isotopes there are no or limited alternatives to our current suppliers.

While we are making investments to secure additional access to and capabilities for manufacturing isotopes, we may encounter supply shortages which could affect our business operations and results of operations. There can be no assurance that our suppliers will renew existing contracts on acceptable terms, or even at all. Additionally, failure to acquire enough medical-grade isotopes for specific product candidates would make it impossible to effectively complete clinical trials, especially as we scale up for later-stage clinical trials, and to commercialize any product candidates that we may develop, which would materially harm our business.

Isotope suppliers may also have limited production capacity to meet future commercial demand, and there is no guarantee that production will start in the time frame we expect. Even where a contract exists, we may have limited recourse if a supplier is unable to meet its obligations. Suppliers may also be unable to meet their obligations for any

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number of reasons. For example, the U.S. Department of Energy has reserved its ability to cancel private orders when the supply is instead needed for national defense, environmental safety, or in the event of any other sort of lack of supply capacity or for a number of other reasons that are outside of our control.

Radioisotopes or radioactive raw materials may only be available from a limited number of countries, including Russia, Brazil, Türkiye or South Africa. Our isotope suppliers obtain the radioactive materials from source material countries in accordance with applicable laws and export regulations, usually under medical exemption, and then use the raw materials to manufacture the radioisotopes for onward clinical sale and commercial sale to third parties, including governments, hospitals and pharmaceutical companies. We and our suppliers are exposed to a number of environmental and geopolitical risks beyond radioactive raw material availability, including restrictions on trade of certain items with Russia, and other unforeseen geopolitical factors that limit our ability to access our supply of raw material. The ongoing war in Ukraine and subsequent economic sanctions imposed on Russia, including by the U.S., may impact our ability to procure supply of necessary isotopes and may impact our product development timelines. For example, while our current suppliers are not currently designated on any export or sanctions-related restricted party lists maintained by the U.S. government, there is no guarantee our suppliers (or their third-party suppliers of raw materials) will not be designated on such lists in the future. In addition, our dependence on international radioisotope suppliers is increased in the near term because the U.S. Department of Energy restricts usage for certain isotopes for clinical development outside the U.S., and therefore, we must rely on our suppliers for our international operations. To date, the ongoing war in Ukraine has not materially impacted the development of any of our product candidates, nor has it materially impacted the price at which we are able to purchase isotopes. Although we do not expect to encounter additional delays from our suppliers based on the ongoing war in the Ukraine, we may experience delays in the future, and any such delay could have an adverse material impact on our development plans and business. We expect to continue to monitor and adapt our development plans as necessary in response to environmental and geopolitical risks. Any difficulty that our suppliers have in procuring raw materials may also magnify the impact of other risks described in this Annual Report.

Our ability to conduct clinical trials to advance our product candidates is dependent on our ability to either self-generate and/or obtain these radioisotopes and other isotopes we may choose to utilize in the future. While we intend to scale-up our manufacturing facilities to achieve vertical integration and the ability to self-manufacture our final diagnostics and therapeutics products, we are dependent on third-party manufacturers and suppliers for many of our isotopes, and our suppliers will be dependent on third parties to supply the raw radioactive materials. These parties may not perform their contracted services or may breach or terminate their agreements with us. Our suppliers are subject to regulations and standards that are overseen by regulatory and government agencies, and we have no control over our suppliers' compliance with these standards. Failure to comply with regulations and standards may result in their inability to supply an isotope that could result in delays in our clinical trials or commercialization, which could have a negative impact on our business.

Even if we are able to effectively commercialize our Commercial Products or any product candidates for which we obtain approval, the products may not receive coverage or may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, all of which would harm our business.

The legislation and regulations that govern regulatory approvals, pricing, coverage and reimbursement for new imaging and therapy products vary widely from country to country. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to pricing or reimbursement regulations that delay the commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from product sales in that country. In the U.S. and most other major markets internationally, approval and reimbursement decisions are not linked directly, but there is increasing scrutiny from the Congress, government or regulatory authorities, payors, patient organizations of the pricing or reimbursement of pharmaceutical products. Adverse pricing or reimbursement limitations may also hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to successfully commercialize our Commercial Products and any other products that we may develop or acquire will depend, in part, on the extent to which satisfactory pricing, coverage and reimbursement for these products is available from government payors, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Obtaining and maintaining adequate coverage and reimbursement for our Commercial Products and any of our product candidates, if approved, may be difficult. Moreover, the process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for our products. Even with payor coverage, patients may be unwilling or unable to pay the copay required and may choose not to take or use our products.

A primary trend in the healthcare industry in the U.S. and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products.

Third-party payors may also seek, with respect to an approved product, additional clinical evidence that goes beyond the data required to obtain regulatory approval. They may require such evidence to demonstrate clinical benefits and value in specific patient populations or they may call for costly pharmaceutical studies to justify coverage and

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reimbursement or the level of reimbursement relative to other therapies before covering our products. Accordingly, we cannot be sure that reimbursement will be or will continue to be available for our Commercial Products and any product that we commercialize in the future and, if reimbursement is available, we cannot be sure as to the level of reimbursement and whether it will be adequate. Coverage and reimbursement may impact the demand for or the price of our Commercial Products or any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our Commercial Products or any other approved products.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that our Commercial Products or any product candidate for which we obtain approval will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. Third-party payors in the U.S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our products and our overall financial condition.

Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of our Commercial Products or any other products or product candidates that we may develop or acquire.

We face an inherent risk of product liability exposure related to our commercialization of our Commercial Products and the testing of our product candidates in human clinical trials as the administration of our products to humans may expose us to liability claims, whether or not our products are actually at fault for causing any harm or injury. As our Commercial Products are used over longer periods of time by a wider group of patients taking numerous other medicines or by patients with additional underlying conditions, the likelihood of adverse product reactions or unintended adverse events, including death, may increase. For example, we may be sued if any of our Commercial Products or product candidates we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we will incur substantial liabilities or may be required to limit commercialization of our Commercial Products and product candidates, if approved. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our Commercial Products and any other products that we may develop or acquire;
- injury to our reputation and significant negative media attention;
- loss of critical partners and/or partnership agreements;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to successfully commercialize our Commercial Products and any other products that we may develop or acquire.

We currently hold clinical trial liability insurance of up to US$20 million per occurrence in the aggregate and general product liability insurance coverage in the amount of US$20 million in the aggregate, but that coverage may not be adequate to cover any and all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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We may be subject to securities class action litigation or other shareholder litigation, which could result in substantial costs and divert management's attention and resources.

Companies that have experienced volatility in the market price of their securities have frequently been subject to securities class action litigation or other shareholder derivative actions. We may become the target of this type of litigation in the future, particularly if we experience significant stock price volatility or declines, announce material restatements of financial results, fail to meet earnings expectations, or disclose material weaknesses in our internal controls, such as we have disclosed in our management report on internal control over financial reporting. Additionally, public companies are increasingly subject to litigation related to corporate governance matters, executive compensation, environmental, social and governance ("ESG") disclosures, and other matters that may give rise to shareholder claims or derivative actions.

Securities litigation and shareholder derivative actions, regardless of their outcome or merit, can result in substantial costs, including significant legal fees and expenses, damages, and settlement amounts. Such litigation may also divert management's attention and resources away from business operations, which could adversely affect our ability to execute on our strategic initiatives. The defense or settlement of any such litigation could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

Furthermore, any adverse judgment or settlement in connection with shareholder litigation could result in negative publicity and reputational harm, which may further impact our stock price and ability to attract and retain key personnel. The outcome of complex legal proceedings is inherently unpredictable and subject to significant uncertainties, and we may not be able to accurately estimate potential liabilities associated with any pending or threatened litigation.

Our directors' and officers' liability insurance may not cover all potential claims or may not be adequate to indemnify us for all liability that may be imposed. Any future claims could also make it more difficult and expensive to obtain adequate insurance coverage

Risks Related to Regulatory Matters

Even if we complete the necessary preclinical studies and clinical trials for our product candidates, the regulatory approval process is expensive, time-consuming and uncertain and we or they may not receive approvals for the commercialization of some or all of our product candidates in a timely manner, or at all.

Our long-term success and ability to sustain and grow revenue depends on our ability to continue to successfully develop our product candidates and obtain regulatory approval to market our products both in and outside of the U.S. In order to market and sell our products in the European Union and many other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The FDA and comparable foreign regulatory authorities, whose laws and regulations may differ from country to country, impose substantial requirements on the development of product candidates to become eligible for marketing approval, have substantial discretion in the process, and may refuse to accept any application or may decide that the data are insufficient for approval and require additional preclinical studies, clinical trials or other studies and testing. The time required to obtain approval outside of the U.S. may differ substantially from that required to obtain FDA approval. For example, in many countries outside of the U.S., it is required that the drug also be approved for reimbursement before the drug can be sold in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

In addition, the FDA and foreign regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that any product candidate is safe and effective. If we are required to conduct additional clinical trials of our Commercial Products prior to approval of any additional investigational indications we are developing them for, or of any product candidates prior to approval, we may need substantial additional funds, and there is no assurance that the results of any such additional clinical trials will be sufficient for approval.

The process of obtaining marketing approvals, both in the U.S. and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each indication to establish the product candidate’s safety and efficacy.

In addition, changes in or the enactment of additional statutes, promulgation of regulations or issuance of guidance during preclinical or clinical development, or comparable changes in the regulatory review process for each submitted product application, may cause delays in the approval or rejection of an application. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act ("FDORA"), Congress required sponsors to develop and submit a Diversity Action Plan ("DAP"), for each Phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized

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will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance. On January 27, 2025, in response to an Executive Order issued by President Trump on January 21, 2025, on Diversity, Equity and Inclusion programs, the FDA removed this draft guidance from its website. This action raises questions about the applicability of statutory obligations to submit DAPs and the agency's current thinking on best practices for clinical development.

Further, on January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became applicable in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the European Medicines Agency ("EMA"), and available to clinical trial sponsors, competent authorities of the EU Member States and the public. We have not previously secured authorization to conduct clinical studies in the European Union pursuant to this new regulation and, accordingly, there is a risk that we may be delayed in commencing such studies.

The FDA or other regulatory authorities may determine that (i) our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended adverse events, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; (ii) the dose used in a clinical trial has not been optimized and require us to conduct additional dose optimization studies; or (iii) the comparator arm in a trial is no longer the appropriate comparator due to the evolution of the competitive landscape or subsequent data of the comparator product, even if the FDA or other regulatory authority had previously approved the trial design, and we may be required to amend the trial or we may not receive approval of the indication.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or a comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or a comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Further, under the Pediatric Research Equity Act ("PREA"), an NDA, BLA or supplement to an NDA or BLA for certain drugs and biological products must contain data to assess the safety and effectiveness of the drug or biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the U.S. or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act ("APA"). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and Centers for Medicare & Medicaid Services ("CMS"), that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Finally, with the change in presidential administrations in 2025, there is substantial uncertainty as to how, reductions in force, changes in leadership, and modifications or revisions to the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates will impact our business and operations. The uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates.

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The approval of our product candidates for commercial sale could also be delayed, limited or denied or we may be required to conduct additional studies for a number of reasons, including, but not limited to, the following:

- regulatory authorities may determine that our product candidates do not demonstrate safety and effectiveness in accordance with regulatory agency standards based on a number of considerations, including adverse events that are reported during clinical trials;
- regulatory authorities could analyze and/or interpret data from clinical trials and preclinical testing in different ways than we interpret them and determine that our data is insufficient for approval;
- regulatory authorities may require more information, including additional preclinical or clinical data or the conduct of new trials, to support approval;
- regulatory authorities could determine that our manufacturing processes are not properly designed, are not conducted in accordance with federal or other laws or otherwise not properly managed, and we may be unable to obtain regulatory approval for a commercially viable manufacturing process for our product candidates in a timely manner, or at all;
- the supply or quality of our product candidates for our clinical trials may be insufficient, inadequate or delayed;
- the size of the patient population required to establish the efficacy of our product candidates to the satisfaction of regulatory agencies may be larger than we or they anticipated;
- our failure or the failure of clinical sites, and the records kept at the respective locations, including records containing clinical trial data, to be in compliance with the FDA's GCP, requirements or comparable regulations outside of the U.S.;
- regulatory authorities may change their approval policies or adopt new regulations;
- regulatory authorities may not be able to undertake reviews of our marketing applications, conduct applicable inspections or proceed through their approval processes in a timely manner;
- the results of our earlier clinical trials may not be representative of our future, larger trials;
- regulatory authorities may not agree with our regulatory approval strategies or components of our or their regulatory filings, such as the design or implementation of the relevant clinical trials; or
- a product may not be approved for the indications that we request or may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

Accordingly, we may not be able to submit applications for marketing approvals/authorizations and may not receive necessary approvals to commercialize our products in any market. Any failure, delay or setback in obtaining regulatory approval for our product candidates could materially adversely affect our ability to generate revenue from a particular product candidate, which could result in significant harm to our financial position and adversely impact the price of our ordinary shares and ADSs.

Failure to obtain marketing approval in foreign jurisdictions would prevent our medicines from being marketed in such jurisdictions and any of our medicines that are approved for marketing in such jurisdiction will be subject to risk associated with foreign operations.

In order to market and sell our medicines in the European Union and many other foreign jurisdictions, we or our collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., a product must be approved for reimbursement before the product can be approved for sale in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency ("MHRA"), is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland). At the same time, a new international recognition procedure ("IRP"), will apply, which intends to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators ("RRs"). The RRs notably include EMA and regulators in the EU/European Economic Area ("EEA") member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the

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FDA (for product approvals granted in the U.S.). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published on April 26, 2023. In December 2025, the Council of the European Union and the European Parliament reached provisional agreement on a comprehensive overhaul of the EU legislative framework for pharmaceuticals. There are a number of significant changes, including a potential reduction in regulatory data protection, a streamlining of the regulatory approval process potentially allowing products to reach the market in a shorter period of time, and introduction of shortage prevention plans. The agreement still requires formal approval and adoption. If adopted, there will be a transitional period (between 18-36 months) for implementation. The revisions may have a significant impact on the pharmaceutical industry in general and our business in the long term.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the U.S., including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the U.S. In addition, we have limited experience commercializing products outside of the U.S. and such efforts may depend on our ability to find a suitable collaborator.

We intend to conduct certain of our clinical trials globally. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We have conducted and intend to continue conducting certain of our clinical trials globally. The acceptance by the FDA or other regulatory authorities of study data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as tariffs, other trade restrictions, armed conflict, or political instability.

Products utilizing our technology may need to be approved or cleared by the FDA and similar regulatory agencies or certified by notified bodies worldwide as medical devices. We may not receive, or may be delayed in receiving, the necessary approval, clearance or certification for our future medical device products, which would adversely affect business, financial condition, results of operations and prospects.

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We are developing artificial intelligence ("AI") and surgical assistance offerings that may be subject to regulation as medical devices in the U.S. and other jurisdictions. We have not yet utilized our AI platform in the development of our Commercial Products or product candidates. To date, we have not had any discussion with the FDA or other regulatory authorities or notified bodies regarding the regulatory pathways required to market these technologies. The FDA or similar regulatory agencies may subject these offerings to medical device requirements, including premarket review, lengthier or more rigorous processes than we expected that may include the performance of one or more clinical trials. Efforts to achieve requisite governmental clearances and approvals could be costly and time consuming, and we may not be able to obtain any such required clearances or approvals in accordance with our anticipated timeline or in a cost-efficient manner. Any delay or failure to obtain necessary regulatory clearances, approvals or certifications could have a material negative impact on our ability to generate revenues.

The FDA categorizes medical devices into one of three classes - Class I, II, or III - based on the risks presented by the device and the regulatory controls necessary to provide a reasonable assurance of the device's safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation ("QSR") facility registration and product listing, reporting of adverse medical events or certain malfunctions, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Special controls are established by the FDA for a specific device type and often include specific labeling provisions, performance metrics, and other types of controls that mitigate risks of the device. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a premarket approval application ("PMA").

In the U.S., before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food Drug and Cosmetic Act ("FDCA") marketing authorization under the de novo classification pathway, or approval of a PMA, from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. FDA then determines whether the device is as safe and effective as the predicate device by reviewing the scientific methods used to evaluate differences in technological characteristics and performance data. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

If no legally marketed predicate can be identified for a new device to enable use of the 510(k) pathway, the device is automatically classified as Class III, which generally requires PMA approval. This results in some low to moderate risk devices being classified unnecessarily as Class III. To address this, FDA regulations include a pathway to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure and pathway. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. The FDA can also reclassify a product from Class III to Class I or II. If the data and information provided to the FDA in support of a de novo request demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, and the probable benefits of the device outweigh the probable risks, then the FDA will grant the de novo request authorizing marketing of the product subject to the specified controls. After a device receives de novo classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another de novo request or even PMA approval.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is generally much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device or other restrictions or requirements, which may limit the market for the device.

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The FDA, comparable foreign regulatory authorities or notified bodies can delay, limit or deny clearance, approval or certification of a medical device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory authority or notified body that our product candidates are safe or effective for their intended uses or are substantially equivalent to a predicate device;
- the disagreement of the FDA or the applicable foreign regulatory authority with the design or implementation of our clinical studies or the interpretation of data from pre-clinical studies or clinical studies;
- serious and unexpected adverse events experienced by participants in our clinical studies;
- the data from our pre-clinical studies and clinical studies may be insufficient to support clearance, approval or certification where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory authorities to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Subject to the transitional provisions and in order to sell our products in EU member states, our products must also comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces the Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the European Conformity ("CE") mark to our products, without which they cannot be sold or marketed in the European Union. All medical devices placed on the market in the European Union must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. Even if regulatory clearance, approval or certification is obtained, such products will remain subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions. In addition, the cost of compliance with new laws or regulations governing our technology or future products could adversely affect our business, financial condition, results of operations and prospects. New laws or regulations may impose restrictions or obligations on us that could force us to redesign our technology or other future products or services, and may impose restrictions that are not possible or practicable to comply with, which could cause our business to fail.

Our Commercial Products and any of our product candidates for which we obtain marketing approval in the future are subject to post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. Our Commercial Products and any of our product candidates for which we obtain marketing clearance or approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the FDA and other U.S. and foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and related compliance requirements such as price reporting, transparency reporting and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing authorization is granted, it may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including in the case of drug or biological products, the requirement to implement a REMS, which could include requirements for a restricted distribution system.

The FDA and comparable foreign regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a drug or biological product. There are similar potential requirements for medical devices. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive requirements by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA or foreign regulatory authorities to monitor and ensure compliance with cGMPs (and similar foreign requirements) or other regulations.

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If the FDA or another regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authorities may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

- refuse to approve pending applications or supplements to approved applications;
- require us to change the way a product is distributed, conduct additional clinical trials, change the labeling of a product or require us to conduct additional post-marketing studies or surveillance;
- restrict our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- require additional warnings on the product label, such as a “black box” warning, precaution or a contraindication;
- impose restrictions on the products, manufacturers or manufacturing process;
- require warning or untitled letters;
- seek injunctions or civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- seize or detain products or implement import bans;
- impose voluntary or mandatory product recalls and publicity requirements;
- totally or partially suspend production; and
- impose restrictions on operations, including costly new manufacturing requirements.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business will be seriously harmed.

In connection with our Commercial Products and assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post-approval regulatory requirements, our ability to market any future products could be limited, which could adversely affect our ability to sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of products inconsistent with approved labeling. If we are found or alleged to have improperly promoted a product, we may become subject to significant liability.

The FDA and other U.S. or foreign agencies, including the U.S. Department of Justice ("DOJ") closely regulate and monitor the post-approval marketing and promotion of drugs and biological products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers’ communications regarding off-label use, and if we communicate about any of our product candidates for which we, or they, receive marketing approval in a way that regulators assert goes beyond their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Alleged violations of the FDCA or other statutes, including the False Claims Act ("FCA") relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

In September 2021, the FDA published a Final Rule which describes the types of evidence that the agency will consider in determining the intended use of a drug or biologic.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining the agency’s non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This final guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act ("PIE Act") signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved

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drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our Commercial Products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission ("FTC") and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "*qui tam*" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Similar to the U.S., pharmaceutical companies in the European Union, the United Kingdom, and Australia are generally prohibited from promoting drugs for any use that is not consistent with the product's authorized uses. Doing so may result in regulatory enforcement action. While off-label prescribing by clinicians is permitted as part of medical practice, the active promotion of off-label uses by manufacturers is not.

In the European Union, promotion must be consistent with the approved marketing authorization. Promotion that suggests or encourages use of a medicine for an unapproved indication, in an unapproved patient population, or using an unapproved dose, route or regimen is treated as unlawful off-label promotion. EU law distinguishes between the freedom of healthcare professionals to prescribe off-label based on clinical judgment and the strict limits on companies' promotional activities, which may not extend beyond the authorized product information. Limited scientific exchange - such as publication of data in peer-reviewed journals or responses to unsolicited requests from healthcare professionals - may be acceptable, but only where it is clearly non-promotional, balanced, and not designed to increase prescribing.

In the United Kingdom, post-Brexit rules continue to mirror this approach. Advertising of medicines is regulated by the Human Medicines Regulations, enforced by the MHRA, and supplemented by the self-regulatory Association of the British Pharmaceutical Industry ("ABPI") Code. Both require that promotional materials align with the product's current labeling. Communications that directly or indirectly promote an unapproved indication or off-label use breach these rules. The MHRA and the Prescription Medicines Code of Practice Authority ("PMCPA"), which administers the ABPI Code, routinely treat off-label promotion as a serious violation. As in the European Union, manufacturers may provide scientific, non-promotional information—particularly in response to unsolicited, specific questions from healthcare professionals—but must avoid any appearance of encouraging off-label prescribing.

In Australia, the TGA, together with industry codes (such as the Medicines Australia Code of Conduct), prohibit advertising of unapproved medicines and unapproved indications. Any communication that constitutes "advertising" and promotes an off-label use is not permitted, even if directed only to healthcare professionals. Promotional materials, detail aids, and speaker programs must therefore be confined to the indications, populations and regimens approved in the Australian Register of Therapeutic Goods ("ARTG") entry and associated product information. As in the European Union and United Kingdom, companies may engage in limited scientific exchange, but this must be clearly separated from promotional activities and must not function as de facto marketing for off-label uses.

We may seek certain designations for our product candidates in the U.S., including breakthrough therapy, fast track and priority review designations, and PRIME designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A breakthrough therapy-designated product candidate is defined as a product candidate that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Breakthrough therapy

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designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that any product candidate that receives a breakthrough therapy designation will receive marketing approval.

The FDA may also issue fast track designation to a product candidate if it is intended, alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track-designated product candidates, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product candidate's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective.

We may also seek priority review for one or more of our product candidates. If the FDA determines that a product candidate has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition, and if approved would provide a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of such disease or condition, the FDA may designate the product candidate for priority review upon submission of a marketing application seeking approval of that product. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and reject our request for designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to product candidates considered for approval under conventional FDA procedures, and the designation does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification and rescind the designation or decide that the time period for FDA review or approval will not be shortened.

In the European Union, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and the sponsor intends to apply for an initial MAA through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria with respect to its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables a sponsor to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we or our collaborators receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of the EMA's grant of a marketing authorization.

We may submit an application for a Commissioner's National Priority Voucher ("CNPV") from the FDA but there can be no assurance that we will receive a voucher and, if a voucher is received, we may not be able to comply with the requirements of the program. It is also possible that a competitor may receive a voucher which could harm our competitive position in the marketplace.

In June 2025, the FDA announced the CNPV pilot program which was designed to accelerate the development and review of certain drugs and biologics that are aligned with U.S. national health priorities, such as addressing a U.S. public health crisis, developing more innovative cures for the American people, addressing a large unmet medical need, onshoring drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency, and increasing affordability. The FDA has stated that voucher recipients will receive a decision with respect to an application on an accelerated basis, as well as enhanced communication with review staff throughout the review process. The FDA expects the CNPV program to accelerate the application review timeline from 10-12 months to 1-2 months by convening a multidisciplinary team of physicians and scientists for a team-based review, interacting frequently with the sponsor of the application to clarify questions, and completing review of the application concurrently. The FDA retains full discretion to extend the review window if the data or application components submitted are insufficient or incomplete, if the results of the pivotal trial(s) are ambiguous, or if the review is particularly complex. The FDA has indicated that the CNPV program does not change the FDA's rigorous safety and efficacy standards for review and approval. In late 2025, FDA began issuing approvals for drugs with CNPVs within the 1-2 month review timeframe. The CNPV program is new, limited in scope, and subject to evolving guidance, and available FDA resources. The FDA retains broad discretion to modify the criteria, processes, or benefits of the program and may rescind participation or alter timelines or the intended benefits at any time. Adding to the uncertainty, concerns have been raised regarding the legality of the CNPV program.

We may seek approval of our product candidates from the FDA or comparable foreign regulatory authorities through the use of accelerated development pathways. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining,

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and delay or prevent the receipt of, necessary marketing approvals. Moreover, even if we receive accelerated approval from the FDA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw accelerated approval.

Under the Food, Drug, and Cosmetic Act ("FDCA"), and implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit. Prior to seeking such accelerated approval, we will continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval.

There can be no assurance that the FDA or foreign regulatory agencies will agree with our surrogate endpoints or intermediate clinical endpoints in any of our clinical trials, or that we will decide to pursue or submit any additional NDAs or BLAs seeking accelerated approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we will continue to pursue or apply for accelerated approval. Furthermore, for any submission of an application for accelerated approval, there can be no assurance that such submission will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

Finally, there can be no assurance that we will satisfy all FDA requirements, including new provisions that govern accelerated approval. For example, with passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation (i) authorized FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded; (ii) requires a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to FDA every six months until the study is completed; and (iii) authorizes FDA to use expedited procedures to withdraw accelerated approval of an NDA or a BLA if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissioner's designee and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's latest thinking on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

In the European Union, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Accordingly, a failure to obtain and maintain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period until commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may not be able to obtain orphan drug designation or exclusivity for any product candidates we may develop, and even if we do, that exclusivity may not prevent the FDA or foreign regulatory authorities from approving other competing products.

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Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, meaning that the product is intended for a condition or disease with a patient population of fewer than 200,000 individuals annually in the U.S., or more than 200,000 individuals in the U.S. for which there is no reasonable expectation that the cost of developing and making available in the U.S. the drug or biologic will be recovered from sales in the U.S. for that drug or biologic. For example, we have received orphan drug designations from the FDA for TLX101-Tx for the treatment of glioma, for TLX101-Px for the imaging of glioma and for TLX66-Tx as a conditioning treatment prior to hematopoietic stem cell transplant. TLX090-Tx has also been granted orphan drug designation by the FDA for the treatment of osteosarcoma, and TLX102-Tx has been granted orphan drug designation for the treatment of multiple myeloma and malignant glioma. In addition, in the European Union, a medicinal product may be designated as orphan if its sponsor can establish that (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than 5 in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the medicinal product will be of significant benefit to those affected by the condition. For example, TLX101-Tx and TLX66-Tx have been granted orphan drug designation in Europe. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that any product candidate that receives an orphan drug designation will receive marketing approval.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or foreign regulatory authorities, as applicable, from approving another marketing application for the same product for the same disease or condition for a prescribed time period. The applicable period is seven years in the U.S. and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if, at the end of the fifth year, a product no longer meets the criteria for Orphan Designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified. Even if we obtain the designation and if, upon approval, we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same disease or condition. In addition, even after an orphan drug or biologic is approved, the FDA and comparable foreign regulatory authorities, such as the European Commission, can subsequently approve the same product for the same condition if the FDA or such other authorities conclude that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or comparable foreign regulatory authorities determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term “same disease or condition” means the designated “rare disease or condition” and could not be interpreted by the FDA to mean the “indication or use.” Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the “indication or use.” Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future or whether Congress will take legislative action, and it is uncertain how any changes might affect our business. Depending on what changes the FDA or Congress may make to orphan drug regulations and policies, our business could be adversely impacted.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing certain product candidates for which we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act") added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA’s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval.

If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing shareholders to the extent we issue equity securities or convertible debt. We cannot guarantee that we would be able to

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obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot guarantee that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Disruptions at the FDA, the SEC and other government agencies, including from inadequate funding, government shut downs, reductions in force, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, if at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. In addition, changes in FDA policies or regulations, resulting from the foregoing disruptions or otherwise, could adversely impact the development of our product candidates and, ultimately, our ability to receive approval for and commercialize them.

The ability of the FDA and comparable foreign regulatory authorities (or notified bodies) to review and approve or certify new products can be affected by a variety of factors, including government budget and funding levels, reductions in force, government shutdowns, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA, other agencies, and authorities (or notified bodies) may also slow the time necessary to meet with and receive agency feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. Moreover, changes in FDA's policies or regulations, whether as a result of personnel and budgetary constraints described above, changes in leadership or otherwise, could adversely impact the development of our product candidates and, ultimately, our ability to receive marketing authorization. Decisions about the development of product candidates are often based on interactions with FDA and regulatory guidance provided by the agency following such interactions. If FDA does not agree with our decisions resulting from such interactions and guidance or there are subsequent policy changes, review and approval of our product candidates may be delayed or not occur at all. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, other agencies, and authorities (or notified bodies) may also slow the time necessary for new product candidates to be reviewed and/or approved (or certified) by necessary government agencies, foreign regulatory authorities (or notified bodies), which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times, including most recently in October and November 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities.

In addition, disruptions may result from events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the U.S. facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

If another prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our or our collaborators' product candidates, if approved, and affect the prices we, or they, may obtain.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, restrict or regulate post-approval activities and affect our ability to profitably sell or commercialize our Commercial Products or any product candidate for which we, or our collaborators, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

Because our Commercial Products are generally reimbursed under Medicare Part B which covers drugs administered by healthcare providers in outpatient settings, changes to CMS coverage, packaging or bundling policies and site-of-service payment could directly affect utilization and net pricing. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we, or any collaborators, may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively "the ACA") was enacted. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS, an agency within the U.S. Department of Health and Human Services ("HHS") to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least US$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers, which went into effect in April 2013 and will remain in effect through 2032. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, with the passage of the Inflation Reduction Act ("IRA") in August 2022, Congress authorized Medicare drug price negotiation for certain high-expenditure, single-source drugs and biologics (beginning with 10 Part D products in 2026 and increasing over time), imposed Medicare Part B and Part D inflation rebates, and redesigned Part D to cap beneficiary out-of-pocket spending at US$2,000 beginning in 2025.

In May 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, the Department of Health and Human Services, in coordination with other federal agencies, is directed to take actions to ensure that the price of prescription drugs paid by federal health insurers, including Medicare and Medicaid, is in line with the prices paid in comparably developed nations. It is unclear how this policy will impact our business.

As an alternative to the Affordable Care Act, President Trump recently announced the Great Healthcare Plan. As presented, the plan is intended to lower drug prices by increasing competition and benchmarking U.S. drug prices to other countries, reduce insurance premiums by redirecting subsidies from insurers to individuals, increase accountability and transparency from insurers, and promote consumer choice by giving individuals more direct control over how healthcare dollars are spent. Legislative and regulatory action will be required to fully implement the plan. It is unclear how these proposed changes will impact our business and the pharmaceutical industry in general.

These and other executive and legislative efforts may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our products or product candidates for which we may obtain regulatory approval or the frequency with which any such product is prescribed or used. For example, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

In the European Union, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it began to apply from January 2025 onwards and will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the

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innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria and new payment methodologies that govern our Commercial Products or any product candidate, if approved, and/or the level of reimbursement physicians receive for administering our Commercial Products or any other product candidate, if approved, we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from our Commercial Products or from product candidates for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

The insurance coverage and reimbursement status of newly approved products is uncertain. Our Commercial Products and product candidates, if approved, may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain coverage and adequate reimbursement for our Commercial Products or any product candidates for which we obtain approval could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs and other medical products vary widely from country to country. In the U.S., healthcare reform legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in our Commercial Products or product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our Commercial Products and product candidates, if approved, also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments. Sales of our Commercial Products or product candidates, if approved, that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our Commercial Products and product candidates, if approved, will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our Commercial Products or product candidates, if approved. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products and product candidates. Accordingly, in markets outside the U.S., the reimbursement for products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the U.S., the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

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Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the U.S. and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for our Commercial Products or any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, if approved, and our overall financial condition. Further, the number of uninsured individuals in the U.S. may increase, which may adversely affect our ability to commercialize our Commercial Products or any product candidates for which we receive marketing authorization, In the U.S., we have various programs to help patients afford our Commercial Products, including patient assistance programs and co-pay coupon programs for eligible patients.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for our Commercial Products any product candidates that we develop and for which we obtain marketing authorization could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate for which we receive marketing authorization and that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product or product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard-of-care drugs, including lower-priced generic versions of standard-of-care drugs. We expect to experience pricing pressures in connection with the sale of our Commercial Products and our product candidates, if approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. Additionally, we may develop companion diagnostic tests for use with our therapeutic product candidates. We may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which we receive approval.

The prices of prescription pharmaceuticals in the U.S. and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when approved.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the U.S.. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program ("SIP") to import certain prescription drugs from Canada into the U.S. Section 804 of the FDCA allows importation of prescription drugs from Canada to significantly reduce the cost of these drugs to the American consumer without imposing additional risk to public health and safety. Importation program proposals must be submitted to FDA for review and authorization. Several states have passed laws allowing for the importation of drugs from Canada.

Several states have passed legislation establishing workgroups to examine the impact of a state importation program. In May 2025, FDA announced that it will offer individual states the opportunity to submit draft proposals for pre-review and obtain initial feedback from FDA prior to formally submitting their program proposal. States will have an opportunity to meet with FDA with the goal of reducing the burden on the states and to help them develop robust proposals. FDA is also working to assist states with options to streamline the required cost savings analysis, and to provide input regarding the information the states may rely on to estimate cost savings for American consumers.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It was originally set to go into effect on January 1, 2022, but with passage of the IRA, has been delayed by Congress to January 1, 2032.

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On August 16, 2022, the IRA was enacted. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (which began in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The law also capped Medicare out-of-pocket drug costs at approximately US$4,000 a year in 2024 and, thereafter beginning in 2025, at US$2,000 a year (indexed for inflation in subsequent years).

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the negotiated "maximum fair prices" for ten selected Part D drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs became effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. The negotiated prices for this second group of drugs will be effective on January 1, 2027. While there had been some questions about the Trump Administration's position on this program, on September 30, 2025, CMS issued final guidance for the third negotiation cycle. On January 27, 2026, CMS announced its selection of 15 additional drugs (covered under either Part B or Part D) for the third cycle of negotiations. The negotiated prices for this third group will be effective on January 1, 2028. CMS also selected one previously negotiated drug for the program's first renegotiations.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. As of October 2025, Merck's action is pending motions for summary judgment, and the other lawsuits have been largely unsuccessful for plaintiffs. Multiple federal district courts have granted summary judgment in favor of the HHS, and several of these decisions have been affirmed by federal appellate courts. For example, in 2025, the U.S. Court of Appeals for the Third Circuit rejected appeals from several manufacturers, including AstraZeneca and Novartis, upholding the program's constitutionality. The Second and Sixth Circuits have also affirmed dismissals of similar challenges. In September 2025, AstraZeneca filed a petition for writ of certiorari, asking the U.S. Supreme Court to review the Third Circuit's decision. Accordingly, while the IRA is actively being implemented, the pending appeal to the Supreme Court creates uncertainty regarding the program's ultimate legal status. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

In May 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, the Department of Health and Human Services, in coordination with other federal agencies, is directed to take actions to ensure that the price of prescription drugs paid by federal health insurers, including Medicare and Medicaid, is in line with the prices paid in comparably developed nations. It is unclear how this policy will impact our business.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our Commercial Products and our product candidates, if approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our Commercial Products or our product candidates, if approved, or additional pricing pressures.

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Finally, outside of the U.S., in some countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, official list price country pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies.

These measures, as well as others adopted in the future, may result in additional downward pressure on the price that we receive for our Commercial Products or any of our product candidates, if approved. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from our Commercial Products or from product candidates that we may successfully develop and for which we, or they, may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

Our relationships with radiopharmacies, healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare professionals, including but not limited to physicians, nurses, medical directors, hospitals, pharmacies, pharmacy benefit managers, group purchasing organizations, wholesalers, insurers, and all individuals employed by such entities, which we refer to collectively as HCPs, may influence the recommendation and prescription of our Commercial Products or any of our product candidates, if approved. Our arrangements with HCPs and others who have the ability to improperly influence the recommendation and prescription of our Commercial Products or any of our product candidates, if approved may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our Commercial Products or any of our product candidates, if approved. Restrictions under applicable federal, state and foreign healthcare laws and regulations include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, arranging for or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- the FCA imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal transparency requirements under the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the HHS, information related to payments and other transfers of value to physicians (as defined by statute), other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and

- international, federal or state laws, regulations, or rules that oversee the compounding, administration or distribution of radiopharmaceutical products by licensed pharmacists.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring

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of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain advisory agreements we have entered into with physicians who are paid, in part, in the form of shares or share options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Liabilities they incur pursuant to these laws could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

As a condition of reimbursement by various federal and state health insurance programs, we are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumptions involve subjective decisions and estimates. We are required to report any revisions to our calculation, price reporting and payment obligations previously reported or paid. Such revisions could affect our liability to federal and state payors and also adversely impact our reported financial results of operations in the period of such restatement. Further, a number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to significant penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If we become subject to investigations, restatements, or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of our Commercial Products and any of our product candidates, if approved, and thus have an adverse impact on our financial position or business operations.

Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in us having to carry a liability on our consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, our financial position and results of operations could be adversely affected.

In addition to retroactive rebates and the potential for 340B Program refunds, if we are found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS, we may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for our covered outpatient drugs.

Additionally, if we overcharge the government in connection with the Federal Supply Schedule pricing program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our collaborators are also subject to similar requirements outside of the U.S. and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

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We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personal information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the U.S., European Union, United Kingdom, Australia, and other countries in which we may conduct business. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA, establish privacy and security standards that limit the use and disclosure of protected health information and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. HHS's Office for Civil Rights ("OCR") has been especially active in investigating and enforcing actual or alleged non-compliance with the HIPAA rules. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. Some new state laws, such as the state of Washington's My Health My Data Act, include a private right of action. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In addition to potential enforcement by the HHS, we could also be potentially subject to privacy enforcement from the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be “unfair” under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security. We will need to account for the FTC’s evolving rules and guidance for proper privacy and data security practices in order to mitigate risk for a potential enforcement action, which may be costly. Finally, both the FTC and HHS’s enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the U.S. to certain foreign countries. The Protecting Americans’ Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the Department of Justice recently finalized a rule which creates similar restrictions related to the transfer of sensitive U.S. data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the California Consumer Privacy Act ("CCPA"), which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA’s requirements are similar to those found in the European Union's General Data Protection Regulation ("GDPR"), which is further described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, including use in marketing, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of “sales” of "sharing" of their personal information under certain circumstances. The CCPA contains significant penalties for companies that violate its requirements.

In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act ("CPRA"), which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency or CPPA – the sole responsibility of which is to enforce the CPRA and other California privacy laws, which will further increase compliance

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risk. The CCPA also has rulemaking authority under the CCRA with recent regulations finalized for, among other things, cybersecurity audits, risk assessment, and use of automated decision-making technologies. The provisions in the CPRA may apply to some of our business activities. In addition to California, at least 19 other states have passed comprehensive privacy laws. These laws may impact our business activities if and to the extent applicable to our business, including our identification of research subjects, relationships with business partners, and ultimately the marketing and distribution of our Commercial Products and our product candidates, if approved.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other tracking technologies, chatbots, and session replay technologies. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act and Electronic Communications Protection Act. The rise in these types of lawsuits creates potential risk for our business. Additionally, privacy breach class actions under various U.S. state laws remain highly active which could result in potential litigation exposure in the event that we experience a privacy breach.

Similar to the laws in the U.S., there are significant privacy and data security laws that apply in Europe, the United Kingdom, and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the group of companies of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

Certain privacy and data protection laws, including the GDPR, restrict the cross-border transfer of personal data from the original jurisdiction to countries that have not been found to offer "adequate protection" for personal data. Privacy advocates have successfully challenged prior compliance mechanisms, such as the EU-U.S. Privacy Shield, prompting ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries.

In October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. An adequacy decision, adopted by the European Commission on July 10, 2023 permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the U.S. To date, the EU-U.S. Data Privacy Framework has withstood challenges from privacy advocates, including in a September 2025 decision by the European General Court upholding the validity of the European Commission's 2023 adequacy decision in Latombe v. Commission. However, if any subsequent challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business. Following the withdrawal of the United Kingdom from the European Union, the United Kingdom Data Protection Act 2018 ("UK Data Protection Act") applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the United Kingdom and the European Union have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act and the GDPR, respectively. The United Kingdom and the U.S. have also agreed to a U.S.-UK "Data Bridge", which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the United Kingdom to the U.S.

Switzerland has also approved an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which functions similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the U.S.). Any changes or updates to these developments have the potential to impact our business.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of Commercial Products, through increased compliance costs, costs associated with contracting and potential enforcement actions.

In Australia, we are subject to the Privacy Act 1988 (Cth) and the Australian Privacy Principles ("APPs"), which regulate the collection, use, disclosure, storage and security of personal information, including health information, which is treated as sensitive information subject to heightened protections. The Privacy Legislation Amendment (Enforcement and Other Measures) Act 2022 significantly increased maximum penalties for serious or repeated interferences with privacy to the greater of A$50 million, three times the value of any benefit obtained from the breach, or 30% of adjusted turnover in the relevant period. We are also subject to the Notifiable Data Breaches scheme, which requires entities to notify affected individuals and the Office of the Australian Information Commissioner ("OAIC"), of eligible data breaches that are likely to result in serious harm. The Australian government has signaled further reforms to privacy legislation, including proposals to strengthen individual rights, expand the definition of personal information, and introduce a statutory tort for serious invasions of privacy. If enacted, such reforms could impose additional compliance obligations and increase our exposure to regulatory enforcement and private claims. Failure to comply with Australian privacy requirements could result in

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significant penalties, reputational harm, regulatory investigations and remedial orders, any of which could have a material adverse effect on our business, financial condition or results of operations.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and Australia and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the U.S. regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

If we fail to comply with environmental, health and safety laws and regulations, including those governing radiopharmaceutical products and radioactive materials, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and radiation safety regulations, including those governing laboratory procedures and the handling, use, storage, treatment, transportation and disposal of hazardous materials and wastes. Our operations involve the use, storage, treatment, and transportation of hazardous and flammable materials, including chemicals and biological and radioactive materials. While most of the activities are conducted by third-party partners on our behalf or by pharmacists or healthcare professionals consistent with their own professional obligations on their own behalf, our operations also produce hazardous waste products and allow the decay of radioactive material (where legally allowed) on site prior to disposal as non-radioactive waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Transportation of radioactive, biological, and/or hazardous materials is highly regulated by each governmental jurisdiction we operate in. Additionally, the physical transportation of these materials puts us at risk of vehicular accidents which could result in the loss of control of these materials and potential environmental and human health risks and related regulatory actions against us.

Our use of facilities that use and produce radioactive materials subjects us to compliance with D&D requirements when we close those facilities, exposing us to potentially significant costs. Our product candidates are manufactured using radioactive components. When a cyclotron reaches the end of its useful life at one of our facilities or if we need to abandon such facility for any other reason, we are obligated under the laws and regulatory rules of the various jurisdictions in which we operate to decommission and decontaminate such facility or cyclotron. Estimating the amount and timing of such future D&D costs includes, among other factors, country-specific requirements and projections as to when a facility will retire or the useful life of a cyclotron. If we do not conduct D&D properly at any of our sites, we may suffer significant additional costs to remediate any D&D deficiencies, fines, regulatory or criminal charges or other sanction or legal action, any of which could have a material adverse effect upon our business, financial condition and results of operations. Although we have estimated our future D&D costs and recorded a liability for such costs, there can be no assurances that we will not incur material D&D costs beyond such estimates or our provisions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

The use of hazardous materials, including radioactive and biological materials, in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.

Our research, development and manufacturing activities involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials, such as radioisotopes. We and our third-party manufacturers are subject to federal, state, local and foreign environmental laws and regulations governing, among other matters, the handling, storage, use, transportation and disposal of these materials and some waste products.

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Our use of chemicals in the manufacturing process for our Commercial Product and product candidates is also subject to chemicals approvals, registrations and regulations around the world, including a regulation in the European Union known as Registration, Evaluation, Authorization and Restriction of Chemicals, and similar laws and regulations in certain other jurisdictions in which we operate. In addition, we are required to obtain and maintain a hazardous materials license, pursuant to which we are required to perform annual self-audits, and that may result in random inspections by regulators. If such audit or inspection were to result in adverse findings, it may impact our ability to maintain our license, which would in turn adversely affect our ability to conduct our business.

Additionally, we cannot completely eliminate the risk of contamination or injury from these materials, and we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with such federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts.

Although we intend to validate that any third-party manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Comparable restrictions and related risks regarding the use of potentially hazardous substances are also applicable outside the U.S. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, financial condition, results of operations and prospects.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain products outside of the U.S. and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside of the U.S. in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The U.S. Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. The FCPA is enforced by the DOJ and the SEC.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals, clinics, universities and similar institutions are operated by the government, and doctors and other healthcare professionals are considered foreign officials. Certain payments to healthcare professionals in connection with clinical trials, regulatory approvals, sales and marketing, and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Because the FCPA applies to indirect payments, the use of third parties and other collaborators can increase potential FCPA risk, as we could be held liable for the acts of third parties that do not comply with the FCPA's requirements.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Like the FCPA, the Australian Criminal Code, the U.K. Bribery Act and other anti-corruption laws throughout the world similarly prohibit offers and payments made to obtain improper business advantages, including offers or payments to healthcare professionals and other government and non-government officials. These other anti-corruption laws also can result in substantial financial penalties and other collateral consequences.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the U.S., has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates, if approved, outside of the U.S., which could limit our growth potential and increase our development costs.

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Changes in U.S. and international trade policies may adversely impact our business and operating results.

The U.S. government has made statements and taken certain actions that have led to significant changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting products manufactured in certain foreign jurisdictions. Although trade policies continue to evolve, there is ongoing uncertainty as to whether there will be further changes. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry.

Further, some of our manufacturers and suppliers are located outside the United States, including in China. We are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of countries in which we or our suppliers operate. Certain foreign biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. Such disruptions could have adverse effects on the development of our product candidates and our business operations.

For example, the pharmaceutical industry generally, and in some instances our Company or our collaborators or other third parties on which we rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the U.S. and China, including as a result of the escalation of tariffs or other trade restrictions or the recently enacted BIOSECURE Act. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our or our collaborators' ability to manufacture or supply marketed products and product candidates or advance our or our collaborators' preclinical research or clinical development programs, which could materially and adversely affect our business and future prospects.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our Commercial Products and product candidates and platform materials, affect the demand for our Commercial Products and product candidates, if approved, the competitive position of our Commercial Products and product candidates, if approved, and import or export of raw materials and finished Commercial Products and product candidates used in our and our collaborators' preclinical studies and clinical trials, particularly with respect to any materials that we import from China. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

With the passage of the CREATES Act, we are exposed to possible litigation and damages by competitors who may claim that we are not providing sufficient quantities of our approved products on commercially reasonable, market-based terms for testing in support of their abbreviated new drug applications ("ANDAs"), 505(b)(2) NDAs and biosimilar product applications.

In December 2019, President Trump signed legislation intended to facilitate the development of generic and biosimilar products. The bill, previously known as the CREATES Act, authorizes sponsors of ANDAs, 505(b)(2) NDAs, or biosimilar product applications to file lawsuits against companies holding NDAs or BLAs that decline to provide sufficient quantities of an approved reference drug or biological product on commercially reasonable, market-based terms. Drug or biological products on FDA's drug shortage list are exempt from these new provisions unless the product has been on the list for more than six continuous months or the FDA determines that the supply of the product will help alleviate or prevent a shortage.

To bring an action under the statute, the developer of a product candidate that seeks to develop the product and seek approval under an ANDA, 505(b)(2) NDA, or biosimilar product application must take certain steps to request the reference product from the reference product manufacturer, which, in the case of products covered by a REMS with elements to assure safe use, include obtaining authorization from the FDA for the acquisition of the reference product. If the reference product manufacturer does not provide the reference product and the ANDA, 505(b)(2) NDA, or biosimilar product sponsor does bring an action for failure to provide a reference product, there are certain affirmative defenses available to the reference product manufacturer, which must be shown by a preponderance of evidence, including that the NDA or BLA holder sells the reference product through agents, distributors, or wholesalers and has placed no restrictions, explicit or implicit, on selling the reference product to ANDA, 505(b)(2) or biosimilar sponsors. If the sponsor prevails in litigation, it is entitled to a court order directing the reference product manufacturer to provide, without delay, sufficient quantities of the applicable product on commercially reasonable, market-based terms, plus reasonable attorney fees and costs.

Additionally, the new statutory provisions authorize a federal court to award the product developer an amount "sufficient to deter" the reference product manufacturer from refusing to provide sufficient product quantities on commercially reasonable, market-based terms, up to a certain maximum amount based on revenue earned while in noncompliance, if the court finds, by a preponderance of the evidence, that the reference product manufacturer did not have a legitimate business justification to delay providing the product or failed to comply with the court's order. For the purposes of the statute, the term "commercially reasonable, market-based terms" is defined as (i) the nondiscriminatory price at or below

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the most recent wholesale acquisition cost for the product, (ii) a delivery schedule that meets the statutorily defined timetable, and (iii) no additional conditions on the sale.

Although we intend to comply fully with the terms of these statutory provisions, we are still exposed to potential litigation and damages by competitors who may claim that we are not providing sufficient quantities of our Commercial Products on commercially reasonable, market-based terms for testing in support of ANDAs, 505(b)(2) NDA applications or biosimilar product applications. Such litigation would subject us to additional litigation costs, damages and reputational harm, which could lead to lower revenues. The CREATES Act may facilitate future competition with our Commercial Products and any of our product candidates, if approved, which could impact our ability to maximize product revenue.

We are required to comply with governmental economic and trade sanctions and export and import controls that could impair our or our collaborators' ability to compete in international markets due to licensing requirements and subject us or them to liability if we or they are not in compliance with applicable laws.

Our Commercial Products and product candidates are subject to international, national and state export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and we are required to comply with these laws as well as various economic and trade sanctions, including those administered by the U.S. Treasury Department's Office of Foreign Assets Controls. These laws and regulations restrict our ability to transact or deal with certain countries, regions, governments, persons and entities. Our activities, including our procurement of materials and exports of our Commercial Products and product candidates, must be in compliance with these laws and regulations. While we have policies and procedures designed to ensure that we maintain compliance with these laws and regulations, there is a risk that our employees, agents, or business partners may take actions in violation of our policies and applicable law, for which we may be ultimately held responsible.

If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us or our collaborators and the respective responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers. Investigations of alleged violations can be expensive and disruptive, and such violation (or allegation of a violation) could materially adversely affect our reputation, business, financial condition and results of operations.

In addition, changes in our Commercial Products or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our Commercial Products in international markets, prevent customers from using our Commercial Products or, in some cases, prevent the export or import of our Commercial Products to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our Commercial Products could adversely affect our business, financial condition and results of operations.

Risks Related to Our Dependence on Third Parties

We depend on collaborations with third parties for certain aspects of the development, marketing and/or commercialization of Commercial Products and our product candidates, if approved. If those collaborations are not successful, or if we are not able to maintain our existing collaborations or establish additional collaborations, we may have to alter our development and commercialization plans and may not be able to capitalize on the market potential of Commercial Products or our product candidates, if approved.

Our product development programs and the commercialization of our Commercial Products and product candidates, if approved, require local expertise and substantial additional cash to fund expenses. We expect to maintain our existing collaborations and collaborate with additional pharmaceutical and biotechnology companies for certain aspects of the development, marketing and/or commercialization of our Commercial Products and product candidates. For example, we expect to rely on additional partners to develop and commercialize our Commercial Products outside of the U.S., including our ongoing partnership with Grand Pharmaceutical Group Limited ("Grand Pharma") for our imaging and therapeutic product candidates in Greater China. In addition, we intend to utilize collaborators to aid in the further development, potential marketing and/or commercialization of our product candidates. We also have a license agreement with Eli Lilly and Company Ltd ("Lilly") for the exclusive worldwide rights to develop and commercialize radiolabeled forms of olaratumab together with our linker and our other proprietary licensed technology, for the diagnosis and treatment of human cancers.

Potential collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies and we face significant competition in seeking appropriate collaborators, including as a result of a significant number of recent business combinations among large pharmaceutical companies that have reduced the number of potential collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon the assessment of the potential collaborator's expertise, its current and expected resources and competing priorities, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or foreign regulatory authorities, the potential market for the product or product candidate, the costs and complexities of manufacturing and delivering such product or product candidate, if approved, to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of intellectual property, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. A potential collaborator may also consider alternative product candidates or

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technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

Collaborations are complex and time-consuming to negotiate, document and manage. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all, or we may be restricted under then-existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. If we are unable to maintain our current collaboration agreements or enter into new collaboration agreements, we may have to curtail, reduce or delay the development or commercialization programs for our Commercial Products or product candidates, if approved, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our Commercial Products or product candidates or bring them to market and generate product revenue, if approved.

Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements, and our collaboration agreements may not lead to the development or commercialization of future products or our product candidates, if approved, in the most efficient manner, or at all, and may result in lower product revenues or profitability to us than if we were to market and sell our Commercial Products or our product candidates, if approved, ourselves. In connection with any such arrangements with third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development, marketing and/or commercialization of our Commercial Products or product candidates. Further, if our collaborations do not result in the successful development and commercialization of our future products or product candidates, if approved, or if any one of our collaborators terminates its agreement with us, we may not receive any future milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, the development and commercialization of future products or product candidates, if approved, could be delayed and we may need additional resources to develop product candidates.

Collaborations involving our Commercial Products and product candidates pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected or in compliance with applicable local and national laws and regulatory requirements;
- collaborators may de-emphasize or may not pursue development, marketing and/or commercialization of our Commercial Products or product candidates or may elect not to continue or renew development, marketing or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our Commercial Products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more products or product candidates may not commit sufficient resources to the marketing and distribution of our Commercial Products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities for us with respect to our Commercial Products or product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- we may lose certain valuable rights under circumstances identified in any collaboration arrangement that we enter into, such as if we undergo a change of control;

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- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development, marketing and/or commercialization of the applicable products or product candidates or to enter into new collaboration agreements;
- collaborators may learn about our discoveries and use this knowledge to compete with us in the future;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- the number and type of our collaborations could adversely affect our attractiveness to other collaborators or acquirers.

If any of these events occurs, the market potential of our Commercial Products and product candidates, if approved, could be reduced, and our business could be materially harmed.

If we are unable to establish and maintain our agreements with third parties to distribute our Commercial Products to patients, our results of operations and business could be adversely affected.

We rely substantially on third parties to commercially distribute our Commercial Products to patients. For example, we have contracted with a distribution network of specialty pharmacies, which sell our Commercial Products directly to patients, and specialty distributors, which sell our Commercial Products to healthcare entities who then resell to patients. While we have entered into agreements with each of these pharmacies and distributors to distribute our Commercial Products in the U.S., they may not perform as agreed or they may terminate their agreements with us. We may also need to enter into agreements with additional pharmacies or distributors, and there is no guarantee that we will be able to do so on a timely basis, at commercially reasonable terms, or at all. If we are unable to maintain and, if needed, expand, our network of specialty pharmacies and specialty distributors, we would be exposed to substantial distribution risk. In addition, and particularly as we expand into less-mature markets or into countries where corruption may be more prevalent, we will need to conduct robust due diligence with third-party collaboration partners to best ensure that our Commercial Products and our other product candidates, if approved, are able to be manufactured, compounded, or distributed on a timely basis that complies will all applicable laws, regulations, and rules, including but not limited to, those that deal with anti-corruption, anti-kickback, marketing authorization and distribution of pharmaceutical products, the environment, and the safe use of the products with patients.

The use of specialty pharmacies and specialty distributors involves certain risks, including, but not limited to, risks that these organizations will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using our Commercial Products or serious adverse reactions, events and/or product complaints regarding our Commercial Products;
- not effectively sell or support our Commercial Products or communicate publicly concerning our Commercial Products in a manner that is contrary to FDA rules and regulations;
- reduce their efforts or discontinue to sell or support, or otherwise not effectively sell or support, our Commercial Products;
- not devote the resources necessary to sell our Commercial Products in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others;
- not be able to obtain or maintain all necessary licenses; or
- cease operations.

Any such risks may apply to future products and product candidates we develop, and for which we receive marketing authorization, such events may result in decreased product sales, which would harm our results of operations and business.

We rely on third parties as we conduct our clinical trials and some aspects of our research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We rely on third parties, such as strategic partners, CROs, clinical data management organizations, medical institutions and clinical investigators, as we conduct our clinical trials. For example, in China, during 2025 we completed enrollment for a Phase 3 study of TLX591-Px (marketed as Illuccix in the U.S.) in collaboration with our strategic partner for the Greater China region, Grand Pharma, and we aim for this study to support future marketing authorization applications for Illuccix in China. A new drug application was submitted in December 2025 and accepted for review in January 2026 by the Chinese National Medical Products Administration ("NMPA") Center for Drug Evaluation ("CDE"). We also currently

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rely and expect to continue to rely on third parties to conduct some aspects of our research and preclinical studies. Any of these third parties may terminate their engagements with us at any time in accordance with agreements or applicable laws. If we need to enter into alternative arrangements, our product development activities may be delayed.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards when conducting, recording and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA and TGA also require us to comply with comparable standards. Regulatory authorities ensure compliance with these requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of the third parties that we rely on in connection with our clinical trials fail to comply with applicable requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with such requirements. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our Commercial Products or our product candidates, if approved. In such an event, our financial results and the commercial prospects for our Commercial Products or product candidates, if approved, could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of such third parties could delay clinical development or regulatory approval of our product candidates or commercialization of our Commercial Products, producing additional losses and depriving us of potential product revenue.

In addition, as discussed above, the third parties upon whom we rely to conduct our clinical trials could be negatively impacted as a result of disruptions caused by, for example, pandemics or epidemics including difficulties in initiating clinical sites or enrolling participants, travel or quarantine policies, and other factors, including ongoing and future environmental or geopolitical concerns. If these third parties are so affected, our business prospects and results of operations could be severely adversely impacted.

We rely on third parties to conduct investigator-sponsored clinical trials of our product candidates. Any failure by a third-party to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates.

We partly rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We do not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or foreign regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design, execution of the trials, safety concerns or other trial results.

Such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, such as access to and the ability to use and reference the data resulting from the investigator-sponsored trials, including for our own regulatory submissions and marketing authorization applications. However, we do not have control over the timing for patient recruitment and reporting of the data from investigator-sponsored trials, nor do we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to rely on the data from the investigator-sponsored trials in our clinical development plans may be adversely affected.

Additionally, the FDA or foreign regulatory authorities may disagree with the sufficiency of our right to reference the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, our right for exclusive commercial use of the data or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or foreign regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our planned trials and/or may not accept such additional data as adequate to initiate our planned trials.

We are currently dependent on third parties for the manufacture, distribution and patient dose preparation of our Commercial Products and product candidates and any difficulties, disruptions, delays or unexpected costs, or the

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need to find alternative sources, could adversely affect our results of operations, profitability and future business prospects.

While we have acquired some laboratory capability with Optimal Tracers in Sacramento, IsoTherapeutics in Angleton, and the facility purchased from ImaginAb, Inc. in Los Angeles, completed Stage 1 of the buildout of our European manufacturing site in Brussels South, which is operational for selected research and development activities and is good manufacturing practice ("GMP") accredited for production of Illuccix, progressed the buildout of our TMS North Melbourne facility for early-stage clinical research and radiopharmaceutical production, and established our first cyclotron facility in the APAC region in Yokohama, Japan, we currently rely, and expect to continue to rely, on third-party contract manufacturers to manufacture our Commercial Products and product candidates for our commercial and clinical use.

Facilities used by our third-party manufacturers may be inspected by the FDA or applicable foreign regulatory authorities after we submit a marketing application and before potential approval of the product candidate and are also subject to ongoing periodic unannounced inspections by the FDA or applicable foreign regulatory authorities for compliance with cGMPs (or similar foreign requirements) and other regulatory requirements following approval. Similar regulations apply to manufacturers of our Commercial Products and our product candidates for use or sale in foreign countries. We do not control the manufacturing processes of, and are completely dependent on, our third-party manufacturers for compliance with the applicable regulatory requirements for the manufacture of our products and product candidates. Third-party manufacturers may not be able to comply with cGMPs or similar regulatory requirements outside of the U.S.. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If these facilities are not approved for commercial manufacture or are not able to maintain approval, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our Commercial Products or product candidates as alternative qualified manufacturing facilities may not be available on a timely or cost-efficient basis, or at all. Failure by any of our manufacturers to comply with applicable cGMPs (and similar foreign requirements) or other regulatory requirements could result in sanctions being imposed on us or the contract manufacturer, including fines, injunctions, civil penalties, delays, suspensions or withdrawals of approvals, operating restrictions, interruptions in supply and criminal prosecutions, any of which could significantly and adversely affect supplies of our Commercial Products or product candidates and have a material adverse impact on our business, financial condition and results of operations.

We currently have long-term supply agreements with our third-party contract manufacturers to manufacture the clinical and commercial supplies of our Commercial Products and for our product candidates. Our ability to have our Commercial Products and product candidates manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of our third-party contract manufacturers' facilities. Reliance on third-party manufacturers entails risks, including:

- reliance on the third-party for regulatory compliance and quality assurance;
- the possible breach, termination or nonrenewal of a manufacturing agreement by the third-party, including at a time that is costly or inconvenient to us;
- the possible failure of the third-party to manufacture our Commercial Products or our product candidates according to our schedule, or at all, including if the third-party manufacturer gives greater priority to the supply of other products over our Commercial Products or our product candidates, or otherwise does not satisfactorily perform according to the terms of the manufacturing agreement;
- equipment malfunctions, power outages or other general disruptions experienced by our third-party manufacturers or distributors to their respective operations and other general problems with a multi-step manufacturing or distribution process;
- the possible disruptions to supply chain and logistics processes that are required to store, transport, and deliver our Commercial Products to customers that require timely delivery given the need to inject a dose of our Commercial Products within a specific window of radioactivity; and
- the possible misappropriation or disclosure by the third-party or others of our proprietary information, including our trade secrets and know-how.

We currently rely on a single source supplier for our active pharmaceutical ingredient for our Commercial Products and our related product manufacturing requirements, although additional sources and back-up suppliers are being validated and implemented. Any performance failure on the part of our existing or future manufacturers could delay clinical development, regulatory approval or commercialization of our product candidates, if approved. If our suppliers or contract manufacturers are so affected, our supply chain could be disrupted, our product shipments could be delayed, our costs could be increased and our business could be adversely affected. If our current contract manufacturers cannot perform as agreed, we may be required to replace those manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our Commercial Products or our product candidates, we could incur added costs and delays in identifying and qualifying any such replacement. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could negatively impact revenues

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from sales of our Commercial Products or delay commercialization of any product candidates that are subsequently approved.

If, because of the factors discussed above, we are unable to have our Commercial Products or our product candidates manufactured on a timely or sufficient basis, we may not be able to meet clinical development needs or commercial demand for our Commercial Products or our product candidates or we may not be able to manufacture our Commercial Products or our product candidates in a cost-effective manner. As a result, we may lose sales, fail to generate projected revenues or suffer development or regulatory setbacks, any of which could have an adverse impact on our profitability and future business prospects.

We are currently party to and may seek to enter into additional collaborations, licenses and other similar arrangements and may not be successful in maintaining existing arrangements or entering into new ones, and even if we are, we may not realize the benefits of such relationships.

We are currently parties to license and collaboration agreements with a number of pharmaceutical companies and universities and expect to enter into additional agreements as part of our business strategy. The success of our current and any future collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- we may not be able to enter into critical strategic collaborations or enter into them on favorable terms;
- collaborators may have significant discretion in determining the efforts and resources that they will apply to collaborations, and they may not perform their obligations as agreed, expected, or in compliance with applicable legal requirements;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our Commercial Products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than our Commercial Products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, which may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Additionally, we may seek to enter into additional collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, if approved, due to capital costs required to develop or commercialize the product candidate, if approved, or manufacturing constraints. We may not be successful in our efforts to establish such collaborations for our product candidates because our R&D pipeline may be insufficient, our

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product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Risks Related to Our Intellectual Property

If we are unable to obtain and/or maintain commercially valuable regulatory exclusivity and intellectual property or to protect our patents, trademarks, know-how and trade secrets, our ability to successfully commercialize our Commercial Products and product candidates, if approved, would be adversely impacted.

We rely on effective exclusivity and IP protection and our success will depend in part on our ability to obtain and/or maintain commercially valuable regulatory exclusivity and patent claims and to protect our patents, trademarks, know-how and trade secrets. We and our collaboration partners face numerous risks and uncertainties with respect to our licensed patents and those that may subsequently be licensed or issued to us, including that:

- lodged regulatory filings may not result in intended market or data exclusivity;
- governments may change data and market exclusivity provisions;
- know-how and trade secrets may be published, derived independently by third parties, or otherwise publicly disclosed, resulting in a loss of protections;
- patent or trademark applications may not result in issued patents or registered trademarks or may take longer than expected to be issued or registered;
- the claims of any patents or trademarks that are issued or registered may not provide meaningful protection;
- patent term extensions may not be granted or, if granted, may be subject to revision;
- we and our research partners may not be able to develop additional proprietary technologies that are patentable or otherwise protectable under regulatory exclusivity principles;
- patents issued to us, or our industry partners, may not provide a competitive advantage;
- other companies may challenge our issued patents or trademarks;
- other companies may independently develop similar or alternative technologies to ours or duplicate or design around our technology;
- other companies may hold patents or trademarks that are relevant to our technology or activities and enforce their rights against us; and
- if patents are not issued, then the value of our underlying IP rights may be significantly diminished.

Additionally, any information contained in our licensed patents could become part of the public domain, so that it will not be protected as confidential information or trade secrets. As legal regulations and standards relating to the validity and scope of regulatory exclusivity and IP continue to evolve around the world, the degree of future protection for our proprietary rights is uncertain. We may also be subject to arbitrary compulsory licenses or governmental acts reducing IP protection outside our reasonable control. We may incur significant costs in asserting any patent or trademark IP rights and in defending legal action against us relating to rights. Such disputes could delay our product development or commercialization activities. Parties making claims against us may be able to obtain injunctive or other equitable relief that could prevent us from further developing discoveries or commercializing products or require the payment of damages or royalties.

In addition, in the event a successful claim of infringement is made against us, we may be required to pay damages and obtain one or more licenses from the prevailing third-party. If we are not able to obtain these licenses at a reasonable cost, if it all, we may encounter delays and lose substantial resources while seeking to develop or commercialize alternative products.

There is a risk that third parties may have IP that is relevant to our proposed activities which could prevent us from conducting these activities or may require us to license in the third-party's IP, find alternatives to the third-party IP, or seek to challenge the third-party IP, either at an administrative stage or through the courts. We may need to acquire or license IP from third parties to develop and commercialize our own pipeline of IP and products. There is no guarantee such acquisitions or licenses can be obtained or, if obtained, that they will be on reasonable commercial terms. Additionally, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside

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scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, there can also be no assurance that any of these parties will not breach confidentiality, or infringe or misappropriate our IP, which could cause material loss to us.

If we are unable to obtain and maintain patent protection for our products or product candidates and other discoveries, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and other discoveries similar or identical to ours, and our ability to successfully commercialize our products or product candidates and other discoveries may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary products and product candidates and other discoveries. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our products and product candidates and other discoveries that are important to our business. For a description of our patent portfolio, see "Item 4. Information on the Company — B. Business Overview." We intend to continue to apply for patents with claims covering our key products, product candidates or other discoveries when and where we deem it appropriate to do so.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As such, our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. and we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally, which could result in substantial costs and divert our efforts and attention from other aspects of our business.

In addition, geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, due to the Russia-Ukraine conflict, the U.S. and other foreign governments have implemented various economic sanctions and trade and activity restrictions involving Russia and Belarus. It is possible that additional sanctions and restrictions will be imposed by the U. S. or other jurisdictions as the Russia-Ukraine conflict continues, and such actions may include limiting or preventing filing, prosecution, and/or maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates or other discoveries, or which effectively prevent others from commercializing competitive products and discoveries. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. The patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the U.S. Patent and Trademark Office ("USPTO") and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Composition of matter patents for biological and pharmaceutical products and product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering compositions of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the U.S. or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

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Assuming the other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside of the U.S., the first to file a patent application is entitled to the patent. In March 2013, the U.S. transitioned to a first-inventor-to-file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, or post-grant or inter partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our discoveries or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative discoveries or products in a non-infringing manner.

The issuance of a patent is not conclusive of its inventorship, its scope, validity or its enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical discoveries and products, or limit the duration of the patent protection of our products, product candidates and discoveries. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology or pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Europe's Unified Patent Court may in particular present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. On June 1, 2023, the EU unitary patent system was launched, providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC"), for litigation involving European patents. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents that have not been opted out of the UPC, and allow for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU unitary patent system, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates.

We cannot be certain that we are aware of all third-party patents and pending applications in the U.S. and abroad that are relevant to or necessary for the commercialization of our product candidates in any jurisdiction. We may not be able to conduct complete and thorough searches, we may not be able to identify all relevant third-party patents, and we may not be able to fully predict the scope of the patent claims or the expiration of relevant third-party patent applications that may issue as patents. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

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In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Our rights to develop and commercialize our products and product candidates are subject in part to the terms and conditions of licenses granted to us by others, and the patent protection, prosecution and enforcement for some of our products and product candidates may be dependent on our licensors.

We currently are reliant upon licenses of certain intellectual property rights and proprietary technologies from third parties that are important or necessary to the development of our proprietary technologies, including technologies related to Illuccix and our product candidates. These licenses, and other licenses we may enter into in the future, may not provide adequate rights to use such intellectual property and proprietary technologies in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology and product candidates in the future. Licenses to additional third-party proprietary technology or intellectual property rights that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our proprietary technology or product candidates or to develop or license replacement technology, which may not be feasible on a technical or commercial basis. If we are unable to do so, we may not be able to develop and commercialize technology and product candidates in fields of use and territories for which we are not granted rights pursuant to such licenses, which could harm our competitive position, business, financial condition, results of operations and prospects significantly.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

Moreover, some of our owned and in-licensed patents or patent applications or future patents are or may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain and enforce the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our products or product candidates and proprietary technologies. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize product candidates, we may be unable to maintain profitability. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses

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to a portion of the intellectual property rights that are subject to our existing licenses. Any of these events could have a material adverse effect on competitive position, business, financial conditions, results of operations, and prospects.

Our technology licensed from third parties may be subject to retained rights.

Any license we may enter into could provide for the retention by the licensor of certain rights under their agreements with us, including the right to use the underlying technology for non-commercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether any future licensors will limit their use of the technology to these uses, and we may incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act ("the Bayh-Dole Act"). The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. The Bayh-Dole Act also imposes other obligations, including the requirement that products covered by the government funded patents be manufactured in the U.S.. We sometimes collaborate with academic institutions to accelerate our preclinical research or development. In the future, we may own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act. If the federal government exercises its rights under the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or these agreements are terminated or we otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to various agreements that we depend on to develop Illuccix, Gozellix and our product candidates and various proprietary technologies, and our rights to use currently licensed intellectual property, or intellectual property to be licensed in the future, are or will be subject to the continuation of and our compliance with the terms of these agreements. For example, under certain of our license agreements we are required to use commercially reasonable efforts to develop and commercialize product candidates covered by the licensed intellectual property rights, maintain the licensed intellectual property rights, and achieve certain development milestones, each of which could result in termination in the event we fail to comply.

In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the licensing agreement;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaboration agreements;
- our rights to transfer or assign the license;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, certain provisions in our and our license agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected products or product candidates, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. We are generally also subject to all of the same risks with respect to protection of intellectual property that we may

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license as we are for intellectual property that we own, which are described herein. If we or any of our current or future licensors fail to adequately protect this intellectual property, our ability to commercialize product candidates could suffer.

Issued patents covering our products and product candidates could be found invalid or unenforceable if challenged in courts or patent offices.

If we or one of our licensing partners initiated legal proceedings against a third-party to enforce a patent covering one or more of our products or product candidates, the defendant could counterclaim that the asserted patent covering the relevant product or product candidate is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including subject matter eligibility, novelty, obviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or made a misleading statement, during prosecution with the intent to deceive the USPTO. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination inter partes review, post grant review, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection would have a material adverse impact on our business. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors or commercial supply companies or others may infringe our patents and other intellectual property rights. To counter infringement, we may be required to file infringement actions, which can be expensive and time-consuming. In an infringement proceeding, a defendant may assert and a court may agree with a defendant that a patent or other intellectual property right of ours is invalid or unenforceable (or both), or the factfinder may refuse to stop the other party from using the allegedly infringed intellectual property at issue.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. An adverse result in any litigation could put one or more of our patents or registered trademarks at risk of being invalidated or interpreted narrowly and could limit our ability to assert our patents or trademark rights against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of any current and future collaborators to develop, manufacture, market and sell our Commercial Products and our product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products or product candidates and technology, including post-grant proceeding or interference proceedings (patents) or opposition or cancellation proceedings (trademarks) before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. No litigation asserting such infringement claims is currently pending against us, and we have not been found by a court of competent jurisdiction to have infringed a third-party's intellectual property rights.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates and Commercial Products. Our product candidates and other proprietary technologies that we may develop may infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. We may not be aware of patents that have already been issued and that a third-party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including

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claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, Commercial Products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. If such patent claims were to survive an invalidity challenge, and if they were asserted against us, we could incur substantial costs in the resulting litigation, including possible payment of treble damages for willful infringement and an injunction requiring us to cease sale of our products.

If we are found to infringe or think there is a risk we may be found to infringe, a third-party's intellectual property rights, we could be required or choose to obtain a license from such third-party to continue developing, marketing and selling our products, product candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us. We could be forced, including by court order, to cease commercializing the infringing intellectual property or product or to cease using the infringing technology. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our products or product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Intellectual property disputes could delay or prevent our compassionate use or magisterial preparation access programs and commercialization, expose us to injunctions, damages (including potential royalty back payments) and additional costs, and require additional public disclosures that could adversely affect our business and the market price of our ordinary shares and ADSs.

Intellectual property disputes including patent invalidity actions against 3rd party patents and patent infringement actions against competitor products are a routine business activity. In February 2026, Telix filed an invalidity action against an Australian patent owned by the Purdue Research Foundation. Patent disputes are costly, uncertain, and time-consuming. Patent disputes can result in injunctions, damages (including enhanced damages in some jurisdictions), or compulsory licensing that disrupt development or commercialization and divert significant management attention and resources. These risks are heightened where a counterparty seeks injunctive or other equitable relief that could limit or halt lawful compassionate use or magisterial preparation or commercial supply while a dispute is pending or permanent.

These matters often take years to finalise. Litigation and claims can be expensive and disruptive regardless of their merit, and we may not prevail. Even if we prevail, such proceedings often involve extensive discovery, may require disclosure of confidential information, and entail substantial legal expenses and management attention.

Unfavorable outcomes in validity or infringement patent disputes can limit our ability to exclude competitors or operate without a license, and required licenses may be unavailable on reasonable terms or delayed. Adverse rulings can also result in damages, ongoing royalty obligations that diminish program economics, or could result in our being enjoined from importing, making, using, offering to sell, or selling technologies critical to development of our product candidates and/or commercialization of our Commercial Products.

Public announcements or interim developments may also negatively affect investor perception and the market price of our ordinary shares and ADSs. Significant developments may necessitate public communications and additional disclosure in our public filings or offering documents, increasing legal, accounting, and compliance costs and contributing to volatility in the trading price of our ADSs. Public announcements or interim developments may also negatively affect investor perception and the market price of our ordinary shares and ADSs. Significant developments may necessitate public communications and additional disclosure in our public filings or offering documents, increasing legal, accounting, and compliance costs and contributing to volatility in the trading price of our ADSs.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees may have been previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares and ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

Further, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings, which typically last for years before they are concluded. Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patent or trademark rights, any patents that may be issued as a result of our pending or future patent applications, pending or future trademark applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders, or it may be otherwise impractical or undesirable to enforce our intellectual property rights against some third parties. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace and could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with such provisions, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patent rights are of limited duration. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years after its first effective filing date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the U.S., a patent's life can be increased based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may be available in the U.S.. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family.

Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

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If our product candidates or any of our future product candidates obtain regulatory approval, additional competitors could enter the market with generic or similar versions of such products, which may result in a material decline in sales of our competing products.

Under the Hatch-Waxman Act, a company may submit an ANDA, seeking approval of a generic version of an approved innovator product. Under the Hatch-Waxman Act, a company may also submit an NDA under section 505(b)(2) of the FDCA that references the FDA's prior approval of the innovator product or preclinical studies and/or clinical trials that were not conducted by, or for, the sponsor and for which the sponsor has not obtained a right of reference. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA.

In certain circumstances, third parties may submit an ANDA or NDA under Section 505(b)(2) as early as the so-called "NCE-1" date that is one year before the expiry of the five-year period of New Chemical Entity exclusivity or more generally four years after NDA approval. The third parties may rely on certain safety and efficacy data of the innovator's product, may not need to conduct clinical trials and can market a competing version of a product after the expiration or loss of patent exclusivity or the expiration or loss of regulatory exclusivity and often charge significantly lower prices. Upon the expiration or loss of patent protection or the expiration or loss of regulatory exclusivity for a product, the major portion of revenues for that product may be dramatically reduced in a very short period of time. If we are not successful in defending our patents and regulatory exclusivities, we will not derive the expected benefit from them.

In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for the applicable, approved innovator product, a generic or 505(b)(2) sponsor that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability, or claiming non-infringement, of the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our product candidates that are regulated as drugs are approved, competitors could file ANDAs for generic versions of these products or 505(b)(2) NDAs that reference our products. If there are patents listed for such drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA sponsor does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

If we do not successfully extend the term of patents covering our product candidates under the Hatch-Waxman Act and similar foreign legislation, our business may be materially harmed.

Depending upon the timing, duration and conditions of FDA marketing approval, if any, of our products or product candidates, one or more of our U.S. patents may be eligible for patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years for one patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. The total patent term, including the extension period, may not exceed 14 years following FDA approval. Accordingly, the length of the extension, or the ability to even obtain an extension, depends on many factors.

In the U.S., only a single patent can be extended for each qualifying FDA approval, and any patent can be extended only once and only for a single product. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family.

If we are unable to obtain a patent term extension for a product or product candidate or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product or product candidate, if any, in that jurisdiction will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue could be materially reduced.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our products, product candidates and other discoveries, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidates, including processes for their preparation and manufacture, involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as

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through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also may not have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. To the extent that we are unable to timely enter into confidentiality and invention or patent assignment agreements with our employees and consultants, our ability to protect our business through trade secrets and patents may be harmed. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. To the extent inventions are made by a third-party under an agreement that does not grant us an assignment of their rights in inventions, we may choose or be required to obtain a license.

Not all of our trademarks are registered. Failure to secure those registrations could adversely affect our business.

In total, as of December 31, 2025, we own 26 registered U.S. trademarks, 14 pending U.S. trademark applications, 179 foreign trademarks registered in jurisdictions such as Australia, Europe, China, Brazil and Japan, and 93 pending foreign trademark applications applied for in jurisdictions such as Australia, Europe, China, Brazil and Japan.

For a description of our registered and pending trademarks, see "Item 4. Information on the Company — B. Business Overview."

If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would, which could adversely affect our business. During trademark registration proceedings in the U.S. and foreign jurisdictions, our trademark applications may receive rejections or may face post-registration rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark applications or registrations may not survive such proceedings.

In addition, any proprietary name we propose to use with our key product candidates in the U.S. must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed drug names, including an evaluation of potential for confusion with other drug names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary drug names for any of our product candidates, if approved, we may be required to expend significant additional resources in an effort to identify a suitable proprietary drug name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks, common law trademarks (in territories where such claims are permitted under local laws) or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the trademarks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks, and may be forced to expend resources to identify, protect, and promote a new trademark to allow for commercialization of certain products.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property.

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If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our proprietary rights may not adequately protect our technologies and product candidates, and do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others, including inventors or developers of our or our owned or in-licensed patented technologies who may become involved with competitors, may independently develop similar technologies that function as alternatives or replacements for any of our technologies without infringing our intellectual property rights;
- we or our licensors or our other collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own or license or will own or license;
- we or our licensors or our other collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license;
- we or our licensors may fail to meet obligations to the U.S. government with respect to in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct R&D activities in countries where we do not have patent rights, or in countries where R&D safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership, validity or enforceability of our or our licensors' patents or patent applications may be challenged by third parties; and
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain key members of our management team and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, technical and scientific expertise of principal members of our management and scientific teams, including Christian Behrenbruch, our Managing Director and Group Chief Executive Officer. Although we have entered into formal employment agreements with our executive officers, these agreements do

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not prevent them from terminating their employment with us at any time by providing notice within the notice period specified in such agreements, subject to certain exceptions. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of our key employees could impede the achievement of our research, development, commercialization and other business objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to continue to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have experienced rapid growth since our inception in 2017. We expect continued growth in the number of our employees and the scope of our operations, particularly to continue our clinical operations, preclinical and IND-enabling studies or studies approved by comparable foreign authorities and to establish regulatory, quality, and manufacturing supply chain logistics and facility operations.

To manage our anticipated future growth, we will continue to seek to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the complexity in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, we are completing the commissioning of a European manufacturing facility in Brussels South and have limited experience in managing the manufacturing processes necessary for delivering potent therapeutic radioisotopes. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating new employees; managing our internal development efforts effectively, including the clinical and FDA, or comparable foreign regulatory authority, and review process for our Commercial Products and any product candidates, while complying with our contractual obligations to third parties; and improving our operational, financial and management controls, reporting systems, and procedures. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development, and research and development services, as well as certain aspects of regulatory approval and manufacturing. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed or on reasonable terms, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants, CROs, or CMOs is compromised for any reason, our preclinical or clinical trials may be extended, delayed, or terminated, and we may not be able to obtain and/or maintain regulatory approval of our Commercial Products or any of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new qualified employees and expanding our groups of consultants and contractors, we may experience delays or may not be able to successfully implement the tasks necessary to further develop and commercialize our Commercial Products and any product candidates we develop and, accordingly, we may not achieve our research, development, and commercialization goals.

Our business and operations may be materially adversely affected in the event of information technology system failures or security breaches, and the costs and consequences of implementing data protection measures could be significant.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber incidents initiated by malicious third parties. Cyber incidents are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect, respond to and recover from. Cyber incidents could include the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber incidents also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company, including personal data of our employees, patients and clinical trial participants. In addition, we face other kinds of risks related to our commercial and personal data, including lost or stolen devices or other systems (including paper records) that collect and store our personal and commercial information, including clinical trial data.

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If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development and commercialization programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our reputation or competitive position could be damaged, and the further development and commercialization of our products or product candidates could be delayed or halted. In addition, we may in certain instances be required to provide notification to individuals or others in connection with the loss of their personal or commercial information.

If a material breach of our security or that of our vendors occurs, our financial or other confidential information could be compromised and could adversely affect our business or result in legal proceedings. In addition, the cost and operational consequences of implementing further data protection measures could be significant. The development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. Moreover, the possibility of these events occurring cannot be eliminated entirely.

Our employees, independent contractors, consultants, clinical trial investigators, collaborators and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and/or requirements and insider trading, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, collaborators and vendors. Misconduct by these partners could include intentional, reckless and/or negligent conduct or unauthorized activities that violate FDA regulations or similar regulations of comparable foreign regulatory authorities; provide inaccurate information to the FDA or comparable foreign regulatory authorities; fail to comply with manufacturing standards, federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities; fail to comply with state drug pricing transparency filing requirements; fail to report financial information or data accurately; or fail to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state laws, and requirements of foreign jurisdictions, including GDPR. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from significant penalties, governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Legal claims and proceedings could adversely impact our business.

We have been in the past the subject of employment-related claims, and may in the future be a party to employment-related litigation, and any future litigation related to such actions could materially adversely affect us. We consider our historical experiences with such claims and proceedings to be in the normal course of our business or typical for our industry; however, it is difficult to assess the outcome of these matters, and we may not prevail in any future proceedings or litigation. Regardless of their merit, any threatened or actual claims or proceedings can require significant time and expense to investigate and defend. Since litigation is inherently uncertain, there is no guarantee that we will be successful in defending ourselves against such claims or proceedings, or that our assessment of the materiality of these matters, including any reserves taken in connection therewith, will be consistent with the ultimate outcome of such matters.

Risks Related to Sustainability

We may experience sustainability risks, including: physical climate-related risks such as extreme weather events that could disrupt internal operations, suppliers, and logistics, and increase operational costs; resource and energy risks such as increasing energy prices, regulatory actions and increased resource efficiency standards that may increase operating expenses and capital expenditure for facility upgrades; and, non-compliance with increased social and governance regulations that could lead to fines, reputational damage, and increased compliance costs.

The Group identifies and manages sustainability risks through a structured process aligned with global reporting standards and investor expectations. In 2025, the Group completed a Double Materiality Assessment ("DMA"), which evaluates both impact materiality (how operations affect the environment and society) and financial materiality (how these impacts influence enterprise value). This assessment informs strategic priorities, and we have identified the following risk areas:

- **Physical Climate Risk:** Extreme weather events such as floods, storms, and heatwaves may disrupt suppliers and logistics, increase operational costs, and threaten facility safety.

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- **Resource and Energy Risk:** Rising energy prices and regulatory actions on resource efficiency standards may increase operating expenses and capital requirements for facility upgrades and sustainable alternatives.

- **Social and Governance Risks:** Non-compliance with health and safety, end-user data privacy, and anti-corruption regulations may result in fines, reputational damage, and increased compliance costs.

These risks and others are described in greater detail in the following risk factors and in our Sustainability report.

Physical Climate Risks

Increasing frequency and severity of climate-related events could disrupt our manufacturing, key suppliers, logistics and workforce and adversely affect our business and we may not be sufficiently resilient to physical climate risks, requiring significant investment and potentially constraining our site selection.

Our global operations are exposed to acute and chronic physical risks associated with climate change, including more frequent and severe storms, floods, heatwaves, wildfires, and other extreme weather events. These events can damage or impair our manufacturing facilities, laboratories, warehouses, clinical trial sites, data centers and office locations, and can disrupt utilities and critical infrastructure on which we depend. They may also interrupt our logistics and distribution networks, including air, sea and land transport routes, and compromise the ability of our employees and contractors to safely travel to and from company and third-party sites. Any such disruption could delay the manufacture, testing, release and delivery of our Commercial Products and regulatory trial materials, increase operating and capital costs surrounding repairs, hardening, redundancy and insurance, and result in product shortages, lost revenue and damage to our relationships with customers, healthcare providers and partners. If these climate-related events increase in frequency or severity or occur in regions that are strategically important to us, our business, financial condition and results of operations could be materially and adversely affected.

Certain of our existing facilities and those of our critical suppliers and contract manufacturers are located in regions that are exposed to increased physical climate risks. Enhancing the resilience of these sites through elevation, hardening, redundancy in utilities, flood protection, enhanced cooling or other measures may require significant capital expenditures and extended project timelines. In addition, as we consider new manufacturing, research or distribution sites, physical climate risk is increasingly a factor in site selection. Suitable locations that offer both operational advantages and acceptable climate risk profiles may be limited, more expensive, or subject to competing demand from other companies. If we are unable to adequately assess and mitigate climate-related physical risks at our existing and future sites, we could experience higher operating and transportation costs, more frequent disruptions, and constraints on our ability to expand capacity in a timely and cost-effective manner.

Water scarcity and wastewater management regulations may adversely affect our manufacturing operations, quality controls and expansion plans.

Many of our Commercial Products and active pharmaceutical ingredients ("APIs") are manufactured using water-intensive processes which require access to reliable sources of water of appropriate quality, as well as adequate wastewater treatment and discharge infrastructure. In some regions where we operate or may expand, climate change is contributing to water scarcity, drought, flooding, or changes in water quality and regulatory requirements. Governments in the countries where we manufacture our products may impose stricter limits on industrial water use, require additional investments in water treatment, or restrict new permits and expansions in water-stressed areas. In some regions, tighter regulation of industrial water use, wastewater discharge, waste management, and renewable energy procurement is affecting the feasibility and cost of pharmaceutical operations. We may face requirements to invest in additional on-site water or waste infrastructure, secure long-term renewable energy contracts, or demonstrate compliance with local climate and environmental standards as a condition to permitting or operating. If we are unable to identify targets or sites that meet our operational needs and ESG expectations, or if environmental and resource constraints materially increase the cost or complexity to secure sufficient, reliable and compliant water and wastewater capacity on acceptable terms, we may be forced to reduce production volumes, reconfigure or relocate manufacturing operations, or materially alter strategic plans or expansions. We may also incur higher costs to treat, recycle or transport water and wastewater, or to install alternative water technologies. Any of these developments could adversely affect our manufacturing reliability, product quality, cost structure and growth strategy.

Climate-related disruptions to transportation and cold-chain logistics could impair the distribution and integrity of our products.

Many of our products, drug substances and intermediates, including temperature-sensitive biologics and, where applicable, radiopharmaceuticals and other hazardous materials, must be stored and transported under strict temperature-controlled conditions and delivered within defined time windows. Climate-related impacts and extreme weather events, including, but not limited to heatwaves, arctic storms, tropical storms, flooding, and potential resulting infrastructure failure, can disrupt air and ground transportation, reduce availability of cargo capacity, and increase the risk of temperature excursions or delays during shipping. We substantially rely on third-party logistics providers, specialty couriers, and in some cases just-in-time manufacturing and delivery models. Any failure in transport infrastructure or cold-chain logistics due to physical climate events, power outages, or related issues could result in spoilage, loss, or delays of finished products or clinical supplies. This could lead to product shortages, recalls, regulatory non-compliance, contractual penalties, or damage to our reputation, any of which could materially and adversely affect our business.

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Resource and Energy Risks

Our operations depend on reliable access to energy and increasing energy costs, supply disruptions and decarbonization pressures could adversely affect our business.

Our manufacturing, research, information technology systems, and office operations require significant and growing amounts of energy to operate. Climate change and the global transition to a lower-carbon economy are contributing to energy price volatility, changes in energy mix, and, in some regions, constraints on grid reliability and capacity. We also anticipate higher energy demand for temperature control in our facilities and across our distribution network as global average temperatures rise. We are implementing measures to reduce greenhouse gas emissions, which may include entering into virtual power purchase agreements and power purchase agreements, investing in on-site renewable energy installations, and improving energy usage efficiency. These initiatives require capital and may not be available on acceptable terms in all jurisdictions, particularly where competition for renewable energy is increasing. If we experience sustained energy price increases, energy supply interruptions, or are unable to execute our energy strategy effectively, our capital expenditures and operating costs could increase and our ability to meet sustainability commitments could be impaired, causing our business and results of operations to be adversely affected.

Limited availability or regulatory constraints on critical raw materials, including biologics and other specialized inputs, could increase our costs and disrupt production.

We rely on a wide range of raw materials, packaging materials and specialized inputs sourced from third parties worldwide. These include, but are not limited to, materials derived from biological sources (such as components used in certain quality control tests), as well as materials that are manufactured using fossil fuel-based feedstocks or complex chemical processes. Environmental degradation, biodiversity loss, such as declines in certain species used in pharmaceutical testing or production, regulatory restrictions, and changes in conservation or harvesting policies may reduce the availability or increase the cost of some of these inputs. If key materials become scarce, become subject to new environmental or animal-welfare regulations, or are concentrated among a small number of suppliers able to meet evolving ESG standards, we may incur higher procurement costs, need to invest in reformulation or alternative technologies, or experience delays or interruptions in manufacturing. Any significant interruption in the supply of critical biologics or raw materials could adversely affect our ability to manufacture and deliver products on a timely basis and could negatively impact our financial performance.

Transitioning our operations and supply chain to a lower-carbon model may require substantial investment and may not proceed as planned.

Regulators, investors, customers and other stakeholders increasingly expect pharmaceutical companies to reduce greenhouse gas emissions, including Scope 3 emissions across their supply and value chains. Meeting these expectations may require us to modify processes, invest in new equipment or technologies, change product designs or packaging, restructure logistics networks, and shift to lower-carbon energy and materials. For certain specialized technologies, such as energy-intensive manufacturing steps or generation of medical isotopes where applicable, economical low-carbon alternatives may not yet be available or scalable. If we are unable to implement our decarbonization initiatives on commercially reasonable terms, or if regulation accelerates faster than technology and markets evolve, we may face higher compliance costs, potential carbon pricing or taxes, and constraints on operations or expansion in certain markets. Failure to meet our stated climate or energy targets could also adversely affect our reputation and our relationships with investors, customers and partners.

We generate hazardous and, at times, radioactive and biologically active waste where evolving environmental, health and safety requirements may increase our costs and liabilities.

Our manufacturing, research and development, and where relevant, radiopharmaceutical operations, generate hazardous, chemical, biological and, in some cases, radioactive waste that must be collected, handled, stored, transported, treated and disposed of in compliance with complex and evolving environmental, health and safety laws and regulations. Regulators may impose more stringent requirements over time, including with respect to waste minimization, tracking, treatment technology, emissions limits and long-term disposal obligations. As the scale and complexity of our operations expand, the volume of such waste we generate is likely to increase. We may need to invest in additional on-site infrastructure, contract with specialized third-party waste management providers, or adapt to changes in available disposal capacity or technology. Any failure of our ability to properly manage hazardous or radioactive materials and waste could result in regulatory enforcement, cleanup obligations, operational restrictions, civil or criminal penalties, or claims for personal injury, property damage, or environmental harm. Such events could materially and adversely affect our business, financial condition, results of operations and reputation.

Social and Governance Risks

Failure to meet evolving environmental, social and governance disclosure expectations and regulatory requirements could adversely affect our access to capital, valuation and reputation.

Evolving expectations and regulatory requirements relating to ESG matters, including climate-related issues, could adversely affect our business, financial condition and prospects. Regulators and standard-setting bodies in the European Union and other jurisdictions in which we operate are implementing or may implement new requirements regarding climate-related and broader ESG disclosures, including with respect to greenhouse gas emissions, climate risk

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governance and supply chain transparency. Investors, lenders, customers and other stakeholders are also increasingly relying on ESG ratings, benchmarks and voluntary disclosures in making investment, procurement and business decisions. Collecting, verifying and reporting ESG data across our global operations and value chain is exceptionally complex and resource-intensive while being subject to evolving standards and methodologies. Failure to adequately integrate ESG considerations, including climate resilience, resource use, human rights and compliance with environmental and safety regulations, into our governance structures, risk management processes, strategic planning, capital allocation and expansions could lead to suboptimal decisions, stranded assets, unanticipated compliance and remediation costs, and underperforming acquisitions. If our ESG-related disclosures or actions are perceived as incomplete, inaccurate, inconsistent or not aligned with emerging regulatory, customer or investor expectations, we could face regulatory scrutiny, investigations, sanctions, fines, litigation, reduced access to capital or less favorable financing terms, and damage to our reputation, and our ability to attract and retain certain investors could be adversely affected.

ESG practices, especially regarding diversity, equity and inclusion ("DEI"), have been increasingly subject to political controversy in the United States in recent years. Our policies and practices regarding DEI and other ESG-related matters, including those that may be required by non-U.S. law, may expose us to legal, reputational and other risks, including anti-ESG and anti-DEI-related orders, investigations, legislation, litigation, media coverage and scrutiny, boycotts and negative publicity from investors and other stakeholders. We cannot predict what regulatory or other changes may occur in the future as a result of this controversy, and we may not be able to meet any conflicting expectations of some or all of our investors, customers, employees and other third parties (including governmental entities and officials and non-governmental organizations) regarding various aspects of our business, including with respect to DEI and other ESG matters.

Failure to manage ESG risks across our operations, workforce and global value chain could result in legal, operational and reputational harms.

Inadequate management of ESG risks across our operations, workforce and global value chain, including labor, human rights, modern slavery and climate-related health and safety risks, could adversely affect our operations, reputation and competitive position. We operate in, and source products and services from, multiple countries, including regions with higher risks relating to labor practices, human rights and modern slavery. We substantially rely on third-party suppliers, contract manufacturers, distributors, logistics providers and other partners, some of which in turn rely on their own complex supply chains, and we may not have complete visibility into or control over their practices. Stakeholders and regulators are increasingly scrutinizing companies' efforts to prevent forced labor, child labor, unsafe working conditions and other human rights abuses in their operations and supply chains. Our employees and contractors work in manufacturing plants, laboratories, offices, distribution centers and in the field, and climate change can exacerbate occupational health and safety risks, including heat stress, vector-borne diseases, air quality issues and extreme weather events. Inadequate planning for emergency response, workplace adaptation, remote work capabilities or business continuity in the face of climate-related events could lead to increased absenteeism, reduced productivity, higher healthcare and insurance costs, and difficulties recruiting and retaining talent, particularly in climate-stressed regions. Public and private healthcare systems, hospital groups, group purchasing organizations and other customers are increasingly considering suppliers' environmental and social performance, including carbon footprint, waste and water management, supply chain practices and human rights, when making procurement and reimbursement decisions, and some tenders and contracts include ESG criteria or require detailed ESG disclosures.

If we or our partners fail to meet applicable modern slavery, human rights, labor or climate-related health and safety standards, or if we are unable to demonstrate ESG performance, climate risk management and supply chain transparency that meet the expectations of key stakeholders, we could face regulatory investigations, fines, litigation, supply disruptions, product boycotts, loss of customers, reduced pricing power, exclusion from preferred supplier lists and restrictions on access to certain markets, and our reputation and demand for our products could be adversely affected.

Risks Related to an Investment in the ADSs

An active and liquid market for our securities may not continue to be developed or sustained, which could harm the market price of the ADSs.

While our ordinary shares have been listed on the ASX since 2017, prior to the November 2024 listing of the ADSs on Nasdaq, there was no public market on a U.S. national securities exchange for our ordinary shares or ADSs. Given the limited trading history, an active trading market for the ADSs may not continue to be developed or sustained. In the absence of an active trading market for the ADSs, investors may not be able to sell their ADSs.

Future sales of ordinary shares or ADSs by existing holders could depress the market price of the ordinary shares or ADSs.

Sales of a substantial number of shares or ADSs in the public market, or the perception that such sales could occur, could adversely affect the market price of our ordinary shares or ADSs. As of December 31, 2025, we had 338,777,049 outstanding ordinary shares, and approximately 31,744,502 in ordinary shares underlying outstanding share options and other equity securities convertible into or exercisable for ordinary shares. In addition, as of December 31, 2025, there were approximately 26,230,831 ordinary shares underlying outstanding Convertible Bonds, which may be converted at

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the option of the holders, subject to the conditions in the trust deed, at any time on or after September 9, 2024, at an initial conversion price of A$24.78 per ordinary share, subject to adjustment.

Ordinary shares underlying these securities may become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Sales of a large number of the ordinary shares in the public market could depress the market price of the ordinary shares or the ADSs. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of the ordinary shares and ADSs could decline substantially, which could impair our ability to raise additional capital through the issuance of ordinary shares, ADSs or other securities in the future.

Our shareholders may experience dilution if we issue ordinary shares or ADSs in future financings, and, as a result, the price of the ordinary shares or ADSs may decline.

We may from time-to-time issue additional ordinary shares or ADSs and such issuance may occur at a discount from the trading price of the ordinary shares or ADSs. Additionally, we have in the past issued debt securities convertible into equity, and we may do so again in the future. For example, in July 2024, we issued the Convertible Bonds, which may be converted into ordinary shares. As a result, holders of the ADSs could experience immediate dilution upon the issuance of any of our ordinary shares, including as a result of the conversion of some or all of the Convertible Bonds. As opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preference shares or shares. If we issue ordinary shares or other equity or equity-linked securities, holders of ADSs would experience additional dilution and, as a result, the trading price of the ordinary shares or ADSs may decline.

The rights of holders of ADSs to participate in any future preferential subscription rights offering or to elect to receive dividends in ordinary shares may be limited, which may cause dilution to their holdings.

The deposit agreement provides that the depositary will not make rights available to holders of ADSs unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the U.S. Securities Act of 1933, as amended ("Securities Act"). If we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case holders of ADSs will receive no value for these rights.

Our principal shareholders and management own a significant percentage of our ordinary shares and may be able to exert significant influence over matters subject to shareholder approval.

As of December 31, 2025, our executive officers, directors, holders of 5% or more of our outstanding equity interests and their respective affiliates beneficially owned approximately 7.71% of our outstanding ordinary shares. These shareholders may be able to determine all matters requiring shareholder approval and they may have interests that differ from other shareholders and may be adverse to the interests of other shareholders. For example, these shareholders may be able to propose elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction, and may be able to exert significant influence over matters subject to shareholder approval. Please see "Item 7. Major Shareholders and Related Party Transactions - A. Major Shareholders" for more information on the beneficial ownership of our executive officers, directors and holders of 5% or more of our outstanding equity interests.

ADS holders may not be entitled to a trial by jury with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in any such action.

The deposit agreement governing our ADSs provides that, to the fullest extent permitted by applicable law, ADS holders, including holders who acquire ADSs in the secondary market, irrevocably waive the right to a trial by jury for any claim they may have against us or the depositary arising out of or relating to the deposit agreement, the shares or the ADSs, including claims under U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the U.S. Supreme Court. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a trial by jury. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining

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whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that potential owners or holders of ADSs consult legal counsel regarding the jury waiver provision before acquiring any ADS(s) and thereby becoming subject to the terms of the deposit agreement.

If any owner or holder of our ADSs, including purchasers of ADSs in secondary market transactions, brings a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, such owner or holder may incur increased costs of bringing a claim and may not be entitled to a trial by jury with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depositary. If a lawsuit is brought against us or the depositary under the deposit agreement, it may be heard only by a judge of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiffs in any such action. The deposit agreement governing our ADSs provides that any legal suit, action or proceeding against or involving us brought by the depositary or any holder or beneficial owner of ADSs, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, may be instituted only in any state or federal court in New York, New York. This forum provision may increase costs to owners or holders of ADRs and limit their ability to bring a claim in a judicial forum that they find favorable for disputes with the depositary or us, or the depositary's or our respective directors, officers or employees, which may discourage such lawsuits against the depositary, us and the depositary's and our respective directors, officers or employees. However, it is possible that a court could find this choice of forum provision to be inapplicable or unenforceable. The enforceability of similar choice of forum provisions has been challenged in legal proceedings. Any legal suit, action or proceeding against or involving the depositary brought by us, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby, may only be instituted in a state or federal court in New York, New York. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of U.S. federal securities laws and the rules and regulations promulgated thereunder.

Limitations in the deposit agreement may not be effective to waive claims against the Company based on compliance with the federal securities laws.

Although the deposit agreement provides a waiver of trial by jury as described above, we have been advised that no condition, stipulation or provision of the deposit agreement or ADSs can serve as a waiver by any owner or holder of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

The market price and trading volume of the ADSs may be volatile and may be affected by economic conditions beyond our control.

The market price of the ADSs may be highly volatile and subject to wide fluctuations. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In addition, the trading volume of the ADSs may fluctuate and cause significant price variations to occur. If the market price of the ADSs declines significantly, you may be unable to resell the ADSs at or above the purchase price, if at all. We cannot assure you that the market price of the ADSs will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of the ADSs or result in fluctuations in their price and trading volume include:

- adverse results or delays in our preclinical studies or clinical trials;
- reports of adverse events or other negative results in clinical trials of third parties' product candidates that target our products' or product candidates' target indications;
- an inability for us to obtain additional funding on reasonable terms or at all;
- any delay in submitting an IND, BLA or NDA (or similar foreign application) for our product candidates and any adverse development or perceived adverse development with respect to the FDA's (or comparable foreign regulatory authority's) review of that IND, BLA or NDA (or similar foreign application);
- failure to develop successfully and commercialize our products and product candidates;
- announcements we make regarding our current products and product candidates, acquisition of potential new products/product candidates and companies and/or in-licensing;
- failure to maintain our existing license arrangements or enter into new licensing and collaboration agreements;
- failure by us or our licensors to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to current and future products;

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- inability to obtain adequate clinical or commercial supply for our product candidates or the inability to do so at acceptable prices;
- adverse regulatory decisions, including failure to reach agreement with applicable regulatory authorities on the design or scope of our planned clinical trials;
- failure to obtain and maintain regulatory exclusivity for our products and product candidates;
- regulatory approval or commercialization of new products or other methods of treating our target disease indications by our competitors;
- failure to meet or exceed financial projections we may provide to the public or to the investment community;
- publication of research reports or comments by securities or industry analysts;
- the perception of the pharmaceutical and biotechnology industries, and especially the radiopharmaceutical industry, by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions to or departures of our key scientific or management personnel;
- significant lawsuits, including patent or shareholder litigation, against us;
- changes in the market valuations of similar companies;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- changes in trading volume of ADSs on Nasdaq and of our ordinary shares on the ASX;
- sales or perceived potential sales of the ADSs or ordinary shares by us, our directors, executive officers or our shareholders in the future;
- announcement or expectations of additional financing efforts; and
- conditions in the U.S. or Australian financial markets or changes in general economic conditions.

ADS holders are not our shareholders and do not have shareholder rights.

JPMorgan Chase Bank, N.A., as depositary, issues, registers and delivers the ADSs. After purchasing an ADS, holders hold ADSs with underlying ordinary shares in an Australian publicly listed company. ADS holders are not treated as our shareholders and do not have shareholder rights. The depositary is the holder of our ordinary shares underlying the ADSs. Holders of ADSs have ADS holder rights, which are solely contractual in nature. A deposit agreement among us, the depositary, ADS holders, and the beneficial owners of ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. We and the depositary may amend or terminate the deposit agreement without the ADS holders' consent in a manner that could prejudice ADS holders. For a description of ADS holder rights, see "Item 12. Description of Securities Other than Equity Securities — D. American Depositary Shares." Our shareholders have shareholder rights. Australian law and our Constitution govern shareholder rights. For a description of our shareholders' rights, see "Item 10. Additional Information — B. Memorandum and Articles of Association."

ADS holders do not have the same voting rights as our shareholders. Shareholders are entitled to receive our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions that may be attached to any shares. ADS holders may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. ADS holders may instruct the depositary to vote the ordinary shares underlying their ADSs. Otherwise, ADS holders are not entitled to exercise their right to vote unless they surrender their ADSs and withdraw the ordinary shares underlying their ADSs prior to both the ordinary share and ADS record dates for such meeting.

However, ADS holders may not have sufficient advance notice about the meeting to surrender their ADSs and withdraw the shares. If we ask for ADS holders' instructions, the depositary will notify registered holders of ADSs of the upcoming vote and arrange to deliver our voting materials and form of notice to them. If we ask the depositary to solicit voting instructions, the depositary will try, as far as practical, subject to Australian law and the provisions of the depositary

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agreement, to vote the shares as ADS holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of ADS holders. We cannot assure ADS holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their shares. In addition, there may be other circumstances in which ADS holders may not be able to exercise voting rights.

ADS holders do not have the same rights to receive dividends or other distributions as our shareholders. Subject to any special rights or restrictions attached to any shares, the directors may determine that a dividend will be payable on our ordinary shares and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary shares and we do not anticipate paying any cash dividends in the foreseeable future). Dividends may be paid on our ordinary shares of one class but not another and at different rates for different classes. Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares represented by ADSs will be paid to the depositary, which has agreed to pay to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Before the depositary makes a distribution to you in respect of your ADSs, any withholding taxes that must be paid will be deducted. Additionally, if the exchange rate fluctuates during a time when the ADS depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.

ADS holders will receive these distributions in proportion to the number of ordinary shares their ADSs represent. In addition, there may be certain circumstances in which the depositary may not pay to ADS holders amounts distributed by us as a dividend or distribution.

There are circumstances where it may be unlawful or impractical to make dividends or other distributions to the holders of the ADSs.

The deposit agreement requires the depositary to convert foreign currency distributions it receives on deposited ordinary shares into U.S. dollars and distribute the net U.S. dollars to ADS holders if it can do so on a reasonable basis and transfer the money to the U.S. If it cannot make that conversion and transfer, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. If a dividend or other distribution is payable by us in Australian dollars, the depositary will hold the foreign currency it cannot convert for the account of ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, ADS holders may lose some of the value of the dividend or other distribution. The depositary is not responsible if it decides that it is unlawful or impractical to make a dividend or other distribution available to any ADS holders. This means that ADS holders may not receive the dividends or other distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to them.

There may be limited ability to bring an action against us or against our directors and executive officers, or to enforce a judgment against us or them, because we are incorporated in Australia and certain of our directors and executive officers reside outside of the U.S.

We are incorporated under the laws of Australia. Certain of our directors and executive officers are residents of countries other than the U.S. and a portion of our and their assets are located outside of the U.S. As a result, it may not be possible or practicable for owners or holders of ADSs to effect service of process within the U.S. upon such persons or to enforce against us or them judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the U.S. Even if a plaintiff is successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the U.S. or elsewhere may be unenforceable in Australia or elsewhere outside the U.S. An award for monetary damages under U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Australia will depend on the particular facts of the case as well as the laws and treaties in effect at the time. As a result, our holders of our ADSs may have more difficulty in protecting their interests through actions against us, our management or our directors than would shareholders of a corporation incorporated in a jurisdiction in the U.S. In addition, as a company incorporated in Australia, the provisions of the Corporations Act 2001, regulate the circumstances in which shareholder derivative actions may be commenced, which may be different to the circumstances for companies incorporated in the U.S.

The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs.

Our ordinary shares are listed on the ASX and our ADSs are listed on Nasdaq. We cannot predict the effect of our dual listing on the value of our ordinary shares and the ADSs. However, the dual listing of our ordinary shares and the ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the U.S. The price of the ADSs could also be adversely affected by trading in our ordinary shares on the ASX.

We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.

Our ordinary shares are quoted in Australian dollars on the ASX and the ADSs are quoted in U.S. dollars. In the past year, the Australian dollar has fluctuated against the U.S. dollar. As such, any significant change in the value of the Australian

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dollar may have a negative effect on the value of the ADSs in U.S. dollars. In addition, if the Australian dollar weakens against the U.S. dollar, then, if we decide to convert our Australian dollars into U.S. dollars for any business purpose, appreciation of the U.S. dollar against the Australian dollar would have a negative effect on the U.S. dollar amount available to us. While we engage in limited hedging transactions to manage our foreign exchange risk, these activities may not be effective in limiting or eliminating foreign exchange losses. Consequently, appreciation or depreciation in the value of the Australian dollar relative to the U.S. dollar would affect our financial results reported in U.S. dollar terms without giving effect to any underlying change in our business or results of operations. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations.

As a foreign private issuer, we are permitted to follow, and we do follow, certain home country corporate governance practices in lieu of certain Nasdaq requirements applicable to domestic issuers.

As a foreign private issuer listed on Nasdaq, we are permitted to follow, and we do follow, certain home country corporate governance practices in lieu of certain Nasdaq practices. In particular, we follow home country law instead of Nasdaq practice, and expect to continue to follow home country law instead of Nasdaq practice, regarding the following:

- We rely on an exemption from the requirement that our independent directors meet regularly in executive sessions. The ASX Listing Rules and the Australian Corporations Act 2001 (Cth) do not require the independent directors of an Australian company to have such executive sessions and, accordingly, we rely on this exemption.

- We rely on an exemption from the requirement that the responsibility for the appointment of the independent registered public accounting firm be made by the audit committee. While our Audit and Risk Committee is directly responsible for remuneration and oversight of the independent registered public accounting firm, the ultimate responsibility for the appointment of the independent registered public accounting firm rests with our shareholders in accordance with Australian law and our Constitution. In accordance with Rule 10A-3 of the U.S. Securities Exchange Act of 1934, as amended ("Exchange Act") our Audit and Risk Committee is responsible for the annual auditor engagement and if there is any proposed change to the independent registered public accounting firm, the committee will make a recommendation to our board of directors, which would then be considered by our shareholders at an annual meeting of shareholders.

- We rely on an exemption from the quorum requirements applicable to meetings of shareholders under Nasdaq rules. Our Constitution provides that two shareholders present and entitled to vote on a resolution at the meeting shall constitute a quorum for a general meeting. Nasdaq requires that an issuer provide for a quorum as specified in its bylaws for any meeting of the holders of ordinary shares, which quorum may not be less than 33 1/3% of the outstanding shares of an issuer's voting ordinary shares. Accordingly, because applicable Australian law and rules governing quorums at shareholder meetings differ from Nasdaq's quorum requirements, we rely on this exemption.

- We rely on an exemption from the requirement prescribed by Nasdaq that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, changes of controls or private placements of securities, or the establishment or amendment of certain stock option, purchase or other compensation plans. Applicable Australian law and rules differ from Nasdaq requirements, with the ASX Listing Rules providing generally for the ability to seek prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% of our issued share capital in any 12 month period (but, in determining the available issue limit, securities issued under an exception to the rule or with shareholder approval are not counted), (ii) issuance of equity securities to related parties, certain substantial shareholders and their respective associates (as defined in the ASX Listing Rules) and (iii) directors or their associates acquiring securities under an employee incentive plan. Due to differences between Australian law and rules and the Nasdaq shareholder approval requirements, we rely on this exemption.

As long as we remain subject to the rules of the ASX, we will be unable to access equity capital without shareholder approval if such equity capital sales would result in an equity issuance above regulatory thresholds and, consequently, we could be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite shareholder approvals.

Our ability to access equity capital is subject to ASX Listing Rules 7.1 and 7.4, which provides that a company must not, without shareholder approval, issue or agree to issue any equity securities, or other securities with rights to conversion to equity, if such issue of securities, when aggregated with securities issued by the company during the previous 12-month period, would be an amount that would exceed 15% of the number of ordinary shares on issue at the commencement of the 12-month period, subject to certain adjustments and permitted exceptions.

Our equity issuances are subject to limitations under ASX Listing Rule 7.1 as long as we continue to be listed on the ASX and this constraint may prevent us from raising the sufficient equity capital needed to conduct our operations as planned without shareholder approval.

As a foreign private issuer, we are permitted to file less information with the SEC than a company that files as a domestic issuer.

As a foreign private issuer, we are exempt from certain rules under the Exchange Act that imposes disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery

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provisions of Section 16 of the Exchange Act; although, absent an exemption from the SEC, and effective March 18, 2026, our officers and directors will be subject to the insider reporting obligations under Section 16(a) of the Exchange Act, including the requirements to file Forms 3, 4 and 5, pursuant to the Holding Foreign Insiders Accountable Act enacted on December 18, 2025. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a domestic issuer whose securities are registered under the Exchange Act. Under Australian law, we prepare financial statements on an annual and semi-annual basis, and we are not required to prepare or file quarterly financial information.

For as long as we are a "foreign private issuer," we intend to file our annual financial statements on Form 20-F and furnish our semi-annual financial statements on Form 6-K to the SEC as long as we are subject to the reporting requirements of Section 13(g) or 15(d) of the Exchange Act. However, the information we file or furnish is not the same as the information that is required in periodic reports for U.S. domestic issuers. Accordingly, there may be less information publicly available concerning us than there is for a company that files as a U.S. issuer.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur additional legal, accounting and other expenses.

While we currently qualify as a foreign private issuer, we will be required to determine our status as a foreign private issuer on an annual basis at the end of our second fiscal quarter. In order to maintain our current status as a foreign private issuer, either (i) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the U.S. or (ii) (a) a majority of our executive officers or directors must not be U.S. citizens or residents, (b) more than 50 percent of our assets cannot be located in the U.S. and (c) our business must be administered principally outside the U.S. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC rules and Nasdaq listing standards. Further, we would be required to comply with U.S. GAAP, as opposed to IFRS Accounting Standards, in the preparation and issuance of our financial statements for historical and current periods. If we are required to comply with the reporting requirements applicable to a U.S. domestic issuer, the regulatory and compliance costs to us may be higher than the cost we incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs.

If we fail to maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

The Sarbanes-Oxley Act ("Sarbanes-Oxley") requires our management to evaluate the effectiveness of our internal control over financial reporting and disclose its conclusions, which includes identifying any material weaknesses in our internal control over financial reporting. Beginning with this annual report that we are filing with the SEC, our management is required to provide an annual report on internal control over financial reporting, and in the future, we expect that our independent registered public accounting firm will be required to issue an annual report that addresses the effectiveness of our internal control over financial reporting.

In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we will need to expend significant resources and provide significant management oversight.

Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control and preventing fraud.

If we are unable to conclude that we have effective internal control over financial reporting or, at the appropriate time, if required, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal control over financial reporting as required by Sarbanes-Oxley, investors may lose confidence in our operating results, the price of the ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Sarbanes-Oxley, we may not be able to remain listed on Nasdaq.

We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our ADSs.

We have identified a material weakness in our internal control over financial reporting as of December 31, 2025 as disclosed in Item 15. Disclosure Controls and Procedures of this Annual Report on Form 20-F. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As a result of the material weakness, management has concluded that our internal control over financial reporting was not effective as of December 31, 2025. As a consequence of the material weakness, we have also determined that our disclosure controls and procedures were not effective.

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The material weakness related to segregation of duties, which have not been sufficiently established across the key business and financial processes to maintain appropriate segregation of duties over certain manual and information technology ("IT") business controls. Segregation of duties is an internal control principle that helps prevent errors and fraud by dividing tasks and responsibilities among different individuals. In our current control environment, due to the size of our finance team, this segregation has not been adequately maintained. A consequence of the lack of segregation of duties is a heightened risk of fraud or material misstatement where no appropriate mitigating controls are in place.

We have developed and begun to implement a remediation plan designed to improve our internal control over financial reporting to remediate this material weakness. The remediation plan includes, and we have undertaken, redesigning roles and access rights to enforce segregation of duties, implementing system-based workflow approvals, and enhancing documentation of review controls.

As previously disclosed in Item 15 of the Annual Report on Form 20-F for the year ended December 31, 2024, we identified a material weakness related to a lack of appropriately designed, implemented and documented procedures and controls at both the entity-level and process-level to allow us to achieve complete, accurate and timely financial reporting. We remediated this material weakness as of December 31, 2025, see "Item 15. Disclosure Controls and Procedures."

We cannot provide assurance that the measures we have taken to date, and measures we plan to implement, will be sufficient to remediate the control deficiencies that led to the identified material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weakness in our internal control over financial reporting, or identify any additional material weaknesses in the future, or otherwise fail to maintain an effective system of internal controls, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and the market price of our ADSs may decline as a result.

We have incurred and will continue to incur significant increased costs as a result of operating as a company whose ADSs are publicly traded in the U.S., and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a company whose ADSs are publicly traded in the U.S., we have incurred and will continue to incur significant legal, accounting, insurance and other expenses that we did not previously incur. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and internal controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives, and we will need to add additional personnel and build our internal compliance infrastructure. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company in the U.S., we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

We do not anticipate paying dividends in the foreseeable future.

We do not anticipate paying dividends in the foreseeable future. We currently intend to retain future earnings, if any, to finance the development of our business. Dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors on the basis of our earnings, financial requirements and other relevant factors, and subject to Australian law. As a result, a return on an investment in our ADS will only occur if the ADS price appreciates. We cannot provide assurances that the ADSs will appreciate in value or even maintain the price at which they are purchased. Investors may not realize a return on their investment in the ADSs and may even lose their entire investment in the ADSs.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the market price and trading volume of our ordinary shares or ADSs could decline.

The trading market for our ordinary shares and ADSs is influenced, in part, by the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may discontinue research on us, to the extent such coverage currently exists, or in other cases, may never publish research on us. If no or too few securities or industry analysts cover our Company, the trading price for our ordinary shares and the ADSs would likely be negatively affected. If one or more of the analysts who cover us downgrade the ADSs or publish inaccurate or unfavorable research about our business, the market price of the ordinary shares and ADSs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for the ordinary shares and ADSs could decrease, which might cause our ordinary share and ADS prices and trading volumes to decline.

You may be subject to limitations on transfers of the ADSs.

The ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the

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depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders and ADS holders.

As an Australian company listed on the ASX, we are subject to different corporate requirements than a corporation organized under the laws of the U.S. Our Constitution, as well as the Australian Corporations Act 2001 (Cth) and ASX Listing Rules, set forth various rights and obligations that are applicable to us as an Australian company listed on the ASX. These requirements may operate differently than those of many U.S. companies. You should carefully review the summary of these matters set forth under the section entitled "Item 10. Additional Information — B. Memorandum and Articles of Association," as well as our Constitution, which is included as an exhibit to this Annual Report, prior to investing in the ADSs.

Australian takeover and foreign investment laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADSs.

We are incorporated in Australia and are subject to the takeover and foreign investment laws of Australia. Among other things, we are subject to the Australian Corporations Act 2001 (Cth) and Foreign Acquisitions and Takeovers Act.

Subject to a range of exceptions (including a takeover bid, scheme of arrangement or with shareholder approval), the takeover provisions in the Australian Corporations Act 2001 (Cth) prohibit the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing from 20% or below to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover and foreign investment laws may discourage takeover offers being made for us or may discourage or prevent the acquisition of a significant position in our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may limit the ability of our shareholders and ADS holders to obtain a premium from a control transaction.

We currently report our financial results under IFRS Accounting Standards, which differs in certain significant respect from U.S. GAAP.

Currently we report our financial statements under IFRS Accounting Standards. There have been and there may in the future be certain significant differences between IFRS Accounting Standards and U.S. GAAP, and those difference may be material. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they were prepared in accordance with U.S. GAAP. In addition, we do not intend to provide a reconciliation between IFRS Accounting Standards and U.S. GAAP unless it is required under applicable law. As a result, you may not be able to meaningfully compare our financial statements under IFRS Accounting Standards with those companies that prepare financial statements under U.S. GAAP.

There can be no assurance that we will not be a passive foreign investment company for any taxable year, which could result in adverse U.S. federal income tax consequences to U.S. investors.

In general, a corporation organized outside the U.S. will be classified for U.S. federal tax purposes as a passive foreign investment company ("PFIC"), for any taxable year in which either (i) 75% or more of its gross income consists of "passive income," or (ii) 50% or more of the value of its assets (generally determined on an average quarterly basis) consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a foreign corporation that owns (or is treated as owning) at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of that other corporation and received directly its proportionate share of the income derived by that other corporation. "Passive income" generally includes dividends, interest, rents, royalties and certain gains. Cash is a passive asset for these purposes.

Based on the expected nature and amount of our estimated gross income, the anticipated nature and estimated average value of our gross assets, the anticipated cash needs of our group's operations and the nature and extent of the active businesses conducted by our "25% or greater" owned subsidiaries, we do not expect that we will be classified as a PFIC in the current taxable year or for the foreseeable future. However, our PFIC status for any taxable year can be determined only after the end of such year and will depend on the composition of our income and assets and the value of our assets from time to time (which may be determined, in part, by reference to the market price of our ADSs or ordinary shares, which could be volatile). Furthermore, the composition of our income and assets for the current and future taxable years will be affected by how, and how quickly, we spend the cash we have on hand.

Accordingly, there can be no assurance that we will not be a PFIC for our current or any future taxable year. If we were a PFIC for any taxable year during which a U.S. investor is treated as owning our ADSs or ordinary shares, the U.S. investor generally would be subject to adverse U.S. federal income tax consequences, possibly including increased tax liability on disposition gains and "excess distributions," and additional reporting requirements. See "Item 10. Additional Information — E. Taxation."

Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

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Our tax treatment is subject to the enactment of, or changes in, tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, including those related to the Organization for Economic Co-Operation and Development's Base Erosion and Profit Shifting Project, the imposition of a minimum global effective rate for multinational businesses (Pillar Two) and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. We are unable to predict what tax reforms may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non-realization of expected benefits.

We are subject to taxation in multiple jurisdictions. A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, although we believe we are compliant with applicable transfer pricing requirements in various countries, a tax authority could challenge our allocation of income and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies. In the event a tax authority assesses a deficiency, contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

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General Risk Factors

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations and prospects and the trading price of our ordinary shares and the ADS.

Global credit and financial markets have experienced extreme disruptions over the past several years. Such disruptions have resulted, and could in the future result, in diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Our general business strategy may be compromised by economic downturns, a volatile business environment and unpredictable and unstable market conditions, such as pandemics or epidemics of infectious diseases, ongoing or future wars or other geopolitical conflicts, imposition of tariffs or other trade restrictions, rising inflation, increasing interest rates and slower economic growth or recession. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult to secure, more costly or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy and financial performance and could require us to delay or abandon plans with respect to our business, including clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers or other third parties with which we conduct business may not survive difficult economic times, including ongoing or future wars or other geopolitical conflicts, and the uncertainty associated with current worldwide economic conditions, which could directly affect our ability to attain our operating goals on schedule and on budget.

Artificial intelligence-based platforms may present new risks and challenges to our business.

AI technologies may exacerbate existing risks, including risks associated with data privacy, cybersecurity, intellectual property ("IP"), healthcare fraud and abuse, drug development and manufacturing, and risks to patients or human subjects in clinical trials. AI also introduces new risks, due to the autonomous nature of the technology, which, in some cases, may be deployed to perform tasks, inform decisions, automate decisions, and make predictions. AI may amplify biased and discriminatory decision making, perform unreliably and malfunction, generate insights which are difficult to interpret and explain, and cause direct harm to individuals or groups.

Regulators are proposing, adopting, and implementing new AI laws and regulations, including with respect to the development of drugs and devices. We may be required to change our business practices and policies as a result of such laws and regulations and may incur substantial compliance-related costs.

Regulators are also using existing laws and regulations to take enforcement actions related to the deployment of AI in ways that result in non-compliance with current laws and regulations. If we fail to comply with AI laws and regulations, we may be subject to sanctions, fines, and reputational damage, orders to stop certain processing of personal data, orders to delete certain data or destroy AI algorithms derived from data collects, legal action on behalf of impacted individuals or other enforcement or other actions. If we fail to take steps to protect our confidential data, trade secrets, IP and personal data, we may be subject to legal, regulatory, financial, and reputational risks. AI technologies present significant opportunities and risks to our business. Harnessing AI's transformative potential may enable us to speed up the discovery and development of new drugs and devices, optimize our manufacturing processes, and drive efficiencies. Our failure to use AI technologies in a way that maintains trust, quality and control in our business activities and to capitalize on opportunities presented by AI may also place us at a competitive disadvantage. Failure to address AI risks will reduce our ability to deliver strategic objectives. Also, investments in AI may not realize the benefits that were anticipated.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations and the operations of our suppliers, CROs, CMOs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers or suppliers to produce our Commercial Products and our product candidates and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of our product candidates. Our ability to obtain sufficient supplies for our Commercial Products and our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Global climate change, as well as increasing laws, regulation and litigation in the area of climate change, may have an adverse effect on our results of operations, financial condition or liquidity.

There is widespread consensus in the scientific community that there is a long-term upward trend in global air and sea temperatures that, along with shifting demographic trends in catastrophe exposed regions, has increased the severity and frequency of severe weather events and other natural catastrophes, and is likely to further increase the average economic value of expected losses in the future. Rising sea levels are also expected to increase the risk of coastal flooding in many geographical areas. Extreme weather events can disrupt business continuity by negatively impacting our infrastructure, systems and processes including, but not limited to, manufacturing and supply arrangements in geographical locations exposed to severe weather events. In addition, global climate change could impair our ability to predict the costs associated with future weather events. We cannot predict with certainty the frequency or severity of hurricanes, tropical cyclones, wildfires or other natural catastrophes, and our risk assessments may not accurately reflect shifting environmental and climate related risks. Unanticipated factors could lead to additional insured losses that exceed our current estimates, resulting in disruptions to or adverse impacts on our business, the market or our third-party collaborators.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal name is Telix Pharmaceuticals Limited. Our company was incorporated under the laws of Australia in January 2017. In November 2017, we completed an initial public offering of our ordinary shares and the listing of our ordinary shares on the ASX. Since November 13, 2024, we have been dual listed with our ADSs listed on the Nasdaq Global Select Market, with each ADS representing one of our ordinary shares. JP Morgan Chase Bank, N.A., acts as depositary for the ADSs.

Our corporate headquarters and registered offices are located at 55 Flemington Road, North Melbourne, Victoria, 3051, Australia. Our reception telephone number is +61 3 9093 3855. Our agent for service of process in the U.S. is Telix Pharmaceuticals (US) Inc., located at 11700 Exit 5 Pkwy, Suite 200, Fishers, Indiana 46037. Our website address is www.telixpharma.com. All information we file with the SEC is available through the SEC's Electronic Data Gathering, Analysis and Retrieval system, which may be accessed through the SEC's website at www.sec.gov.

The majority of our workforce is in the U.S., based out of our U.S. headquarters in Indianapolis, Indiana or our Dallas, Texas office, our R&D and manufacturing facilities in Angleton, Texas and Los Angeles and Sacramento, California, working remotely, or in one of our network of RLS Radiopharmacies that we acquired in January 2025. We also have R&D and manufacturing facilities in Australia (North Melbourne, in completion phase), Belgium (Brussels South), Canada (Vancouver) and Japan (Yokohama) and offices in Australia (Melbourne, Sydney and Brisbane), Belgium (Brussels and Liège), Switzerland (Geneva), and Japan (Kyoto).

See "— B. Business Overview" (below) for a discussion of significant events and developments relating to our business and "Item 5. Operating and Financial Review and Prospects — B. Liquidity and Capital Resources" for a discussion of our capital expenditures.

B. Business Overview

Introduction

We are a global, commercial-stage biopharmaceutical company, focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. We are committed to the principles of precision oncology. By this we mean developing both therapeutic and diagnostic modalities for the benefit of patients, an innovative precision medicine concept generally referred to as 'theranostics'.

As an established leader and innovator in this field, Telix is differentiated by our deep expertise in radiopharmaceutical drug development and commercialization, our innovative pipeline that spans the cancer care continuum, and our ability

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to deliver patient outcomes globally. In order to achieve our mission and deliver on our strategy, Telix has structured the business into five operating segments: Therapeutics (Tx), Precision Medicine (Px), International, MedTech and Telix Manufacturing Solutions (TMS). We report financial results by the three reportable segments: Tx, Px (including International and MedTech) and TMS. A brief overview is provided below.

- **Therapeutics** are at the core of the Telix portfolio, as we work to improve and extend patient life. We are currently focused on developing targeted radionuclide therapies for urologic and neurologic oncology, and other solid tumors.

- **Precision Medicine** is the commercial arm of Telix, focused on bringing diagnostic imaging solutions to market and expanding into new geographies and indications. Precision medicine plays a fundamental role in managing patients and delivering personalized therapeutic solutions. **MedTech** is advancing surgical solutions and digital products that power Telix's precision medicines and therapeutics. **International** is focused on "rest of world" (ex-U.S.) commercial operations for the Europe, Middle East and Africa ("EMEA"), Asia Pacific ("APAC") and Latin America regions.

- **Telix Manufacturing Solutions** is our global network of facilities designed to deliver patient doses worldwide. We are investing in building manufacturing capacity, as well as improving the technology and processes to allow us to deliver products at scale, including next generation alpha therapies. This investment in world-class infrastructure is helping Telix to develop new products and secure critical supplies required to commercialize the future of cancer treatments.

This commitment to end-to-end treatment differentiates Telix and is at the core of our radiopharmaceutical approach.

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Australian Disclosure Requirements

Review of operations, likely developments and expected results; Business strategies and prospects for future years

A review of the Group's operations for the financial year ended December 31, 2025, together with Telix's business strategies and prospects for future years, can be found in "Item 5. Operating and financial review and prospects" of this Annual Report. Certain information regarding developments in operations in future years and expected results is excluded, to the extent permitted by law, on the basis that such information relates to the impending developments or matters in the course of negotiation and disclosure would likely result in unreasonable material prejudice to the Group.

Telix discloses its financial performance by operating segments. The Group's operating segments represent components of the Group that engage in distinct business activities. This provides the most meaningful insight into the nature and financial outcomes of Telix's activities and is consistent with the way in which the MD & CEO monitors and assesses business performance and resource allocation decisions. Further details on Telix's segment reporting can be found in Note 3 of the Financial report.

Principal activities of the Company in the year under review

Telix's principal activities during the year ended December 31, 2025 were directed to further advancing our standing as a globally recognized theranostics company through executing on our strategy across four strategic pillars:

- **Delivering our late-stage therapeutic pipeline:** Development of TLX591-Tx (for prostate cancer), TLX250-Tx (for kidney and other CAIX-expressing cancers), TLX101-Tx (for glioblastoma) and TLX66-Tx (for hematologic cancers).

- **Building the next generation of radiopharmaceuticals:** Development of TLX592-Tx (TAT candidate for prostate cancer), TLX252-Tx (TAT candidate for kidney and other CAIX-expressing cancers), TLX102-Tx (TAT candidate for GBM and LMD), TLX300-Tx (TAT candidate for soft tissue sarcoma ("STS") and other PDGFRα expressing cancers), TLX090-Tx (bone seeking candidate for bone metastases and pain palliation), and TLX400-Tx (FAP-targeting therapeutic candidate with pan-cancer potential).

- **Growing our industry leading precision medicine business:** Development and commercialization of Gozellix and Illuccix (focus on additional markets and indications), and development of TLX250-Px (Zircaix) and TLX101-Px (Pixclara) and commercialization, if approved.

- **Expanding our global infrastructure for product delivery:** Grow manufacturing footprint and capabilities across North America, Europe and the Asia Pacific region.

For more information on these four strategic pillars, refer to the "Our Strategy" section below.

Our Product Portfolio

Overview

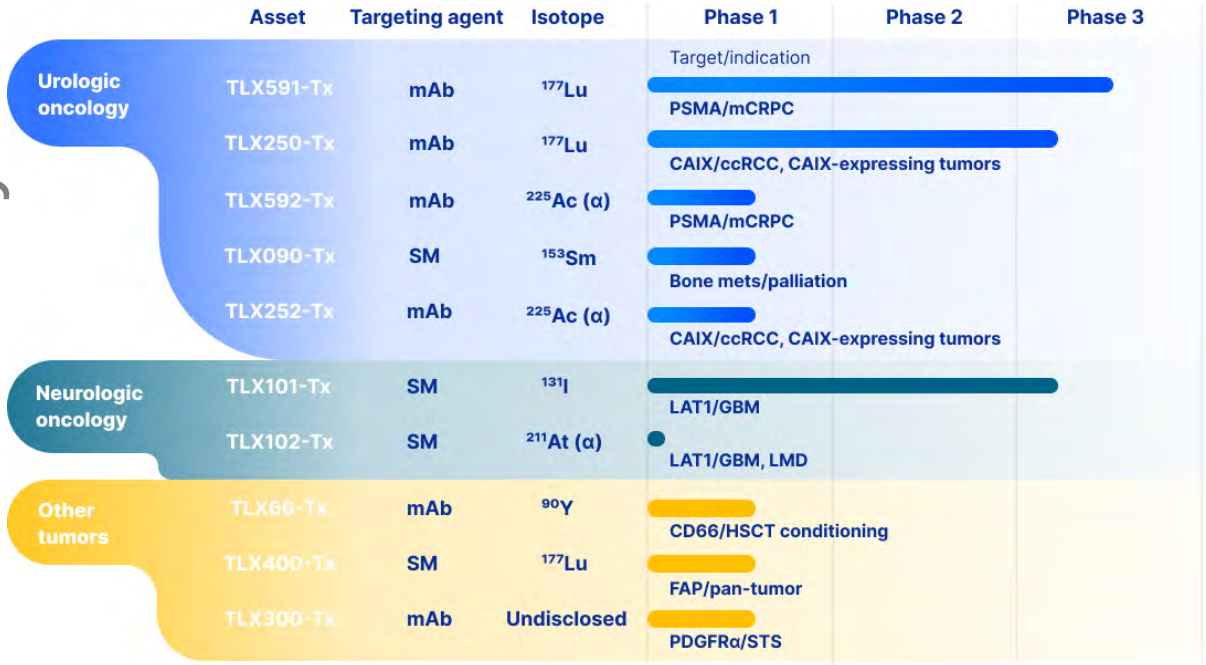
Our portfolio includes both therapeutic and diagnostic radiopharmaceutical product candidates designed for use throughout the continuum of the patient journey, from diagnosis and staging to treatment and ongoing care. We also

intend to use our therapeutic and diagnostic radiopharmaceutical product candidates in combination with one another, as a theranostic treatment approach. Our clinical programs include several product candidates that are being evaluated in Phase 1, Phase 2 and Phase 3 clinical trials with multiple expected upcoming data readouts and regulatory filings.

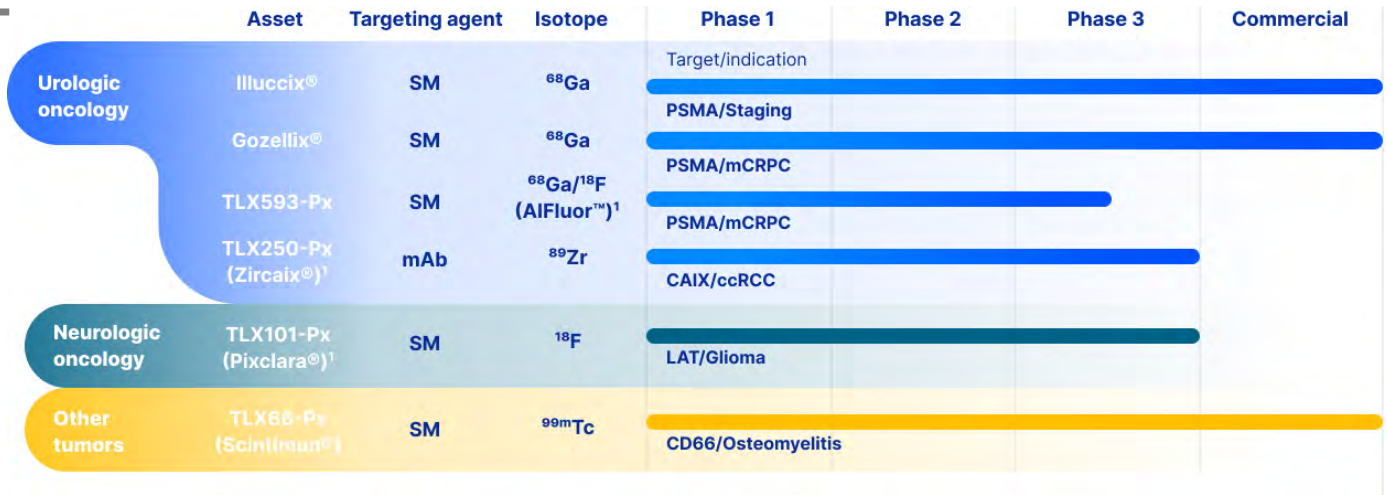
For most of our programs, particularly the prostate, kidney and brain programs, we have generated extensive clinical data that we believe demonstrate the potential of our product candidates to offer meaningful benefits to patients. We believe the targets and indications we are pursuing are well validated and are well suited for the delivery of therapeutic and diagnostic targeted radiation. We believe that our use of imaging to select patients for therapy is also a differentiated aspect of our commercial strategy. We believe that this precision medicine or theranostic approach may increase the potential of our therapeutic development programs, as patients can be selected for therapy with greater confidence that the drug target is sufficiently present to potentially confer therapeutic benefit. This may, in turn, lead to more streamlined and efficient clinical trials, and enable improved patient outcomes.

A summary of our core development pipeline is illustrated below.

Therapeutic pipeline



Precision medicine portfolio



In addition to the development pipeline above, we are also exploring product and indication expansion opportunities with our commercial and late-stage diagnostic portfolio through our lifecycle management programs. Lifecycle management and product development includes two substantial prostate cancer indications for PSMA imaging, AlFluor™, a novel PET radiochemistry solution based on ^{18}F-aluminum fluoride ("AlF"), a staging indication for TLX250-Px, and an expansion into brain metastases for TLX101-Px.

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Prostate Cancer and PSMA

Our prostate cancer programs target PSMA, a well-validated protein target for the delivery of both therapeutic and diagnostic radiopharmaceuticals that is highly expressed on prostate cancer cells with low expression on healthy cells.

We believe that our approach to PSMA therapy is unique because our lead product candidates, TLX591-Tx and TLX592-Tx, use a monoclonal antibody carrier to target prostate cancer, whereas commercially available agents use a small molecule peptide carrier. This approach allows for specific targeting of tumor tissue, differentiated pharmacokinetics and excretion profiles, and prolonged treatment effect enabled by efficient irradiation of tumors. We are also developing a small molecule PSMA therapeutic, TLX597-Tx, and a small molecule-based theranostic pair (RHN001-Tx for therapy and RHN001-Dx for imaging, through our wholly-owned subsidiary Rhine Pharma), which are intended to enable access to PSMA theranostics in select geographies.

TLX591-Tx

Our lead therapeutic product candidate TLX591-Tx (lutetium (Lu177) rosopatamab tetraxetan) is a lutetium-labelled rADC that we believe has the potential to deliver improved patient outcomes with an efficient dosing regimen. The targeting and pharmacology of TLX591-Tx differs significantly from PSMA-targeting small peptide molecules used in commercially available compounds, and was designed for high internalization, long retention and to be highly selective for tumor-expressed PSMA. This profile was designed with the goal of enabling a short, patient-friendly dosing regimen that delivers a meaningful therapeutic index and low occurrence of off-target adverse events that are common with the currently marketed PSMA-targeted small peptide molecules.

TLX591-Tx has demonstrated positive safety and efficacy signals following treatment of 242 patients across eight Phase 1 and Phase 2 clinical trials, including up to 42.3 months median survival in a single-arm Phase 2 clinical trial in 17 patients with mCRPC when delivered under a fractionated dosing regimen (Tagawa et al. *Cancer.* 2019). These studies were not powered for or designed to demonstrate efficacy and results should be interpreted with caution. Efficacy outcomes are presently being evaluated for statistical and clinical significance in a larger Phase 3 randomized controlled trial.

ProstACT Global is a randomized, multinational, multicenter, open-label Phase 3 trial for the treatment of PSMA-positive mCRPC patients in combination with the standard of care, compared to the standard of care alone. In August 2025, Part 1 of this trial, a dosimetry and safety lead-in portion, completed target enrollment of 30 patients. The results will be presented to the FDA to obtain their agreement for the commencement of the randomized treatment expansion arm (Part 2), in the U.S. Part 2 already has regulatory approvals to commence in Australia, Canada, China, New Zealand, Singapore, South Korea, Türkiye and the United Kingdom. We dosed the first patients in Part 2 in Australia in December 2025, and are actively dosing patients at multiple clinical trial sites outside the U.S.

This is the first Phase 3 trial to evaluate TLX591-Tx in combination with the standard of care (androgen receptor pathway inhibition or docetaxel) compared to the standard of care alone. The use of TLX591-Tx with current real-world standard of care is intended to differentiate ProstACT Global from other PSMA-targeted trials and reflects our continued innovation in prostate cancer care and commitment to patient outcomes.

TLX592-Tx

TLX592-Tx (^{225}Ac-RADmAb), is our next generation prostate cancer therapy candidate for targeted alpha therapy ("TAT") and is our first clinical program based on our proprietary RADmAb-engineered antibody technology. The engineered antibody vector is designed for faster elimination from circulation than standard antibodies. Therefore, it is expected to reduce bone marrow residence time, mitigating the risk of hematologic toxicities while retaining PSMA-mediated tumor localization and exertion of cytotoxic activity. TLX592-Tx is designed to be cleared by the liver without exocrine uptake.

Prior to commencing therapeutic studies with the alpha emitting isotope ^{225}Ac, we conducted the Phase 1 CUPID trial in which we evaluated TLX592-Tx radiolabeled with the imaging isotope ^{64}Cu, in patients with advanced prostate cancer. We used ^{64}Cu as a surrogate for ^{225}Ac, since ^{64}Cu is detectable by PET, whereas ^{225}Ac is not. We investigated patients with PSMA avid disease based on Illuccix imaging, across three mass dose levels, to assess the safety profile, pharmacokinetics, biodistribution and dosimetry. Based on data from 11 evaluable patients, we observed accelerated elimination from blood circulation compared to the original antibody used in TLX591-Tx, with similar on-target and off-target biodistribution. There were no treatment-related adverse events observed in the trial.

We have received regulatory approval to commence the Phase 1 FIH therapeutic trial, AlphaPRO, in Australia, designed to evaluate the safety profile of ^{225}Ac-labelled TLX592-Tx.

TLX597-Tx

We are also developing a novel lutetium-labelled, small molecule-based, targeted radionuclide therapy candidate, designated TLX597-Tx (^{177}Lu-DOTA-HYNIC-panPSMA). This candidate is being developed to enable access to lutetium therapy patients in select geographies, and is the subject of the ongoing Phase 2 OPTIMAL PSMA investigator-initiated trial ("IIT"), which is expected to enroll 120 mCRPC patients in Australia.

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RHN001-Tx

RHINO is an IIT sponsored by the Nuclear Medicine Research Infrastructure ("NuMeRI") at the University of Pretoria in South Africa, exploring clinical utility of a theranostic pair derived from RHN001 (PSMA-GCK01), a PSMA-targeting small molecule. RHN001 was developed through a collaboration between Telix and Heidelberg University Hospital ("UKHD"), which resulted in pre-clinical validation and FIH evaluation of rhenium-188 (^{188}Re) based radiopharmaceutical therapy and technetium-99m (^{99m}Tc) based SPECT imaging (Cardinale et al. *J Nucl Med.* 2023).

This theranostic pair, designated RHN001-Tx (for therapy) and RHN001-Dx (for imaging), have the potential to enable access to radiopharmaceuticals for patients in certain geographies where ^{177}Lu availability may be limited. They can be produced using compact, easily-transportable generators, potentially under practice of pharmacy as with other generator-based radiopharmaceuticals, with imaging performed using widely available SPECT scanners.

The RHINO trial is a Phase 1/2a theranostic trial exploring the safety profile and dosimetry of both RHN001-Tx and RHN001-Dx in patients with advanced prostate cancer. Its primary objective is to identify the recommended Phase 2 dose ("RP2D"), and schedule of administration for RHN001-Tx in men with progressive PSMA-positive prostate cancer who have had adjuvant androgen deprivation therapy and/or taxane-based chemotherapy. Secondary objectives are to assess the overall safety profile and the dosimetry of RHN001-Tx and RHN001-Dx in men with prostate cancer and health-related quality of life.

The first cohort of patients received RHN001-Dx for safety and dosimetric analysis. The second cohort received RHN001-Tx for safety and dosimetric analysis, while the third cohort (in progress) will receive escalating doses of RHN001-Tx to identify the RP2D and schedule of administration for RHN001-Tx.

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PSMA-PET imaging

Our prostate cancer portfolio also includes Illuccix and Gozellix, our commercially available ^{68}Ga-labelled PSMA-PET imaging agents. The “cold kit” format enables rapid radiolabeling at room temperature with high radiochemical purity and production consistency, suited to the commercial and hospital radiopharmacy setting. Illuccix is approved in the U.S., Australia, Brazil, Canada, the United Kingdom and in 19 European Economic Area member states. Gozellix was approved in the U.S. in March 2025 and the U.S. Centers for Medicare & Medicaid Services ("CMS") granted Transitional Pass-Through ("TPT") payment status in September 2025. This designation enables separate reimbursement for Gozellix under the Hospital Outpatient Prospective Payment System ("HOPPS"), taking effect from 1 October 2025 for three years, marking a significant milestone in Telix’s U.S. commercial strategy. Approved indications for patients with prostate cancer include staging of high-risk patients, identification of suspected recurrence, and selection for PSMA-directed therapy (Illuccix only). In September we received a Prior Approval Supplement ("PAS") to update the U.S. Prescribing Information for Illuccix. The Illuccix label now includes patient selection for RLT in the pre-taxane setting. During FY 2025, our Precision Medicine business generated revenue of $621.9 million, primarily through sales of Illuccix and Gozellix.

We are exploring potential future utilization in additional indications for prostate cancer patients through our lifecycle management program and growing our global PSMA-PET imaging presence through expansion into new geographies.

In June 2025, we launched a novel PET radiochemistry solution based on ^{18}F-aluminum fluoride ("AlF"), named "AlFluor™". The AlFluor platform technology enables flexible radiolabeling of PSMA with either AlF or ^{68}Ga. It also has the potential to be used with ligands targeting neuroendocrine tumors ("NETs") and FAP, as well as other novel imaging agents under development by Telix and our strategic partners. Developed to combine the imaging benefits of ^{18}F with the convenience of ^{68}Ga kit-based workflows, the AlFluor platform supports both centralized cyclotron manufacturing and distributed “shake-and-inject” kit production. This flexibility allows a complementary product with the same targeting agent to be labeled with either isotope, catering to clinical setting or physician preference. As part of AlFluor’s development, we signed a strategic agreement with University Hospital Ghent and Ghent University for a novel [^{18}F]AlF-PSMA-11 targeting agent, which we have designated as TLX593-Px.

Bone Metastases and Pain Palliation

TLX090-Tx

TLX090-Tx (^{153}Sm-DOTMP) is our novel kit-based bone-seeking targeted radiopharmaceutical product candidate that uses a next generation chelating agent, DOTMP, to deliver a proprietary lower specific activity formulation of Samarium-153 radioisotope, and is optimized for improved targeting, safety and clinical versatility. Importantly, TLX090-Tx builds on FDA’s prior approval of the active moiety Samarium-153 (^{153}Sm, used in Quadramet) while overcoming key limitations of legacy formulations, such as skeletal saturation and calcium-binding risks.

^{153}Sm is a beta-emitting radioisotope with a 46-hour half-life, and the chelating agent DOTMP selectively targets sites of high bone mineral turnover, a known characteristic of bone metastases, while minimizing off-target migration. We believe that TLX090-Tx may be administered as a single dose, multiple doses and higher dose regimens for pain management of bone metastases and osteosarcoma therapy, including in pediatric patients. We believe that TLX090-Tx is highly aligned with our existing therapeutic focus areas of prostate cancer, glioma and sarcoma.

In October 2025, we dosed the first patient in a Phase 1 clinical trial of TLX090-Tx called SOLACE (Samarium Optimized for Long-lasting Analgesia in Cancerous End-stage bone pain). This open-label Phase 1 clinical trial is expected to enroll up to 33 patients with advanced cancer that has metastasized to the bony skeleton and is designed to evaluate the

pharmacokinetics, dosimetry, safety, and pain palliation of TLX090-Tx. Data from SOLACE aims to establish clinical comparability to legacy ^{153}Sm treatments, which we believe may support a streamlined registration pathway as an analgesic, paving the way for a much-needed, non-opioid solution for patients living with bone pain in the late stages of advanced cancer. The novel cold-kit formulation and pharmacy-based distribution of TLX090-Tx may also aid in overcoming barriers to treatment due to cost and supply chain limitations associated with legacy products.

Kidney Cancer and CAIX

Our target for kidney cancer is carbonic anhydrase IX ("CAIX"), a scientifically validated target in ccRCC, which is the most prevalent and one of the most aggressive subtypes of kidney cancer. CAIX is a cell surface protein that is highly expressed in ccRCC, and in many other solid tumors in the hypoxic tumor micro-environment. We believe this association between hypoxia, disease progression, and therapeutic resistance underscores the relevance of this target. To target CAIX, we use a monoclonal antibody, girentuximab, which is designed to have a high degree of selectivity and affinity for the target. A single hepatically cleared agent is used for both imaging and therapy, with differing radioisotopes, to minimize renal excretion, an advantage for assessing or treating primary disease. We believe the target profile and properties of girentuximab make the ccRCC phenotype promising as the first therapeutic indication for TLX250-Tx, our targeted radiation therapeutic product candidate.

TLX250-Tx

Our CAIX-targeting therapeutic candidate is TLX250-Tx (^{177}Lu-DOTA-girentuximab), a rADC that we are developing for the treatment of advanced metastatic kidney cancer.

We have had our ethics application approved in Australia and are presently initiating the LUTEON study, a global Phase 2/3 trial of of TLX250-Tx as a monotherapy in participants with recurrent ccRCC, who have progressive disease on or after two and no more than three prior lines of therapy. The primary objective in Part 1 is to select the recommended Phase 3 dose ("RP3D") to be administered in Part 2 from the two dose regimens administered in Part 1. The primary objective in Part 2 is to compare the median progression free survival ("mPFS") of treatment with TLX250-Tx with that of the SOC comparator as assessed by blinded independent central review.

TLX250-Tx is currently under investigation in the Phase 1b/2 STARLITE-1 investigator-initiated trial for kidney cancer, where it is being evaluated in combination with immune checkpoint and tyrosine kinase inhibitors in up to 100 patients. This single arm, Phase 2 study is evaluating the efficacy of TLX250-Tx in combination with nivolumab and cabozantinib in patients with previously untreated ccRCC.

We believe the combined diagnostic and therapeutic potential of the girentuximab platform may also extend into other cancers that significantly express CAIX, including certain Von Hippel Landau ("VHL") induced cancers, ovarian cancer, triple-negative breast cancer and bladder cancer. We believe that proof-of concept imaging data in patients with triple-negative breast cancer and bladder cancer supports future development of TLX250-Tx in these indications.

TLX252-Tx

TLX252-Tx (^{225}Ac-DOTA-girentuximab) is a CAIX-targeting rADC alpha therapy candidate being developed as a potential follow-on to the TLX250-Tx (beta) program.

TLX250-Px is used as an imaging surrogate for TLX252-Tx. The ZIRDOSE Phase 1 study characterized the biodistribution and dosimetry of TLX250-Px in patients with ccRCC, enabling extrapolation to ^{225}Ac (Merkx et al. *EJNMMI.* 2021). Additionally, investigator-initiated trials demonstrated effective tumor targeting with TLX250-Px in triple-negative breast cancer (Rousseau et al. *EJNMMI.* 2025) and non-muscle-invasive bladder cancer (Rousseau et al. *Cancers.* 2025), indicating the potential for CAIX-targeted alpha therapy beyond ccRCC.

These findings, along with preclinical studies demonstrating efficacy for TLX252-Tx, support initiation of an administered-activity escalation trial of TLX252-Tx for patients with advanced metastatic kidney cancer and other CAIX-expressing tumors. Regulatory approval has been obtained in Australia for ALPHIX, a Phase 1 FIH study.

TLX250-Px

Our imaging candidate TLX250-Px is a PET diagnostic imaging agent that is under development to characterize indeterminate renal masses as ccRCC or non-ccRCC in a non-invasive manner. The pivotal Phase 3 ZIRCON trial evaluating TLX250-Px in 300 patients, of which 284 were evaluable, met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a 93% positive-predictive value ("PPV"), for ccRCC across three independent readers (Shuch et al. *Lancet Oncol.* 2024). We believe this demonstrated the ability of TLX250-Px to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing ccRCC. Confidence intervals exceeded expectations in all three readers, showing evidence of high accuracy and consistency of interpretation.

We submitted a BLA for TLX250-Px to the FDA for regulatory approval in December 2023 for characterization of masses as ccRCC. The BLA was granted on a rolling review process. We completed the BLA submission in May 2024, and in July 2024, the FDA declined to review the BLA and issued an RTF determination. The denial of acceptance for filing was based on a filing concern related to demonstrating adequate sterility assurance during dispensing of TLX250-Px in the

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radiopharmacy production environment. In December 2024 we resubmitted our BLA to the FDA for TLX250-Px, and the FDA accepted our application in February 2025. In August 2025, the FDA issued a Complete Response Letter ("CRL") citing deficiencies relating to the Chemistry, Manufacturing, and Controls ("CMC") package. The FDA requested additional data to establish comparability between the drug product used in the ZIRCON Phase 3 clinical trial and the scaled-up manufacturing process intended for commercial use. Additionally, the FDA documented notices of deficiency (Form 483) issued to two third-party manufacturing and supply chain partners that required remediation prior to resubmission. In December 2025 we participated in a Type A meeting with the FDA to align on plans to address CMC deficiencies cited, and in January 2026 we participated in an additional Type A meeting to align on plans to address comparability between the clinical drug product and that intended for commercial use. Following these meetings, Telix believes it has alignment with the Agency on key resubmission aspects, and is working both internally and with third-party vendors to implement these items for resubmission. While we believe that the planned remediation of the BLA for TLX250-Px will meet FDA requirements, there can be no assurance that, once resubmitted, the FDA will accept our BLA for review, or approve TLX250-Px. If approved, TLX250-Px would be the first targeted radiopharmaceutical imaging agent for kidney cancer to be approved in the U.S.

In October 2025, TLX250-Px was included for the first time in joint guidelines from the Society of Nuclear Medicine and Molecular Imaging ("SNMMI"), the European Association of Nuclear Medicine ("EANM") and The American College of Nuclear Medicine ("ACNM") for molecular imaging of renal masses (Rowe et al. *J Nucl Med.* 2025). This is an important development for Telix and will help raise awareness of this breakthrough precision diagnostic. Subject to regulatory approval, endorsement by this expert global multidisciplinary panel will help to drive adoption and implementation into clinical workflows, supporting clinical utility and enhancing decision-making to improve patient outcomes.

In November 2025, we announced new data from the ZIRCON-X study, which found that almost half of all patients (48.6%) imaged with TLX250-Px PET/CT would undergo a change in clinical management, when compared with SOC imaging. ZIRCON-X was a non-interventional, prospective, post-hoc study sponsored by Telix – using imaging data from Telix's parent pivotal Phase 3 ZIRCON study – that assessed the impact of TLX250-Px imaging on clinical decision-making versus SOC contrast-enhanced diagnostic imaging in 294 patients with indeterminate renal masses ("IRMs").

As part of our commitment to provide access to medicine, we are running an expanded access program ("EAP") in the U.S., named patient programs ("NPPs"), in Europe, and a special access scheme ("SAS") in Australia to allow access to TLX250-Px outside of a clinical trial to patients for whom there are no comparable or satisfactory alternative options.

We also intend to conduct a label-expanding Phase 3 trial of TLX250-Px for the imaging of patients with metastatic ccRCC. We believe TLX250-Px is a natural follow-on product to Illuccix as it is targeted at the same clinician users, the urologist and urologic oncologist, and leverages our existing commercial infrastructure.

In June 2023, we dosed the first patient in the Phase 2 STARBURST trial of TLX250-Px exploring CAIX expression in patients with a diverse range of solid tumors for potential therapeutic and diagnostic applications. This trial was designed to identify new therapeutic indications for TLX250-Tx through the use of molecular imaging with TLX250-Px. In May 2025 the decision was taken to conclude the trial in the interests of utilizing clinical resources and patient time more effectively - directing our focus towards theranostic studies that could offer both diagnostic insight and a novel treatment option to the patients. We believe the integrated approach will yield greater clinical benefits for patients.

Glioma and LAT1/LAT2

Our targets for glioma are L-type amino acid transporters 1 and 2 ("LAT1" and "LAT2"), validated targets that are highly expressed in several solid tumors, including malignancies of the central nervous system ("CNS"). We believe that the LAT1 and LAT2 receptors, which are expressed on both sides of the blood-brain barrier, are suitable targets for the delivery of radiation to both primary CNS malignancies and metastases from non-CNS cancers such as lung and breast cancer. As such, we believe there are several potential indications for theranostic radiopharmaceuticals targeting LAT1 and LAT2.

TLX101-Tx

Our therapeutic product candidate, TLX101-Tx (iodofalan ^{131}I), is a systemic therapy directed at the LAT1 receptor for the treatment of glioblastoma. We are using a small molecule for this therapy due to the need to cross the blood-brain barrier to reach its target. TLX101-Tx has received orphan drug designation in the U.S. and Europe for the treatment of glioma. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX101-Tx will receive marketing approval.

We are evaluating TLX101-Tx in the front-line and recurrent disease settings where we have observed preliminary clinical evidence of anti-tumor effect and disease stabilization. We completed the Phase 1/2 IPAX-1 trial of TLX101-Tx in combination with external beam radiation therapy in patients with recurrent glioblastoma. IPAX-1 enrolled ten patients, met its primary endpoint of safety and tolerability of TLX101-Tx and demonstrated preliminary efficacy data that supports continued development (Pichler et al. *Neuro-Oncology Advances*. 2024). The Phase 1 IPAX-2 trial is designed to enroll up to 15 patients to evaluate the safety of treatment of patients with newly diagnosed glioblastoma with TLX101-Tx in combination with standard of care external beam radiation and chemotherapy. In IPAX-2, the second patient cohort has completed and the third cohort is fully enrolled. As the primary goal of a Phase 1 study is to demonstrate safety and tolerability criteria in a small patient population, these studies are not powered for or designed to demonstrate efficacy.

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TLX101-Tx was also the subject of the investigator-led Phase 2 IPAX-Linz trial, in patients with recurrent glioblastoma, which reported positive preliminary results in April 2025.

In July 2025, we received ethics approval in Australia to commence a Phase 3 trial of TLX101-Tx in patients with recurrent glioblastoma, and in November 2025 we received health authority approval to commence the trial in Europe. TLX101-Tx is the first radiopharmaceutical candidate for recurrent glioblastoma to enter Phase 3 development.

TLX102-Tx

TLX102-Tx (^{211}At astato-L-phenylalanine, or ^{211}At-APA) is a LAT1-targeting small molecule-based alpha therapy candidate that we are developing as a potential complement to the TLX101-Tx and TLX101-Px programs. TLX102-Tx has demonstrated pre-clinical proof-of-concept (Watabe et al. *Oncotarget*. 2020) and we believe that TLX102-Tx has the potential for favorable efficacy and safety profile in future human clinical trials in patients with glioblastoma, leptomeningeal disease, and multiple myeloma. Due to comparable target binding and molecular structure, we expect that data from our existing LAT1 theranostic programs, TLX101-Px and TLX101-Tx, will complement and inform the clinical and regulatory development strategy for TLX102-Tx. In August 2020, TLX102-Tx was granted orphan drug designation from the FDA in the U.S. for the treatment of multiple myeloma and in November 2025, TLX102-Tx was granted orphan drug designation from the FDA for the treatment of malignant gliomas. Orphan drug designation may not lead to a faster development or regulatory review or approval process in multiple myeloma or glioma and does not increase the likelihood that TLX102-Tx will receive marketing approval in either of these disease areas.

TLX101-Px

Our imaging candidate, TLX101-Px, also known as floretyrosine F18, is a PET diagnostic agent designed to image cancerous lesions in the brain by targeting the LAT1 and LAT2 receptors. ^{18}F-FET is widely used in many jurisdictions and is recommended by the joint guidelines from the European Association of Nuclear Medicine ("EANM"), European Association of Neuro-Oncology ("EANO"), Society of Nuclear Medicine and Molecular Imaging ("SNMMI"), Response Assessment in Neuro-Oncology ("RANO"), The European Society for Pediatric Oncology and The Response Assessment in Pediatric Neuro-Oncology for the characterization of recurrence in glioma patients (Galldiks et al. *Lancet Oncol.* 2025). In June 2025, TLX101-Px was included in updated National Comprehensive Cancer Network® ("NCCN") Clinical Practice Guidelines in Oncology ("NCCN Guidelines®") for Central Nervous System Cancers (V1.2025) for PET imaging of gliomas: Delineation of tumor extent, diagnostic biopsy planning, radiotherapy planning for better visualization of tumor margins, and differentiating tumor progression- and treatment-related changes per RANO/EANO/SNMMI guidelines. In October 2020, TLX101-Px was granted orphan drug designation by the FDA in the U.S. for the imaging of glioma. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX101-Px will receive marketing approval.

In August 2024, we submitted a NDA to the FDA for TLX101-Px for the characterization of progressive or recurrent glioma from treatment related changes in both adult and pediatric patients through the 505(b)(2) NDA regulatory pathway. In October 2024, the FDA accepted the NDA, granted priority review and assigned a PDUFA goal date of April 26, 2025. In April 2025, the FDA issued a CRL citing the need for additional confirmatory clinical evidence to progress the application. In September 2025 we reached agreement with the FDA regarding the required resubmission package, which includes a retrospective analysis to supplement clinical data. We are currently finalizing our resubmission package and will provide an update upon filing. There is no guarantee that the FDA will approve the NDA by the PDUFA goal date, if at all. TLX101-Px was granted fast track designation by the FDA for this indication in April 2024. Fast track or orphan drug designations may not lead to a faster development or regulatory review or approval process, and do not increase the likelihood that TLX101-Px will receive marketing authorization.

In February 2026, we submitted a MAA for TLX101-Px in a selection of European countries, with France acting as RMS. The French National Agency for Medicines and Health Products Safety, ANSM, in its capacity as RMS is responsible for coordinating and leading the scientific evaluation of the dossier, in collaboration with the Concerned Member States. There can be no assurance that the MAA will be validated, or that marketing authorizations for TLX101-Px will ultimately be granted.

As part of our commitment to provide access to medicine, we are running an EAP in the U.S. to allow access to TLX101-Px outside of a clinical trial to patients for whom there are no comparable or satisfactory alternative options.

We also intend to conduct a label-expanding Phase 3 trial of TLX101-Px for the imaging of patients with brain metastases from non-brain cancers, including lung and breast cancer.

Other Solid Tumors and Hematologic Oncology

Soft Tissue Sarcoma and PDGFRα: TLX300-Tx and TLX300-Px

Our product candidates TLX300-Tx and TLX300-Px employ antibody-directed targeted radiation for both therapeutic and patient selection applications against platelet-derived growth factor receptor alpha ("PDGFRα"); activation of PDGFRα is associated with cancer proliferation, metastasis, invasion, and angiogenesis. Eli Lilly Kinsale Limited provided us with a license for olaratumab, a naked antibody that was formerly marketed as Lartruvo. We re-purposed olaratumab as a radiopharmaceutical product candidate.

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In April 2025, we dosed the first patient in ZOLAR, a first-in-human Phase 1 proof-of-concept targeting and biodistribution trial using TLX300-Px. We intend to develop the therapeutic application of TLX300-Tx for the treatment of advanced soft tissue sarcoma ("STS") and other PDGFRα expressing cancers. We have not yet determined the specific therapeutic isotope that we will use in therapeutic trials.

TLX300-Px (^{89}Zr-DFOsq-olaratumab, including our proprietary DFO-squaramide chelator) is an imaging candidate that we are developing for use with TLX300-Tx as a theranostic pair.

Hematologic Oncology and CD66

In hematologic oncology and bone marrow conditioning ("BMC"), we are exploring the potential utility of targeted radiation to ablate bone marrow as part of a pre-conditioning regimen for bone marrow transplantation, novel stem cell therapies and gene therapies, each of which requires conditioning prior to treatment. The standard of care involves using highly toxic chemo-ablation techniques that require long hospitalization times and significant treatment-related morbidity and mortality risks, which considerably limit patient access to these therapeutic interventions. We believe that a safe, durable and short internment treatment could be transformative to many facets of cancer and autoimmune disease treatments that require BMC.

TLX66-Tx

Our antibody-based product candidate TLX66-Tx (^{90}Y-DTPA-besilesomab) is designed to target cluster of differentiation 66 ("CD66"), a well-validated leukocyte and neutrophil target. TLX66-Tx has been evaluated as a therapeutic bone marrow conditioning agent in approximately 80 patients with results that support continued development, both as a monotherapy and in combination with low dose chemotherapy conditioning regimes (Orchard et al. *Bone Marrow Transplantation*. 2024). In June 2025, the first patient was dosed in a Phase 2 IIT in pediatric high-risk leukemia. We also plan to evaluate TLX66-Tx in a Phase 2 clinical trial as a BMC agent in patients with acute myeloid leukemia who are not suitable for conventional BMC regimes.

In March 2022, TLX66-Tx was granted orphan drug designation by the FDA in the U.S. as a conditioning treatment prior to hematopoietic stem cell transplant ("HSCT"). TLX66-Tx was granted orphan drug designation in Europe in October 2019. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX66-Tx will receive marketing approval.

We believe that the imaging application of besilesomab could support patient selection for TLX66-Tx by informing healthcare providers whether sufficient activity will be absorbed by a patient's bone marrow. TLX66-Px, an imaging application of besilesomab, has already been commercialized and is an approved product (marketed as Scintimun) for imaging osteomyelitis (bone infection) in 32 European countries and Mexico. Scintimun was previously manufactured and distributed by Curium Pharma through an out-license from Telix via the acquisition of TheraPharm in 2020. Following a strategic review of the asset, we brought sales and marketing in-house during 2025, with plans to significantly augment commercial distribution and indication expansion. TLX66-Px has not received marketing approval in the U.S.

Pan-Cancer, CAIX and FAP

Our pan-cancer programs target CAIX and fibroblast activation protein ("FAP"), two well-validated targets with pan-cancer potential. This complementary approach targeting CAIX and fibrosis is a potential "double hit" at the tumor micro-environment, with potential to provide a synergistic benefit when combined with other systemic treatments such as immuno-therapies.

We have observed encouraging preliminary clinical data in bladder and breast cancers with our CAIX-targeting TLX250 platform, and in March 2025, we completed a transaction to expand our theranostic pipeline with a portfolio of next generation FAP-targeting assets. Our FAP development program is exploring potential in a range of solid tumors, as many cancers are known to express this target either in the tumor micro-environment, like breast cancer, or directly on malignant lesions, like sarcomas. Our lead therapeutic candidate, TLX400-Tx, has been administered in approximately 150 patients in a compassionate use setting covering multiple tumor types.

Operations and Manufacturing Activities

Our corporate headquarters are located in Melbourne, Australia. The majority of our workforce is in the U.S., based out of our U.S. headquarters in Indianapolis, Indiana, or our Dallas, Texas office, our R&D facilities in Angleton, Texas and Los Angeles and Sacramento, California, working remotely, or in one of our network of radiopharmacies that we acquired in January 2025 as part of our acquisition of RLS. We also have facilities in Australia (Melbourne, Sydney and Brisbane), Belgium (Brussels and Liège), Switzerland (Geneva), Japan (Kyoto and Yokohama) and Canada (Vancouver). We are investing significantly to build a world-class vertically integrated supply chain, superior manufacturing and distribution capabilities, and the ability to deliver radiopharmaceuticals to all major global markets.

We believe the impact of our investment into supply chain, manufacturing, distribution, and commercial capabilities to date is clearly demonstrated through the successful commercial launch of Illuccix. Leveraging our extensive network of partners, we have expanded manufacturing capabilities to support the scale-up of commercial sales of Illuccix and, since 2025, Gozellix. Furthermore, our widespread distribution network, encompassing over 225 radiopharmacies across the U.S., is designed to ensure flexibility and reliability in delivering Illuccix and Gozellix imaging doses to patients.

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We continue to invest to strengthen our vertically integrated supply chain and manufacturing model. In 2023 we opened our TMS facility located in Brussels South, Belgium. At approximately 30,000 square feet, it is one of the largest radiopharmaceutical production facilities in Europe, with nine GMP lines, clean rooms, a radiopharmacy, and two cyclotrons. We expect this facility to deliver significant flexibility and reliable supply for our growing commercial production requirements. It also serves as a vital hub for research and development, specifically in manufacturing scale-up and production of next generation radiopharmaceuticals, including both alpha-emitters and beta-emitters. In May 2025, TMS Brussels South received notice of GMP accreditation for Illuccix, and delivered first GMP grade commercial radiopharmaceutical doses in June 2025.

In December 2022, we acquired Optimal Tracers, a Sacramento-based company that provides radiochemistry process development services and research tracers for use in clinical trials. The acquisition expanded our translational radiochemistry capability and established a U.S.-based laboratory (now known as TMS Sacramento) and production footprint for manufacturing doses of radiopharmaceutical to support clinical trials.

In April 2024, we acquired IsoTherapeutics, which is enabling us to internalize select aspects of our development programs, with the goal of reducing cost and time to achieve technical milestones.

In April 2024, we acquired ARTMS, further enhancing the vertical integration of our supply chain and manufacturing, with the goal of facilitating broader patient access to therapeutic and diagnostic radiopharmaceuticals through ARTMS' high-yield production techniques. In March 2025, ARTMS' drug master file ("DMF"), for gallium-68 production using its QUANTM Irradiation System® ("QIS®") cyclotron technology was referenced for the first time with a FDA-approved product, with Gozellix. This approval enables radiopharmacies and hospitals using QIS and associated targets to produce multi-Curies of ^{68}Ga for use with Gozellix. We believe that the expanded distribution radius and increased dose production capacity, compared to existing gallium-based PET tracers, will facilitate broader and more equitable access. In January 2026, ARTMS' DMF for gallium-68 production using QIS was referenced with Illuccix. In addition, use of ARTMS' technology is being expanded internationally including at Telix cyclotron facilities. This includes TMS Brussels South, where QIS was installed on both cyclotrons during 2025, with zirconium-89 and gallium-68 subsequently produced.

In January 2025, we acquired RLS (USA) Inc., the only Joint Commission-accredited U.S. radiopharmacy network distributing PET, SPECT and therapeutic radiopharmaceuticals. The RLS acquisition – including over 30 radiopharmacies across the U.S. – augments our existing distribution network for last-mile delivery and provides expansionary space to build out a radiometal production network to meet future demand for radiopharmaceuticals. The process to install cyclotrons at selected RLS radiopharmacy locations is underway.

In March 2025, we announced the establishment of a joint venture with R2PHARMA, structured as Telix Innovations Brazil Ltda. (the "JV"), to commercialize and distribute our therapeutic and diagnostic radiopharmaceutical products in Brazil, The JV further strengthens the partnership established in 2019, with a commitment to jointly bring to market innovative and first-in-class therapeutic radiopharmaceuticals and imaging agents in Brazil. The JV is expected to hold an exclusive license to commercialize and distribute Illuccix, as well as future product candidates, once all required regulatory, licensing, and governmental authorizations are obtained. Until such authorizations are granted, Illuccix continues to be distributed in Brazil by one of the JV's affiliated companies within the R2PHARMA Group.

In June 2025, we established TMS Yokohama in Japan, Telix's first cyclotron facility in the APAC region. TMS Yokohama will serve as a hub for commercial and clinical supply, and future research and development. It expands Telix's global production network which includes in-house and partner facilities. Originally opened in 2018, the site comprises a cyclotron and multiple production hot cells and was designed and built by JFE Engineering ("JFE"), as the Contract Manufacturing Organization ("CMO"), for TLX250-Px in Japan and China, including for the ZIRCON-CP study. We believe that taking over the lease and operational management of this facility will provide greater control over existing clinical supply with the possibility to expand production to other Telix investigational and future commercial products in the region, including Illuccix, and TLX101-Px for Greater Tokyo, and TLX591-Tx for the APAC region, if marketing authorization of the product candidates is granted. Further, we plan to install ARTMS' QIS cyclotron technology, which we believe will facilitate standardized, high-efficiency and cost-effective production of zirconium-89 supporting TLX250-Px production.

During 2025, we progressed the construction of a new facility in Melbourne, Australia, to be known as TMS North Melbourne, for early-phase clinical research and radiopharmaceutical production, to support APAC translational research and clinical trials. In September 2025, both TMS North Melbourne and TMS Yokohama were granted radiation licenses for a broad range of clinically and commercially important medical isotopes.

Our Opportunity

The global radiopharmaceutical industry is undergoing a period of transformative growth with theranostics emerging as a key pillar in the armamentarium of oncology treatment. We believe that with increasing integration of nuclear medicine and traditional oncology clinical practice, radiopharmaceuticals will become a core component of the multi-disciplinary approach to cancer treatment with a proportionate benefit to patients.

Our therapeutic radiopharmaceutical platform harnesses the power of radioactive isotopes combined with multi-platform targeting agents to deliver targeted radiation directly to the tumor site. These therapeutic product candidates have the potential to be stand-alone treatments or as complements to existing treatment modalities to address areas of high

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unmet medical need. Due to our expertise in the multiple components of radiopharmaceuticals we believe we are able to create theranostics in an “agnostic” manner, pairing the right delivery mechanism with the right isotope most likely to be suited for the tumor being treated.

We intend to pair each therapeutic with a diagnostic imaging agent, this underpins the “theranostic” approach whereby two conjugates are used to target the same cell-surface receptor, one for detection, localization or staging, and the other for selective destruction of target cancer cells. When used in tandem to plan and execute treatment, and then to assess response and monitor for progression, we believe this approach allows the delivery of truly personalized therapy to patients.

Our Strategy

Our strategy is to launch innovative imaging agents in our core disease areas, while financing the development of therapeutic product candidates, including next generation radiopharmaceuticals. This strategy is underpinned by a vertically integrated approach to supply and manufacturing, and is supported by a first-class commercial organization ensuring global patient access to our products and product candidates, if approved.

Our strategy is designed to deliver on our purpose and mission and reflects the evolution of our business into a global, multi-product commercial-stage company with a deep theranostic pipeline. This approach, we believe, will deliver benefits to patients and returns to shareholders over the near and long-term.

The four strategic pillars central to achieving our mission are:

1. Deliver our late-stage therapeutic pipeline

We aim to build both breadth and depth in oncology and to address areas of significant unmet medical need, both for large oncology indications such as prostate cancer and kidney cancer, as well as rare oncology indications such as glioma. This is based on a target selection process that is aligned with our expertise in radiation biology.

In August 2025, we completed target enrollment in Part 1 of the Phase 3 ProstACT Global study of TLX591-Tx (lutetium (Lu177) rosopatamab tetraxetan), our lead rADC candidate for advanced prostate cancer. In December 2025, we dosed first patients in Part 2 (randomization) in Australia with sites also recruiting in Canada and New Zealand. The study is also approved to commence in China, Japan (Part 1 only), Singapore, South Korea, Türkiye and the United Kingdom. This multinational Phase 3 study is to investigate and evaluate the potential benefits and risks associated with TLX591-Tx, when administered together with SOC and compared to SOC alone.

We are also advancing TLX250-Tx and TLX101-Tx into late-stage clinical trials for the treatment of kidney cancer and glioblastoma, respectively. In 2025, we received regulatory approval in Australia and the European Union to commence the Phase 3 IPAX-BrIGHT pivotal trial of TLX101-Tx with sites open for enrollment, and received regulatory approval in Australia to commence LUTEON, a global Phase 2/3 trial of TLX250-Tx. We believe that each of our product candidates is currently the most advanced systemic radiotherapy in its respective indication.

2. Build the next generation of radiopharmaceuticals

We have established a track-record in identifying validated clinical product candidates that can be optimized as radiopharmaceutical therapies to develop them through to commercial products. We are leveraging this capability to expand our pipeline with next generation radiopharmaceuticals, particularly targeted alpha-emitting therapies, through business development, as well as internal R&D programs and collaborations. Through our existing clinical programs and dedicated research facilities in the U.S., Australia and Europe, we are focused on the development of alpha therapy candidates as a future pipeline expansion opportunity, and on building supply and manufacturing capabilities required to support an eventual commercial launch.

We are advancing TLX592-Tx, TLX252-Tx and TLX102-Tx, our next generation (alpha) therapy candidates for prostate, kidney and brain cancer into clinical trials. In 2025, we received regulatory approval to commence Phase 1, first-in-human studies of TLX592-Tx and TLX252-Tx. During the year, we dosed first patients in a Phase 1, first-in-human imaging study of TLX300-Px, aiming to demonstrate proof of concept for therapy in soft tissue sarcoma ("STS") and other platelet derived growth factor receptor alpha ("PDGFRα") positive tumors. In 2025, we dosed first patients in the Phase 1 SOLACE study of TLX090-Tx, Telix's therapy candidate for pain palliation of osteoblastic bone metastases, and also acquired a suite of clinically validated theranostic candidates (including TLX400-Tx) targeting fibroblast activation protein ("FAP"), widely considered to be one of the most promising targets for both cancer imaging and therapy.

In January 2025, we acquired a pipeline of next generation therapeutic candidates, a proprietary novel biologics technology platform, and a protein engineering and discovery research facility based in Los Angeles, California, from antibody engineering company ImaginAb, Inc. ("ImaginAb"), to enhance existing innovation capabilities. This provides us with a pipeline of early-stage drug candidates against high-value targets including delta-like ligand 3 ("DLL3"), and integrin αvβ6, as well as several other novel targets in discovery stage. We believe these next generation drug candidates fit synergistically with our therapeutics pipeline, enabling expansion to future therapy areas with unmet clinical need. The acquired intellectual property utilizes small engineered antibody formats that enable highly specific cancer targeting, combined with fast tumor uptake and blood clearance. This technology has the potential to be highly effective for imaging and treating tumors with a broad range of radioisotopes, with alpha emitters of particular interest.

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In March 2025, we announced a validated breakthrough generator technology for the production of the alpha-emitting isotope, lead-212 (^{212}Pb) and successfully completed first production. The new generator technology, being developed internally by our IsoTherapeutics team, produces ^{212}Pb via a Thorium-228 (^{228}Th) emanation source, and significantly increases the amount of radioactivity, yield and shelf life compared to currently available ^{212}Pb generators. The production footprint has been designed to be deployed throughout Telix's (and select partner) manufacturing and distribution networks, including RLS Radiopharmacies.

3. Grow our industry-leading Precision Medicine business

Leveraging the success of our first commercial product, Illuccix, we intend to broaden our commercial footprint in precision medicine by:

- Expanding Illuccix and Gozellix into new indications and geographies and the continued successful launch of Gozellix in 2026.
- Obtaining marketing authorization for TLX250-Px, which will expand our urology portfolio with potential to become the first-in-class targeted radiopharmaceutical imaging agent for ccRCC.
- Obtaining marketing authorization for TLX101-Px for the imaging of glioma.

4. Expand our global infrastructure for product delivery

To develop and deliver radiopharmaceuticals, which have a relatively short shelf life due to their unique properties, supply chain, manufacturing and logistics are vitally important. TMS is a global network of facilities, where our continued focus and investment in infrastructure and technologies is equipping Telix to deliver patient doses worldwide.

Telix has made a number of strategic acquisitions to grow our manufacturing capability and footprint. Going forward, TMS will be focused on activities including:

- Preparing selected RLS Radiopharmacies sites for cyclotron installation with ARTMS QIS technology, to increase efficiency and improve yields when producing radioisotopes, and establish a next generation radiometal production network.
- Expanding the deployment of the ARTMS QIS technology including at our state-of-the-art TMS facility in Brussels South, Belgium – one of the largest of its kind in Europe, and TMS Yokohama.
- Increasing GMP production at TMS Brussels South.
- Completing the fit-out at TMS North Melbourne and scaling up of operations at TMS Yokohama.

Our Theranostic Approach

Our approach enables us to design and develop product candidates to deliver targeted radiation to cancer cells, regardless of where the cancer is in the body, via a systemic radioactive infusion. We aim to use imaging and therapy together to "see and treat" cancer. We refer to this approach as theranostic, which we believe is a powerful way to tackle unmet need in cancer and rare diseases.

We believe that our ability to harness the power of targeted radiation throughout the patient journey to enhance patient outcomes is a key differentiator.

Targeted Radiation Overview

We are developing targeted radiation across the continuum from diagnosis and staging to treatment, both as stand-alone and combination therapies.

Many existing cancer therapies are non-selective and as a result can act against healthy tissue and vital organs while treating disease. Existing external beam radiation therapy ("EBRT"), approaches are effective but typically only deliver localized treatment and cause damage to surrounding tissue. Localized therapeutic approaches rely on the treating physician making assumptions about the extent of disease and can result in imprecise application of treatment. Treatments that miss small amounts of cancer cells can lead to a recurrence of the cancer or disease.

Targeted radiation uses a radioactive isotope as a payload that is attached to a targeting agent, such as a small molecule or antibody, with an affinity for specific biomarkers found on the surface of cancerous or diseased cells. Depending on the choice of radioisotope payload, these target agents can deliver either imaging or therapy.

The targeted radiation drug or antibody is administered into the bloodstream and circulates throughout the body. Once administered, the targeted radiation seeks cancerous or diseased cells, including primary tumors and small metastases (where the cancer has spread), upon which it is designed to bind selectively to its target. Some radioactive isotopes have physical properties that may be used to image cancer or rare diseases, for diagnosis and staging purposes. Higher dose radiation with different alpha- and beta-emitting radioisotopes can be used as therapies to kill cancerous or diseased cells, by damaging their DNA.

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The Targeting Agent

The targeting agent guides the radiation payload to the targeted cancer cells. The agent is designed to be cancer-specific due to selective affinity for tumor targets that are prevalent in tumors but not healthy tissues. The targeting agents can be either an antibody, engineered antibody fragment, peptide or small molecule, and the choice of targeting agent can impact the other properties of the drug, including:

- **Pharmacokinetics:** Peptides and small molecules have a short circulation time (several hours) and therefore require a higher dose of radiation payload to sufficiently irradiate the tumor in therapeutic contexts, which comes at the expense of a resulting higher radiation exposure to the kidney. Antibodies have a longer circulation time (several days), are cleared though the liver and are lost slowly, which can transiently impact the levels of blood cells but results in higher amounts of radiation payload in tumors to maximize the therapeutic effect. The calculations and study required to determine the optimal dose of radiation to be delivered for maximum therapeutic effect with an acceptable safety profile are referred to as "dosimetry".

- **Binding and cancer specificity:** Antibodies have evolved in the immune system to be highly selective and, as a well-known class of agents, can be generated to be highly specific to their target. Small molecules and peptides are not as predictable as a delivery platform, however they can be engineered for high selectivity and affinity; their metabolism properties and off-target toxicity are unique to each molecule.

- **Internalization and residualization in the tumor:** Once bound to their biological targets, targeting agents can be taken up by cancer cells through a process called "internalization". Peptides tend to be returned to the blood or otherwise degraded relatively quickly after internalization. By contrast, antibodies tend to be retained within cancer cells and, with their sustained presence in the blood, tend to accumulate or ‘residualize’ their radiation payload over time which can favor the localization of higher amounts of radiation to the tumor than peptides or small molecules. The slow excretion of antibodies and their ability to highly effectively residualize radiation in tumors means that lower doses of radiation are needed to treat patients; thereby improving supply chain capability and cost of goods.

- **Route of excretion from the body:** Small molecules and peptides are primarily excreted in the urine rapidly passing through from the blood into the bladder via the kidneys. Antibodies are cleared via the liver, which is a more radio-tolerant organ.

In general, the properties of small molecules and peptides suit diagnostic targeted radiation agents, as the excess or unbound radiation drug is rapidly lost from the body, resulting in a good contrast between the tumor and background tissues and enabling favorable imaging within hours, allowing patients to be dosed and imaged within the same day. Conversely, the high specificity of antibodies, along with their well validated, predictable characteristics in the body and long retention in the tumor largely favor therapeutic use.

Radio Antibody-Drug Conjugate (rADC)

We refer to our antibody-based candidates as rADCs. These rADCs are radiopharmaceuticals that use an antibody as both a homing device and a carrier to deliver a therapeutic radiation payload to a specific target. This property differentiates them from chemotherapy, which cannot distinguish between healthy cells and tumor cells. rADCs are designed to combine the targeting properties of monoclonal antibodies, which can discriminate between healthy and cancerous tissue, with the cancer-killing capabilities of cytotoxic radiation.

We are pioneering a novel technology platform designed to optimize the therapeutic window for rADCs, which we refer to as RADmAbs. This proprietary technology uses antibody engineering to modulate the pharmacokinetics of ‘full length’ antibodies such that they are designed to clear faster from the blood while maintaining the same high specificity to their target and tumor localization properties. Since they retain the same overall structure as traditional antibodies, they also share similar characteristics important for commercial development including a standard manufacturing pathway, biological stability, immunogenicity and regulator familiarity.

In January 2025, we acquired patents, know-how and other intellectual property from ImaginAb comprising a proprietary drug discovery platform, a pipeline of early-stage drug candidates against high-value targets, and several other novel targets in discovery stage. The acquired intellectual property utilizes small engineered antibody formats that enable highly specific cancer targeting, combined with fast tumor uptake and blood clearance.

We believe that this technology, alongside our other radiolabeling knowhow and technologies, can be applied to any existing cancer-targeting antibody agent to potentially provide new intellectual property and a life-cycle management option for prospective partners.

The Radiation Payload

The radioisotope is strongly bound to the target agent molecule either using traditional chemistry or trapping it using a ‘chemical cage’ called a 'linker' or 'chelator'. Different chelators are paired with certain isotopes, such as deferoxamine, a linker that selectively binds with ^{89}Zr (which we use in TLX250-Px), and the tetraxetan chelator, which binds isotopes like ^{177}Lu (which we use in TLX591-Tx and TLX250-Tx) and ^{225}Ac (which we use in TLX592-Tx and TLX252-Tx).

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The choice of radioisotope and its decay profile impacts properties of the targeted radiation drug.

- *Diagnostic radioisotopes for imaging*: Radioisotopes emitting positrons can be detected by a PET camera. Gamma emissions can be detected by a single photon emission computed tomography (SPECT) camera. These are commonly referred to as "scanners."

- *Diagnostic radioisotopes for surgery*: Both gamma and beta emitting radioisotopes can be used for the intraoperative detection of tumors, using a handheld or robotic probe. The most commonly used isotope in radio-guided surgery is ^{99m}Tc.

- *Radioisotopes for therapy*: Radioisotopes with the ability to kill cells for therapeutic effect are classified as either beta- or alpha-emitters, based on their emission profile. Beta emitters (such as ^{177}Lu and ^{131}I) have a longer penetration and may be more suitable for bulky metastatic disease. Alpha-emitters (such as ^{211}At, ^{212}Pb and ^{225}Ac) are substantially larger isotopes than beta-emitters and have the potential to deliver very high amounts of energy to cancer cells in closer proximity to these particles, which can decrease the risk of damage to surrounding healthy cells and increase the selectivity and potency of the radiation treatment. Alpha and beta therapies may be complementary, with alpha therapies being more suitable for smaller or disseminated tumors (including micro metastatic disease) and beta therapies being more suitable for treatment of bulkier tumors.

Our Prostate Cancer and PSMA programs

Overview

Our prostate cancer portfolio programs target PSMA, a protein that is overexpressed on the surface of prostate cancer cells and is low or absent on most normal healthy cells. PSMA has become a major breakthrough in the staging, treatment and management of prostate cancer. Imaging with targeted radiation can identify prostate cancer wherever it is in the body and help guide patient treatment. The PSMA receptor is expressed in over 80% of prostate cancer tumors. This expression of PSMA provides a specific target to design therapeutic and diagnostic agents for the treatment and imaging of prostate cancer.

Market and Opportunity for Prostate Cancer Therapy

According to Pharma Intelligence, global incidence of prostate cancer was estimated to be 1,349,000 in 2022 and is expected to reach approximately 1,455,000 by 2027 and in the U.S., the incidence of prostate cancer was estimated to be 244,000 in 2022 and is expected to reach approximately 268,000 by 2027. The U.S. market opportunity for PSMA-PET imaging agents in their approved indications is estimated to represent over US$2.5 billion per year, based on current approved indications. The U.S. market opportunity for PSMA-targeted therapeutic agents is estimated at almost US$8 billion dollars per year based on Datamonitor patient-based forecasts for mCRPC and mHSPC.

High rates of screening in developed countries mean many men are diagnosed and treated early before their disease has spread. These men receive local therapy, either prostatectomy or EBRT, and may be cured of their disease. However, approximately 15% of patients develop advanced forms of the disease that can spread to other parts of the body. This is known as metastatic prostate cancer.

According to Datamonitor's patient-based forecast, there were approximately 51,000 patients treated for mCRPC in the U.S. in 2025. Approved treatment options for patients with mCRPC include androgen deprivation therapy, androgen receptor pathway inhibitors, docetaxel chemotherapy, radium-223 for patients with bone-only metastases, PSMA-targeted lutetium-therapy for patients having received prior docetaxel, and poly (ADP-ribose) polymerase (PARP) inhibitors for patients with deleterious germline or mutated somatic homologous recombination repair gene. The global market for systemic treatments for patients with mCRPC is estimated at approximately US$6.9 billion per year.

Pluvicto (lutetium (^{177}Lu) vipivotide tetraxetan), marketed by Novartis, was approved by the FDA for the treatment of patients with PSMA-positive mCRPC who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy in March 2022. In March 2025, Pluvicto was approved by the FDA for earlier use prior to chemotherapy, in PSMA-positive mCRPC. Pluvicto is the only FDA-approved PSMA-targeted therapy for the treatment of prostate cancer. Novartis disclosed that Pluvicto recorded net sales of US$1,390 million in 2024 and US$1,994 million in 2025. Pluvicto uses a small-molecule approach to target the PSMA receptor and is administered in up to six cycles. In a pivotal clinical trial, patients treated with Pluvicto showed an overall response rate of 30%, a median progression-free survival of 8.7 months, and a median overall survival of 15.3 months.

Several other systemic radiotherapies are being investigated in clinical trials in the mCRPC setting and across other stages of prostate cancer, and potentially could be commercialized in the future. We consider our most direct potential competitors to be companies developing PSMA-targeted therapies in the mCRPC space, including Novartis, Convergent, Point Biopharma, Eli Lilly & Company Ltd, Lantheus Holdings, Inc, Curium Holding France S.A.S, ARTBIO, Inc., Blue Earth Therapeutics Ltd, Clarity Pharmaceuticals, Astra Zeneca PLC/Fusion Pharmaceuticals, Inc., Bayer AG, Orano Med SAS, Isotopia Molecular Imaging Ltd, ITM Isotope Technologies Munich SE, Janssen Pharmaceuticals, AdvanCell Isotopes Pty Ltd, Alpha-9 Theranostics, Cancer Targeted Technologies, FutureChem Co Ltd., Sinotau Pharmaceutical Group, RadioPharm Theranostics, Precision Molecular, StarPharma, Ambrx Biopharm, Inc., Amgen Inc., Crescendo Therapeutics, Poseida Therapeutics, Janux Therapeutics, Bivision Pharmaceuticals and Full-Life Technologies. Our competitors also

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include companies developing other modalities to treat patients with mCRPC. (See “Business—Competition” for additional information).

Market and Opportunity for Prostate Cancer Imaging

PSMA-PET imaging is used by clinicians to locate prostate cancer lesions and inform clinical decisions for patients. PSMA-PET imaging is indicated in the U.S. for prostate cancer patients:

- with suspected metastasis who are candidates for initial definitive therapy;
- with suspected recurrence based on elevated serum PSA level; and
- for selection of patients who are indicated for PSMA-directed therapy as described in the prescribing information of the therapeutic products.

We estimate that the PSMA-PET imaging market opportunity in the U.S. for these indications represents over 645,000 scans per year, which may be worth more than US$2.5 billion.

Guidelines and clinical research suggest potential future utilization of PSMA-PET imaging for:

- monitoring for progression in non-metastatic and mCRPC patients; and
- monitoring response to PSMA-directed therapy.

We estimate that these areas represent over 250,000 scans per year. We estimate that the combined addressable market based on current and future guideline driven indications may be more than US$3.5 billion per year. Telix is exploring ^{68}Ga-PSMA-PET with Illuccix or Gozellix for diagnosis as a new indication, not currently FDA approved or included in clinical guidelines. Combining ^{68}Ga-PSMA-PET for diagnosis with current and guideline-driven indications, has potential to bring the total addressable market to more than US$6.7 billion per year.

Our main competitors in the prostate cancer imaging market are companies with approved PSMA-PET diagnostics, including Novartis, Lantheus Holdings, Inc. ("Lantheus"), Curium Pharma Ltd., Bracco Imaging S.p.A. (through its Blue Earth Diagnostics affiliate) and Isotopia Molecular Imaging Ltd. Certain academic institutions, such as UCLA and UCSF, also hold a license for a commercial PSMA-PET diagnostic.

In 2020, UCLA and UCSF obtained FDA approval for ^{68}Ga-PSMA-11, which was the first PSMA-PET imaging agent to be approved by the FDA. Pylarify (^{18}F-piflufolastat), marketed by Lantheus, and Illuccix were subsequently approved by the FDA in 2021. Locametz (^{68}Ga-PSMA-11), marketed by Novartis, received FDA approval in 2022 and Posluma (^{18}F-flotufolastat), marketed by Blue Earth Diagnostics, received FDA approval in 2023. Gozellix was approved by the FDA in March 2025. In August 2025, Lantheus announced that its NDA for a new formulation of its fluorine-18 based PSMA imaging agent, had been accepted by the FDA with a PDUFA goal date of March 6, 2026. In May 2025, RadioMedix submitted an Abbreviated New Drug Application ("ANDA") for ^{68}Ga-PSMA-11. Several other PSMA-PET product candidates are being evaluated in clinical trials for prostate cancer imaging and may be commercialized in the future.

Companies developing PSMA-PET imaging agents include ABX-CRO, Clarity Pharma Ltd., Curium Pharma Ltd., Isotopia Molecular Imaging Ltd, Itelpharma, ITM Isotope Technologies Munich SE, Five Eleven Pharma, Fortis Therapeutics, RadioMedix, HTA Co. Ltd and Jiangsu Hengrui Pharmaceuticals Co., Ltd.

Currently approved PSMA-PET imaging compounds use either a gallium-68 isotope (^{68}Ga), such as Illuccix or Gozellix, or a fluorine-18 isotope (^{18}F) for PET imaging. Recent scientific publications illustrate evidence of important clinical differences between ^{68}Ga and ^{18}F based imaging agents, including a lower rate of false positives with ^{68}Ga, which can potentially provide more accurate interpretation and understanding of the extent of disease (Fendler et al. *EJNMMI*. 2023; Kroenke et al. *J Nucl Med*. 2021). Also, ^{68}Ga-based imaging agents have been shown to help clinicians detect prostate cancer in patients with low disease burden (Burgard et al. *Cancers*. 2023). This early detection can lead to a change in management and better outcomes for patients. Additionally, approved ^{68}Ga-based imaging agents can use a lower radiation dose than approved ^{18}F-based agents, reducing radiation exposure for nuclear medicine physicians and patients.

Therapy – TLX591-Tx

TLX591-Tx (lutetium (Lu177) rosopatamab tetraxetan) is a rADC directed at PSMA. We are evaluating the safety and efficacy of TLX591-Tx in the ProstACT series of clinical trials. The key evidence from Phase 1 and Phase 2 studies supporting the development of TLX591-Tx includes:

- Evidence that treatment with TLX591-Tx is well tolerated, including data from the Phase 1 ProstACT SELECT trial, common grade 3 and 4 hematological events included thrombocytopenia, lymphopenia and neutropenia. All hematological events were transient and manageable;
- Positive efficacy outcomes demonstrated following treatment of 242 patients across eight Phase 1 and Phase 2 clinical trials, including up to 42.3 months median survival in a single-arm Phase 2 clinical trial in 17 patients with

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mCRPC when delivered under a fractionated dosing regimen. Data from Cohort 2 in the ProstACT SELECT trial reported median rPFS of 8.8 months, an encouraging efficacy signal that should be considered directional in nature given the small sample size in this Phase 1 clinical study;

- Evidence of low rates of off-target organ exposure observed in ProstACT SELECT; and
- Convenient two-dose regimen administered over 14 days with low radiation exposure.

As an rADC with an antibody targeting agent, we believe that TLX591-Tx may be differentiated from PSMA-targeted therapies leveraging a small molecule approach as it has the potential for:

- Functional specificity for tumor-expressed PSMA, whereas small-molecule PSMA is taken up by endogenous PSMA;
- Reduced off-target radiation, with reduced potential for undesirable adverse events including dry eye, xerostomia, and back pain from ganglia irradiation;
- Longer circulation time and tumor retention, while small molecule PSMA is rapidly excreted with approximately 70% of activity lost after 12 hours; and
- Shorter dosing regimen of two doses, 14 days apart compared to dosing regimens lasting up to 30 weeks with PSMA-targeted small peptide RLT.

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Clinical Data

To date, 242 patients have been treated across eight Phase 1 and 2 trials of TLX591-Tx. We believe these data cumulatively support the clinical validity of our intended fractionated dosing, which is designed to split a dose over a longer treatment cycle to decrease toxicity without compromising efficacy. In an open-label, single-arm Phase 2 clinical trial with six experimental dose cohorts of TLX591-Tx of 33 patients, we reported a 42.3 month median survival in 17 patients with advanced mCRPC treated at the higher dose level when TLX591-Tx was delivered under a fractionated dosing regimen. Median survival was 19.6 months at the lower dose level and was 27.8 months across those dose cohorts. At the higher dose level, 23.5% and 35.3% of patients had grade 3 and 4 neutropenia, respectively, and 29.4% and 58.8% of patients had grade 3 and 4 thrombocytopenia, respectively. The trial met its primary endpoint, which was to identify the maximum tolerated dose of TLX591-Tx when administered in two doses two weeks apart. The survival benefits were a secondary endpoint. This trial did not contain a control group and was not powered to measure statistical significance of the survival benefit, which is a limitation of single-arm trials.

ProstACT SELECT was a Phase 1 trial evaluating the safety and tolerability of TLX591-Tx in combination with standard of care treatment in patients with mCRPC. The purpose of the ProstACT SELECT trial was to evaluate the ability of ^{68}Ga-PSMA-PET imaging to select patients for rADC-based PSMA therapy and to confirm the biodistribution of TLX591-Tx when administered as two doses 14 days apart. The primary objectives of the study were to determine the whole body distribution and organ radiation dose, and assess the safety and tolerability profile of TLX591-Tx, when administered in combination with standard of care in second-line mCRPC. The evaluable population comprises a total of 30 patients enrolled in the trial. In Cohort 1 comprising 5 patients, each patient received a 27 mCi dose followed by a 76 mCi therapeutic dose for accuracy of biodistribution determination. In Cohort 2, 23 of 25 patients each received two therapeutic 76 mCi doses. These patients included a heterogeneous patient population of low, medium and high disease burden, with the majority of patients having undergone two prior lines of therapy.

Data from the ProstACT SELECT trial suggested evidence of high on-target PSMA tumor-binding and radiation delivery to bone, nodal, and visceral metastases while minimizing uptake and toxicity in kidney and salivary glands. We believe this biodistribution is significant when compared to small molecule therapeutic and diagnostic PSMA agents, which may have greater off-target binding and subsequent radioactive dose to those organs.

We also observed evidence of consistent lesion delineation between TLX591-Tx and ^{68}Ga-PSMA-11 imaging, within the detection sensitivity and resolution limits of SPECT, evidence of uptake and retention in tumor and metastases up to 14 days post injection, the highest absorbed dose being in the liver (clearance organ) with minimal uptake in salivary glands, and a long retention period that was evidence of internalization.

ProstACT SELECT Cohort 2 data also provides evidence of the potential clinical advantage of the short, simple treatment regimen of two therapeutic doses administered 14 days apart. Hematologic treatment emergent adverse event ("TEAE") rates were: Grade 3 thrombocytopenia (16% of patients, or 4/25), grade 3 neutropenia (28%, 7/25), grade 4 thrombocytopenia (20%, 5/25) and grade 4 neutropenia (4%, 1/25). All hematologic events were transient and manageable. The trial demonstrated a median radiographic progression-free survival of 8.8 months, a secondary objective, based on an evaluable patient population in Cohort 2 of 16 patients who each received two 76 mCi doses of TLX591-Tx and did not have important protocol deviations. Based on these data, the trial appears to have achieved its primary safety and tolerability objectives.

We are currently investigating TLX591-Tx in the Phase 3 ProstACT Global clinical trial in mCRPC patients previously treated with one prior androgen receptor pathway inhibitor ("ARPI") in the metastatic castration-sensitive prostate cancer ("mCSPC"), non-metastatic castration-resistant prostate cancer ("nmCRPC"), and first line (1L) mCRPC settings. The trial is a multi-national, multi-center, prospective, randomized, controlled, open label study designed to investigate

and confirm the benefits and risks associated with TLX591-Tx a high-affinity PSMA-targeted rADC that delivers DNA breaking radiation directly to PSMA-positive bone, nodal, or visceral metastases in patients with mCRPC. The trial will enroll patients that have PSMA-positive mCRPC who have experienced disease progression following treatment with an androgen receptor pathway inhibitor (abiraterone or enzalutamide) that was received in either the metastatic castration-sensitive prostate cancer or first-line mCRPC treatment setting. The primary endpoint of the randomized portion of the trial is radiographic progression-free survival and secondary endpoints include overall survival, objective response rate, time to first symptomatic skeletal events, PFS, PSA decline of more than 50%, quality of life, and safety and tolerability.

In August 2025, this trial completed target enrollment of 30 patients in Part 1, a dosimetry and safety lead-in portion, replicating the prior study using the product candidate specifications intended for commercial release. We dosed the first patients in Part 2, the randomized treatment expansion arm, which we expect to enroll up to approximately 490 patients, in Australia in December 2025. Part 1 data will be submitted to the FDA to obtain agreement to expand Part 2 of the trial to U.S. sites. A public disclosure of preliminary results from Part 1 of the study will be aligned to engagement with the FDA.

Therapy - TLX592-Tx (alpha-PSMA)

Through our TLX592 program, we are also exploring how the conjugation of an antibody vector with an alpha-emitting isotope might deliver a next generation rADC with a different therapeutic profile. We believe that TLX592-Tx may be suitable for patients with early-stage mCRPC with a low disease burden and for patients with late-stage mCRPC who are no longer responding to lutetium therapy.

TLX592-Tx (^{64}Cu/^{225}Ac-RADmAb), is our next generation prostate cancer therapy candidate for targeted alpha therapy and is our first clinical program based on our proprietary RADmAb-engineered antibody technology. The engineered antibody vector is designed for faster elimination from circulation than standard antibodies. Therefore, it is expected to reduce bone marrow residence time, mitigating the risk of hematologic toxicities while retaining PSMA-mediated tumor localization and exertion of cytotoxic activity. TLX592-Tx is designed to be cleared by the liver without exocrine uptake.

We have conducted in vivo animal studies using an LNCaP (PSMA positive) tumor model and observed that treatment with TLX592-Tx resulted in a significant improvement in survival time of nude mice compared to a phosphate buffered saline treated control group (Fletcher et al. *Mol Pharmaceutics.* 2025). We studied the toxicological profile in CD1 mice and did not observe any treatment-related toxicity up to the highest dose level (single administration).

Clinical Data

Prior to commencing therapeutic studies with the alpha emitting isotope ^{225}Ac, we conducted the Phase 1 CUPID trial in which we evaluated TLX592-Tx radiolabelled with the imaging isotope ^{64}Cu, in patients with advanced prostate cancer. We used ^{64}Cu to understand the safety profile, pharmacology and dosimetry prior to the use of ^{225}Ac, since ^{64}Cu is detectable by PET, whereas ^{225}Ac is not. We investigated patients with PSMA avid disease based on Illuccix imaging, across three mass dose levels, to assess the safety profile, pharmacokinetics, biodistribution and dosimetry. Based on data from 11 evaluable patients, we observed accelerated elimination from blood circulation compared to the standard antibody used in TLX591-Tx, with similar on-target and off-target biodistribution. There were no treatment-related adverse events observed in the trial.

In July 2025, we received regulatory approval in Australia to commence the Phase 1 FIH therapeutic trial, AlphaPRO, designed to evaluate the safety profile of ^{225}Ac-labelled TLX592-Tx.

Therapy - TLX597-Tx (small molecule-based targeted radionuclide therapy)

TLX597-Tx (^{177}Lu-DOTA-HYNIC-panPSMA) is our novel small-molecule lutetium-PSMA therapy being developed to enable access for prostate cancer patients in select geographies.

Clinical Data

Initial data from an Australian IIT showed TLX597-Tx could be effective with reduced salivary gland uptake versus current standard of care, and a retrospective translational study of 145 patients highlighted positive efficacy outcomes versus a control group (Luna-Gutiérrez et al. *Pharmaceutics.* 2023). In the IIT, early dosimetry data from 12 of 120 patients suggests TLX597-Tx delivers approximately one-third of the radiation dose to the salivary glands and one-half to the kidney, compared to the current approved PSMA-directed lutetium therapy. We believe this could lead to reduced incidence of acute renal injury and xerostomia (dry mouth), while facilitating dose intensification versus current standard of care, to improve efficacy.

This candidate is being developed to enable access to lutetium therapy in select geographies, and is the subject of the ongoing Phase 2 OPTIMAL PSMA IIT, which is expected to enroll 120 mCRPC patients in Australia.

Imaging – Illuccix

Illuccix (also referred to as TLX591-Px in territories where approval has not yet been granted, ^{68}Ga-PSMA-11) is a preparation for imaging prostate cancer with PET.

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The “cold kit” format of Illuccix enables rapid radiolabeling at room temperature with high radiochemical purity and production consistency, suited to the commercial and hospital radiopharmacy setting. Illuccix is approved in the U.S., Australia, Austria, Belgium, Brazil, Canada, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden and the United Kingdom. Approved indications for patients with prostate cancer include staging of high-risk patients, identification of suspected recurrence, and selection for PSMA-directed therapy. We are also exploring potential future utilization in additional indications for prostate cancer patients through our lifecycle management program. These include monitoring progression in metastatic and non-metastatic castration resistant patients, monitoring response to PSMA-directed therapy, and as an adjunct to MRI for the diagnosis and detection of prostate cancer.

The key evidence supporting the use of Illuccix include:

- Broad availability in the U.S. through over 225 radiopharmacies and with flexible scheduling;
- Validated accuracy compared to other PSMA imaging agents, including lower rate of false positives and efficacy in patients with low disease burden; and
- Potential for expanded clinical utility based on guidelines and clinical research.

In May 2025, our pivotal Phase 3 registration study of TLX591-Px for prostate cancer imaging in Chinese patients completed target patient enrollment. Illuccix China is a prospective, open-label, single-arm, multicenter study conducted in collaboration with our strategic partner for the Greater China region, Grand Pharma. The study, which enrolled 140 patients, aims to demonstrate equivalence of TLX591-Px in imaging prostate cancer in Chinese and Western patients, in order to bridge to the marketing authorization granted to Illuccix by the FDA. In December 2025, Telix and Grand Pharma announced preliminary data from the Illuccix China study, indicating that the primary endpoint had been met. The data was used to file a new drug application for TLX591-Px with the Chinese National Medical Products Administration ("NMPA") Center for Drug Evaluation ("CDE"), which was accepted for review in January 2026.

In January 2026, we announced that the first patient had been dosed in our pivotal Phase 3 registration study of TLX591-Px for prostate cancer PET imaging in Japanese patients. Illuccix Japan is a prospective, open-label, single-arm, intra-patient, multicenter study designed to evaluate the visualization efficacy and safety profile of ^{68}Ga-PSMA-11 PET/CT compared with conventional imaging (computed tomography ("CT") and bone scintigraphy) in Japanese patients with biochemically recurrent ("BCR") prostate cancer following prior radical prostatectomy. The study will enroll up to 105 Japanese men at up to 10 sites and data is intended to support a future marketing authorization application for TLX591-Px in Japan.

Imaging – Gozellix

Gozellix (^{68}Ga PSMA-11) is Telix's next generation cold kit for the preparation of PSMA-PET imaging for prostate cancer, and was approved by the FDA in March 2025. Gozellix is designed to have an extended distribution profile compared to currently approved ^{68}Ga PSMA-PET imaging agents due to the use of ^{68}Ga sourced from newer high activity generators and cyclotrons.

We believe that Gozellix may further expand the availability and distribution of PSMA-PET imaging due to its longer shelf life and resulting expanded distribution radius. We believe that Gozellix has the potential to address unmet needs by extending availability of PSMA-PET imaging to substantially all PET/CT locations in the U.S. Many PET/CT imaging sites that are not served by approved PSMA-PET imaging agents are located in rural and underserved areas.

Gozellix was granted transitional pass-through payment status by CMS, effective October 2025 for a three-year period. This status enables CMS to provide separate payments for Gozellix and the PET-CT scan when performed in the hospital outpatient setting.

We are also exploring potential future utilization in additional indications for prostate cancer patients through our lifecycle management program. These include monitoring progression in metastatic and non-metastatic castration resistant patients, monitoring response to PSMA-directed therapy and as an adjunct to MRI for the diagnosis and detection of prostate cancer.

Imaging – TLX593-Px

In June 2025 we launched a novel PET radiochemistry solution based on ^{18}F-aluminum fluoride ("AlF"), named AlFluor™. As part of AlFluor’s development, we signed a strategic agreement with University Hospital Ghent and Ghent University for a novel [^{18}F]AlF-PSMA-11 targeting agent, which we have designated as TLX593-Px. The agreement includes a comprehensive chemistry, manufacturing and controls ("CMC") package suitable for the preparation of a Drug Master File ("DMF") and provides exclusive access to TLX593-Px clinical safety and efficacy data, including a Phase 3 trial in 96 prostate cancer patients, where PSMA-11 (gozetotide) was labeled interchangeably with ^{18}F and ^{68}Ga.

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Bone Metastases and Pain Palliation

TLX090-Tx

TLX090-Tx (^{153}Sm-DOTMP) is a novel kit-based bone-seeking targeted radiopharmaceutical product candidate that uses a next generation chelating agent to deliver a proprietary formulation of Samarium-153 radioisotope. It is a combination of patented, lower specific activity form of Samarium-153, a beta-emitting radioisotope with a 46-hour half-life, and the chelating agent DOTMP (1,4,7,10-tetraazacyclododecane-1,4,7,10-tetramethylene-phosphonate), which selectively targets sites of high bone mineral turnover, a known characteristic of bone metastases, and minimizes off-target migration.

We believe that TLX090-Tx may be administered as a single dose, multiple doses and higher dose regimens for pain management of bone metastases and osteosarcoma therapy, including in pediatric patients. We believe that TLX090-Tx is highly aligned with our existing therapeutic focus areas of prostate cancer, glioma and sarcoma.

Clinical Data

In August 2021, the FDA cleared the IND application to commence Phase 1, open-label, dose escalating study for TLX090-Tx (originally CycloSam®) in patients with osteosarcoma and other solid tumors metastatic to bone, with the primary objective of establishing the maximum tolerated dose ("MTD") and evaluating pharmacokinetics, dosimetry, and safety. Patients received an imaging dose of 0.5 mCi/kg on Day 1 and then a therapeutic dose on Day 8, with escalation planned up to 3.0 mCi/kg. A total of five patients were enrolled and treated in the first two cohorts (three patients at 0.5 mCi and two patients at 1 mCi/kg). SPECT/CT scans of these patients showed that TLX090-Tx was highly targeted to bone and had preferential uptake in bone tumors, with no evidence of soft tissue activity and rapid elimination via the kidney and bladder. Complete blood count and comprehensive metabolic panel blood testing data indicated no toxicities or drug-related adverse events, some mild and transient drop in white blood cell counts that recovered by Week 6 without intervention, and there were no clinically significant changes in liver and kidney function. No transfusions or stem cell recovery procedures were necessary. While pain relief was observed in patients, this was exploratory and not a primary endpoint. Visual analogue scale pain scores taken at baseline and then weekly after dosing suggest fast-acting, long-lasting pain relief, improved mobility and improved quality of life. We believe that pain relief is evidence of that TLX090-Tx may not have similar risks or the potential adverse events of opiate pain medications, and may offer a viable alternative for pain palliation in patients with advanced cancer and painful osteoblastic bone metastases.

We believe that TLX090-Tx has the potential to deliver significant improvements to existing bone-seeking agents for the palliation of painful osteoblastic bone metastases in late-stage metastatic disease. We believe TLX090-Tx may enable the pain management of prostate cancer bone metastases, where there remains a significant unmet medical need particularly after progression from other forms of radionuclide and radiation therapy. We also believe that TLX090-Tx may benefit patients with metastatic lung and breast cancer, where many patients develop painful bone metastases, and disease management often focuses on quality-of-life palliative care.

TLX090-Tx has also been granted orphan drug and rare pediatric disease designations by the FDA for the treatment of osteosarcoma. These designations apply only to the osteosarcoma indication and do not apply to the current pain palliation indication being pursued in the SOLACE trial. The rare pediatric disease designation may enable TLX090-Tx to be brought to market more rapidly for osteosarcoma through regulatory incentives, including eligibility for a pediatric rare disease priority review voucher that may be applied to this or other programs. The orphan drug designation and the rare pediatric disease designation do not increase the likelihood of marketing approval.

In October 2025, we dosed the first patient in an open-label Phase 1 clinical trial designed to evaluate the pharmacokinetics, dosimetry, safety, and pain palliation of TLX090-Tx. SOLACE (Samarium Optimized for Long-lasting Analgesia in Cancerous End-stage bone pain) is expected to enroll up to 33 patients with advanced cancer and painful osteoblastic bone metastases. Data from SOLACE aims to establish clinical comparability to legacy ^{153}Sm treatments, which in turn is expected to support a streamlined registration pathway as an analgesic, paving the way for a much-needed, non-opioid solution for patients living with bone pain in the late stages of advanced cancer.

Our Kidney Cancer and CAIX programs

Overview

CAIX is a protein expressed on the surface of ccRCC and other solid tumors, including bladder or urothelial, breast, brain, cervix, colon, esophagus, head and neck, lung, ovarian, pancreatic and vulval cancers. CAIX is overexpressed in over 95% of ccRCC tumor cells and has limited expression on healthy tissue.

CAIX is often expressed in hypoxic (oxygen deficient) tumor cells. Hypoxic tumors are also typically more aggressive and less responsive to current treatments, particularly immunotherapies. A published study has shown that tumor sections from patients that failed to respond to PD-1 blockade therapy showed significantly higher CAIX expression than those that responded (n = 19), suggesting that CAIX expression is associated with poor response to immunotherapy. Furthermore, a published study has demonstrated that in 117 hepatocellular carcinoma patients, positive CAIX expression correlated with reduced disease-free survival and overall survival.

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We believe the association between hypoxia, disease progression, and therapeutic resistance underscores the relevance of this target. Whereas normal endogenous expression of CAIX is very low, CAIX has been found to be differentially expressed on Tregs in the tumor micro-environment in a number of solid tumors. We are developing products for the detection and treatment of ccRCC and investigating the potential of CAIX as a pan-cancer target in multiple tumor types.

Market and Opportunity for Kidney Cancer Therapy

We estimate that over 25% of ccRCC patients, equivalent to over 16,000 patients per year in the U.S., have metastatic RCC. Approved treatment options for ccRCC patients include immunotherapy, tyrosine kinase inhibitors, mTOR inhibitors, and HIF-2α inhibitors. The U.S. market for systemic RCC treatment is estimated to be approximately US$6.7 billion per year based on Datamonitor's patient-based forecast, and the global market is estimated at approximately US$9.2 billion.

We are exploring the use of TLX250-Tx for the treatment of ccRCC, either in combination with an immunotherapy or as a monotherapy, to treat metastatic disease expressing the CAIX receptor. There is a significant need for new therapeutic options for patients with advanced kidney cancer, given its inherent resistance to conventional chemotherapy. Despite the transformative impact of immunotherapies on the prognosis of patients with metastatic kidney cancer, a considerable number fail to respond adequately and eventually progress.

An increasing body of scientific evidence suggests low doses of targeted radiation can potentially overcome immune resistance. This approach, known as immunological "priming," has the potential to render tumors more susceptible to cancer immunotherapy. Several pre-clinical studies have shown an enhanced therapeutic outcome of checkpoint inhibitors when they are administered after a systemic radiotherapy, including rendering immunologically inert tumors sensitive to treatment.

There is currently no CAIX-targeted radiopharmaceutical therapy approved to treat ccRCC. Several other systemic radiotherapies are being investigated to treat ccRCC targeting CAIX, and potentially could be commercialized in the future.

We consider our most direct competitors to be companies developing CAIX-targeted systemic radiotherapies, including ITM Isotope Technologies Munich SE/Debiopharm SA, Precision Molecular, Inc., Bristol Myers Squibb Company/RayzeBio, Inc., AstraZeneca PLC/Fusion Pharmaceuticals Inc. and PeptiDream Inc. Our competitors will also include companies developing other modalities to treat ccRCC.

Market and Opportunity for Kidney Cancer Imaging

According to the Global Cancer Statistics 2022: GLOBOCAN survey, global incidence of kidney cancer was 434,840 in 2022. In the U.S., the incidence of kidney cancer was 81,800 in 2022 according to the American Cancer Society. Approximately 80-90% of malignant kidney tumors are ccRCC. It is one of the subtypes with the worst prognosis and survival often depends on how early it is detected.

Kidney cancer is typically discovered incidentally and diagnosed using a number of modalities including CT scanning, MRI scanning, ultrasound, and biopsy.

The detection of renal masses is increasing due to widespread use of cross-sectional imaging. Many of these are small and represent a diagnostic challenge as current imaging techniques, including ultrasound and MRI, cannot reliably distinguish benign or malignant lesions from renal cell carcinoma, leading to invasive biopsy or partial nephrectomy (kidney removal) to confirm the diagnosis. These procedures are cumbersome and often lead to complications.

Currently, there are major unmet needs for the improvement in diagnosis of ccRCC from indeterminate renal masses as well as improving the staging of more advanced ccRCC through more accurate and specific imaging techniques. In the U.S., we estimate that there are at least 116,000 patients per year with renal masses that could require a biopsy or nephrectomy. We believe that an additional 50,000 patients with ccRCC could benefit from more accurate staging or improved identification of recurrence using molecular imaging. This market is estimated to represent approximately US$1.5 billion per year. We also believe that there may be patients that may benefit from more than one scan and from active surveillance.

Currently, there is no approved agent for CAIX imaging. We consider our most direct competitors to be companies developing ccRCC or CAIX-targeted imaging agents, including ITM Isotope Technologies Munich SE/Debiopharm SA, Philogen S.p.A., Precision Molecular, Inc., PeptiDream Inc., Norroy Bioscience Co. Ltd., and Five Eleven Pharma. Our competitors will also include companies developing other modalities to image ccRCC and CAIX.

Therapy – TLX250-Tx

TLX250-Tx (^{177}Lu-DOTA-girentuximab) is a rADC therapeutic product candidate for the treatment of kidney cancer. TLX250-Tx is currently under investigation for the treatment of patients with ccRCC in an investigator-initiated trial in combination with checkpoint and tyrosine kinase inhibitors in up to 100 patients (Phase 1b/2 STARLITE-1). In October 2025 we received ethics approval in Australia to commence LUTEON, a global Phase 2/3 trial of TLX250-Tx as a monotherapy in participants with recurrent ccRCC, who have progressive disease on or after two and no more than three prior lines of therapy.

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We are using girentuximab to target CAIX as it is designed to have a high degree of selectivity and affinity for the target and is cleared from the body by the liver. The lack of kidney excretion is an advantage for patients with primary kidney disease. We believe the target profile and the properties of girentuximab make the ccRCC phenotype promising as the first therapeutic indication for TLX250-Tx. We believe the therapeutic potential of TLX250-Tx may also extend into other cancers that significantly express CAIX, including certain VHL-induced cancers, ovarian cancer, triple-negative breast cancer and bladder cancer. We believe that our preliminary clinical data in triple-negative breast cancer and bladder cancer supports future development of TLX250-Tx in these indications.

Clinical Data

TLX250-Tx is being evaluated for the treatment of patients with ccRCC, both as a monotherapy and in combination with checkpoint inhibitors.

In October 2025 we received ethics approval in Australia to commence LUTEON, a global Phase 2/3 trial of TLX250-Tx as a monotherapy in advanced metastatic ccRCC. This global, multicenter, open-label trial will be conducted in two parts, a safety and dosimetry lead-in (Part 1), followed by randomized efficacy assessment (Part 2). The objective of Part 1 is to determine the recommended Phase 3 dose ("RP3D") for use in Part 2.

STARLITE-1 is a single arm Phase 1/2 IIT of TLX250-Tx in combination with cabozantinib and nivolumab in treatment naïve patients with advanced ccRCC. The trial, which has a target enrollment of 100 patients, is sponsored by the MD Anderson Cancer Center and commenced dosing patients in September 2025.

We believe that tumor-targeted radiation stimulates remodeling of the tumor micro-environment and can kill immunosuppressive cells and stimulate T-cell recruitment to attack tumor cells. This immune re-programming may increase the therapeutic response to treatment with checkpoint inhibitors.

TLX250-Tx was previously the subject of the exploratory Phase 2 STARLITE-2 IIT in combination with nivolumab, and the Phase 1b STARSTRUCK trial in combination with peposertib, a DNA-dependent protein kinase ("DNA-PK") inhibitor in collaboration with Merck KGaA, Darmstadt, Germany. We are now initiating the LUTEON study, a global Phase 2/3 trial of TLX250-Tx as a monotherapy in treatment-refractory disease. We believe LUTEON will generate the pivotal data required to define the optimal therapeutic activity, schedule, and treatment window for TLX250-Tx. These data are essential to inform any future development including combination regimens. In light of this, we have made the decision to close STARLITE-2 and STARSTRUCK trials at this time to ensure that any future combination-therapy development is aligned with the most robust and clinically validated dosing framework.

Therapy – TLX252-Tx

In our TLX252-Tx (^{225}Ac-DOTA-girentuximab) program, we are developing girentuximab radiolabeled with the alpha-emitting isotope actinium-225 as a potential follow-on for the TLX250-Tx (beta) program by addressing unmet need in radiation-resistant CAIX-positive disease. TLX252-Tx has demonstrated pre-clinical proof-of-concept in several published studies (Merkx et al. *Pharmaceuticals*. 2022), which we believe supports the initiation of an administered-activity escalation trial of TLX252-Tx for patients with advanced metastatic kidney cancer and other CAIX-expressing tumors.

We expect that data from our existing CAIX-targeting programs (TLX250-Px diagnostic and TLX250-Tx therapy) will complement and inform the clinical and regulatory development strategy for TLX252-Tx. In September 2025 we received ethics approval in Australia to commence ALPHIX, a first-in-human Phase 1 study of TLX252-Tx in patients with advanced metastatic kidney cancer and other CAIX-expressing tumors. CAIX is a broad indicator of aggressive, treatment-resistant disease in most solid tumors and we believe that the use of an alpha-emitter like ^{225}Ac for CAIX-targeted radiation may help overcome treatment resistance in these aggressive tumors given the unique properties of α-particles, which make this treatment modality impervious to conventional cellular resistance mechanisms.

Imaging – TLX250-Px

TLX250-Px (^{89}Zr-DFO-girentuximab) is a PET imaging candidate for the characterization of renal masses as ccRCC. We evaluated TLX250-Px in the Phase 3 ZIRCON trial in 300 patients, of which 284 were evaluable. The trial met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a mean positive predictive value of 93% for ccRCC across three independent readers. We believe this demonstrated the ability of TLX250-Px to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing ccRCC. TLX250-Px was granted breakthrough therapy designation by the FDA in 2020.

We submitted a BLA for TLX250-Px to the FDA for regulatory approval in December 2023. The BLA was granted on a rolling review process. We completed the BLA submission in May 2024, and in July 2024, the FDA declined to approve the BLA and issued an RTF determination. The denial was based on a filing concern related to demonstrating adequate sterility assurance during dispensing of TLX250-Px in the radiopharmacy production environment. In December 2024 we resubmitted our BLA to the FDA for TLX250-Px, and the FDA accepted our application in February 2025. In August 2025, the FDA issued a CRL, citing deficiencies relating to the CMC package. The FDA requested additional data to establish comparability between the drug product used in the ZIRCON Phase 3 clinical trial and the scaled-up manufacturing process intended for commercial use. Additionally, the FDA documented notices of deficiency (Form 483) issued to two third-party manufacturing and supply chain partners that required remediation prior to resubmission. In December 2025

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we participated in a Type A meeting with the FDA to align on plans to address CMC deficiencies cited, and in January 2026 we participated in an additional Type A meeting to align on plans to address comparability between the clinical drug product and that intended for commercial use. Following these meetings, Telix believes it has alignment with the Agency on all key resubmission aspects, and is working both internally and with third-party vendors to implement these items for resubmission. While we believe that the planned remediation of the BLA for TLX250-Px will meet FDA requirements, there can be no assurance that, once resubmitted, the FDA will accept our BLA for review, or approve TLX250-Px. If approved, TLX250-Px would be the first targeted radiopharmaceutical imaging agent for kidney cancer to be approved in the U.S.

The key attributes supporting development of TLX250-Px include:

- High affinity for CAIX, expressed in up to 95% of ccRCC and many hypoxic solid tumors, low expression in normal tissue;
- Positive results in Phase 3 ZIRCON trial including key secondary endpoints that demonstrated detection of ccRCC even in small renal masses (less than 4cm); and
- Breakthrough therapy designation from the FDA granted in 2020.

Breakthrough therapy designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that TLX250-Px will receive marketing approval.

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Clinical Data

In 2022, we completed the pivotal Phase 3 ZIRCON trial evaluating TLX250-Px in 300 patients, and primary results were published in Lancet Oncology in 2024 (Shuch et al. *Lancet Oncol.* 2024). The trial met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a 93% PPV for ccRCC across three independent readers. We believe this trial demonstrated the ability of TLX250-Px to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing ccRCC. Confidence intervals exceeded expectations in all three readers, showing evidence of high accuracy and consistency of interpretation.

The data from the trial demonstrated the ability of TLX250-Px to characterize renal masses as ccRCC, which could support improved clinical decision making and limiting the need for invasive procedures like biopsies and nephrectomies. A total of 300 patients were dosed with TLX250-Px in the trial and 284 patients had a central histology reading and evaluable TLX250-Px PET scan at central review.

The study also met the key secondary endpoint, achieving 85% sensitivity and 89% specificity in detecting ccRCC in tumors ≤4cm (T1a classification), currently a significant clinical challenge in the diagnosis of ccRCC. In very small renal lesions (≤2cm, a secondary endpoint), sensitivity was 84% for all three independent readers, with specificity ranging from 90.0% to 100%.

The table below provides a breakdown of the three independent reader scores, overall score and confidence intervals of the full analysis set.

	Reader 1	Reader 2	Reader 3	Overall % (95 % CI)
Sensitivity, %	84.13	85.19	87.30	**85.50**
Lowest bounds, Wilson 95% CI	78.24	79.42	81.80	(79.80; 89.80)
Specificity, %	88.42	88.42	84.21	**87.00**
Lowest bounds, Wilson 95% CI	80.45	80.45	75.57	(78.80; 92.30)
Positive predictive value, %	93.53	93.60	91.67	**93.00** (88.00; 96.00)
Negative predictive value, %	73.68	75.00	76.92	**75.00** (66.00; 82.00)
Accuracy, %	85.56	86.27	86.27	**86.00** (81.50; 89.60)

The majority of adverse events in the trial were post-surgical complications and not treatment related. A total of 261 treatment-emergent adverse events were reported in 122 of 300 patients (40.7%), of which 146 were mild, 50 were moderate and 49 were severe. Four of the treatment-emergent adverse events were life-threatening and one was fatal. 13 treatment-emergent adverse events were considered to be treatment related, of which, nine occurred before surgery and four occurred after surgery. No unexpected safety signals were observed and tolerability data were consistent with experience of girentuximab in previous therapeutic and imaging studies.

In November 2024, we dosed the first patient in the Phase 3 ZIRCON-CP study of TLX250-Px PET imaging of ccRCC in Chinese patients. The study, which will enroll up to 82 patients, is being conducted in collaboration with the Company's strategic partner for the Greater China region, Grand Pharmaceutical Group Limited ("Grand Pharma"), to demonstrate

that the diagnostic utility of TLX250-Px is equivalent in Chinese and Western populations. The clinical data from ZIRCON-CP is intended to support future marketing authorization applications for this breakthrough technology in the region.

In October 2024, we announced that we dosed the first patient in the Phase 2 CA-NINE trial, which is an investigator-initiated Phase 2 trial evaluating TLX250-Px in patients with ccRCC after surgery. The trial plans to enroll 91 patients with intermediate-to-high risk ccRCC post-surgery and is designed to identify ccRCC where it has recurred, including metastatic disease, and may inform future label expansion for TLX250-Px.

There are several other investigator-led trials of TLX250-Px that have recently completed enrollment, including the Phase 1 ZiP-UP trial in patients with metastatic urothelial carcinoma or bladder cancer, the Phase 2 OPALESCENCE trial in patients with triple-negative breast cancer, and the Phase 1 PERTINENCE trial in patients with non-muscle invasive bladder cancer ("NMIBC"). The OPALESCENCE and PERTINENCE trials reported positive preliminary data during 2022 at the European Association of Nuclear Medicine Annual Congress, with early results suggesting theranostic potential in these difficult to treat diseases. In May 2025, final positive results from the PERTINENCE trial along with preclinical data were published in *Cancers* demonstrating the promising therapeutic role of ^{211}At-girentuximab in NMIBC. In November 2025, final positive results from the OPALESCENCE trial were published in the *European Journal of Nuclear Medicine and Molecular Imaging*, demonstrating the potential for TLX250-Px to detect metastatic triple negative breast cancer ("TNBC") lesions that may be resistant to chemotherapy and therefore have a more aggressive profile resulting from hypoxia.

In November 2025, we announced results from the ZIRCON-X study which found that almost half of all patients imaged with TLX250-Px would have undergone a change in clinical management, when compared with baseline SOC imaging. ZIRCON-X was a non-interventional, prospective, post-hoc study sponsored by Telix – using imaging data from Telix's parent pivotal Phase 3 ZIRCON study – that assessed the impact of TLX250-Px imaging on clinical decision-making versus SOC contrast-enhanced diagnostic imaging in 294 patients with indeterminate renal masses ("IRMs"). The study found that 143 patients (48.6%) would have undergone a change in clinical management if imaged with TLX250-Px, and over 20% of these patients (31 out of 143) could have potentially avoided invasive biopsy. Of all evaluable patients, more than one third (110 out of 294, or 37.4%) would have had a major change in clinical management based on defined categories, with approximately 30% having their treatment escalated or de-escalated. A subset of 18 patients initially selected for active surveillance would have been escalated to immediate treatment.

Our Brain Cancer Programs and LAT1/LAT2

Overview

According to the Global Cancer Statistics 2022: GLOBOCAN survey, global incidence of brain and nervous system tumors was 321,731 in 2022. Gliomas make up approximately 30% of all brain and central nervous system tumors and 80% of all malignant brain tumors. In the U.S., according to the 2025 CBTRUS Statistical Report, the incidence of malignant glioma was 22,836.

Glioblastoma is the most aggressive sub-type of glioma, representing 14,190 cases per year in the U.S. It has a poor prognosis, primarily due to there being few effective treatment options. Glioblastoma has a median survival from initial diagnosis of 12-15 months with a 5-year survival of 7%.

The mainstay of treatment for glioblastoma is surgical resection, followed by combined radiotherapy and chemotherapy. Despite such treatment, recurrence occurs in almost all patients. Our brain cancer program targets membrane transport proteins called LAT1 and LAT2, which are important targets in cancer development as they supply tumors with essential amino acids, promoting cell proliferation, angiogenesis and mediating drug and nutrient delivery across the blood-brain barrier. LAT1 and LAT2 are highly expressed in the blood-brain barrier and in various types of cancer, including glioblastoma.

Market and Opportunity for Brain Cancer Treatment

While surgical resection plus radiation therapy are the mainstays of treatment, the vast majority of patients experience disease recurrence. Thus, there remains an important need for therapies targeted towards glioblastoma in patients in both the front-line treatment setting, as well as for patients experiencing disease recurrence following surgical intervention.

There are several systemic radiotherapies being evaluated in clinical trials for the treatment of glioblastoma. We consider our most direct competitors to be companies developing systemic radiotherapies for brain tumors, including ITM Isotope Technologies Munich SE, Molecular Targeting Technologies, Inc., EvaThera Theranostics, Novartis, RadioPharm Theranostics, Plus Therapeutics and Cellectar Biosciences, Inc. Our competitors will also include companies developing other modalities to treat brain cancer.

Market and Opportunity for Brain Cancer Imaging

We believe there are a number of opportunities to address unmet needs in the market for imaging of glioma. The first is improving the characterization of recurrence. Although MRI is the current standard of care for imaging of glioma patients, the accurate identification of recurrence remains an important unmet medical need. The U.S. market opportunity for imaging in this setting is estimated at 20,000 scans per year. This market is estimated to represent approximately US$100 million to US$140 million per year.

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The second is improving adjuvant radiation treatment planning in glioblastoma patients, which is also an important unmet medical need. The U.S. market opportunity imaging in this setting is estimated to be 15,000 scans per year.

The third opportunity is improved identification of recurrence in patients with brain metastases. The incidence of brain metastases in the U.S. is estimated to be approximately 168,000 cases per year. The U.S. market opportunity for imaging in this setting is estimated at approximately 100,000 scans per year. This aggregate market is estimated to represent approximately US$600 million per year.

There are several molecular imaging agents being evaluated in clinical trials for the imaging of glioma and brain metastases. We consider our most direct competitors to be companies developing imaging agents for brain tumors, including Novartis, Blue Earth Diagnostics, RadioPharm Theranostics, Curasight, Molecular Targeting Technologies, Inc., and EvaThera Theranostics. Our competitors could also include companies developing other modalities to image brain cancer.

Therapy – TLX101-Tx

TLX101-Tx (iodofalan ^{131}I) is our lead therapeutic product candidate for the treatment of patients with brain cancer that targets the LAT1 receptor. TLX101-Tx is a novel approach that is designed to readily pass through the blood-brain barrier, the normal protective barrier that prevents many potential drug candidates from entering the brain.

We are currently evaluating TLX101-Tx in front line and recurrent glioblastoma in the IPAX series of trials. TLX101-Tx has been granted orphan drug designation in the U.S. and Europe for the treatment of glioma. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX101-Tx will receive marketing approval.

The key attributes supporting development of TLX101-Tx include:

- IPAX-1 Phase 1 trial, demonstrated evidence of tumor responses in recurrent glioblastoma including some patients with prolonged disease stabilization, and evidence of rapid clearance of TLX101-Tx from the brain;
- IPAX-2 Phase 1 trial extended TLX101-Tx into the front-line setting, building upon experience in recurrent setting;
- TLX101-Tx has been granted orphan drug designation in the U.S. and Europe for the treatment of glioma.

In 2025, we received regulatory approval in Australia and the EU to commence the Phase 3 IPAX-BrIGHT pivotal trial of TLX101-Tx with sites open for enrollment. IPAX BrIGHT is designed to assess the safety and tolerability of TLX101-Tx in combination with chemotherapy (lomustine), compared to chemotherapy alone. The global, multicenter, open-label study is enrolling patients with radiographically confirmed recurrent glioblastoma at first recurrence. The trial consists of two parts: Part 1, a safety and dosimetry lead-in with a minimum of 18 patients, and Part 2, randomized efficacy assessment, with enrollment numbers to be determined following Part 1. Patient dosing in IPAX-BrIGHT will mark the first targeted radionuclide therapy to enter Phase 3 development for recurrent glioblastoma.

Clinical Data

In 2022, we reported the final results from the IPAX-1 Phase 1/2 trial evaluating TLX101-Tx in combination with EBRT in patients with recurrent glioblastoma. In 2024, results were published in *Neuro-Oncology Advances*, confirming the trial met its primary safety and tolerability objective.

We enrolled ten patients in the trial, nine of whom received the full dose of ~2GBq (2000 MBq) of TLX101-Tx, either in the form of a single administration or one of two triple-fractionated regimens. All dosing regimens were well tolerated. Dosimetric analysis demonstrated that radiation exposure to key organs was well within acceptable safety limits.

The trial also demonstrated a median overall survival of 23 months from initial diagnosis, or 13 months from the initiation of treatment in the recurring setting. Of the nine patients who received conventional imaging, four (44%) exhibited stable disease at day 135 and two (22%) at day 180, determined by longitudinal imaging.

The most frequent treatment emergent adverse events ("TEAEs") were decreased lymphocyte count, fatigue, headache and hiccups, which occurred in three patients (30%), followed by decreased platelet count, diarrhea, cerebral oedema (swelling), and insomnia, which occurred in two patients (20%). Except for cerebral oedema (swelling), a common adverse event following radiation to the brain, adverse events were of low grade, did not show any trends or patterns and were clinically manageable, with a significant proportion deemed unrelated to therapy.

In 2023, we initiated a Phase 1 trial, IPAX-2, to further evaluate the safety of TLX101-Tx in up to 15 patients as a front-line therapy for the treatment of glioblastoma in combination with EBRT and temozolomide. In IPAX-2, the second patient cohort has completed and the third cohort is fully enrolled.

TLX101-Tx was investigated in the recurrent setting in the investigator-initiated IPAX-Linz Phase 2 trial, which reported preliminary results in April 2025. Treatment with TLX101-Tx was well tolerated with no serious adverse events reported. IPAX-Linz demonstrated encouraging preliminary efficacy data, indicating a median overall survival ("OS") of 12.4 months from the initiation of treatment with TLX101-Tx, or 32.2 months from initial diagnosis. Five of the eight patients enrolled in

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IPAX-Linz had unmethylated MGMT promoter status, which is typically associated with poorer outcomes. These results are consistent with the positive efficacy outcomes generated in the IPAX-1 study. In comparison, recurrent glioblastoma patients treated with EBRT alone have a reported median survival of 9.9 months from treatment.

Therapy – TLX102-Tx

In our TLX102-Tx (^{211}At astato-L-phenylalanine) program, we are also exploring how phenylalanine, the same LAT1 targeting small molecule substrate used in TLX101-Tx, radiolabeled with an alpha-emitting isotope might deliver a different therapeutic profile. Astatine-211 is an alpha-emitting radioisotope with comparable halogen chemistry to Iodine-131 that can cross the blood-brain barrier. TLX102-Tx has demonstrated pre-clinical proof-of-concept and we believe that TLX102-Tx has the potential to have a favorable efficacy and safety profile in future human clinical trials in patients with glioblastoma, leptomeningeal disease, and multiple myeloma. Astatine chemistry has been demonstrated, scaled up and automated, ready for clinical production. Due to comparable target binding and molecular structure, we expect that data from our existing LAT1 theranostic programs TLX101-Px and TLX101-Tx will complement and inform the clinical and regulatory development strategy for TLX102-Tx.

In August 2020, TLX102-Tx was granted orphan drug designation from the FDA in the U.S. for the treatment of multiple myeloma, and in November 2025, TLX102-Tx was granted orphan drug designation from the FDA for the treatment of malignant gliomas. Orphan drug designation may not lead to a faster development or regulatory review or approval process in multiple myeloma or glioblastoma and does not increase the likelihood that TLX102-Tx will receive marketing approval in either of these disease areas.

In December 2025, the FDA provided positive written feedback on our proposed two-part FIH study design in patients with leptomeningeal disease ("LMD"), and acknowledged that LMD from solid tumors represents a significant unmet medical need. The FDA has also provided guidance on a combined protocol for imaging and therapy to enable a true theranostic evaluation, including potential future label expansion for TLX101-Px.

Imaging – TLX101-Px

TLX101-Px (^{18}F-FET) is a radiolabeled amino acid PET agent for imaging of gliomas that is used in clinical research settings, including in our IPAX series of trials of TLX101-Tx, as a complementary diagnostic agent. Clinical data suggest that TLX101-Px can facilitate the identification of recurrence of brain metastases. ^{18}F-FET is widely used in many jurisdictions and is recommended by the joint guidelines from the European Association of Nuclear Medicine, European Association of Neuro-Oncology, Society of Nuclear Medicine and Molecular Imaging, The European Society for Pediatric Oncology and The Response Assessment in Pediatric Neuro-Oncology for the characterization of recurrence in glioma patients. ^{18}F-FET is also included in latest NCCN Guidelines® for Central Nervous System Cancers (V1.2025) for PET imaging of gliomas.

In October 2020, TLX101-Px was granted orphan drug designation from the FDA in the U.S. for the imaging of glioma. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX101-Px will receive marketing approval.

We used TLX101-Px to select patients and track disease response in our IPAX-1 Phase 1/2 clinical trial and the recently completed IPAX-Linz investigator-initiated trial. We are using TLX101-Px in the Phase 1 IPAX-2 trial, which is actively dosing patients, and for patient selection in our pivotal IPAX BrIGHT trial, as well as assessing metabolic tumor response according to PET-based response assessment criteria for diffuse gliomas ("PET RANO 1.0").

In August 2024, we submitted an NDA to the FDA for TLX101-Px for the characterization of progressive or recurrent glioma in both adult and pediatric patients from treatment related changes through the 505(b)(2) NDA regulatory pathway. In October 2024, the FDA accepted the NDA, granted priority review and assigned a PDUFA goal date of April 26, 2025. In April 2025, the FDA issued a CRL, stating that additional confirmatory clinical evidence was required to progress the application. Following engagement with the FDA, including a successful Type A meeting, in September 2025 we reached agreement regarding the required resubmission package, which includes a retrospective analysis to supplement clinical data. We are currently finalizing our resubmission package and will provide an update upon filing. There can be no assurance that the FDA will accept our resubmitted NDA for review, or approve TLX101-Px. TLX101-Px was granted fast track designation by the FDA for this indication in April 2024. Fast track designation may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that TLX101-Px will receive marketing approval.

In February 2026 we submitted a MAA for TLX101-Px in a selection of European countries, with France acting as RMS. The French National Agency for Medicines and Health Products Safety, ANSM, in its capacity as RMS is responsible for coordinating and leading the scientific evaluation of the dossier, in collaboration with the Concerned Member States. There can be no assurance that the MAA will be validated, or that marketing authorizations for TLX101-Px will ultimately be granted.

We also intend to conduct a label-expanding Phase 3 trial of TLX101-Px for the imaging of patients with brain metastases from non-brain cancers, including lung and breast cancer.

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The key attributes supporting development of TLX101-Px include:

- Potential tool for management of progression and treatment monitoring;
- Orphan drug designation, potential to meet major unmet need; and
- Widely used in Europe and recommended in the joint guidelines for imaging of gliomas.

Clinical Data

The ability of ^{18}F-FET PET to characterize gliomas across tumor grades and clinical settings has been evaluated in multiple prospective and retrospective clinical studies (Dunet et al. *J Nucl Med.* 2012). Various imaging techniques were used to compare ^{18}F-FET PET with magnetic resonance imaging ("MRI"), ^{18}F-fluoro-2-deoxy-D-glucose ("FDG-PET"), ^{18}F-fluorothymidine, and perfusion-weighted MRI (Juhász et al. *Mol Imaging.* 2014). The findings from these trials indicated that ^{18}F-FET PET generally demonstrated higher sensitivity and specificity (Galldiks et al. *EJNMMI.* 2015; Galldiks et al. *Neuro Oncol.* 2015; Albert et al. *EJNMMI.* 2016). ^{18}F-FET was the subject of a systematic review and meta-analysis (Dunet et al. *J Nucl Med.* 2012) that included multiple studies and patient lesions, concluding that ^{18}F-FET PET may serve as a complementary modality to standard of care MRI in managing brain malignancies.

As part of our commitment to provide access to medicine, we are running an EAP in the U.S. to allow access to TLX101-Px outside of a clinical trial to patients for whom there are no comparable or satisfactory alternative options.

We are also exploring applications of TLX101-Px imaging in radiation treatment planning through the ^{18}F-FET in glioblastoma ("FIG") investigator-initiated trial. This aim is to show that TLX101-Px can help improve radiation treatment planning in a prospective, multi-center PET/CT trial.

Our Other Solid Tumors and Hematologic Oncology Programs

Soft Tissue Sarcoma and PDGFRα

Soft tissue sarcoma ("STS") is a rare, complex disease that encompasses a diverse group of relatively rare cancers, with more than 50 histological subtypes. According to the National Cancer Institute, there were an estimated 13,400 new cases and 5,140 deaths were caused by STS in 2023 in the U.S. Standard treatment for STS includes surgery, radiation therapy and/or chemotherapy. For patients with advanced, unresectable, or metastatic disease, treatment typically involves chemotherapy with single agents (e.g., doxorubicin) or anthracycline-based combination regimens. However, the prognosis for these patients remains poor, with treated patients with metastatic disease having a median overall survival of around 12–18 months.

STS is usually diagnosed using imaging tests (CT, MRI and/or FDG-PET) and/or biopsy, depending on the tumor location. Conventional imaging and biopsy are also used for staging.

There are several programs in clinical development for the treatment of STS, none of which is a targeted systemic radiotherapy. We consider our most direct competitors to be companies developing systemic radiotherapies in the soft-tissue sarcoma space, including OncoTherapy Science, RadioPharm Theranostics and Cellectar Biosciences, Inc. Our competitors will also include companies developing other modalities to treat STS.

Therapy – TLX300-Tx

In April 2022, we entered into a licensing agreement with Lilly that granted us exclusive worldwide rights to develop and commercialize radiolabeled forms of olaratumab as a targeting agent for radiopharmaceutical imaging and therapy of cancer. Lilly originally developed olaratumab a non-radiolabeled monoclonal antibody targeting PDGFRα, a protein expressed in multiple tumor types that is involved in fibrogenesis. Olaratumab has a well-established clinical and toxicology profile as a non-radiolabeled agent.

Olaratumab was granted accelerated approval in the U.S. and conditional approval in the European Union based on Phase 2 trial data. Lilly began marketing olaratumab as Lartruvo in 2016.

Sales of Lartruvo peaked at US$304.7 million in 2018. Olaratumab was voluntarily withdrawn from the market by Lilly following the failure of the Phase 3 ANNOUNCE clinical trial, in which olaratumab in combination with standard chemotherapy did not improve survival for patients compared to chemotherapy alone. We believe that the therapeutic limitations of Lartruvo can be overcome through the re-purposing of olaratumab as a radiopharmaceutical.

Our initial development focus for radiolabeled olaratumab is on advanced or metastatic STS and other PDGFRα positive tumors. Our therapeutic product candidate, TLX300-Tx, employs antibody-directed targeted radiation against PDGFRα. We believe that the ability of olaratumab to target PDGFRα makes it a promising candidate for use as a targeted radionuclide therapy.

We completed pre-clinical validation of TLX300-Tx in 2023 and initiated a FIH Phase 1 proof-of-concept targeting and biodistribution trial, ZOLAR, in April 2025. The aim of the trial is to evaluate the safety, pharmacokinetics, biodistribution and dosimetry, and establish the optimal dose of TLX300-Px using PET imaging, prior to therapeutic studies, based on a

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theranostic approach. Patient dosimetry and target expression characteristics from ZOLAR will inform selection of the therapeutic radionuclide for TLX300-Tx, in conjunction with currently active non-clinical radiation biology studies.

The key attributes supporting development of TLX300-Tx include:

- Well-established clinical and toxicology profile of olaratumab as a non-radiolabeled agent;
- First-in-human, Phase 1 proof-of-concept and biodistribution trial dosing patients in Australia; and
- Potential application in STS and a range of other cancers (e.g., bone, brain, breast, lung, ovarian and prostate cancers).

In a preclinical study of a dose of 10 MBq of TLX300-Tx in mice, we observed a significant increase in survival to tumor endpoint (P=0.0004, Log-Rank test).

Imaging – TLX300-Px

TLX300-Px (^{89}Zr-DFOsq-olaratumab) is an investigational imaging agent that we are developing for use with TLX300-Tx as a theranostic pair. DFO-squaramide ("DFOsq") is our proprietary chelator technology, designed to optimize the bioconjugate manufacture, conjugate stability and serum stability for use with this isotope. If approved, TLX300-Px would be the first imaging agent to specifically detect the presence of PDGFRα in patients with STS or other PDGFRα positive tumors.

Following the completion of pre-clinical studies, we are conducting a first-in-human Phase 1 proof-of-concept targeting and biodistribution trial in Australia using TLX300-Px. This dose-finding study is assessing safety, tolerability, dosimetry, pharmacokinetics and imaging properties of TLX300-Px in participants with STS and other PDGFRα-positive tumors, prior to therapeutic studies. We have not yet determined the specific isotope(s) that we will use in therapeutic trials.

The pre-clinical studies of radiolabeled-olaratumab have demonstrated that olaratumab can be bioconjugated with chelators and radiolabeled with imaging and therapeutic radionuclides. In a biodistribution study of TLX300-Px in mice tumor targeting reached 55% of ID/g at 120 hours post-injection, accompanied by accumulation in main clearance organs as predicted based on radiolabeled antibody clearance. We believe results of these pre-clinical studies demonstrate the viability of radiolabeling olaratumab, high uptake of the imaging agent in tumors and subsequent clearance and demonstrated anti-tumor activity with the therapy agent. Animal or pre-clinical results should be interpreted with caution as they may not correlate to results in human clinical trials.

Hematologic Oncology and CD66

Hematopoietic stem cell transplantation ("HSCT") is an important lifesaving treatment opportunity for various hematological malignancies and a variety of non-malignant conditions such as severe aplastic anemia, inherited bone marrow failure syndromes, sickle cell disease, transfusion-dependent thalassemia, inherited immune deficiency syndromes, and certain metabolic disorders. Experimentally, HSCT has been used in severe refractory autoimmune diseases.

Conditions such as acute myeloid leukemia, multiple myeloma and systemic amyloid light chain amyloidosis may also benefit from more tolerable bone marrow conditioning regimens. The utilization of novel cell and gene therapies may increase by replacing toxic chemotherapy conditioning approaches with bone marrow conditioning.

Our hematologic oncology program targets distinct members of CD66, a family of receptors expressed on specific types of immune or blood cells that serve as attractive biomarkers for novel experimental conditioning radiopharmaceuticals.

Market and Opportunity for Bone Marrow Conditioning Treatment

According to the World Wide Network of Bone and Marrow Transplantation, there were approximately 90,000 first HSCT performed in 2019, of which 47% were allogeneic. According to the U.S. Health Resources and Services Administration, there were approximately 22,000 HSCT performed in the U.S. in 2020, 41% of which were allogeneic.

Prior to undergoing HSCT for the treatment of hematologic malignancies patients undergo a bone marrow conditioning treatment. Current standard of care typically requires bone marrow conditioning with multi-drug chemotherapy regimens. However, these regimens are highly toxic, and patients may not tolerate treatment. This creates an important unmet medical need for more tolerable bone marrow conditioning regimens.

There are several systemic radiotherapies being evaluated in clinical trials as conditioning agents for HSCT. We consider our most direct competitors to be companies developing systemic radiotherapies in the hematology space, including Actinium Pharmaceuticals, Inc., Acrotech Biopharma, Inc., Cellectar Biosciences, Inc. and Jasper Therapeutics, Inc.

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Market and Opportunity for Imaging of Bone Marrow Infection (Osteomyelitis)

The incidence of osteomyelitis is estimated to be as high as 21.8 cases per 100,000 persons per year. The diagnosis of osteomyelitis is a challenge for diagnostic imaging and timely identification/localization of pathology can be of critical importance for appropriate management of patients.

Imaging modalities used to diagnose osteomyelitis can include X-ray, bone scintigraphy, CT, and MRI. These are typically combined with imaging of white blood cells to distinguish infection, sterile inflammation, and other disorders. White blood cell imaging is typically performed using *in vitro* separation and labeling of white blood cells, which requires preparation time and carries the inherent risk of contamination.

Therapy – TLX66-Tx

TLX66-Tx (^{90}Y-DTPA-besilesomab), is a product candidate for bone marrow conditioning for HSCT conditioning, a broad clinical indication.

Our HSCT conditioning agent, TLX66-Tx, has been evaluated in acute myeloid leukemia, multiple myeloma and systemic amyloid light chain amyloidosis through investigator-initiated trials. Clinical data suggest TLX66-Tx could be a well-tolerated (and therefore highly versatile) bone marrow conditioning agent which could be utilized as a single agent or in combination with either reduced or high intensity conditioning agents preceding both autologous or allogeneic HSCT. Orchard et al. (*Bone Marrow Transplantation*. 2024) reported that "All patients engrafted, treatment-related mortality 1-year post-transplant was zero. Toxicities were no greater than those anticipated for similar conditioning regimens without targeted radiation. The ability to substantially intensify conditioning prior to haematopoietic stem cell transplantation without increasing toxicity warrants further testing to determine efficacy."

TLX66-Tx is currently being studied in a Phase 2 IIT in pediatric high-risk leukemia and we plan to evaluate TLX66-Tx in a Phase 2 clinical trial as a BMC agent in patients with acute myeloid leukemia who are not suitable for conventional BMC regimes.

TLX66-Tx was granted orphan drug designation status in the U.S. and Europe. Orphan drug designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that TLX66-Tx will receive marketing approval.

The key attributes supporting the development of TLX66-Tx include:

- Minimal uptake in non-hematopoietic organs such as liver, kidneys and gut;
- Approximately 80 patients treated in several Phase 1 and 2 investigator-initiated trials of TLX66-Tx in different hematological diseases requiring autologous or allogeneic stem cell transplantation; and
- Orphan drug designation granted in the U.S. and Europe for TLX66-Tx for bone marrow conditioning.

Manufacturing TLX66-Tx and TLX66-Px utilizes a small amount of Triton X-100, which is a non-ionic surfactant, in the antibody manufacturing process. Triton X-100 is subject to a regulation in the European Union known as Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH"). We are permitted to manufacture TLX66-Tx for research and clinical development in the European Union pursuant to a self-certified exemption applicable to research and development activity. We would need to obtain authorization under REACH in order to use Triton X-100 for the future commercial manufacturing of TLX66-Tx or re-design the commercial manufacturing process for TLX66-Tx such that Triton X-100 is not used. We are currently planning to re-design the commercial manufacturing process for TLX66-Tx and potentially for TLX66-Px. We believe that any improvements to the manufacturing process we may make could also result in an increase in productivity and a potential reduction in manufacturing costs. If we re-design the manufacturing process for TLX66-Tx, we may be required to conduct additional clinical trials of TLX66-Tx or meet alternative regulatory standards.

Clinical Data

TLX66-Tx has been evaluated in over 80 patients in several IITs as a conditioning agent preceding HSCT in patients with a range of hematological malignancies, including a Phase 1 dose-escalation trial in 55 patients with hematological malignancies, a Phase 1 trial in nine patients with pediatric relapsed/refractory leukemia, a Phase 1/2a trial in nine patients with AL-amyloidosis and a Phase 2 randomized controlled trial in 25 patients with multiple myeloma. In these trials, there have not been significant toxicities and there have not been detectable non-hematological toxicities such as mucositis/colitis. In the pediatric population, TLX66-Tx has been well tolerated with no serious toxicities.

In a Phase 2 trial using TLX66-Tx and HD-melphalan in 24 patients as a conditioning agent for multiple myeloma autologous HSCT, the complete response rate in the combination cohort (12 patients) was 50%, compared to 25% in the HD-melphalan control group (12 patients).

In reported data from 30 patients out of 55 patients treated in a Phase 1 trial of TLX66-Tx, patients were given increasing doses of TLX66-Tx followed by reduced intensity conditioning and HSCT. The overall survival rate was 73% ten years after the HSCT procedure with low toxicity for TLX66-Tx. There were no severe non-hematological adverse events

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detected and efficient myeloablation, both in bone marrow and peripheral blood (the anticipated therapeutic effect and prerequisite for both successful autologous and allogeneic HSCT), was observed.

The Phase 1/2a trial evaluating TLX66-Tx in nine patients with AL amyloidosis evaluated the safety and toxicity of TLX66-Tx as a bone marrow conditioning agent prior to HSCT. All nine patients were successfully engrafted following bone marrow conditioning with TLX66-Tx and autologous HSCT without any chemotherapy. TLX66-Tx was well tolerated by all patients and had a very low toxicity profile when compared to chemotherapy-based conditioning regimes. There were no serious adverse events or transplant-related deaths.

TLX66-Tx is currently being evaluated in a Phase 2 IIT in high-risk pediatric leukemia and we also plan to develop TLX66-Tx as a bone marrow conditioning agent in high-risk acute myeloid leukemia patients in complete remission with minimal residual disease in combination with reduced intensity conditioning preceding allogenic HSCT.

Imaging – TLX66-Px

TLX66-Px (^{99m}Tc-besilesomab) is our commercial imaging agent for osteomyelitis, approved in 32 European countries and Mexico (marketed as Scintimun). Scintimun was previously manufactured and distributed by Curium Pharma through an out-license from Telix via the acquisition of TheraPharm in 2020. Curium Pharma received marketing authorization for Scintimun in the European Union in 2010 for scintigraphic imaging, in conjunction with other modalities, for determining the location of inflammation/infection in peripheral bone in adults with suspected osteomyelitis. Following a strategic review of the asset, we elected to bring sales and marketing in-house in 2025. TLX66-Px has not received marketing approval in the U.S. We are evaluating the feasibility of filing for a marketing authorization application in the U.S. where we retain the rights.

The key attributes supporting the use of TLX66-Px include:

- EMA approval for imaging of peripheral osteomyelitis in 2010; and
- Phase 3 trial showed that Scintimun imaging is accurate and well-tolerated in diagnosing infection of the peripheral skeleton and provides comparable information (Richter et al. *EJNMMI.* 2011).

Clinical Data

The approval of Scintimun was based on the results of a multicenter study performed in 22 European centers. This multinational, Phase 3 clinical study was undertaken to compare anti-granulocyte imaging using Scintimun with ^{99m}Tc-labelled white blood cells in patients with peripheral osteomyelitis. The results of this Phase 3 trial showed that Scintimun imaging is accurate and well-tolerated in diagnosing infection of the peripheral skeleton and provides comparable information to ^{99m}Tc-labelled white blood cells in patients with chronic osteomyelitis.

MedTech

Our MedTech business is advancing surgical solutions and digital products that power our precision medicines and therapeutics across the entire patient journey from diagnosis to surgical intervention and therapy. We anticipate applying this first in urology, for prostate and kidney cancer, and then across the breadth of indications we are pursuing.

Radio-Guided Surgery ("RGS")

Bringing molecular imaging into the operating theater is a key part of our portfolio strategy for urologic oncology.

In November 2023 we acquired the SENSEI radio-guided surgery business from Lightpoint Medical Ltd ("Lightpoint"). SENSEI is a miniature gamma probe device used to detect radiation in patients and guide surgery. The probe is inserted into a surgical port and can then be controlled by the clinician during the procedure. When used with targeted imaging agents, SENSEI may enable the intraoperative detection of cancer in real time, supporting greater precision in the removal of tumors.

The utility of SENSEI has been demonstrated in several studies. These include a prospective multicenter trial assessing the safety and performance of the SENSEI probe for prostate cancer sentinel lymph node biopsy. The primary objective was the sentinel lymph node dissection rate with a 100% detection rate achieved by the drop-in probe and no adverse events linked to the probe. The study concluded that the SENSEI probe meets performance and safety requirements for sentinel lymph node biopsy in prostate cancer, offering improved maneuverability and sentinel lymph node detection compared to the conventional rigid laparoscopic gamma probe. Another study covering ten patients concluded that using the probe is also safe and feasible for sentinel lymph node detection in early-stage cervical cancer. Ongoing studies in the U.S. (Weiner et al. *European Urology Open Science.* 2024) and Germany (Falkenbach et al. *Current Opinion in Urology*. 2025; Harke et al. *Clin Nucl Med.* 2024; Bravi et al. *Eur Urol Focus.* 2025) are using a PSMA-targeted radiotracer in conjunction with the SENSEI drop-in probe to detect and remove metastatic lymph nodes. One study reported successful removal in 88% of patients, with 71% achieving complete biochemical response (PSA < 0.2 ng/mL). A multicenter analysis across 11 sites (259 men) found that PSMA-radio-guided surgery led to lower postoperative PSA levels, longer time to follow-up (7 vs 24 months), and higher two-year cancer control rates (18% vs 30% BCR-free survival, 51% vs 73% CR-free survival) compared to standard surgery. These findings suggest PSMA-radio-guided surgery offers more precise treatment and better short-term outcomes for prostate cancer patients with nodal recurrence, with longer term oncological benefit still under investigation. SENSEI has a Conformité Européenne ("CE")

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mark for sentinel lymph node biopsy applications in prostate, endometrial and cervical cancers, and is registered with the FDA as a class I, 510(k) exempt medical device.

In September 2025, we announced a collaboration with IMRA Surgical, an Australian-based company at the forefront of disruptive technology for surgical training solutions, to accelerate the development of advanced training models and enhance the integration of cutting-edge radio-guided surgical technologies. IMRA Surgical has established itself as a leader in the development of synthetic surgical phantoms, medical models made from hydrogel that accurately simulate the response of actual human tissue. These models are transforming surgical training by enabling trainees to practice complex procedures in nearly lifelike conditions, without relying on cadavers or animal tissue. The company's innovative models are designed to reduce the learning curve for surgeons, ensuring that they gain hands-on experience with greater precision and efficiency, ultimately leading to fewer mistakes and better patient outcomes. As part of the collaboration, IMRA Surgical will develop a groundbreaking new hydrogel model designed specifically to support education and training in the use of Telix's SENSEI drop-in technology. This hydrogel model will be the first of its kind, providing practitioners with a realistic, hands-on training experience and facilitating a faster learning curve when adopting advanced radio-guided technology.

Through the IRiS (Imaging and Robotics in Surgery) Alliance with Mauna Kea Technologies ("Mauna Kea"), a leading medical device company pioneering the development of real-time intraoperative visualization of cancer tissue during surgery, we are exploring new hybrid pharmaceutical-device products through the combination of our cancer-targeting agents with Cellvizio, Mauna Kea's confocal surgical laser endomicroscopy in vivo cellular imaging platform.

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Dosimetry

In April 2024, we entered into an agreement to commercially partner the QDOSE dosimetry software platform with ABX-CRO and its development partner, Quantinm AB. QDOSE is a 510(k) cleared, CE-marked and Korean-FDA approved software platform designed to enable reliable estimation of patient-specific dosimetry for both therapeutic and diagnostic radiopharmaceuticals, supporting the safe and effective integration into clinical practice. We believe that personalized targeted radionuclide therapy administration based on individual patient dosimetry has the potential to improve clinical outcomes by optimizing treatment response while reducing effects on normal healthy organs and optimizing the use of isotope supply chains.

Telix holds the intellectual property rights and leads development of QDOSE. Together with our distributors that serve as manufacturer and customer support providers, we aim to advance dosimetry and make it more accessible, reliable, and impactful for healthcare providers.

Artificial Intelligence (AI)

Imaging using targeted radiation relies heavily on digital data processing and input from highly skilled and trained technicians and radiologists to correctly interpret the data. We believe that AI technology can recognize complex patterns in large datasets and conduct predictive analysis, with potential to transform imaging analysis and improve the accuracy of decision making for clinicians.

In 2023, we acquired Dedicaid GmbH and its AI platform capable of rapidly generating indication specific clinical decision support software ("CDSS") applications from available datasets, for use with PSMA-PET amongst other imaging modalities. Each CDSS application will be trained to predict outcomes such as the severity of disease, risk to the patient and/or inform treatment decisions. The platform also houses an automated machine learning engine ("AutoML"). We believe that this platform is differentiated from commercially-available AI solutions currently used in PSMA-PET imaging, which are limited to supporting clinicians in the interpretation and reading of images – without a prediction capability. The platform is designed to reduce the time, cost and level of expertise required to build, test and validate new CDSS applications, facilitating a streamlined development and regulatory pathway for each new application. We are conducting final validation of the Dedicaid platform.

The Dedicaid acquisition also included a lead medical device tool that is designed to interpret the risk of prostate cancer advancement from a PSMA-PET scan image by correlating it to a well-known histopathology indicator (the Gleason Grade). A second AI asset supporting Illuccix is designed to automate the identification and classification of prostate cancer lesions from PSMA-PET scans to support greater efficiency and standardization in the imaging workflow.

Our focus for the AI platform is to develop AI-powered solutions that support our product candidates and to enable these solutions for use by the nuclear medicine community as approved medical devices. We aim to use AI across our development pipeline by utilizing clinical imaging and outcome data as they become available and to develop and validate medical device applications supporting approved products.

Research and Development

Telix continues to diversify its drug pipeline through the advancement of a new generation of proprietary targeted biologics and with the expansion of its protein engineering and discovery research facility in Los Angeles, CA. Efforts underway are synergistically adding several early-stage drug candidates against high-value targets, including DLL3 and integrin αvβ6, enabling expansion into therapy areas with unmet clinical need. This platform of biologics is based on small, engineered antibody formats that enable highly specific cancer targeting, combined with rapid tumor uptake and blood clearance. These features allow for more directed payload delivery, helping to minimize off-target therapeutic side

effects. This technology has the potential to be highly effective for imaging and treating tumors with a broad range of radioisotopes, with diagnostic and therapeutic alpha- and beta-emitters of particular interest.

In addition to developing targeting agents, Telix is committed to utilizing isotopes with the most appropriate physical characteristics to help deliver the best possible treatments and, ultimately, improved patient outcomes. To support this, the company is continuously exploring new ways to produce and source these critical components of our drugs. One emerging alpha-emitter with significant promise is lead-212 (^{212}Pb), an isotope to which Telix has steadily increased access through the design and scale-up of a thorium-228 (^{228}Th)–based generator. Telix is preparing to introduce a fully automated, high-output generator with a small, single hot-cell footprint, sufficient ^{212}Pb production capacity for multiple clinical doses per elution, and the potential to scale based on demand. This production footprint is designed for deployment throughout Telix's manufacturing and distribution networks, including the recently acquired RLS Radiopharmacies network. This development opens new opportunities for the creation of alpha-emitting radiopharmaceuticals with a simplified production infrastructure compared with other alpha-emitting radioisotopes. The alpha-emitting profile of ^{212}Pb also offers practical synergies with the engineered antibodies described above.

Telix Manufacturing Solutions (TMS)

We are focused on enhancing our existing global manufacturing and supply chain with a balance of external and in-house capabilities, securing a robust and innovative manufacturing infrastructure and supply chain to serve our patients. Manufacturing and supply chain supporting our portfolio broadly cover the following areas: radioisotopes, radiochemistry, biologics, small molecules, fill/finish, packaging and labeling, and storage and distribution.

Since 2022, we have made significant progress with the buildout of our radioisotope manufacturing facility in Brussels South. We have been granted an updated radiation license by the Belgian Federal Agency for Nuclear Control, enabling site activation subject to the regulatory inspections and approvals.

Our approximately 30,000 square foot radioisotope manufacturing facility is one of Europe's largest radiopharmaceutical production facilities. The site will enable improved access to radiopharmaceuticals for patients across the EMEA region and the world as a primary GMP-capable manufacturing site for our clinical and Commercial Products. The site also has extensive R&D capabilities, with a focus on alpha-emitting isotopes. We believe the proximity of an alpha radiopharmaceutical laboratory to a production GMP environment is a differentiated capability to our competition. We expect the site to evolve and develop as a hub for strategic collaborations via R&D facilities and manufacturing line designated for university and SME partners.

We aim to have a degree of vertical integration in our three operating regions. In line with this goal, in 2022 we acquired Optimal Tracers, a California-based company that provides radiochemistry process development services and research tracers for use in clinical trials. The acquisition of Optimal Tracers expanded our translational radiochemistry capability and establishes a U.S.-based laboratory and production footprint for clinical trial doses, now known as TMS Sacramento.

In April 2024, we acquired IsoTherapeutics Group, LLC ("IsoTherapeutics"), a specialty radiopharmaceutical development and bioconjugation firm, based in Texas. We expect that the acquisition will further enhance our internal drug development capabilities.

In April 2024, we also acquired ARTMS Inc. ("ARTMS"), a radioisotope production technology company based in Canada, and its advanced cyclotron-based isotope production platform, manufacturing plant and stockpile of ultra-pure rare metals required for consumable target production. We expect that the acquisition will further enhance the vertical integration of our supply chain and manufacturing by providing a greater level of control and security over each of our diagnostic isotopes.

In January 2025, we acquired RLS (USA) Inc., America's only Joint Commission-accredited radiopharmacy network distributing PET, SPECT and therapeutic radiopharmaceuticals. The RLS acquisition augments our existing distribution network for last-mile delivery and provides expansionary space to build out a radiometal production network to meet future demand for radiopharmaceuticals.

In June 2025, we established TMS Yokohama, in Yokohama, Japan. Telix's first cyclotron facility in the Asia Pacific region represents a significant milestone in our global manufacturing strategy. TMS Yokohama will serve as a hub for commercial and clinical supply, and future research and development in the region. It expands our global production network which includes in-house and partner facilities. Originally opened in 2018, the site comprises a cyclotron and multiple production hot cells and was designed and built by JFE Engineering ("JFE") as the Contract Manufacturing Organization ("CMO") for TLX250-Px in Japan and China, including for the ZIRCON-CP study.

Assuming operational management of this facility will provide greater control over existing clinical supply with the possibility to expand production to other Telix investigational and future commercial products in the region, including Illuccix and Pixclara for Greater Tokyo, and TLX591-Tx for the Asia Pacific region.

During 2025, we progressed the construction of a new facility in Melbourne, Australia, to be known as TMS North Melbourne, for early-phase clinical research and radiopharmaceutical production, to support APAC translational research and clinical trials. In September 2025, both TMS North Melbourne and TMS Yokohama were granted radiation licenses for a broad range of clinically and commercially important medical isotopes.

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Our biologics, small molecule, aseptic fill/finish and commercial secondary packaging manufacturing and supply chain are accomplished through relationships with external contract manufacturing and development organizations ("CDMOs"). We have agreements with ABX-CRO, Abzena Holdings (U.S.) LLC., Curia Global, Dalton, DiverChim CDMO, Eurofins, GenScript ProBio, Goodwin Biotechnology Inc., Grand Rapids Aseptic Manufacturing, Patheon Pharma Services, PCI Pharma Services, Sharp Packaging, Sharp Sterile Manufacturing, and UPS. We are also pursuing the addition of in-house capabilities (secondary packaging, antibody conjugation, and fill/finish) where appropriate through vertical integration.

With respect to producing radiolabeled drug product, we aim to continue to deepen our relationship with key manufacturing networks in the U.S.: PharmaLogic for ^{18}F and ^{89}Zr products, and Cardinal Health for ^{68}Ga and ^{89}Zr and ^{225}Ac products. We have agreements with Evergreen Theragnostics, AtomVie Global Radiopharma, Eckert & Ziegler SE, Seibersdorf Laboratories and South Australian Health and Medical Research Institute for the manufacture of our therapeutic product candidates across multiple regions, and we are working on establishing additional key manufacturers in APAC and the European Union. Our current capabilities encompass products radiolabelled with ^{177}Lu, ^{131}I, and ^{89}Zr, and we aim to build-up our capabilities with respect to producing products radiolabelled with alpha-emitters such as ^{225}Ac and ^{212}Pb.

We are dedicated to enhancing our global supply chain capabilities, particularly for the clinical and commercial supply of isotopes used in radiolabeling, as well as for supplying generators. We have established a series of strategic supply agreements with leading industry partners to supply starting material for internal production as well as the final radioisotope used in radiolabeling. These partnerships include the Australian Nuclear Science and Technology Organisation, Cardinal Health, Eckert & Ziegler SE, Isotopia, ITM, PanTera, Radnostix, SHINE Technologies, Thor Medical, and Van Overeem Nuclear, and are pivotal in ensuring a broad and robust supply network for both therapeutic and diagnostic isotopes. By diversifying our supply chain through these contracts, we aim to create a resilient system that eliminates dependencies on a single supply chain. This approach is intended to ensure uninterrupted supply and to enhance our capability to meet growing demand.

Through these strategic agreements, we aim to maximize the available production process methods and diversify the reactors used for irradiation and production. This not only ensures a steady and diverse supply but also allows us to adapt quickly to changing market demands and regulatory environments.

We aim to actively pursue the development and supply of future isotopes. Understanding the critical role these materials play in advancing medical and scientific endeavors, we are dedicated to ensuring a robust and resilient supply chain that can adapt to the evolving needs of the industry.

Our approach is multi-faceted, focusing on strategic partnerships, technological innovation, and sustainable practices. We continuously seek to expand our network of suppliers and collaborators, forming alliances with leading entities in the field. This not only diversifies our supply sources but also fosters innovation through shared expertise and resources.

Moreover, we are investing in cutting-edge technologies and processes that enhance our production capabilities, ensuring efficiency and reliability. Our commitment to sustainability, particularly in the recycling of materials, further strengthens our supply chain, reducing environmental impact while maximizing resource utilization.

We recognize that the future of isotope supply lies in our ability to anticipate and respond to market changes and scientific advancements. Therefore, we are dedicated to ongoing research and development, ensuring that we remain at the forefront of isotope supply. Our goal is not just to meet current demands but to be a driving force in the development of new isotopes, paving the way for groundbreaking applications that can transform industries and improve lives.

Our commitment to a robust and resilient supply chain for future isotopes is unwavering. We understand the significance of our role in this dynamic field and are dedicated to maintaining the highest standards of quality, reliability, and innovation in all our endeavors.

Through these comprehensive efforts, we are seeking to position ourselves as a leader in the supply of isotopes for radiolabeling, backed by a supply chain that is as diverse as it is robust, ensuring the highest standards of quality and reliability for our clients.

Sales and Marketing Operations

Our commercial operations span the Americas, EMEA, and APAC Regions. Illuccix is approved in the U.S., Australia, Brazil, Canada, the United Kingdom, 19 European Economic Area member states, and permitted to be sold in New Zealand, and we are commercializing this product in these countries through local sales forces, which currently include over 40 associates, and together with distributor partners. Gozellix is approved in the U.S. We have secured a number of commercial partnerships covering certain geographies to enable distribution and/or commercialization of our products.

In the U.S., we have established a commercial radiopharmacy network of over 225 commercial radiopharmacies to distribute Illuccix, including partnerships with Cardinal Health, Inc., PharmaLogic Holdings, Corp., and Jubilant Pharma Ltd. We also have a distribution agreement with Isologic Innovative Radiopharmaceuticals Ltd for the Canadian market.

In Asia Pacific, we have secured a strategic collaboration with Grand Pharmaceutical Group Limited ("Grand Pharma") in the Greater China area including Mainland China, Taiwan, Hong Kong and Macau. Grand Pharma has been appointed as our partner for this territory with exclusive development and commercialization rights to our portfolio.

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In Europe, we have exclusive distribution agreements for the upcoming launch of Illuccix in a number of geographies, including with Eckert & Ziegler SE in Germany, Xiel Ltd in the United Kingdom, IRE Elit S.A. in France, Radius S.r.l. in Italy, Biokosmos S.A. in Greece and Cyprus, Sociedade Avanço, Unipessoal, Lda in Portugal, THP Medical Products Vertriebs GmbH in Austria, Czech Republic and Slovak Republic and WIIK Pharma ApS in Denmark, Finland, Norway and Sweden.

Competition

Our potential competitors include all entities developing and commercializing diagnostics and therapies in the field of oncology, through nuclear medicine and other modalities. This includes companies, academic institutions, government agencies, hospitals, other organizations involved in research, manufacturing, and commercialization of diagnostics and therapies. In addition to the current standard of care for patients, commercial and academic clinical trials are being pursued by a number of parties in the field of radiopharmaceuticals. Early results from these trials have fueled continued interest in radiopharmaceuticals, which is being pursued by several biotechnology companies, as well as by large pharmaceutical companies.

There are several companies with approved beta-based radiopharmaceuticals, including Novartis AG, Bayer AG, Sirtex Medical, Inc., Boston Scientific Corporation, Acrotech Biopharma LLC and Q BioMed Inc. and other companies developing beta-based radiopharmaceuticals, including Lantheus Holdings, Inc., Eli Lilly & Company Ltd., ITM Isotope Technologies Munich SE, Curium Holding France S.A.S, Clarity Pharmaceuticals Limited, The Bracco Group (through its Blue Earth Therapeutics Ltd. Subsidiary), and Y-mAbs Therapeutics, Inc. The beta emitting isotopes used by these companies include iodine-131, lutetium-177, strontium-89, copper-67, and yttrium-90.

There are several companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer, including Bayer AG, Novartis AG, AstraZeneca PLC/Fusion Pharmaceuticals Inc., Alpha Tau Medical, ARTBIO, Inc., Orano Med SAS, Johnson & Johnson, Abdera Therapeutics, Inc., Actinium Pharmaceuticals, Inc, Aktis Oncology, Inc., Convergent Therapeutics, Inc., ITM Isotope Technologies Munich SE, Perspective Therapeutics, Inc., Eli Lilly & Company Ltd., RadioMedix, Inc., Bristol Myers Squibb Company and Y-mAbs Therapeutics, Inc. The only approved alpha particle-based therapy is Bayer's Xofigo (Radium-223) which was approved in 2013 for the treatment of prostate cancer with symptomatic bone metastases.

We consider our most direct competitors to be companies developing and commercializing diagnostics and therapies in our core therapy areas, including prostate cancer, kidney cancer, bladder cancer, brain cancer, sarcoma, and hematology.

In prostate cancer therapy, Pluvicto (lutetium (^{177}Lu) vipivotide tetraxetan), marketed by Novartis AG, was approved by the FDA for the treatment of patients with PSMA-positive mCRPC who have been treated with androgen receptor pathway inhibition and taxane-based chemotherapy in March 2022. In March 2025, Pluvicto was approved by the FDA for earlier use prior to chemotherapy, in PSMA-positive mCRPC. Pluvicto is the only FDA-approved PSMA-targeted therapy for the treatment of prostate cancer. Several other systemic radiotherapies are being investigated in clinical trials in the mCRPC setting and across other stages of prostate cancer, and potentially could be commercialized in the future.

In mCRPC treatment, there are several companies developing PSMA-targeted therapies in the mCRPC space, including Novartis AG, Convergent Therapeutics, Inc., Eli Lilly & Company Ltd., Lantheus Holdings, Inc, Curium Holding France S.A.S, ARTBIO, Inc., The Bracco Group (through its Blue Earth Therapeutics Ltd. subsidiary), Clarity Pharmaceuticals Ltd., AstraZeneca PLC, Bayer AG, Orano Med SAS, Isotopia Molecular Imaging Ltd, ITM Isotope Technologies Munich SE, Johnson & Johnson, AdvanCell Isotopes Pty Ltd, Alpha-9 Theranostics, Inc., Cancer Targeted Technology, LLC, FutureChem Co Ltd., Sinotau Pharmaceutical Group, Norroy Biosciences Co. Ltd., RadioPharm Theranostics Limited, Precision Molecular, Inc., CellBion Co., Ltd., StarPharma Holding Limited, Amgen Inc., Crescendo Biologics Limited, Poseida Therapeutics, Inc., Janux Therapeutics, Inc., Vir Therapeutics, Inc., Bivision Pharmaceuticals, Inc., GlyTherix Ltd, Jiangsu Hengrui Pharmaceuticals Co., Ltd and Full-Life Technologies Limited. Our competitors also include companies developing other modalities to treat patients with mCRPC.

In prostate cancer imaging, UCLA and UCSF obtained FDA approval for ^{68}Ga-PSMA-11 in 2020, this was the first PSMA-PET imaging agent to be approved by the FDA. Pylarify (^{18}F-piflufolastat), marketed by Lantheus Holdings, Inc, was approved by the FDA in 2021. Locametz (^{68}Ga-PSMA-11), marketed by Novartis, received FDA approval in 2022 and Posluma (^{18}F-flotufolastat), marketed by The Bracco Group (through its Blue Earth Diagnostics Ltd. subsidiary), received FDA approval in 2023. Several other PSMA-PET product candidates are being evaluated in clinical trials for prostate cancer imaging and may be commercialized in the future. Companies developing PSMA-PET imaging agents include Curium Holding France S.A.S., Clarity Pharmaceuticals Limited, ABX advanced biochemical compounds GmbH, Isotopia Molecular Imaging Ltd, Itel Telecomunicazioni Srl, ITM Isotope Technologies Munich SE, Five Eleven Pharma, Inc., RadioMedix, Inc., CellBion Co., Ltd., Norroy Biosciences Co. Ltd., HTA Co. Ltd and Jiangsu Hengrui Pharmaceuticals Co., Ltd.

In kidney cancer therapy, there are several companies developing CAIX-targeted systemic radiotherapies, including ITM Isotope Technologies Munich SE, Precision Molecular, Inc., Norroy Biosciences Co. Ltd., AstraZeneca PLC/Fusion Pharmaceuticals Inc., PeptiDream Inc., Bayer AG and Bristol Myers Squibb Company. Our competitors also include companies developing other modalities to treat patients with kidney cancer.

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In kidney cancer imaging, there are several companies developing ccRCC or CAIX-targeted imaging agents, including ITM Isotope Technologies Munich SE, Philogen S.p.A., ImaginAb, Inc., Precision Molecular, Astellas Pharma, Inc., Norroy Biosciences Co. Ltd., PeptiDream Inc., and Five Eleven Pharma, Inc.

In bladder cancer therapy, there are several companies developing systemic radiotherapies, including Aktis Oncology, Inc., Glytherix Ltd., AstraZeneca PLC and NuView Life Sciences, Inc. Our competitors also include companies developing other modalities to treat patients with bladder cancer.

In glioblastoma therapy, there are several companies developing systemic radiotherapies for brain tumors, including ITM Isotope Technologies Munich SE, PeptiDream Inc., Molecular Targeting Technologies, Inc., EvaThera Theranostics, Novartis AG, RadioPharm Theranostics Limited, Plus Therapeutics, Inc., Ariceum Therapeutics GmbH, Boston Scientific Corporation, and Cellectar Biosciences, Inc. Our competitors also include companies developing other modalities to treat patients with glioblastoma.

In brain cancer imaging, there are several companies developing imaging agents for primary brain tumors and brain metastases, including Novartis AG, The Bracco Group (through its Blue Earth Diagnostics Ltd. subsidiary), RadioPharm Theranostics Limited, Curasight A/S, Molecular Targeting Technologies, Inc., and BoomRay Pharmaceuticals Co., Ltd.

In sarcoma, there are several companies developing systemic radiotherapies in the soft-tissue sarcoma space, including OncoTherapy Sciences, Inc., RadioPharm Theranostics Limited, Ratio Therapeutics, Inc., Y-mAbs Therapeutics, Inc., and Cellectar Biosciences, Inc.

In hematology, there are several companies developing systemic radiotherapies in the hematology space, including Actinium Pharmaceuticals, Inc., Bayer AG, Sensei Biotherapeutics, Inc., ImaginAb, Inc. Acrotech Biopharma Inc., Nordic Nanovector ASA, Orano Med SAS, Samus Therapeutics, Inc., Cellectar Biosciences, Inc. and Jasper Therapeutics. Inc.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe adverse events, are more convenient to administer, are less expensive or with a more favorable label than our product candidates. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be efficacy, safety, convenience, price, availability of the relevant isotope, the effectiveness of imaging diagnostics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

Overview

Patent Protection

By their very nature, radiopharmaceuticals must be delivered through a complicated supply chain and go-to-market model requiring specialized physics, chemistry and biological expertise for successful development and commercialization protected by know-how and trade secrets. This specialization provides a practical barrier to competitor entry without the same specialist expertise. Additionally, we aim to build, maintain and continuously improve our exclusivity and patent position to protect our innovation contribution. We aim to integrate regulatory filing strategy designed to maximize regulatory market or data exclusivity and through targeted patent protection across the spectrum of compound, dosing, radiolabeling technology, handling, preparation process and manufacturing inventions.

Older radiopharmaceuticals were historically routinely used in the public domain for many years under practice of pharmacy or individual named patient prescribing regulatory pathways. This has the benefit of established use and real-life clinical application and experience for such products when made commercially available, but does potentially create the result that patent protection is not available or has only limited remaining patent term.

Our original third-party licensed products were in-licensed and were accepted on an “as-is” basis. We have limited opportunity to determine or influence territory and scope of third-party licensor portfolio and the time to make changes to scope or territory has long since passed under applicable patent laws. However even for these earlier products, we have expanded our patent portfolio where possible and seek to obtain related new patents for updates in handling, dosing and manufacturing to maximize patent exclusivity where feasible, in addition to our supply chain know-how and trade secrets.

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For our newer programs and next generation radiopharmaceuticals, the patent protection is deeper and wider across the spectrum of compound, method of treatment, dosing, radiolabeling technology, handling, preparation process and manufacturing inventions based on our newer proprietary technologies or due to our innovation in the end-to-end process.

We have in-licensed registered intellectual property associated with our key therapeutic products: TLX591-Tx, TLX250-Tx, TLX101-Tx, TLX102-Tx, TLX090-Tx, TLX300-Tx, TLX66-Tx, TLX597-Tx, and related imaging product TLX250-Px in addition to supplementary intellectual property owned by us. Intellectual property for Illuccix, Gozellix, TLX592-Tx, TLX252-Tx, TLX400-Tx. RHN001-Tx and RHN001-Dx, and TLX101-Px is wholly owned by us. We have also filed our own applications for registered patents and trademarks in respect of our key products.

Patents are granted by national and regional intellectual property offices in accordance with the corresponding national laws. Granted patents provide a right to exclude others from making, using, selling, offering to sell, or importing the invention as set forth in the claims of the patent. Protection is generally limited to actions in or relating to the countries in which protection is obtained, and enforcement is generally by litigation.

Patents generally have a maximum term of 20 years after its earliest effective filing date, subject to the payment of renewal fees in all the relevant countries.

In the field of pharmaceuticals, patent term extensions or supplementary protection certificates may extend the term of a patent beyond 20 years in certain jurisdictions. Examples of important jurisdictions where these regimes are available are the U.S., Europe, China, Japan and Australia. Many of the patents and patent applications, if granted, that are in-licensed or owned by us may be able to be extended under the patent term extension or supplementary protection certificate regimes (in jurisdictions where these regimes are available) once the key products have been the subject of regulatory approval as the claims are directed to pharmaceutical products and their uses. The extensions in term are typically up to five years in duration and are often related to the delay between the grant of the patent and regulatory approval of the pharmaceutical product.

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Requirement for Patentability

The requirements for patentability differ in detail from country to country. However, in general terms the main requirements are that the invention relate to patentable subject matter; that the invention is novel and has an inventive step; and that the patent contain an adequate disclosure of performing or making the invention. In order to be novel, the invention must not have been disclosed in writing or otherwise in public, or offered for sale, before the priority date. The requirement of inventive step is, in general terms, that the invention must go beyond what the skilled worker in the field would arrive at as a matter of course when attempting to address the same problem as the invention.

Procedure for Obtaining Patent Protection

Patents are granted on a national basis. International patent protection is based upon a system of well-established and widely adopted international conventions. The first application for a patent for an invention is called the priority application, and its filing date is known as the priority date. If patent applications having the same specification are filed within a year from the priority date in other countries, then (in accordance with the Paris Convention, World Trade Organization ("WTO") Treaty and bilateral agreements) they retain the effective filing date of the priority application for the purpose of assessing novelty and inventive step.

There are three different types of patent application of relevance. A provisional application acts as a filing to obtain a priority date. It does not proceed to grant and is not examined by the patent authorities; rather, a later application must be filed within a year of its priority date to claim the benefit of that filing. A national filing is a regular patent application in a particular country or region. It will be examined in most cases by the local or regional patent authorities. Applications can be filed directly in the country or region, or using another convention called the Patent Cooperation Treaty ("PCT"). The PCT allows for a single application to be filed in a single patent office, designating all the member states, obtain a preliminary search and opinion, and delay filing into the national and regional intellectual property offices for a period of 30 months from the priority date. The PCT currently has 148 members, including all OECD member countries. At the end of this period, national filings must be made in the countries of interest.

The patent application is examined in each country (or in some cases regional offices) according to its national laws and procedures.

Potential Limitations of Patent Protection

Certain limitations are inherent in the patent system. In all relevant countries it is possible to challenge the validity of a patent even after it has been granted by the intellectual property office. This may be possible by administrative processes at the relevant patent office, court procedures, or both. However, the laws of some jurisdictions do not protect intellectual property rights in the same manner and to the same extent as laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all jurisdictions outside the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement of such patent protection is not as strong as that in the U.S. These products may compete with our products and any then-

approved product and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

A successful challenge to validity will result in the claims of the patent being narrowed in scope, or the patent being completely revoked. The grant of a patent by a patent office does not mean it is valid. Because of the limited scope of material searchable by the patent office, compared to the potential to use documents or act before the priority date that may not have been identified by the patent office to attack validity, there is a risk that presently unknown disclosures or actions relevant to patentability will be discovered at a later time, with consequent risks to validity. The scope of a granted patent may be significantly different to a pending application, and so it is not possible to advise with certainty in relation to infringement of a pending application.

Pending patent applications may never proceed to be granted patents. It is not generally possible to commence a patent enforcement action based on a pending application; it is necessary to obtain a granted patent. However, damages in some instances and in some jurisdictions may be backdated for part of the period of pendency. To our knowledge, none of the patents and patent applications in-licensed or owned by us are presently the subject of a challenge by a third-party. EP0956506 has previously been challenged in opposition proceedings before the European Patent Office but the opposition was successfully dismissed.

Trademarks

Registered trademarks protect indications which serve to distinguish the goods or services of one competitor from those of others, and provide the trademark owner with the exclusive right to use or authorize others to use the trademark in relation to the goods and services for which it is registered. Trademarks are granted generally on a national or territorial basis. International filings are governed by international treaties to simplify the process of securing trademark protection at the national or territorial level of parties to the relevant international treaties, in a similar manner to patents. In particular, international trademark applications made through the World Intellectual Property Organization under the Madrid Protocol offer a six-month priority period from the application filing date. Generally, the intellectual property offices in each country or territory conduct searches and examination of trademark applications prior to registration. Trademark applications are subject to the pace of examination in the relevant national intellectual property office. It is not unusual for a trademark application to be pending for a period of six months to two years prior to grant, but some trademark applications may be pending for years. Trademarks may be subject to challenge by third parties in most jurisdictions before and after registration, with many national or territorial intellectual property offices offering administrative and/or judicial processes to address challenges to the relevant trademark on various grounds, which often include likelihood of confusion concerns with senior trademark registrations.

In total, as of December 31, 2025, we own 26 registered U.S. trademarks, 14 pending U.S. trademark applications, 179 foreign trademarks registered in jurisdictions such as Australia, Europe, China, Brazil and Japan, and 93 pending foreign trademark applications applied for in jurisdictions such as Australia, Europe, China, Brazil and Japan. We currently have trademark registrations in the U.S. for the Telix Pharmaceuticals name, the Illuccix name and logo, the Gozellix name and logo, the Pixclara name and logo, the ANMI name, the SENSEI name, the ARTMS name, and the RADMAB name and other trademarks are pending in the U.S. such as Zircaix. Outside of the U.S., Illuccix is registered in Australia, Brazil, Canada, China, the European Union, India, Israel, Japan, Malaysia, New Zealand, Norway, Peru, Philippines, South Korea, Singapore, Switzerland, Taiwan, Türkiye, the United Kingdom and is pending in Thailand. We have also selectively filed the following names and logos outside of the U.S.: Pixclara, Gozellix, Zircaix, ANMI, ARTMS, and RADMAB.

Data and Market Exclusivity Provisions

Data and market exclusivity provisions relating to the regulatory approval of pharmaceutical products exist in each relevant jurisdiction. The provisions provide periods during which a competitor is limited in their ability to seek and/or obtain regulatory approval for a generic or similar product. Data exclusivity relates to the period in which information relating to the safety and efficacy of a product, provided to a regulatory authority for the purposes of obtaining regulatory approval, remains confidential, or cannot be relied upon by the regulatory authority or a third-party in order to obtain regulatory approval of another. Data exclusivity is separate from other forms of exclusivity, such as the monopoly provided by patents. In some instances, the period of data exclusivity may extend beyond the term of any patent which protects the same product. Market exclusivity refers to a period where a party wishing to sell a product is prohibited from doing so, even if regulatory approval has been obtained.

As our key products are radio pharmaceutical products, they will have the benefit of periods of data and market exclusivity available in each jurisdiction following regulatory approval. These are typically five years or more in duration (and eight years data exclusivity plus two years market exclusivity for European jurisdictions).

Our Patent Portfolio

Our commercial success depends in part on our ability to obtain and maintain regulatory exclusivity, proprietary or intellectual property protection for our products and product candidates, our core technologies, and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary or intellectual property rights. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and in foreign jurisdictions related to our proprietary technology and products and product candidates. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

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We also in-license patent portfolios relating to our product pipeline and to emerging product candidates as well as technologies that are adjacent such as radiolabeling technologies, linker technologies, chelator technologies, bioconjugation techniques, antibody manufacturing and modifications, isotope manufacture, AI techniques and applications, and medical imaging devices,

In total, as of December 31, 2025, we have in-licensed 40 U.S.-issued patents and 408 foreign-issued patents granted in jurisdictions such as Australia, Canada, Germany, Italy, Spain, the United Kingdom, France, Türkiye, Russia, Japan, China, Korea, Singapore, India, Israel, Mexico, and Brazil. As of December 31, 2025, we have also in-licensed 10 pending non-provisional U.S. patent applications, 66 pending foreign-patent applications applied for in jurisdictions such as in Australia, Canada, Europe, Russia, Japan, China, India, Mexico, and Brazil, and one pending international application filed under the PCT. The PCT is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in each of the member states. Although a PCT application is not itself examined and cannot issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

In total, as of December 31, 2025, we own either solely, or jointly with our commercial partners, 15 U.S.-issued patents and 118 foreign patents granted in jurisdictions such as Australia, Canada, Germany, Italy, Spain, the United Kingdom, France, Türkiye, Russia, Japan, China, India, Israel, Mexico, and Brazil. As of December 31, 2025, we also have pending, either solely or jointly with our commercial partners, 38 non-provisional U.S. patent applications, 182 foreign patent applications applied for in jurisdictions such as in Australia, Canada, Europe, Japan, China, Korea, Singapore, India, Israel, Mexico, and Brazil, and 18 pending international applications filed under the PCT.

The intellectual property portfolios for our key products and product candidates as of December 31, 2025 are summarized below:

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Illuccix and Gozellix

Our Illuccix patent portfolio covers the pharmaceutical product and the unique arrangement of components of the kit as well as methods of making gozetotide. The patent family directed to the pharmaceutical product and the unique arrangement of components of the kit consists of five U.S.-issued patents; 53 foreign-issued patents granted in Australia, Canada, Belgium, Finland, Switzerland, Lichtenstein, the Czech Republic, Denmark, Austria, Greece, Hungary, Ireland, the Netherlands, Norway, Portugal, Sweden, Germany, Italy, Spain, the United Kingdom, France, Türkiye, Russia, Japan, China, India, Israel, Mexico, South Africa, New Zealand and Brazil, six pending foreign patent applications applied for in Europe, India and Hong Kong, and four pending U.S. non-provisional applications. The patent family directed to methods of making gozetotide consists of one pending U.S. non-provisional patent application and ten pending foreign patent applications in Australia, Brazil, Canada, Mexico, China, Europe, Japan, Korea, Hong Kong and Singapore.

There is one U.S. patent registered under the U.S. Orange Book which is directed to methods of imaging using the pharmaceutical product prepared with Illuccix.

Any patents that may issue in the U.S. as part of our patent portfolio directed to the pharmaceutical product or the kit will expire no earlier than 2035, not including any terminal disclaimer, patent term adjustment due to administrative delays by the U.S. Patent and Trademark Office ("USPTO") or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2035. Any patents that may issue in the U.S. directed to methods of making gozetotide will expire in 2042, absent any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire in 2042.

The Illuccix patent portfolio also covers Gozellix. In addition, there is one patent family directed solely to the formulation of Gozellix comprising one pending U.S. non-provisional application and one PCT application which has yet to enter the National Phase. Any patents that may issue in the U.S. as part of our patent portfolio directed to the pharmaceutical product or the kit will expire no earlier than 2045, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO, or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2045.

TLX250-Px (^{89}Zr-DFO-girentuximab) and TLX250-Tx (^{177}Lu-DOTA-girentuximab)

We have in-licensed six patent families from Heidelberg Pharma AG (formerly Wilex AG) directed to the CAIX-targeting girentuximab antibody and various therapeutic and imaging applications thereof.

The in-licensed patent portfolio includes three U.S.-issued patents, 17 foreign-issued patents granted in Australia, Canada, Germany, Spain, Italy, France, the United Kingdom, Korea, New Zealand, South Africa, Israel, Russia and Mexico, and one foreign patent applications applied for in China. Expiry dates vary from 2026 to 2034 across the portfolio, not including any patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, or equivalent provisions in foreign jurisdictions.

We have two patent families directed to aspects of the manufacture of TLX250-Px. These patent families include two pending U.S. non-provisional patent applications and 16 foreign patent applications in Australia, Brazil, Canada, Europe, Korea, Singapore, China and Japan. Any patents that may issue in the U.S. based on the non-provisional U.S. patent applications will expire no earlier than 2042, not including any terminal disclaimer, patent term adjustment due to

administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2042.

We have one patent family directed to the use of TLX250-Px in imaging CAIX-expressing cancers other than ccRCC. This patent family consists of one pending U.S. non-provisional patent application and nine foreign patent applications in Brazil, Singapore, China, Mexico, Australia, Canada, Japan, Korea and Europe. Any patents that may issue in the U.S. based on the pending PCT application will expire no earlier than 2043, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2043.

We have one patent family directed to the use of TLX250-Tx in therapy of CAIX-expressing cancers other than ccRCC. This patent family consists of one pending PCT application. Any patents that may issue in the U.S. based on the pending PCT application will expire no earlier than 2043, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2043.

We have one patent family directed to combinations of TLX250-Tx with checkpoint inhibitors. This patent family consists of one pending U.S. non-provisional patent application and 6 foreign patent applications applied for in Australia, Brazil, Canada, Europe, Mexico and Singapore. Any patents that may issue in the U.S. based on the pending PCT application will expire no earlier than 2043, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2043.

We have one patent family directed to the combination of TLX250-Tx with DNA damage repair inhibitors. This patent family includes one pending U.S. non-provisional patent application and ten foreign patent applications applied for in Australia, Brazil, Canada, Europe, Israel, Korea, Mexico, Singapore, China and Japan, Any patents that may issue in the U.S. based on the U.S. non-provisional patent application will expire no earlier than 2042, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2042.

As biological products, TLX250-Px and TLX250-Tx will be entitled to 12 years data exclusivity from the date of product approval.

TLX252-Tx (^{225}Ac-DOTA-girentuximab)

We have a single patent family patent directed to the composition of matter of TLX252-Tx, its radiolabeled forms and uses in imaging and therapy. The patent family includes one pending U.S. non-provisional patent application and 16 pending foreign patent applications in Canada, Chile, China, India, Japan, Korea, Mexico, Australia, Europe, Eurasia, India, New Zealand, Brazil, Hong Kong, Israel and Singapore. Any patents that may issue in the U.S. will expire no earlier than 2040, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2040.

TLX101-Px (^{18}F-FET)

We have orphan drug and fast track designation for TLX101-Px in the U.S., which we expect to yield up to seven years regulatory exclusivity following product approval.

TLX101-Tx (^{131}I-IPA) and TLX102-Tx (^{211}At-APA)

We have in-licensed a patent portfolio directed to methods of treatment using TLX101-Tx and TLX102-Tx from Dr. Samuel Samnick, a German nuclear medicine researcher. There are two U.S.-issued patents which will expire no earlier than 2028 and 2031 respectively, not including any patent term extension under the Hatch-Waxman Act. There are eight foreign issued patents in Australia, Canada, Germany, the United Kingdom, Spain, France, Japan, and Korea which will expire no earlier than 2026.

We have in-licensed a patent portfolio directed to a method of manufacturing TLX101-Tx and TLX102-Tx from Osaka University. There are two U.S.-issued patents, one pending U.S. non-provisional application, seven foreign-issued patents in Australia, Japan, Switzerland, Lichtenstein, Spain, the United Kingdom, and Türkiye, one foreign issued patent under the European Unified Patent Convention (which covers Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovenia, and Sweden) and two pending foreign applications in Europe and Hong Kong. Any patents in this portfolio that may issue in the U.S. will expire no earlier than 2038, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2038.

We have one PCT application directed to combinations of TLX101-Tx and other chemotherapeutic agents. Any patents that may issue in the U.S. based on this PCT application will expire no earlier than 2045, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2045.

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We have orphan drug designation for TLX101-Tx in the U.S. and Europe and for TLX102-Tx in the U.S. which will grant us the customary regulatory exclusivity, currently expected to be up to seven years from date of product approval.

TLX591-Tx (lutetium (Lu177) rosopatamab tetraxetan)

We have sub-licensed a Cornell University (and associated entities) patent portfolio from Convergent Therapeutics, Inc as successor in title of BZL Biologics LLC. The portfolio is directed to TLX591-Tx and combination therapies of TLX591-Tx with androgen deprivation therapy.

The sub-licensed patent portfolio includes one U.S.-issued patent, one pending U.S. non-provisional patent application, 14 foreign-issued patents in Belgium, Canada, Japan, Germany, France, Spain, the United Kingdom, Luxembourg and the Netherlands, and a pending foreign application in Europe directed to combinations with androgen deprivation therapy.

Any patents that may issue in the U.S. will expire no earlier than 2028, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2028.

As a biological product, TLX591-Tx will be entitled to 12 years data exclusivity from the date of product approval.

TLX592-Tx (^{225}Ac-RADmAb®)

We have a single patent family patent directed to the composition of matter of TLX592-Tx, its radiolabeled forms and uses in imaging and therapy. The patent family includes one pending U.S. non-provisional patent application, one granted Japanese patent, and 16 pending foreign patent applications in Canada, Chile, China, India, Japan, Korea, Mexico, Australia, Europe, Eurasia, India, New Zealand, Brazil, Hong Kong, Israel and Singapore. Any patents that may issue in the U.S. will expire no earlier than 2040, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2040.

TLX592-Tx is currently in early development so regulatory pathway to product approval is not yet confirmed or known, however the customary regulatory exclusivity period is expected to apply.

TLX300-Px (^{89}Zr-olaratumab) and TLX300-Tx

We have two patent families directed to radiolabeled forms of olaratumab and their use in imaging and therapy. The patent family includes two pending U.S. non-provisional patent applications and 16 pending foreign applications filed in Australia, Brazil, Canada, China, Europe, Japan, Korea, and Mexico. Any patents that may issue in the U.S. will expire no earlier than 2043, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents that may issue in foreign jurisdictions will likewise expire no earlier than 2043.

TLX66-Px (^{99m}Tc-besilesomab, Scintimun) and TLX66-Tx (^{90}Y-DTPA-besilesomab)

We have one patent family directed to the use of TLX66-Tx in the treatment of multiple myeloma. The patent family includes one U.S.-issued patent and foreign-issued patents in Canada, Australia, and Europe (validated in Belgium, Germany, Spain, France, the United Kingdom and Italy). The U.S. patent has a maximum expiry date of 2031, not including any patent term extension under the Hatch-Waxman Act. The other patents will expire no earlier than 2026.

A second patent family is directed to the use of TLX66-Tx for treating AL-amyloidosis and for specific bone-marrow conditioning. We have one pending U.S. non-provisional patent application and pending applications in China, Japan and Canada.

The second family includes a granted patent in Europe which has been validated under the unitary patent system (which covers seventeen European countries and includes coverage of Belgium, Germany, France, and Italy) and has also been validated in Switzerland, Spain, and the United Kingdom. There are also foreign-issued patents in Australia and South Africa.

Any patents in the U.S. that may issue in the second family will expire no earlier than 2038, not including any terminal disclaimer, patent term adjustment, or patent term extensions under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2038.

We have one PCT application directed to the use of TLX66-Px (Scintimun) in dosimetry. Any patents that may issue in the U.S. based on the pending PCT application will expire no earlier than 2045, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2045.

TLX090-Tx (^{153}Sm-DOTMP)

We have in-licensed three patent families from IGL Pharma, Inc in connection with our acquisition of QSAM Biosciences, Inc., which are directed to methods of manufacturing TLX090-Tx, kits comprising TLX090-Tx, and its use in treatment.

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The portfolio includes five U.S.-issued patents, 39 foreign-issued patents in Canada, Germany, France, Great Britain, Hungary, Ireland, Iceland, Italy, Luxembourg, the Netherlands, Norway, Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Finland, Poland, Portugal, Slovakia, Slovenia, Sweden, Switzerland, Türkiye and Japan, and three pending foreign patent applications in Japan and Europe. Any patents issued in the U.S. will expire no earlier than 2035, not including any terminal disclaimer or patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2035.

TLX400-Tx (^{177}Lu-DOTAGA.Glu.(FAPi)$_2$)

We have one patent family directed to the composition of matter of TLX400-Tx. The family includes one granted German utility patent, one pending U.S. non-provisional patent application and nine foreign patent applications in Australia, Brazil, Canada, China, Europe, India, Japan, Korea and Hong Kong. The granted German utility patent will expire no earlier than 2031. Any patents issued or that may issue based on the pending application in the U.S. will expire no earlier than 2042, not including any terminal disclaimer or patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2042.

TLX593-Px

We have in-licensed a PCT application from the University of Ghent directed to methods of preparing TLX593-Px and associated compositions of matter. Any patents issued or that may issue based on the pending PCT application in the U.S. will expire no earlier than 2045, not including any terminal disclaimer or patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2045.

TLX597-Tx

We have in-licensed a patent family directed to the composition of matter of TLX597-Tx from Instituto Nacional de Investigaciones Nucleares ("ININ") a nuclear medicine research organization. The license covers all territories except Mexico and South Africa. The patent family includes one U.S. issued patent and foreign issued patents in Eurasia, China, Hong Kong, the United Kingdom, Switzerland and Spain, and one foreign issued patent under the European Unified Patent Convention (which covers Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovenia, and Sweden). There are three foreign patent applications filed in Brazil, Canada, and Egypt. Any patents issued or that may issue in the U.S. will expire no earlier than 2039, not including any terminal disclaimer or patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2039.

We have one unpublished PCT application directed to novel radiolabeled forms of TLX597-Tx. Any patents that may issue in the U.S. based on the pending PCT application will expire no earlier than 2045, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2045.

RHN001-Tx and RHN001-Dx

We have one patent family directed to RHN001-Tx and RHN001-Dx as a composition of matter. The patent family includes one U.S non-provisional patent application and patent applications in Europe, Canada, Australia, India, South Africa, Mexico, China, Eurasia, Brazil and Hong Kong. Any patents that may issue in the U.S. will expire no earlier than 2042, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2042.

TLR602-Tx and TLR603-Tx

We have one PCT application directed to TLX602-Tx as a composition of matter. Any patents that may issue in the U.S. based on the pending PCT application will expire no earlier than 2044, not including any terminal disclaimer or patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2044.

We have one patent family directed to TLX603-Tx as a composition of matter. The patent family includes one U.S non-provisional patent application and patent applications in Europe, China, Korea, Mexico, Japan, Singapore, Brazil, Australia, Canada, and Hong Kong. Any patents that may issue in the U.S. based on the pending PCT application will expire no earlier than 2043, not including any terminal disclaimer, patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2043.

Lightpoint Medical

In connection with our acquisition of Lightpoint's radio-guided surgery business, we acquired a patent portfolio relating to surgical applications of radiopharmaceuticals including the SENSEI probe. The patent portfolio comprises five U.S.-

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issued patents, 25 foreign-issued patents in Australia, China, Belgium, Luxembourg, Switzerland, Germany, Italy, France, the Netherlands, Spain and the United Kingdom, one granted European patent which has been validated in Great Britain, Spain and under the European Unified Patent Convention (which covers Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovenia, and Sweden), and two pending non-provisional U.S. applications. Any patents issued or that may issue based on the pending applications in the U.S. will expire no earlier than 2033, not including any terminal disclaimer or patent term adjustment due to administrative delays by the USPTO or patent term extension under the Hatch-Waxman Act. Any patents issued in foreign jurisdictions will likewise expire no earlier than 2033.

Collaboration and License Agreements

Advanced Nuclear Medicine Ingredients SA

In December 2018, we acquired Advanced Nuclear Medicine Ingredients ("ANMI") including the pre-cursor kit that was ultimately developed to become Illuccix. We paid A$2.7 million in cash and issued 6,090,805 ordinary shares, based on a share price of A$0.637 per share, in connection with the closing of the acquisition.

We are obligated to make deferred earn-out payments to former shareholders of ANMI on an annual basis equal to a percentage in the low teens of net sales of Illuccix in the U.S. and equal to a percentage in the low twenties of net sales of Illuccix outside the U.S., in each case until April 13, 2027, which is five years following the first commercial sale of Illuccix in the U.S. We hold an option to buy out the remaining deferred payments by paying €10 million within 90 days of April 13, 2025. This option was exercised and the final buy out payment was made in July 2025.

Heidelberg License Agreement

On January 16, 2017, we entered into a license agreement, or, as amended, the Heidelberg License, with Wilex AG (now Heidelberg Pharma AG, "Heidelberg"), pursuant to which Heidelberg granted us an exclusive, royalty-bearing license under certain patents and know-how to develop, manufacture and commercialize the CAIX-targeting girentuximab antibody ("girentuximab"), radio-labeled with an isotope in both diagnostic and therapeutic products. We paid Heidelberg US$250,000 in connection with the execution of the Heidelberg License and initial technology transfer. In addition, from 2018 to 2022, we have paid Heidelberg US$1.25 million for achievement of certain manufacturing and regulatory milestones for IND approval and enrollment of the last patient in a Phase 3 clinical trial. Under the agreement, we are obligated to pay milestone payments to Heidelberg of US$2.4 million in the aggregate with payment owed upon FDA approval for a BLA for a diagnostic product and upon first reimbursements for first indication of a diagnostic product. Under the Heidelberg License, Heidelberg retained the right to develop and commercialize products that contain girentuximab that are not radio-labeled. In the event we intend to file a BLA for a therapeutic product that includes girentuximab, we are obligated to notify Heidelberg and may be required to pay up to US$3.0 million to extinguish any of Heidelberg's retained rights that have been granted to a third-party for co-promotion of girentuximab in the U.S. In the event of commercial launch of a diagnostic product, we are obligated to pay Heidelberg royalties in the low twenties on net sales of such product by us or a sublicensee during the first ten years of such sales and mid single-digit royalties on net sales of such product during the second ten years of such sales. In the event of commercial launch of a therapeutic product, we are obligated to pay Heidelberg low single-digit royalties on net sales of such product during the first ten years of such sales. Our obligation to pay royalties on net sales of diagnostic products expires 20 years after first commercial sale of each diagnostic product and our obligation to pay royalties on therapeutic products expires ten years after first commercial sale of each therapeutic product. We are obligated to use commercially reasonable efforts to develop products for regulatory approval worldwide subject to certain excepted countries for therapeutic products. The Heidelberg License expires when we cease selling products subject to the license granted thereunder, subject to customary termination provisions regarding material breach by or bankruptcy of either party. In addition, we can terminate the agreement upon 180 days' written notice for any reason. In the event of termination of the agreement for Heidelberg's material breach or bankruptcy, we have the option to purchase intellectual property relating to the products for nominal consideration.

On March 1, 2024, Heidelberg assigned its rights and obligations under the Heidelberg License to HDP G250, AG & Co. KG, a wholly owned subsidiary of Heidelberg. In connection with the assignment, the subsidiary agreed to perform all obligations of Heidelberg under the Heidelberg License. On March 4, 2024, Heidelberg announced that it entered into a royalty financing agreement with HealthCare Royalty Partners relating to royalty payments that Heidelberg is entitled to receive from us under the Heidelberg License.

Olaratumab License Agreement

In April 2022, we entered into a license agreement ("the Lilly License") with Eli Lilly Kinsale Limited, pursuant to which Lilly granted us an exclusive, royalty-bearing license under certain patents and know-how directed to its proprietary antibody, olaratumab, to develop, manufacture and commercialize radio-labeled forms of olaratumab for the diagnosis and treatment of human cancers. Under the Lilly License, we are obligated to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize radio-labeled forms of olaratumab in several major markets. As consideration for the Lilly License, we paid Lilly an upfront payment of US$5.0 million and are obligated to pay up to a total of US$225.0 million upon satisfaction of specified clinical, regulatory and commercial milestones. In the event of launch of a commercial product, we are also obligated to pay Lilly royalties in the low teens based on net sales of products, with the royalty term being, on a product-by-product and country-by-country basis, the latest of (i) the 12th anniversary of the first commercial sale of such product in such country, (ii) the first day on which there is not at least one of Lilly's patents covering such product in such country, or (iii) the expiration of the last-to-expire data exclusivity

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period for such product in such country, which we refer to as the Telix Royalty Term. The royalties may also be subject to reductions during the Telix Royalty Term in the event the product is not covered by a valid claim of a licensed patent or in the event we are required to obtain a license from a third-party to commercialize the product. In addition to the foregoing royalties on net sales of products, we are obligated to pay Lilly a percentage of any sublicense revenue received pursuant to any sublicense or similar agreement. The Lilly License defines sublicense revenue to include amounts paid for milestones similar to the milestones specified in the Lilly License, but solely to the extent such amounts are above the amount paid to Lilly under the Lilly License, and further defines sublicense revenue to exclude royalties calculated on the basis of sales of the product for which royalties are already due under the Lilly License, reimbursement for patent costs, certain profit sharing payments and any equity or debt investment at fair market value. The Lilly License further specifies that the royalty owed on such sublicense revenue varies based on the date we enter into such sublicense or similar agreement, ranging from mid-teens if entered into within one (1) year of the effective date of the Lilly License down to mid-single digits if entered into following the third (3rd) anniversary of the effective date of the Lilly License.

Under the Lilly License, we also granted Lilly an option to enter into an exclusive license under certain patents and know-how to develop, commercialize and otherwise exploit a companion diagnostic for use with olaratumab, or the companion diagnostic option. To exercise the companion diagnostic option, Lilly is obligated to pay us an option exercise fee of US$5.0 million and would be obligated to pay up to a total of US$30.0 million upon satisfaction of specified regulatory milestones. In the event of launch of a companion diagnostic, Lilly would pay us low single digit royalties on net sales of its products incorporating olaratumab, or Lilly Products, for the labeled use for the treatment of human cancer and mid-single digit royalties on net sales of companion diagnostics, with the royalty term being, on a product-by-product and country-by-country basis, the latest of (i) the 12th anniversary of the first commercial sale of such Lilly Product or companion diagnostic in such country, (ii) the first day on which there is not at least one of our patents covering such Lilly Product or companion diagnostic in such country, or (iii) the expiration of the last-to-expire data exclusivity period for such Lilly Product or companion diagnostic in such country, or the Lilly Royalty Term. The royalties may also be subject to reductions during the Lilly Royalty Term in the event the Lilly Product or companion diagnostic is not covered by a valid claim of a licensed patent or in the event Lilly is required to obtain a license from a third-party to commercialize the product.

The Lilly License continues until the expiration of the last-to-expire Telix Royalty Term or, if Lilly exercises the companion diagnostic option, the Lilly Royalty Term, subject to customary termination provisions regarding material breach by or bankruptcy of either party. Each party, in its capacity as the licensee, may terminate the agreement with respect to the licenses granted to it upon 30 days' written notice to the other party. Lilly may terminate the agreement if a patient has not been enrolled in a Phase 1 or Phase 2 clinical trial using the companion diagnostic by April 8, 2025. If Lilly exercises the companion diagnostic option, we may terminate the agreement if no patient has qualified for enrollment into a registrational study of the Lilly Product for use by patients that have been screened using the companion diagnostic within two years of the date that Lilly exercised the companion diagnostic option.

Lightpoint Medical Share Sale Agreement

In June 2023, we entered into a share sale agreement to acquire the SENSEI business from Lightpoint. We completed the acquisition of Lightpoint on November 1, 2023. The acquisition was implemented through the purchase of Lightpoint Medical Limited's wholly owned subsidiary, Lightpoint Surgical Limited, as the then owner of Lightpoint's business, assets and operation. We paid upfront consideration of US$20.0 million, of which we paid US$19.6 million through the issuance of 3,298,073 ordinary shares at a price of A$9.3659 per share. We are obligated to pay an additional US$15.0 million via an earn-out in the form of performance rights, which may be settled in cash or ordinary shares, at our option, upon achievement of regulatory, commercial and operational milestones relating to the ongoing development and commercialization of SENSEI. As at 31 December 2025, US$4.5 million of these performance rights have been settled by the issue of 269,075 ordinary shares.

Strategic License and Commercial Partnership with Grand Pharma

In November 2020, we entered into a strategic partnership with Grand Pharma, pursuant to which we appointed Grand Pharma as our partner with exclusive development and commercialization rights to our portfolio of imaging and therapeutic products and product candidates in Mainland China, Taiwan, Hong Kong and Macau ("the Grand Pharma Territory"). As part of the strategic partnership, we entered into an Imaging Products Commercialization Agreement and a Therapeutic Products License Agreement with Grand Pharma.

Pursuant to the Imaging Products Commercialization Agreement, we appointed Grand Pharma as our exclusive commercial partner in the Grand Pharma Territory for Illuccix and TLX250-Px. The Imaging Products Commercialization Agreement includes minimum annual purchase obligations of Grand Pharma following marketing authorization in applicable regions in the Grand Pharma Territory in order to maintain exclusivity in the Grand Pharma Territory.

There are currently no approved imaging products in the Grand Pharma Territory under the Imaging Products Commercialization Agreement.

The Imaging Products Commercialization Agreement has a 15-year term for each product beginning on the date of marketing authorization in China and the agreement will automatically renew for five-year renewal terms unless either party gives a written notice of nonrenewal. Either party may terminate the Imaging Products Commercialization Agreement upon material breach or insolvency by the other party.

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Pursuant to the Therapeutic Products License Agreement, Grand Pharma is responsible, at its own cost, for conducting any clinical trials of therapeutic products in the Grand Pharma Territory in accordance with the agreed development plan. Pursuant to the Therapeutic Products License Agreement, we are eligible to receive payments of up to US$69.0 million upon achievement of regulatory milestones with respect to therapeutic products by Grand Pharma and up to US$156.0 million upon achievement of commercial milestones with respect to therapeutic products by Grand Pharma. We are also eligible to receive single-digit percentage royalties on net sales of therapeutics products in the Grand Pharma Territory for ten years after marketing authorization is granted in the Grand Pharma Territory. There are currently no approved therapeutic products in the Grand Pharma Territory and we have not received any milestone payments from Grand Pharma under the Therapeutic Products License Agreement.

We received an upfront, non-refundable cash payment of US$25.0 million upon execution of the Therapeutic Products License Agreement. This upfront payment will be credited against any regulatory or commercial milestone payments owed to us by Grand Pharma.

The Therapeutic Products License Agreement has a ten-year term ending after the date that marketing authorization is granted in respect of each product. Either party may terminate the Therapeutic Products License Agreement upon material breach or insolvency by the other party.

Agreement and Plan of Merger with IsoTherapeutics Group, LLC

On February 27, 2024, we entered into an agreement and plan of merger ("the IsoTherapeutics Agreement") to acquire IsoTherapeutics Group, LLC ("IsoTherapeutics"), a specialty radiopharmaceutical development and bioconjugation firm, based in Texas. IsoTherapeutics provides radiochemistry and bioconjugation development and contract manufacturing services to many companies in the radiopharmaceutical industry. We completed the acquisition of IsoTherapeutics on April 9, 2024.

The acquisition has enhanced our internal drug development capabilities, enabling us to internalize select aspects of our development programs, with the goal of reducing cost and time to achieve technical milestones. The acquisition expanded our U.S. manufacturing footprint with a site that includes a GMP clean room and production infrastructure suitable for clinical use. The site also has extensive capacity to process a wide variety of therapeutic isotopes used in our development portfolio. We are realizing cost savings from internalizing radiochemistry-related R&D activities, as demonstrated by the inter-segment activity during the year.

The purchase price for the acquisition consists of (i) US$8.1 million paid at closing in the form of US$2.1 million in cash and US$6.0 million in our ordinary shares which we paid in the form of 717,587 of our ordinary shares issued at closing, (ii) US$5.0 million in performance-related milestone payments, which are payable in cash and are subject to meeting certain milestone conditions within 12 months of closing, and (iii) a two-year revenue share that is based on actual revenue earned from existing customers of IsoTherapeutics, which we estimate will require total cash payments of approximately US$0.6 million. The upfront cash consideration was subject to customary working capital, debt and transaction expense adjustments. The number of shares issued at closing was determined by converting US$6.0 million to Australian dollars using the Reserve Bank of Australia exchange rate at closing and dividing that amount by the volume weighted average price at which our ordinary shares traded on the ASX over the 10-trading day period prior to closing. The shares issued at closing are subject to voluntary escrow restrictions.

The US$5.0 million in performance-related milestones was paid during the year following satisfaction of the performance conditions. In addition, the first year of the revenue share has been paid totalling US$0.4 million.

Share Purchase Agreement with ARTMS Inc.

On March 5, 2024, we entered into a share purchase agreement ("the ARTMS Agreement") to acquire ARTMS Inc. ("ARTMS"), a radioisotope production technology company based in Canada, and its advanced cyclotron-based isotope production platform, manufacturing plant and stockpile of ultra-pure rare metals required for consumable target production. We completed the acquisition of ARTMS on April 11, 2024. ARTMS is a commercial-stage company that specializes in the physics, chemistry and materials science of cyclotron-produced radionuclides and its technology is used by major manufacturing networks to optimize production of a range of medical radioisotopes. We expect that the acquisition will further enhance the vertical integration of our supply chain and manufacturing by providing a greater level of control and security over each of our diagnostic isotopes.

ARTMS' core technology platform is based on the QUANTM Irradiation System ("QIS"), a complete cyclotron-based isotope production system that is designed to support high efficiency and cost-effective production of commercially important medical isotopes including zirconium-89, gallium-68, technetium-99m and copper-64. We also expect that its advanced cyclotron technologies will have immediate application and differentiation in the production of future commercially important alpha-emitting, therapeutic isotopes, including actinium-225 and astatine-211.

We believe that QIS may be able to produce zirconium-89 that is ready for radiopharmaceutical use with TLX250-Px by irradiating yttrium-89. ARTMS also holds a stockpile of zinc-68, which is used to produce gallium-68 that could be used with Illuccix. Following closing of the acquisition, we intend to work with pharmacy networks and partners to enhance the reliability and routine production of commercially useful cyclotron-produced diagnostic radionuclides such as copper-64 and technetium-99. In particular, ARTMS has a stockpile of nickel-65, an essential raw material for copper-64 production, and which is in limited global supply. As part of the acquisition, we also acquired ARTMS' production facility

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and clean rooms, located in Burnaby, British Columbia. We plan to continue to operate and expand ARTMS' R&D and production capabilities at the Burnaby location to support our in-house and customer needs, subject to applicable laws and transaction terms.

The purchase price for the acquisition consists of: (i) US$57.5 million upfront consideration, US$15.0 million of which we paid in cash and the balance of which we paid in the form of 5,674,635 of our ordinary shares issued at closing, (ii) US$24.5 million million in contingent future earn out payments, payable in cash following achievement of certain regulatory and commercial milestones, and (iii) cash earnouts representing low teens percentage royalties based on net sales of ARTMS products and related services and representing low single-digit percentage royalties based on net sales of Telix products prepared using ARTMS products for up to three years depending on the product location where the sale occurs. All earn-out royalties which have not otherwise expired will terminate on the 10-year anniversary following closing of the ARTMS acquisition. The cash upfront consideration was subject to customary working capital, debt and transaction expense adjustments. The shares issued at closing were subject to voluntary escrow restrictions. As at 31 December 2025, US$2.0 million of the contingent future earn outs have been paid following achievement of the milestones.

Agreement and Plan of Merger with QSAM Biosciences, Inc.

On February 7, 2024, we entered into an Agreement and Plan of Merger ("the QSAM Agreement") with QSAM Biosciences, Inc. ("QSAM") and we completed the acquisition of QSAM on May 3, 2024.

QSAM is developing therapeutic radiopharmaceuticals for primary and metastatic bone cancer. Its lead product candidate is Samarium-153-DOTMP, (^{153}Sm-DOTMP), which is a novel kit-based bone-seeking targeted radiopharmaceutical candidate that uses a next generation chelating agent to deliver a proprietary formulation of Samarium-153 radioisotope. ^{153}Sm-DOTMP, which we have designated as TLX090-Tx, has two potential applications – pain management of bone metastases and osteosarcoma therapy, including in pediatric patients. We believe that TLX090-Tx is highly aligned with our existing therapeutic focus areas of prostate cancer, glioma and sarcoma.

TLX090-Tx has shown evidence of safety, efficacy and future commercial utility in pre-clinical studies and early clinical trials. We believe that it has the potential to deliver significant improvements on prior bone-seeking agents in the treatment and management of late-stage metastatic disease. TLX090-Tx may enable the pain management of prostate cancer bone metastases, where there remains a significant unmet patient need particularly after progression from other forms of radionuclide and radiation therapy. We also believe that TLX090-Tx may benefit patients with metastatic lung and breast cancer, where many patients develop brain and bone metastases, and disease management often focuses on quality-of-life palliative care.

TLX090-Tx has also been granted orphan drug and rare pediatric disease designations by the FDA for the treatment of osteosarcoma. The rare pediatric disease designation may enable TLX090-Tx to be brought to market more rapidly through regulatory incentives, including eligibility for a pediatric rare disease priority review voucher that may be applied to this or other programs. The orphan drug designation and the rare pediatric disease designation do not increase the likelihood of marketing approval.

The total consideration, calculated based on the announced purchase price, for the acquisition consists of: (i) US$33.1 million upfront consideration, US$27.8 million of which was paid in closing consideration through the issuance of 3,671,120 ordinary shares, and the balance of which was paid in certain cash adjustments or through the issuance of approximately 409,026 of our ordinary shares in change of control fees, transaction bonuses and holdback shares reserved for settlement of purchase price adjustments and (ii) up to US$90.0 million in contingent future earn-out payments, in cash and/or ordinary shares, without interest, upon the achievement of certain regulatory and commercial milestones, at the times and subject to the terms and conditions of the contingent value rights agreement. The ordinary shares issued upon closing are subject to voluntary escrow conditions. The ordinary shares issued as part of the upfront purchase price were issued pursuant to an exemption from registration under the Securities Act, in reliance on Section 4(a)(2) and Regulation D thereunder, as a transaction by an issuer not involving a public offering.

Stock Purchase Agreement with RLS (USA) Inc.

On September 20, 2024, we entered into a stock purchase agreement ("the RLS Agreement") to acquire RLS, which we closed in January 2025. The purchase price for the acquisition consists of: (i) US$230.0 million upfront consideration, payable in cash at closing of the acquisition, which amount will be adjusted for transaction expenses, cash and cash equivalents (net of restricted cash), debt and debt equivalents and working capital, and (ii) milestone payments of up to US$20.0 million in the aggregate, payable in cash upon the achievement of certain commercial milestones. The purchase price and related transaction costs incurred prior to closing were funded from existing cash reserves.

RLS is a U.S.-based radiopharmacy company distributing PET, SPECT and therapeutic radiopharmaceuticals. Its network includes over 30 licensed radiopharmacies located in major metropolitan areas in 18 states across the U.S. The RLS footprint includes over 100,000 square feet of licensed expansion space that we believe can be utilized to meet rapidly growing production demand. RLS has approximately 1,500 customers and currently is one of the distributors of Illuccix in the U.S.

The acquisition significantly expands our North American manufacturing footprint and establishes the basis of a next generation radiometal production network. By augmenting our existing distribution network with RLS' capabilities, we aim

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to provide additional supply chain back-up and improve capacity to meet future demand, while broadening access for patients across the entire U.S. market, including under-served populations. We believe the acquisition of RLS is highly aligned with our investment strategy to strengthen our vertically integrated supply chain and manufacturing and distribution capabilities. We expect the acquisition to provide a pathway for deploying ARTMS' QIS technology by enabling us to scale up the production of key isotopes and build a stable and consistent supply of PET and SPECT diagnostic tracers, along with therapeutic radiopharmaceuticals across the U.S.

RLS will continue to service its existing customer base and will operate as part of our Manufacturing Solutions business, which includes ARTMS, IsoTherapeutics, TMS Brussels South in Belgium, TMS North Melbourne in Australia, TMS Sacramento and Telix Targeting Technologies ("T3") in California (U.S.), and TMS Yokohama in Japan. We expect that RLS will become a key node in our network of U.S. manufacturing and distribution partnerships and is geographically complementary to our manufacturing facility in Belgium.

Asset purchase and in-license agreements for FAP-targeting theranostics

On November 19, 2024, we entered into an asset purchase agreement with Medianezia GmbH, a company based in Wiesbaden, Germany, and a separate exclusive, worldwide license and commercialization agreement with SCV GmbH, a company based in Berlin, Germany, which we refer to collectively as the Medianezia/SCV Transaction. The asset purchase completed on March 12, 2025. The technology to be acquired and licensed in the Medianezia/SCV Transaction is comprised of FAP-targeting small molecules, patents and patent applications covering such molecules and their uses, and the related know-how for potential use in diagnostic and therapeutic applications relating to cancer and other diseases. FAP is a cell surface protein expressed in the tumor micro-environment of epithelial cancers and on the surface of some specific cancer types, making FAP an attractive pan-cancer marker for therapeutic and diagnostic radiopharmaceutical applications.

Pursuant to the Medianezia/SCV Transaction, we paid a total of €0.7 million in cash in connection to the signing of the agreements with a further €6.3 million due at closing and will pay a further €3.0 million 12 months from closing, subject to any potential indemnity setoff. We are also obligated to pay up to €132.0 million in contingent future earn-out payments upon achievement of certain clinical development and regulatory milestones related to both the diagnostic and therapeutic products under both agreements and up to €20.0 million in contingent future earn-out payments upon achievement of certain commercial milestones related to the diagnostic product under the license agreement, as well as low- to mid- single-digit royalties on net sales of the diagnostic product and an earlier formulation of the therapeutic product, if used.

Acquisition of ImaginAb Assets

On January 13, 2025, we entered into an asset purchase agreement with ImaginAb ("the ImaginAb Transaction") to acquire a significant portion of the intellectual property and technology assets of ImaginAb. The acquisition closed on January 30, 2025. Upon closing of the ImaginAb Transaction, we acquired patents, know-how and other intellectual property comprising a proprietary drug discovery platform, a pipeline of early-stage drug candidates against high-value targets including DLL3 and integrin αvβ6, and several other novel targets in discovery stage. The acquired intellectual property utilizes small engineered antibody formats that enable highly specific cancer targeting, combined with fast tumor uptake and blood clearance. We believe this technology has the potential to be highly effective for imaging and treating tumors with a broad range of radioisotopes, with alpha emitters of particular interest.

At the closing of the ImaginAb Transaction, we also assumed the lease for a state-of-the-art research facility in Inglewood, California, and hired members of ImaginAb's talented team of discovery, protein engineering and radiopharmaceutical development experts. We expect that these assets will provide us with further in-house capabilities in antibody engineering and preclinical development, as well as a novel biologics platform to create the next generation of Telix precision medicine and therapeutic products, beyond the current clinical-stage pipeline.

The ImaginAb Transaction was conducted through an asset purchase agreement with a concurrent technology license agreement, the latter of which provided us additional exclusive and non-exclusive rights to certain patents and know-how being retained by ImaginAb. The upfront purchase price for the transaction was $67,116,000 which comprised $10,000,000 in cash and 29,895,000 in equity through the issue of 2,053,311 fully paid ordinary Telix shares in January 2025 at a share price of $14.56 per share. A further $60,000,000 in Milestone Rights, or performance rights, is payable in cash and/or in ordinary shares, upon achievement of certain clinical milestones. The purchase price also includes a deferred amount payable of $3,472,000 (up to a maximum of $4,000,000 in equity) at the conclusion of a 15-month non-fundamental indemnity period, which is subject to set-off in the instance we have substantiated claims against ImaginAb.

Upon achievement of specific key development and commercial milestones, Telix will pay up to a total of $185 million, a portion of which may be paid in cash or equity at Telix's election. Royalties are also payable on net sales in the low single digits on a limited number of platform and early-stage products after the first four products have been developed, as well as single-digit sublicense fees, as applicable.

Upfront equity consideration was subject to voluntary escrow (lock-up/leak-out) restrictions with equal tranches being released from escrow 60, 90 and 120 days after closing. The ImaginAb Transaction agreements contain comprehensive fundamental and non-fundamental representations, indemnity protections, and specific non-compete and non-solicitation restrictions for ImaginAb, among other standard terms for such agreements.

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Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions, including the European Union ("EU") extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, pricing, reimbursement, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by government agencies in ways that may have a significant impact on our business.

Review and Approval of Drugs and Biologics in the U.S.

In the U.S., the FDA approves and regulates drugs under the FDCA and related regulations. Biological products are licensed for marketing under the Public Health Service Act ("PHSA") and subject to regulation under the FDCA and related regulations. Pursuant to Section 3621 of the Consolidated Appropriations Act of 2023, which was signed into law on December 29, 2022, contrast agents and radioactive pharmaceuticals are regulated as drugs or biologics.

A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is typically referred to as a sponsor. A sponsor seeking approval to market and distribute a new drug or biological product in the U.S. must typically secure the following:

- Completion of preclinical laboratory tests in compliance with the FDA's good laboratory practice ("GLP") standards and applicable regulations;
- Design of a clinical protocol and submission to the FDA of an Investigational New Drug Application ("IND"), which must take effect before human clinical trials may begin;
- Approval by an IRB representing each clinical site before each clinical trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with GCPs to establish the safety and efficacy of the proposed drug product for each proposed indication or with respect to biologics, the safety, purity and potency of the product candidate for each proposed indication;
- Submission to the FDA of an NDA, for a drug candidate product and a BLA for a biological product requesting marketing for one or more proposed indications;
- Review of the request for approval by an FDA advisory committee, where appropriate or if applicable;
- Completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMPs to assure the product's identity, strength, quality and purity;
- Completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- Payment of user fees pursuant to the PDUFA;
- Securing FDA approval of the NDA or BLA; and
- Compliance with any post-approval requirements, including the potential requirement to implement a REMS and the potential requirement to conduct post-approval studies.

Preclinical Studies

Before a sponsor begins testing a drug or biologic compound with potential diagnostic or therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured substance or active pharmaceutical ingredient and the formulated product, as well as *in vitro* and animal studies to assess the safety and activity of the product candidate for initial testing in humans and to establish a rationale for therapeutic use. These studies are generally referred to as IND-enabling studies. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP standards and regulations and the U.S. Department of Agriculture's Animal Welfare Act, if applicable. With passage of the FDA's Modernization Act 2.0 in December 2022, Congress eliminated provisions in both the FDCA and the PHSA that required animal testing in support of an NDA or BLA. While animal testing may still be conducted, the FDA was authorized to rely on alternative non-clinical tests, including cell-based assays, micro-physiological systems, or bio-printed or computer models. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

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The IND and IRB Processes

An IND is a request for FDA authorization to administer a product candidate to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biologic that is not the subject of an approved NDA or BLA. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects and patients will be exposed to unreasonable health risks. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or continue, if the clinical hold is initiated after the study has begun. The FDA's primary objectives in reviewing an IND are to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety and of the biological product's safety, purity and potency.

A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical protocol or protocols under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols or parts of the protocols may do so. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise demonstrating to the satisfaction of the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval in the U.S.

The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data monitoring committee. This group provides authorization for whether a trial may move forward at designated check points based on access only the group maintains to available data from the trial. Suspension or termination of development during any phase of clinical trials can occur if it is determined the participants or patients are being exposed to an unacceptable health risk.

Human Clinical Studies in Support of an NDA or BLA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

The clinical investigation of an investigational drug or biological product is generally divided into four phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The four phases of an investigation are as follows:

- **Phase 1:** Studies include the initial introduction of an investigational new drug or biological product into humans. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug or biological product in humans, any adverse events associated with increasing doses, and if possible, to gain early evidence on effectiveness.

- **Phase 2:** Includes controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug or biological product for a particular indication(s) in patients with the disease or condition under trial, to determine dosage tolerance and optimal dosage, and to identify possible adverse events and safety risks associated with the drug or biological product. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.

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- **Phase 3:** Clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug or biological product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug or biological product, and to provide an adequate basis for product approval.

- **Phase 4:** Post-approval studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In March 2022, the FDA released final guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology biological product development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to biological product development and reduce developmental costs and time.

In December 2022, with the passage of FDORA, Congress required sponsors to develop and submit a DAP for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates the form and manner for submission of DAPs are specified in FDA guidance. On January 27, 2025, in response to an Executive Order issued by President Trump on January 21, 2025, on Diversity, Equity and Inclusion programs, the FDA removed this draft guidance from its website. This action raises questions about the applicability of statutory obligations to submit DAPs and the agency's current thinking on best practices for clinical development.

In June 2023, the FDA issued draft guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The draft guidance is adopted from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's ("ICH's"), recently updated E6(R3) draft guideline developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise. In addition, the FDA issued draft guidance outlining recommendations for the implementation of decentralized clinical trials.

Finally, sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health ("NIH"). In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. The failure to submit clinical trial information to clinicaltrials.gov, as required, is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to US$10,000 for each day the violation continues. To date, the FDA has issued six notices of non-compliance, thereby signaling the government's willingness to begin enforcing these requirements against non-compliant clinical trial sponsors. These notices of non-compliance did not result in civil monetary penalties.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the candidate product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final product candidate. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate the product candidate does not undergo unacceptable deterioration over its shelf life.

Clinical Studies Outside the U.S. in Support of FDA Approval

In connection with our clinical development programs, we are conducting trials at sites outside the U.S. When a foreign clinical trial is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure the trial complies with certain regulatory requirements of the FDA in order to use the trial as support for an IND or application for marketing approval. Specifically, the trials must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee ("IEC") and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human

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subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for IND trials.

The acceptance by the FDA of trial data from clinical trials conducted outside the U.S. in support of U.S. approval may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the trial is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

Interactions with the FDA During the Clinical Development Program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted annually within 60 days of the anniversary dates that the IND went into effect and more frequently if serious adverse events occur.

These reports must include a development safety update report ("DSUR"). In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. With passage of FDORA, Congress clarified FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to FDA as well as other persons holding study records or involved in the study process.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND ("Pre-IND meeting"), at the end of Phase 2 clinical trial ("EOP2 meeting") and before an NDA is submitted ("Pre-NDA meeting"). Meetings at other times may also be requested. There are five types of meetings that occur between sponsors and the FDA.

Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-NDA meetings as well as end of phase meetings such as EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product, including for example meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. A type D meeting is focused on a narrow set of issues (should be limited to no more than 2 focused topics) and should not require input from more than 3 disciplines or Divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. Nonetheless, from a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Manufacturing and Other Regulatory Requirements

Concurrently with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate, and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, and purity of the finished product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Specifically, the FDA's regulations require that pharmaceutical products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and some state agencies, and they are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements. The

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PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the U.S. prior to being imported or offered for import into the U.S.

Pediatric Studies

Under PREA, an application or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit an initial Pediatric Study Plan ("PSP") prior to the assessment data. The PSP must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although the FDA has recently taken steps to limit what it considers abuse of this statutory exemption.

The Food and Drug Administration Reauthorization Act of 2017 ("FDARA") also established new requirements to govern certain molecularly targeted cancer indications. Any company that submits an application three years after the date of enactment of that statute must submit pediatric assessments with the application if the product is intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. The investigation must be designed to yield clinically meaningful pediatric study data regarding the dosing, safety and preliminary efficacy to inform pediatric labeling for the product.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the sponsor to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the sponsor for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) thus authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products.

If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved as well as for any new indication sought by the Section 505(b)(2) applicant.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation. None of these expedited programs changes the standards for approval but each may help expedite the development or approval process governing product candidates.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must

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pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to help the sponsor design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

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Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM") and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the product. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

With passage of FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissioner's designee and a written appeal, among other things.

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The agency indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's latest thinking on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally

binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

FDA Commissioner's National Priority Review Voucher (CNPV) Pilot Program

In June 2025, the FDA announced the CNPV pilot program which was designed to accelerate the development and review of certain drugs and biologics that are aligned with U.S. national health priorities, such as addressing a U.S. public health crisis, developing more innovative cures for the American people, addressing a large unmet medical need, onshoring drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency, and increasing affordability. The FDA has stated that voucher recipients will receive a decision with respect to an application on an accelerated basis, as well as enhanced communication with review staff throughout the review process. The FDA expects the CNPV program to accelerate the application review timeline from 10-12 months to 1-2 months by convening a multidisciplinary team of physicians and scientists for a team-based review, interacting frequently with the sponsor of the application to clarify questions, and completing review of the application concurrently. The FDA retains full discretion to extend the review window if the data or application components submitted are insufficient or incomplete, if the results of the pivotal trial(s) are ambiguous, or if the review is particularly complex. The FDA has indicated the CNPV program does not change the FDA's rigorous safety and efficacy standards for review and approval. In late 2025, FDA began issuing approvals for drugs with CNPVs within the 1-2 month review timeframe. The CNPV program is new, limited in scope, and subject to evolving guidance, and available FDA resources. The FDA retains broad discretion to modify the criteria, processes, or benefits of the program and may rescind participation or alter timelines or the intended benefits at any time. Adding to the uncertainty, concerns have been raised regarding the legality of the CNPV program.

Submission and Review of an NDA or BLA by the FDA

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, controls, safety updates, patent information, abuse information, and proposed labeling, are submitted to the FDA as part of an application requesting approval to market the product candidate for one or more indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of a drug product, and potency, purity and safety of a biologic product, to the satisfaction of the FDA.

The fee required for the submission and review of an application under PDUFA is substantial (for example, for fiscal year 2026, this application fee is US$4,682,003), and the sponsor of an approved application is also subject to an annual program fee, which for fiscal year 2025 is US$442,213 per eligible prescription product. These fees are typically adjusted annually, and exemptions and waivers may be available under certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the sponsor is a small business submitting its first human drug application for review.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. In pertinent part, the FDA's regulations state that an application "shall not be considered as filed until all pertinent information and data have been received" by the FDA. In the event that the FDA determines that an application does not satisfy this standard, it will issue an RTF determination to the applicant. Typically, an RTF will be based on administrative incompleteness, such as clear omission of information or sections of required information; scientific incompleteness, such as omission of critical data, information, or analyses needed to evaluate safety and efficacy or provide adequate directions for use; or inadequate content, presentation, or organization of information such that substantive and meaningful review is precluded. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. The FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use, whether it has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application that is a new molecular entity, and six months from the filing date for an application with "priority review." The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the sponsor to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of an application to extend beyond the PDUFA goal date.

In connection with its review of an application, the FDA may submit information requests to the sponsor and set deadlines for responses thereto. The FDA will also conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with IND and GCP requirements and the integrity of the clinical data submitted to the FDA.

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Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the NDA. That is because, under certain circumstances, principal investigators at a clinical trial site may also serve as scientific advisors or consultants to a sponsor and receive compensation in connection with such services. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

Additionally, the FDA may refer an application, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval.

The FDA also may require submission of a REMS if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the product. The REMS could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS and the FDA will not approve the application without a REMS.

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The FDA's Decision on an NDA or BLA

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA may issue either a Complete Response Letter ("CRL") or an approval letter. To reach this determination, the FDA must evaluate whether the expected benefits of the proposed product outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the body of evidence about the product's safety and efficacy in the NDA or BLA.

If the FDA decides not to license or approve the application, it will issue a CRL. A CRL will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots (where applicable), and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. If a CRL is issued, the applicant will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the applicant an additional six month extension to respond. For those seeking to challenge the FDA's CRL decision, the FDA has indicated that sponsors may request a formal hearing on the CRL or they may file a request for reconsideration or a request for a formal dispute resolution. The FDA recently announced that, in the interest of transparency, it will release CRLs to the public.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Under the Ensuring Innovation Act, which was signed into law in April 2021, the FDA must publish action packages summarizing its decisions to approve new drug products within 30 days of approval of such products.

Post-Approval Regulation

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, or complete withdrawal of the product from the market or product recalls;
- fines, warning letters or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs, BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of a product in a manner inconsistent with the approved labeling, and a company that is found to have improperly promoted a product uses may be subject to significant liability.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval Information Exchange Act ("PIE Act"), in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance, but the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products. In January 2025, the FDA published final guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This final guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use.

If a company is found to have promoted a product improperly, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice or the Office of the Inspector General of HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Generic Drugs and Regulatory Exclusivity

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs and it also enacted Section 505(b)(2). To obtain approval of a generic drug, a sponsor must submit an ANDA to the FDA. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug, and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug.

Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA

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indicates whether the generic product is “therapeutically equivalent” to the RLD in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD.

Under the Hatch-Waxman Act, the FDA may not approve an ANDA or 505(b)(2) application until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of regulatory exclusivity for a new drug containing a new chemical entity ("NCE"). For the purposes of this provision, the FDA has consistently taken the position that an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, a generic or follow-on drug application may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the sponsor may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of regulatory exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the sponsor and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as new indications, dosage forms, route of administration or combination of ingredients. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; rather, this three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving follow-on applications for drugs containing the original active ingredient.

Five-year and three-year regulatory exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA; however, a sponsor submitting a traditional NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

As part of the submission of an NDA or certain supplemental applications, NDA sponsors are required to list with the FDA each patent with claims that cover the sponsor’s product or an approved method of using the product. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. The FDA’s regulations governing patient listings were largely codified into law with enactment of the Orange Book Modernization Act in January 2021. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book.

Specifically, the ANDA applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; and/or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA applicant would.

If the generic drug or follow-on drug applicant does not challenge the innovator’s listed patents, the FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new generic product will not infringe the already approved product’s listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA owner and patent holders once the ANDA has been accepted for filing by the FDA. The NDA owner and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earliest of 30 months after the receipt of the Paragraph IV notice, expiration of the patent and a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

Biosimilars and Regulatory Exclusivity

The ACA, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, the FDA has approved a number of biosimilars and several interchangeable biosimilar products.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. In December 2022, Congress clarified through

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FDORA that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none have been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the U.S., or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the U.S. for treatment of the disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA or BLA for the candidate product. If the request is granted, the FDA will disclose the identity of the product candidate and its potential use. Orphan drug designation does not shorten the regulatory review and approval process, although it does convey certain advantages such as tax benefits and user fee exemptions.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug or biologic for the same disease or condition for seven years, except in certain limited circumstances. Orphan exclusivity does not block the approval of a different product for the same rare disease or condition, nor does it block the approval of the same product for different indications. If a drug or biologic designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Orphan exclusivity will not bar approval of another product under certain circumstances, including if a company with orphan drug exclusivity is not able to meet market demand and in cases where a subsequent product with the same drug or biologic for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care.

In September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of market exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of regulatory exclusivity. For drug products, the six-month exclusivity may be attached to the term of any existing patent or regulatory exclusivity. For biologic products, the six-month period may only be attached to any existing regulatory exclusivities but not to any patent terms. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of non-patent exclusivity for drugs and biologics, or patent protection that covers a drug product, are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Patent Term Restoration and Extension

A patent claiming a new product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of the IND approval and the submission date of an application, plus the time between the submission date of the regulatory approval application and the ultimate approval date, depending on the amount of that time period in which the subject patent was granted. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in

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question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

U.S. Regulation of Medical Devices

The FDCA defines a medical device in pertinent part to include any instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or to affect the structure or function of the body. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the U.S. In addition to traditional devices, like surgical tools, the FDA regulates certain software, including artificial intelligence and machine learning algorithms, as medical devices depending on their intended use.

Device Classification

The FDA categorizes medical devices into one of three classes—Class I, II, or III—based on the risks presented by the device and the regulatory controls necessary to provide a reasonable assurance of the device's safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse medical events or certain malfunctions, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Special controls are established by the FDA for a specific device type and often include specific labeling provisions, performance metrics, and other types of controls that mitigate risks of the device. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

PMA Pathway

Class III devices generally require PMA approval before they can be marketed. Obtaining PMA approval requires the submission of "valid scientific evidence" to the FDA to support a finding of a reasonable assurance of the safety and effectiveness of the device. A PMA must provide complete analytical and clinical performance data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling.

Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. As part of the FDA's review of a PMA, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose requirements related to design controls, manufacturing controls, documentation and other quality assurance procedures. The user fee costs and the length of FDA review time for obtaining PMA approval are significantly higher than for a 510(k) notification or a *de novo* classification. PMA applications are subject to an application fee, which for federal fiscal year 2026 is $579,272 and the small business fee is $144,818.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant

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that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

510(k) Notification Pathway

To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is "substantially equivalent" to another legally marketed device that itself does not require PMA approval (a predicate device). A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 ("pre-amendments device") and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. FDA then determines whether the device is as safe and effective as the predicate device by reviewing the scientific methods used to evaluate differences in technological characteristics and performance data. The FDA's 510(k) clearance process usually takes from three to 12 months, but often takes longer. FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments. If the FDA agrees that the device is substantially equivalent to a lawfully marketed predicate device, it will grant 510(k) clearance to authorize the device for commercialization. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device, discussed below.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a "letter to file" in which the manufacturer documents the rationale for the change and why a new 510(k) is not required.

However, if the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

If no legally marketed predicate can be identified for a new device to enable use of the 510(k) pathway, the device is automatically classified under the FDCA into Class III, which generally requires PMA approval. However, the FDA can reclassify or a sponsor can seek *de novo* classification for a novel device that is low to moderate risk and would otherwise meet the FDCA standards for a Class I or Class II device, permitting the device to be marketed without PMA approval.

De Novo Classification

The Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA"), a medical device could be eligible for *de novo* classification only if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent to a legally marketed predicate device. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low to moderate risk, or that general controls would be inadequate to control the risks and special controls cannot be developed. After a device receives *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another *de novo* request or even PMA approval.

Investigational Device Exemption Process

Clinical trials are almost always required to support a PMA and *de novo* classification and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE") regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant

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risk" to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials.

A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an IRB for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements.

Expedited Development and Review Programs for Medical Devices

The FDA has implemented a Breakthrough Devices Program, which is a voluntary program offering manufacturers of certain devices an opportunity to interact with the FDA more frequently and efficiently as they develop their products with the goal of expediting commercialization of such products to help patients have more timely access. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and constitutes a device (i) that represents a breakthrough technology, (ii) for which no approved or cleared alternatives exist, (iii) that offer significant advantages over existing approved or cleared alternatives, or (iv) the availability of which is in the best interest of patients. Devices granted Breakthrough Device designation are eligible to rely on certain features of the Breakthrough Device Program, including interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design and priority review of premarket submissions.

Post-market Regulation of Medical Devices

After a device is cleared or approved by the FDA for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

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- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and

- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes subject to FDA oversight are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;

- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;

- imposing operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;

- withdrawing 510(k) clearances or PMA approvals that have already been granted;

- refusal to grant export approvals for our products; or

- criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

In the U.S. and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Under the Outpatient Prospective Payment System ("OPPS") the costs associated with diagnostic radiopharmaceuticals have been packaged into the payment for the nuclear medicine tests with which they are used. In July 2024, CMS recognized that in certain instances the payment amount for the nuclear medicine tests may not adequately account for the cost of certain specialized diagnostic radiopharmaceuticals, even when those agents may be the most clinically

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appropriate. Accordingly, CMS proposed to revise its policies so as to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630 and removing such costs from the payment amounts for the nuclear medicine tests. Any diagnostic radiopharmaceutical with a per-day cost equal to or below that threshold would continue to be policy-packaged, with costs incorporated into the payment rates for the nuclear medicine tests. On November 1, 2024, CMS issued a final rule to these Medicare payment rates for hospital outpatient and Ambulatory Surgical Center services for calendar year, finalizing this proposal effective January 1, 2025.

Healthcare Compliance

In the U.S., biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to healthcare providers and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchase, order, or arranging for or recommending the purchase or order of a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

- federal false claims, false statements, and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- federal Open Payments (or federal “sunshine” law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers and teaching hospitals to CMS within the HHS for re-disclosure to the public, as well as ownership and investment interests held by physicians (as defined by statute) and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly. Similar healthcare laws and regulations exist in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

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Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of drug products, limiting coverage and reimbursement for medical products and other changes to the healthcare system in the U.S.

In March 2010, the U.S. Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for pharmaceutical products under government healthcare programs. Since its enactment, there have been executive, judicial, and Congressional challenges to certain aspects of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers, which went into effect in April 2013 and will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Pursuant to subsequent legislation, these Medicare sequester reductions were suspended and reduced in 2021 and 2022 but, as of July 1, 2022, the full 2% cut has resumed. Under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Act delayed the 4% Statutory Pay-As-You-Go Act of 2010 ("PAYGO") sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into FY 2032 and lowers the payment reduction percentages in FYs 2030 and 2031. On July 4, 2025, President Trump signed into law the 2025 Reconciliation Law (Public Law 119-21, commonly referred to as the "One Big Beautiful Bill Act"), which is estimated to increase the federal deficit substantially. As a result of this deficit increase, PAYGO is expected to be triggered, requiring additional mandatory Medicare payment reductions of up to 4%. There is uncertainty regarding how the Budget Control Act sequestration (2%) and PAYGO sequestration (up to 4%) would be applied if both are simultaneously in effect. Neither statute explicitly addresses whether the reductions would be combined (resulting in up to 6% total reduction) or whether there is an overall cap that would limit the combined reduction.

As an alternative to the Affordable Care Act, President Trump recently announced the Great Healthcare Plan. As presented, the plan is intended to lower drug prices by increasing competition and benchmarking U.S. drug prices to other countries, reduce insurance premiums by redirecting subsidies from insurers to individuals, increase accountability and transparency from insurers, and promote consumer choice by giving individuals more direct control over how healthcare dollars are spent. Legislative and regulatory action will be required to fully implement the plan. It is unclear how these proposed changes will impact our business and the pharmaceutical industry in general.

Pharmaceutical Prices

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the U.S. There have been several recent U.S. Congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program ("SIP") to import certain prescription drugs from Canada into the U.S. Section 804 of the FDCA allows importation of prescription drugs from Canada to significantly reduce the cost of these drugs to the American consumer without imposing additional risk to public health and safety. Importation program proposals must be submitted to FDA for review and authorization. Several states have passed laws allowing for the importation of products from Canada. Other states have passed legislation establishing workgroups to examine the impact of a state importation program. In May 2025, FDA announced it will offer individual states the opportunity to submit draft proposals for pre-review and obtain initial feedback from FDA prior to formally submitting their program proposal. States will have an opportunity to meet with FDA with the goal of reducing the burden on the states and to help them develop robust proposals. FDA is also working to assist states with options to streamline the required cost savings analysis, and to provide input regarding the information the states may rely on to estimate cost savings for American consumers.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It was originally set to go into effect on January 1, 2022, but with passage of the IRA, has been delayed by Congress to January 1, 2032.

On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with

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prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (which began in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The law also capped Medicare out-of-pocket drug costs at approximately US$4,000 a year in 2024 and, thereafter beginning in 2025, at US$2,000 a year (indexed for inflation in subsequent years).

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the negotiated “maximum fair prices” for ten selected Part D drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional Part D drugs for the second cycle of negotiations. The negotiated prices for this second group will be effective on January 1, 2027. While there had been some questions about the Trump Administration’s position on this program, on September 30, 2025, CMS issued final guidance for the third negotiation cycle. On January 27, 2026, CMS announced its selection of 15 additional drugs (covered under either Part B or Part D) for the third cycle of negotiations. The negotiated prices for this third group will be effective on January 1, 2028. CMS also selected one previously negotiated drug for the program’s first renegotiations.

On June 6, 2023, Merck filed a lawsuit against HHS and CMS asserting that, among other things, the IRA’s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. As of October 2025, Merck’s action is pending motions for summary judgment, and the other lawsuits have been largely unsuccessful for the plaintiffs. Multiple federal district courts have granted summary judgment in favor of HSS, and several of these decisions have been affirmed by federal appellate courts. For example, in 2025, the U.S. Court of Appeals for the Third Circuit rejected appeals from several manufacturers, including AstraZeneca and Novartis, upholding the program’s constitutionality. The Second and Sixth Circuits have also affirmed dismissals of similar challenges. In September 2025, AstraZeneca filed a petition for a writ of certiorari, asking the U.S. Supreme Court to review the Third Circuit’s decision. Accordingly, while the IRA is being actively implemented, the pending appeal to the U.S. Supreme Court creates uncertainty regarding the program’s ultimate legal status. We expect that litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

In May 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, the Department of Health and Human Services, in coordination with other federal agencies, is directed to take actions to ensure that the price of prescription drugs paid by federal health insurers, including Medicare and Medicaid, is in line with the prices paid in comparably developed nations. It is unclear how this policy will impact our business.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, and wholesale distributors, to disclose information about pricing of pharmaceuticals. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA’s standards for accelerated approval. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription pharmaceutical and other healthcare programs. These measures could reduce the ultimate demand for our Commercial Products and product candidates, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our Commercial Products and product candidates, if approved, or additional pricing pressures.

Regulation by the Nuclear Regulatory Commission of Radionuclides Used for Medical Purposes

The Nuclear Regulatory Commission ("NRC") and the FDA share federal responsibility for the regulation of medical devices, drugs and biological products that utilize radionuclides. In August 1993, the two agencies established a Memorandum of Understanding ("MOU") outlining the respective responsibilities of each agency and identifying ways in which FDA and NRC should coordinate their regulatory actions involving such products.

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Under the MOU, FDA maintains full responsibility for review and approval of radiopharmaceuticals under the FDCA for drugs and the PHSA for biologics. Pursuant to its authority under the Atomic Energy Act, the NRC regulates the medical use of nuclear materials to protect public health and safety and the environment.

In addition to the MOU, the NRC has issued a Medical Use Policy Statement. It provides that the NRC will: (i) continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public; (ii) not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public; (iii) when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of the radionuclides is in accordance with the physician's directions; and (iv) in developing a specific regulatory approach, consider industry and professional standards that define acceptable approaches for achieving radiation safety.

Consistent with the MOU and to implement its Medical Use Policy, the Commission has established policies and regulations to govern the use, handling and disposal of byproduct materials for medical purposes. Specifically, the Commission regulates the medical use of byproduct material through licensing, inspection and investigation of medical, industrial, academic and commercial facilities and authorization of physician users. These regulations are meant to provide for the radiation safety of workers, the general public, patients, and human research subjects without interfering with treatment protocols established by the physician. To that end, the rules set out procedures and standards to govern the issuance of licenses to facilities seeking to use byproduct material for medical purposes. Medical use licenses are issued by an Agreement State or, in Non-Agreement States, the NRC.

U.S. Data Privacy Laws

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If a sponsor fails to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, it could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents.

In addition to potential enforcement by HHS, a sponsor is also potentially subject to privacy enforcement from the Federal Trade Commission ("FTC"). The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security. Sponsors will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate risk for a potential enforcement action, which may be costly.

States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the GDPR, which is further described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements.

In November 2020, California voters passed a ballot initiative for the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – the sole responsibility of which is to enforce the CPRA and other California privacy laws, which will further increase compliance risk. In addition to California, at least 18 other states have passed comprehensive privacy laws. These laws may impact our business activities, including our identification of research subjects, relationships with business partners, and ultimately the marketing and distribution of our Commercial Products and our product candidates, if approved.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act.

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Review and Approval of Medical Products in the European Union

In addition to regulations in the U.S. there are many other jurisdictions that govern clinical trials and commercial sales and distribution of our products outside of the U.S. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member European Union, before we may commence clinical trials or market products in those countries or areas. In the European Union, our product candidates also may be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the U.S., the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

The approval process and requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement can vary from country to country and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Non-clinical Studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical Studies

Clinical trials of medicinal products in the European Union must be conducted in accordance with EU and national regulations and the ICH guidelines on GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the European Union, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the European Union has been subject to recent changes. On January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became applicable in the European Union and repealed and replaced the prior Clinical Trials Directive 2001/20/EC. Unlike directives, the new Regulation is directly applicable in all EU member states without the need for member states to further implement it into national law. It aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union.

Under the new coordinated procedure, the sponsor of a clinical trial to be conducted in more than one member state will only be required to submit a single application. The Regulation allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU member states and the public.

Beyond streamlining the process, the new Regulation includes a single set of documents to be prepared and submitted for the application and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is subject to a coordinated review by competent authorities of all EU member states in which an application for authorization has been submitted ("member states concerned"). One of the member states concerned ("the reporting member state") prepares a draft assessment report which is submitted to other member states concerned for their joint review, allowing for a single assessment report to be issued at the term of the assessment process. Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications ("CTAs"). The role of the relevant ethics committees in the assessment procedure will continue to be governed at national levels; however, overall related timelines are set out under the Clinical Trials Regulation. The Regulation also provides for simplified reporting procedures for clinical trial sponsors.

All ongoing clinical trials in the European Union approved under the prior Clinical Trials Directive must be transitioned to the Clinical Trials Information System by January 31, 2025. This date marks the end of a three-year transition period that began when the Clinical Trials Regulation became applicable in the European Union on January 31, 2022. Clinical trials that were started under the Clinical Trials Directive and are subject to transition to the Clinical Trials Regulation will by January 31, 2025 have to comply with the obligations of the Clinical Trials Regulation even if these are not included in the previous study protocol, such as (i) obligations of notification via the Clinical Trials Information System; (ii) safety reporting rules; (iii) archiving requirement; and (iv) transparency requirements. Failure to transition ongoing clinical trials to the Clinical Trials Regulation by January 31, 2025 can result in corrective measures under Article 77 of the Clinical Trials Regulation, including revocation of the authorization of the clinical trial or suspension of the clinical trial, as well as criminal sanctions and fines under national law of EU Member States.

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Parties conducting certain clinical trials must, as in the U.S., post clinical trial information in the European Union at the EudraCT website.

Marketing Authorization

In order to market our product candidates in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the European Union, medicinal product candidates can only be commercialized after obtaining a marketing authorization ("MA"). To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application ("MAA"). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs: “Centralized MAs” are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the EMA and are valid throughout the European Union. The centralized procedure is compulsory for certain types of medicines such as (i) medicinal products developed by specified biotechnological processes, (ii) products designated orphan medicinal products, (iii) advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines), and (iv) products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases, and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the European Union, or for products that represent a significant therapeutic, scientific, or technical innovation, or whose authorization would be in the interest of public health.

Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the sponsor in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding stop-clocks.

“National MAs” are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU member state (which acts as the reference member state), in accordance with the national procedures of that member state. Following this, further MAs can be progressively sought from other EU member states in a procedure whereby the member states concerned agree to recognize the validity of the original, national MA produced by the reference member state. Under the decentralized procedure, if the product has not received a national MA in any member state at the time of application, a sponsor may apply for simultaneous authorization in more than one EU member state. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Conditional Marketing Authorization

In particular circumstances, a “conditional” MA may be granted in cases where all the required safety and efficacy data are not yet available. A conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. Conditional MAs are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. Once the pending studies are provided, it can become a “standard” MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional MA, but sponsors can also request the EMA to conduct an accelerated assessment, for instance in cases of unmet medical needs.

Marketing Authorization Granted under Exceptional Circumstances

A MA may also be granted “under exceptional circumstances” when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy. Except conditional MAs, MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, sponsors have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan ("PIP") covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the

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measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA ("PDCO") may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate because (i) the product is likely to be ineffective or unsafe in part or all of the pediatric population; (ii) the disease or condition occurs only in adult population; or (iii) the product does not represent a significant therapeutic benefit over existing treatments for pediatric population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines ("PRIME") scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises ("SMEs") may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated agency contact and rapporteur from the CHMP or Committee for Advanced Therapies are appointed early in the PRIME scheme, facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance to the sponsor on the overall development and regulatory strategies.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety, and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called "sunset clause").

Regulatory Exclusivity

In the European Union, new products authorized for marketing (*i.e.,* reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic sponsors from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic sponsor from commercializing its product in the European Union until ten years have elapsed from the initial authorization of the reference product in the European Union. The ten-year market exclusivity period can be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the European Union.

In this context, it should be noted that the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products was published in April 2023 and includes, among other things, provisions that would potentially reduce the duration of regulatory data protection. The European Parliament requested several amendments in April 2024. At this time, the proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry in the long term, if and when adopted.

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However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Drug Designation and Exclusivity

The criteria for designating an orphan medicinal product in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (i) it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition, (ii) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment, and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term 'significant benefit' is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten year market exclusivity period, the EMA or the competent authorities of the Member States of the European Economic Area ("EEA") cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The sponsor will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if: (i) the second sponsor can establish that its product, although similar, is safer, more effective, or otherwise clinically superior; (ii) the sponsor consents to a second orphan medicinal product application; or (iii) the sponsor cannot supply enough orphan medicinal product.

Pediatric Exclusivity

If a sponsor obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate ("SPC") or alternatively a one year extension of the regulatory market exclusivity from ten to eleven years, as selected by the marketing authorization holder.

Post-Approval Requirements

As in the U.S., both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission, and the competent authorities of EU member states. The MA holder must, for example, comply with EU pharmacovigilance legislation and its related regulations and guidelines which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. In particular, the MA holder must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance ("QPPV") who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAs must include a risk management plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The manufacturing process for medicinal products in the European Union is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, including compliance with EU GMP standards when manufacturing medicinal products and API.

In the European Union, the advertising and promotion of approved products are subject to laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising, and unfair commercial practices. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC") as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is

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prohibited in the European Union. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the EEA.

Failure to comply with European Union and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Supplementary Protection Certificate

The European Union also provides for patent term extension through SPCs. The rules and requirements for obtaining a SPC are similar to those in the U.S. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of 15 years of marketing exclusivity for a drug. In certain circumstances, these periods may be extended for six additional months (*see* "Pediatric Development").

Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Reimbursement and Pricing of Prescription Pharmaceuticals

In international markets including the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA") process, which is currently governed by the national laws of the individual EU member states, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states.

The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

In the European Union, similar political, economic, and regulatory developments to those in the U.S. may affect our ability to profitably commercialize our product candidates, if approved. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of a marketing approval for a product. To obtain reimbursement or pricing approval in some countries, pharmaceutical firms may be required to conduct a clinical trial that compares the cost-effectiveness of the product to other available therapies. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the European Union, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing used by various EU member states, and parallel distribution and parallel trade can further reduce prices. It could also result from the application of external reference pricing mechanisms, which consist of

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arbitrage between low-priced and high-priced member states). There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any product candidates, if approved in those countries.

HTA of medicinal products in the European Union is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas.

Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Regulation of Medical Devices in the European Union

The European Union has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices. Until May 25, 2021, medical devices were regulated by the EU Medical Devices Directive ("MDD") which has been repealed and replaced by the EU Medical Devices Regulation ("MDR"). However, as of May 26, 2021, some of the MDR requirements apply in place of the corresponding requirements of the MDD with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements.

Medical Devices Directive

Under the MDD, all medical devices placed on the market in the European Union must meet the essential requirements laid down in Annex I to the MDD, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards and the aforementioned EU rules is generally applicable in the EEA.

Medical Devices Regulation

The regulatory landscape related to medical devices in the European Union recently evolved. On April 5, 2017, the MDR was adopted with the aim of ensuring better protection of public health and patient safety. The MDR establishes a uniform, transparent, predictable and sustainable regulatory framework across the European Union for medical devices and ensure a high level of safety and health while supporting innovation. Unlike the MDD, the MDR is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the European Union.

The MDR became effective on May 26, 2021. In accordance with its recently extended transitional provisions, both (i) devices lawfully placed on the market pursuant to the MDD prior to May 26, 2021 and (ii) legacy devices lawfully placed on the EU market after May 26, 2021 in accordance with the MDR transitional provisions may generally continue to be made available on the market or put into service, provided that the requirements of the transitional provisions are fulfilled. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the MDR, in particular the obligations described below.

The MDR requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system ("Eudamed"), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along

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with other core data to the unique device identifier ("UDI") database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier ("UDI-DI") specific to a device, and a production identifier ("UDI-PI") to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date.

All manufacturers placing medical devices on the market in the European Union must comply with the EU medical device vigilance system which has been reinforced by the MDR. Under this system, serious incidents and Field Safety Corrective Actions ("FSCAs") must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the MDD continue to apply. Manufacturers are required to take FSCAs, which are defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. A serious incident is any malfunction or deterioration in the characteristics or performance of a device on the market (e.g., inadequacy in the information supplied by the manufacturer, undesirable side-effect), which, directly or indirectly, might lead to either the death or serious deterioration of the health of a patient, user, or other persons, or to a serious public health threat.

An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

The advertising and promotion of medical devices are subject to some general principles set forth in EU legislation. According to the MDR, only devices that are CE marked may be marketed and advertised in the European Union in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the U.S., on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

In the European Union, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties.

The aforementioned EU rules are generally applicable in the EEA.

EU General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. In the United Kingdom, the GDPR is retained in domestic law as the U.K. GDPR and sits alongside an amended version of the UK Data Protection Act. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues of the respective group of companies, whichever is greater.

The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

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For transfers of personal data from the European Union to the U.S., the European Commission has adopted an adequacy decision for the EU-US Data Privacy Framework in July 2023. It is widely expected that this adequacy decision will be challenged in court, so uncertainties around this issue continue.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom's withdrawal from the European Union, commonly referred to as Brexit, took place on January 31, 2020. The European Union and the United Kingdom reached an agreement on their new partnership in the Trade and Cooperation Agreement, which entered into force on May 1, 2021. As of January 1, 2021, the MHRA became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland continues to be subject to EU rules under the Northern Ireland Protocol, as amended by the so called Windsor Framework agreed in February 2023. As of January 1, 2025, the changes introduced by the Windsor Framework resulted in the MHRA being responsible for approving all medicinal products destined for the United Kingdom market (Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916), as amended ("HMR") as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union.

As of January 1, 2024, a new IRP applies which intends to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified RRs. The RRs notably include EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion or an MRDC positive end of procedure outcome is an RR authorization for the purposes of IRP.

EU laws which have been transposed into U.K. law through secondary legislation continue to be applicable as "retained EU law." However, new legislation such as the (EU) Clinical Trials Regulation will not be applicable in GB. Since a significant proportion of the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, MAs, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval, and commercialization of our product candidates in the United Kingdom. For example, the United Kingdom is no longer covered by the centralized procedures for obtaining EU-wide MAs from the EMA, and a separate MA will be required to market our product candidates in the United Kingdom. A new international recognition framework has been in place since January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new GB MA.

The medical device regulatory framework in Great Britain continues to be broadly based on the requirements of the (EU) MDD as implemented into national law. On June 26, 2022, the MHRA published its response to a 10-week consultation on the future regulation of medical devices in the U.K. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the MHRA has confirmed that the core elements of the new framework are now expected to be in place in 2025, while priority measures to enhance post-market surveillance will be put in place first in 2024. Medical devices bearing CE marks issued by EU notified bodies under the (EU) MDR or (EU) MDD are now subject to transitional arrangements. Devices certified under the (EU) MDR may be placed on the market in GB under the CE mark until June 30, 2030. However, devices certified under the (EU) MDD may be placed on the market until June 30, 2028. Following these transitional periods, it is anticipated that all medical devices will require a United Kingdom Conformity Assessed ("UKCA") mark. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the mandatory deadlines.

However, UKCA marking will not be recognized in the European Union. Following the transitional periods, compliance with the United Kingdom regulations will be a prerequisite to be able to affix the UKCA mark to medical devices, without which they cannot be sold or marketed in GB.

In addition, new regulations applicable in GB now require that all medical devices must be registered with the MHRA prior to being placed on the market. Additionally, manufacturers based outside the United Kingdom will need to appoint a U.K. Responsible Person to register devices with the MHRA.

Human Capital Resources

As of December 31, 2025, we had 1,120 full-time employees and 64 part-time employees. Of our 1,184 full- and part-time employees, 18% have Ph.D. or M.D. degrees and 55% have graduate or post-graduate qualifications. 14% of our 1,184 employees are engaged in research and development activities and 73% are engaged in commercialization activities. 13% are engaged in global services activities including finance, legal, risk, people and culture, information technology.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. We support our employees by offering annual performance-based bonus, equity-based incentive program, employee assistance programs, paid wellness days, hybrid work arrangements and support for learning and development.

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Legal Proceedings

See "Item 8. Financial Information - Consolidated Statements and Other Financial Information - Legal Proceedings."

Seasonality

We do not believe that seasonal influences have had a material effect on our business, financial condition, or results of operations. The target disease indications for Illuccix and our other product candidates are not seasonal diseases.

Accordingly, once we have successfully obtained regulatory approvals to commercialize our other product candidates, if ever, we do not anticipate that our business will be materially affected by seasonal influences in the future.

Australian Disclosure Requirements

Environmental regulation and compliance; Sustainability report

Telix seeks to be compliant with all applicable environmental laws and regulations relevant to its operations, including but not limited to Australia, Belgium, Japan, Canada and the U.S. We monitor compliance on a regular basis to minimize the risk of non-compliance.

We conduct our activities at TMS in Brussels South, Belgium, in accordance with applicable environmental regulations, including regular inspections by the Belgian Federal Agency for Nuclear Control ("FANC"). In 2022, TMS received updated authorizations from FANC, aligned with the scope of Telix operations, and Telix is complying with its obligations under these licenses and existing Belgian regulation. In December 2022, TMS was granted an environmental permit from the Regional Authorities, valid until 7 October 2042, and in 2025 an updated operation authorization from FANC, valid until 8 May 2040.

Telix also conducts its activities at, RLS Radiopharmacies, TMS Sacramento, Telix Targeting Technologies, and IsoTherapeutics in the U.S., ARTMS in Canada, TMS North Melbourne in Australia, and TMS Yokohama in Japan in accordance with applicable environmental regulations, including inspections by relevant authorities as required.

There were no known environmental breaches at Telix operations during the reporting period.

Information about Telix's sustainability program, including for environmental matters, is detailed in the Company's Sustainability report.

Beyond these matters, Telix is unaware of any environmental regulations matters applying to the Group's operating activities that require disclosure.

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1. Organizational Structure

The following table sets out for each of our subsidiaries, the state or jurisdiction of incorporation or organization, percentage ownership and voting interest held by us (directly or indirectly through subsidiaries):

Name of Entity	State or Jurisdiction of Incorporation or Organization	Percentage Ownership and Voting Interest (%)
Telix Pharmaceuticals Ltd	Australia	N/A
Telix Pharmaceuticals (Innovations) Pty Ltd	Australia	100
Telix Pharmaceuticals Holdings Pty Limited	Australia	100
Telix Pharmaceuticals International Holdings Pty Ltd	Australia	100
Telix Pharmaceuticals Australia Holdings Pty Ltd	Australia	100
Telix Pharmaceuticals (ANZ) Pty Ltd	Australia	100
Telix Pharmaceuticals (Corporate) Pty Ltd	Australia	100
Telix Pharmaceuticals (Belgium) SRL	Belgium	100
Telix Innovations SA	Belgium	100
Telix Innovations Rph Participacoes Ltda	Brazil	51
Telix Pharmaceuticals (Canada) Inc.	Canada	100
Telix ARTMS Inc.	Canada	100
Telix Pharmaceuticals (France) SAS	France	100
Telix Pharmaceuticals (Germany) GmbH	Germany	100
Rhine Pharma GmbH3	Germany	100
Therapeia GmbH & Co. KG	Germany	100
Therapeia Verwaltungs-GmbH	Germany	100
Telix Pharma Japan KK	Japan	100
Telix Pharmaceuticals (NZ) Limited	New Zealand	100
Telix Pharmaceuticals (Singapore) Pte Ltd	Singapore	100
Telix Pharmaceuticals (Switzerland) GmbH	Switzerland	100
Telix Pharmaceuticals (UK) Ltd	United Kingdom	100
Lightpoint Surgical Ltd	United Kingdom	100
Lightpoint Surgical Spain S.L. (Lightpoint Medical Espana SLU)	Spain	100
Telix Pharmaceuticals (US) Inc.	Delaware	100
Telix Optimal Tracers, LLC	Delaware	100
Telix IsoTherapeutics Group, Inc.	Delaware	100
Telix QSAM, Inc.	Delaware	100
QSAM Therapeutics Inc.	Texas	100
RLS (USA), Inc.	Delaware	100
Las Vegas Radiopharmacy, Inc.	Delaware	100
Telix Targeting Technologies, Inc.	Delaware	100
ARTMS US, Inc.	Delaware	100

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Name of Entity	State or Jurisdiction of Incorporation or Organization	Percentage Ownership and Voting Interest (%)
Telix Pharmaceuticals Holdings Pty Ltd	Australia	100
Telix Pharmaceuticals International Holdings Pty Ltd	Australia	100
Telix Pharmaceuticals Australia Holdings Pty Ltd	Australia	100
Telix Pharmaceuticals (Innovations) Pty Ltd	Australia	100
Telix Pharmaceuticals (ANZ) Pty Ltd	Australia	100
Telix Pharmaceuticals (Corporate) Pty Ltd	Australia	100
Telix Pharmaceuticals (NZ) Limited	New Zealand	100
Telix Pharma Japan KK	Japan	100
Telix Pharmaceuticals (Singapore) Pte Ltd	Singapore	100
Telix Pharmaceuticals (US) Inc.	Delaware	100
Telix Optimal Tracers LLC	Delaware	100
Telix Pharmaceuticals (Canada) Inc.	Canada	100
Telix Innovations SA	Belgium	100
Telix Pharmaceuticals (Germany) GmbH	Germany	100
Telix Pharmaceuticals (Switzerland) GmbH	Switzerland	100
Telix Pharmaceuticals (Belgium) SRL	Belgium	100
Lightpoint Surgical Ltd	United Kingdom	100
Lightpoint Surgical Spain S.L.	Spain	100
Rhine Pharma GmbH	Germany	100
Therapeia GmbH & Co. KG	Germany	100
Therapeia Verwaltungs-GmbH	Germany	100
Telix Pharmaceuticals (France) SAS	France	100
Telix Pharmaceuticals (UK) Ltd	United Kingdom	100
Telix IsoTherapeutics Group Inc.	Delaware	100
Telix ARTMS Inc.	Canada	100
ARTMS US, Inc.	Delaware	100
Telix QSAM, Inc.	Delaware	100
QSAM Therapeutics Inc.	Texas	100
Telix Innovations RPH Participações Ltda.	Brazil	51
RLS (USA) Inc.	Delaware	100
Las Vegas Radiopharmacy, Inc.	Delaware	100
Telix Targeting Technologies, Inc.	Delaware	100

2. Property, Plant and Equipment

Our principal headquarters are located in Melbourne, Australia where we lease office space and have a separate R&D facility. The majority of our workforce is in the U.S., based out of our U.S. headquarters in Indianapolis, Indiana, or our Dallas, Texas office, our R&D facilities in Angleton, Texas and Los Angeles and Sacramento, California, working remotely, or in one of our network of radiopharmacies that we acquired in January 2025 as part of our acquisition of RLS. We also maintain offices in Sydney and Brisbane, Australia, in Brussels, Herstal (near Liège), Belgium, in Geneva, Switzerland, and in Kyoto, Japan, and have R&D facilities in South Brussels, Belgium, Yokohama, Japan, and Vancouver, Canada. We believe that our current facilities are adequate to meet our ongoing needs and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

For additional information on our property, plant and equipment, see Note 19 to our audited consolidated financial statements included elsewhere in this Annual Report.

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ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis are based upon and should be read together with our consolidated financial statements and the accompanying notes and other financial information included elsewhere in this Annual Report. This discussion includes both historical information and forward-looking information based upon current expectations that involve risk, uncertainties and assumptions. Our actual results may differ materially from management's expectations as a result of various factors, including, but not limited to, those discussed in "Item 3. Key Information — D. Risk Factors" and elsewhere in this Annual Report.

Our audited consolidated financial statements *as of December 31, 2025 and 2024 and for the years ended December 31, 2025, 2024 and 2023 have been prepared in accordance with IFRS Accounting Standards.*

A. Operating Results

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Our prostate cancer portfolio includes Illuccix and Gozellix, our commercially available 68Ga-labelled PSMA-PET imaging agents for prostate cancer. The revenues generated from sales of Illuccix (and Gozellix in 2025), the costs associated with such sales and our operating and other expenses resulted in a loss after tax of $7.1 million, and a profit after tax of $33.7 million and $4.2 million for the years ended December 31, 2025, 2024 and 2023, respectively.

We are leveraging our commercial revenues as a source of funding for the development of additional therapeutic and diagnostic product candidates in our pipeline. These product candidates include TLX591-Tx, a therapeutic rADC, being evaluated in a Phase 3 clinical trial for the treatment of patients with prostate cancer and two innovative imaging agents, TLX250-Px for kidney (renal) cancer and TLX101-Px for brain cancer (glioma).

Our operations have been financed primarily through cash generated by our commercial operations and the issuance and sale of ordinary shares. Our total comprehensive loss was $14.1 million for the year ended December 31, 2025. Our total comprehensive income was $36.0 million and $1.7 million for the years ended December 31, 2024 and 2023, respectively. We expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates. In addition, if and when we seek and obtain regulatory approval to commercialize additional product candidates, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our total comprehensive income or loss may fluctuate significantly from period-to-period, depending on the timing of our clinical trials and our expenditures on other research and development activities.

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Results of Operations for the Fiscal Years Ended December 31, 2025, 2024 and 2023

The following table sets forth a summary of our Consolidated statement of comprehensive income or loss for the periods presented.

	Year ended December 31			2025 vs. 2024		2024 vs. 2023	
	2025	2024	2023	Change	Change	Change	Change
	US$'000	US$'000 (Recast)	US$'000 (Recast)	US$'000	%	US$'000	%
	(in thousands, except percentage and per share data)						
Continuing operations							
Revenue from contracts with customers	803,794	516,551	332,978	287,243	56	183,573	55
Cost of sales	(377,356)	(180,388)	(123,445)	(196,968)	109	(56,943)	46
Gross profit	**426,438**	**336,163**	**209,533**	**90,275**	**27**	**126,630**	**60**
Research and development costs	(171,249)	(127,930)	(85,315)	(43,319)	34	(42,615)	50
Selling and marketing expenses	(96,766)	(55,953)	(33,464)	(40,813)	73	(22,490)	67
Manufacturing and distribution costs	(44,593)	(16,670)	(6,251)	(27,923)	168	(10,420)	167
General and administration costs	(95,789)	(85,318)	(49,668)	(10,471)	12	(35,650)	72
Other gains/(losses)(net)	11,735	4,885	(23,827)	6,850	140	28,712	*
Operating profit	**29,776**	**55,177**	**11,008**	**(25,401)**	**(46)**	**44,169**	**401**
Finance income	5,826	7,180	671	(1,354)	(19)	6,509	969
Finance costs	(40,868)	(24,442)	(9,085)	(16,426)	67	(15,357)	169
(Loss)/profit before income tax	**(5,266)**	**37,915**	**2,594**	**(43,181)**	**(114)**	**35,321**	**1,362**
Income tax (expense)/benefit	(1,859)	(4,230)	1,614	2,371	(56)	(5,844)	*
(Loss)/profit for the year	**(7,125)**	**33,685**	**4,208**	**(40,810)**	*	**29,477**	**700**
(Loss)/profit for the year attributable to:							
Owners of Telix Pharmaceuticals Limited	(7,125)	33,685	4,208	(40,810)	*	29,477	700
Other comprehensive (loss)/income:							
Items that will not be reclassified to profit or loss in subsequent periods:							
Changes in the fair value of investments at fair value through other comprehensive income	(1,242)	(3,287)	(612)	2,045	(62)	(2,675)	437
Items to be reclassified to profit or loss in subsequent periods:							
Exchange differences on translation of foreign operations	(5,757)	5,568	(1,863)	(11,325)	*	7,431	*
Total comprehensive (loss)/income for the year	**(14,124)**	**35,966**	**1,733**	**(50,090)**	*	**34,233**	**1,975**
Total comprehensive (loss)/income for the year attributable to:							
Owners of Telix Pharmaceuticals Limited	(14,124)	35,966	1,733	(50,090)	*	34,233	1,975
	US$ Cents	US$ Cents	US$ Cents				
Basic (loss)/earnings per share from continuing operations after income tax attributable to the ordinary equity holders of the Company	**(2.11)**	**10.17**	**1.32**				
Diluted (loss)/earnings per share from continuing operations after income tax attributable to the ordinary equity holders of the Company	**(2.11)**	**9.76**	**1.30**				

* Percentage not meaningful

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Comparison of Years Ended December 31, 2025 and 2024

Revenue from Contracts with Customers

Revenue from contracts with customers was $803.8 million for the year ended December 31, 2025, an increase of $287.2 million, or 56%, compared to $516.6 million for the year ended December 31, 2024. This increase was due to growth in commercial sales from our Precision Medicine business as well as eleven months of revenue from RLS, acquired on January 28, 2025.

Cost of Sales

Cost of sales increased by $197.0 million, or 109%, to $377.4 million for the year ended December 31, 2025 from $180.4 million for the year ended December 31, 2024. The increase was primarily driven by increased sales volumes and the change in product mix following the acquisition of RLS.

Gross margin decreased in 2025 relative to 2024, decreasing to 53% for 2025 (compared to 65% in 2024). This decrease was driven by the change in product mix following the acquisition of RLS and its sales of lower-margin SPECT imaging products.

Research and Development Costs

R&D costs were $171.2 million for the year ended December 31, 2025, an increase of $43.3 million, or 34%, compared to $127.9 million for the year ended December 31, 2024. This increase was primarily driven by:

- preparation for the re-submission of regulatory packages to the FDA for two new imaging agents in the U.S.
- production of inventory for commercial launches
- patient recruitment and clinical manufacturing for the Phase 3 ProstACT Global trial, and
- expanding our clinical trial activity and other R&D activity, as our current product candidates advance through development and as we invest in future product candidates and programs.

Selling and Marketing Expenses

Selling and marketing expenses were $96.8 million for the year ended December 31, 2025, an increase of $40.8 million, or 73%, compared to $56.0 million for the year ended December 31, 2024. This increase was primarily driven by increased investment in promotional activities and sales force operations, deployed to drive higher sales volumes of Illuccix, and to support the launches of Gozellix in the U.S. and Illuccix in Europe.

Manufacturing and Distribution Costs

Manufacturing and distribution costs were $44.6 million for the year ended December 31, 2025, an increase of $27.9 million, or 168%, compared to $16.7 million for the year ended December 31, 2024. This increase was primarily driven by the impact of 11 months of RLS operations on the Group results, and higher costs associated with preparing the Brussels South manufacturing facility for GMP commercial production.

General and Administration Costs

General and administration costs were $95.8 million for the year ended December 31, 2025, an increase of $10.5 million, or 12%, compared to $85.3 million for the year ended December 31, 2024. This increase was driven by:

- the impact of 11 months of RLS operations on the Group results
- costs incurred to implement a Sarbanes-Oxley program, and
- professional fees in connection with the subpoena from the U.S. Securities and Exchange Commission (SEC) Refer to page 268 for further information.

Other Gains/(Losses) (Net)

Other gains (net) were $11.7 million for the year ended December 31, 2025, a change of $6.9 million, compared to other gains (net) of $4.9 million for the year ended December 31, 2024. This resulted from a remeasurement of contingent consideration on ARTMS and RLS based on the probability of achieving certain milestones, and unrealized foreign currency gains.

Finance Income

Finance income was $5.8 million for the year ended December 31, 2025, a decrease of $1.4 million, or 19%, compared to $7.2 million for the year ended December 31, 2024. Following the acquisition of RLS in January 2025 and associated

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cash settlement of the transaction, there was a decrease in cash and cash equivalents placed into short term deposits in the year ended December 31, 2025 compared to the prior year.

Finance Costs

Finance costs were $40.9 million for the year ended December 31, 2025, an increase of $16.4 million, or 67%, compared to $24.4 million for the year ended December 31, 2024. This increase reflects the full year impact of interest paid and the unwind of discount on Convertible Bonds issued in July 2024.

Income Tax Expense

Income tax expense was $1.9 million for the year ended December 31, 2025, a decrease of $2.3 million compared to an expense of $4.2 million for the year ended December 31, 2024. This resulted from the recognition of $12.1 million in deferred tax benefits attributable to temporary differences and unused tax losses. Current tax expense decreased from $18.6 million in 2024 to $14.0 million in 2025 as a result of the decrease in taxable profits generated in the U.S. and Belgium.

Comparison of Years Ended December 31, 2024 and 2023

Revenue from Contracts with Customers

Revenue from contracts with customers was $516.6 million for the year ended December 31, 2024, an increase of $183.6 million, or 55%, compared to $333.0 million for the year ended December 31, 2023. This increase was due to a 55% increase in commercial sales volumes of Illuccix in the U.S. compared to 2023, supported by a combination of increased market share and category growth for PSMA imaging, predominantly in the U.S.

Cost of Sales

Cost of sales increased by $57.0 million, or 46%, to $180.4 million for the year ended December 31, 2024 from $(123.4) for the year ended December 31, 2023. The increase was primarily driven by higher dose administration fees to distributors.

Gross margin improved in 2024 relative to 2023, increasing to 65% for 2024 (compared to 63% in 2023). This increase was supported by a stable selling price for Illuccix® within each market segment.

Research and Development Costs

R&D costs were $127.9 million for the year ended December 31, 2024, an increase of $42.6 million, or 50%, compared to $85.3 million for the year ended December 31, 2023. This increase was primarily driven by preparation for the commercial launches, including scale-up of inventory, of three new imaging agents in the U.S. and patient recruitment and clinical manufacturing for the Phase 3 ProstACT Global trial. We expect our R&D costs to continue to increase as we expand our clinical trial activity and other R&D activity, as our current product candidates advance through development and as we invest in future product candidates and programs.

Selling and Marketing Expenses

Selling and marketing expenses were $56.0 million for the year ended December 31, 2024, an increase of $22.5 million, or 67%, compared to $33.5 million for the year ended December 31, 2023. This increase was primarily driven by increased investment in promotional activities and sales force operations, deployed to drive higher sales volumes of Illuccix, and preparation activities to support the launch of three new imaging products in the U.S.

Manufacturing and Distribution Costs

Manufacturing and distribution costs were $16.7 million for the year ended December 31, 2024, an increase of $10.4 million, or 167%, compared to $6.3 million for the year ended December 31, 2023. This increase was primarily driven by increased personnel costs from the acquisition of ARTMS and IsoTherapeutics, and higher costs associated with preparing the Brussels South manufacturing facility for GMP commercial production.

General and Administration Costs

General and administration costs were $85.3 million for the year ended December 31, 2024, an increase of $35.6 million, or 72%, compared to $49.7 million for the year ended December 31, 2023. This increase was driven by investments in corporate infrastructure to support the expansion of services assisting commercial operations in each region, professional fees incurred in connection with our Nasdaq listing and transaction costs related to the acquisitions of ARTMS Inc, IsoTherapeutics Group, and RLS (USA) Inc.

Other Gains/(Losses) (Net)

Other gains (net) were $4.9 million for the year ended December 31, 2024, a change of $28.7 million, compared to other losses (net) of $23.8 million for the year ended December 31, 2023. This resulted from a lower remeasurement of contingent consideration and unrealized foreign currency gains.

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Finance Income

Finance income was $7.2 million for the year ended December 31, 2024, an increase of $6.5 million compared to $0.7 million for the year ended December 31, 2023. This increase reflects an increase in cash and cash equivalents placed into short term deposits and higher interest rate yields obtained on deposits in the year ended December 31, 2024 compared to the prior year.

Finance Costs

Finance costs were $24.4 million for the year ended December 31, 2024, an increase of $15.3 million, or 169%, compared to $9.1 million for the year ended December 31, 2023. This increase was due to a higher unwind of discount on contingent consideration liability for 2024, reflecting the increased contingent consideration liabilities and finance costs associated with the Convertible Bonds issued during the year.

Income Tax (Expense)/Benefit

Income tax expense was $4.2 million for the year ended December 31, 2024, a change of $5.8 million compared to a $1.6 million benefit for the year ended December 31, 2023. This resulted from the recognition of $14.3 million in deferred tax benefits attributable to temporary differences and unused tax losses. Current tax expense increased from $10.9 million in 2023 to $18.6 million in 2024 as a result of the increase in taxable profits generated in the U.S. and Belgium.

Alternative Performance Measures

In reporting financial information, the Group presents alternative performance measures ("APMs") which are not defined or specified under the requirements of IFRS. The Group believes that these APMs, which are not considered to be a substitute for or superior to IFRS measures, provide stakeholders with additional useful information on the underlying trends, performance and position of the Group and are consistent with how business performance is measured internally. The alternative performance measures are not defined by IFRS and therefore may not be directly comparable with other companies' alternative performance measures. The key APMs that the Group uses are outlined below.

APM	Closest equivalent IFRS measure	Reconciling items to IFRS measure	Definition and purpose
Income statement measures			
Adjusted earnings before interest, tax, depreciation and amortization (Adjusted EBITDA)	Profit/(loss) before income tax	Finance costs, income tax expense, depreciation and amortization, remeasurement of provisions, other income and expenses.	Used to help assess current operational performance excluding the impacts of non-operating expenditure, finance costs and finance income, depreciation and amortization and taxation expense. It is a measure that management uses internally to assess the performance of the Group's segments and make decisions on the allocation of resources.
Adjusted earnings before interest, tax, depreciation and amortization and research and development (Adjusted EBITDAR)	Profit/(loss) before income tax	Finance costs, income tax expense, depreciation and amortization, remeasurement of provisions, other income and expenses and costs associated with product development activities.	Used to assess the Group's performance excluding non-operating expenditure, finance costs and finance income, depreciation and amortization, taxation expense and product development activities. Included as a metric for LTVR targets in 2023, 2024 and 2025.
Adjusted earnings before interest, tax, research and development (Adjusted EBITRD)	Profit/(loss) before income tax	Finance costs, income tax expense, remeasurement of provisions, other income and expenses and costs associated with product development activities.	Used to assess the Group's performance excluding non-operating expenditure, finance costs and finance income, taxation expense and product development activities. Included as a metric for LTVR targets in 2022.
Balance sheet measures			
Net tangible asset per share	None	Net assets excluding intangible assets, deferred tax assets and right-of-use assets divided by the Group's weighted average number of ordinary shares on issue.	Disclosed in the Group's Appendix 4E as required by Rule 4.3A of the ASX listing rules.

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Outlined below is a reconciliation of the Group's APMs used to measure performance.

Metric	Note	Operating segment	2025 $'000	2024 $'000 (Recast)	2023 $'000 (Recast)
Operating profit			29,776	55,177	11,008
Adjusting items:					
Revenue from contracts with customers	4	Therapeutics	(9,273)	(6,226)	(3,496)
Research and development costs	5		171,249	127,930	85,315
U.S. listing costs	7		-	6,026	-
Acquisition transaction costs	7		-	5,750	-
Depreciation and amortization	9		21,506	4,851	4,485
Other (gains)/losses net	10		(11,735)	(4,885)	23,827
Adjusted EBITDAR			**201,523**	**188,623**	**121,139**
Product development revenue and costs			(161,976)	(121,704)	(81,819)
Adjusted EBITDA			**39,547**	**66,919**	**39,320**

Segments

Our three reportable segments are Precision Medicine, Therapeutics and Manufacturing Solutions.

We evaluate the performance of our segments based on Adjusted EBITDA, calculated as earnings before interest, tax, depreciation and amortization, adjusted for the effects of the remeasurement of contingent consideration and other gains and losses which may have an impact on the degree to which earnings reflect the results of core operations, such as an impairment or impairment reversal where the impairment is the result of an isolated, non-recurring event.

Our management uses Adjusted EBITDA to assess the core operating performance of segments and to make decisions about the allocation of resources. We also believe this measure provides useful information to users of our financial statements by allowing for the assessment of underlying trends in our current operational performance by excluding the impacts of non-cash sunk costs.

Precision Medicine

The Precision Medicine segment focuses on the commercial sales of Illuccix, Gozellix and other diagnostic products that may obtain regulatory approvals. This segment includes royalties and sales of goods (which account for the majority of our revenue from operations), as well as the sales and marketing expenses and costs of sales necessary to support those revenues and research and development costs associated with development activities of our diagnostic pipeline.

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The following table sets forth the results of operations for our Precision Medicine segment for the years ended December 31, 2025, 2024 and 2023.

	Year ended December 31,			2025 vs. 2024		2024 vs. 2023	
	2025	2024	2023	Change	Change	Change	Change
	US$'000	US$'000 (Recast)	US$'000 (Recast)	US$'000	%	US$'000	%
	(in thousands, except percentage data)						
Revenue from contracts with customers	621,930	508,508	329,205	113,421	22	179,304	35
Cost of sales	(222,750)	(178,263)	(123,445)	(44,487)	25	(54,818)	31
Gross profit	**399,180**	**330,245**	**205,760**	**68,935**	**21**	**124,485**	**38**
Research and development costs	(71,156)	(71,628)	(53,669)	472	(1)	(17,959)	25
Selling and marketing expenses	(82,359)	(55,358)	(33,358)	(27,001)	49	(22,000)	40
Manufacturing and distribution costs	(10,262)	(5,251)	(4,798)	(5,011)	95	(452)	9
General and administration costs	(22,303)	(27,777)	(20,707)	5,474	(20)	(7,070)	25
Other losses (net)	(3,552)	(5,976)	(24,497)	2,424	(41)	18,521	(310)
Operating profit	**209,548**	**164,255**	**68,731**	**45,293**	**28**	**95,524**	**58**
Other losses (net)	3,552	5,976	24,497	26	-	(18,521)	(310)
Depreciation and amortization	3,333	3,679	3,729	(346)	(9)	(50)	(1)
Adjusted EBITDA	**216,433**	**173,910**	**96,957**	**42,523**	**24**	**76,953**	**44**

Comparison of Years Ended December 31, 2025 and 2024

For the year ended December 31, 2025, revenue from contracts with customers for our Precision Medicine segment consisted of $621.6 million (2024: $508.4 million) in sales of goods and $0.3 million (2024: $0.1 million) in royalty revenue. Sales of Illuccix and Gozellix in the U.S. were the main driver of the 22% increase in revenue from contracts with customers for the Precision Medicine segment. Cost of Sales increased 25% year-over-year, driven by higher manufacturing volumes, distribution costs, and radiopharmacy-related expenses. Gross profit declined slightly to 64% vs. 65% in the prior year, primarily reflecting a balance between commercial rebate levels, supply chain costs, and ongoing operational efficiencies.

R&D expenses were $71.2 million in 2025, compared to $71.6 million in 2024. These similar numbers represent Telix's commitment to furthering our investment in diagnostic programs globally.

Selling and marketing expenses were $82.4 million in 2025, compared to $55.4 million in 2024. The increase was predominantly due to additional sales force, expanded commercial infrastructure and marketing expenditure incurred to drive higher volumes and market share of our prostate imaging agents in the U.S. and Australia, Illuccix launch activities in Europe and pre-launch activities for Zircaix and Pixclara.

Manufacturing and distribution costs were $10.3 million in 2025, compared to $5.3 million in 2024, reflecting an increase in facility and staff costs to support supply chain and quality activities to deliver clinical and commercial products.

General and administration costs were $22.3 million in 2025, compared to $27.8 million in 2024, reflecting operating leverage and stabilization in corporate activities and related overheads.

Adjusted EBITDA increased by $42.5 million, or 24% to $216.4 million for the fiscal year ended December 31, 2025, up from $173.9 million in 2024, reflecting the growth in commercial revenues and stabilization in gross margins, partially offset by higher operating expenditure.

Comparison of Years Ended December 31, 2024 and 2023

For the year ended December 31, 2024, revenue from contracts with customers for our Precision Medicine segment consisted of $508.4 million (2023: $328.9 million) in sales of goods and $0.1 million (2023: $0.3 million) in royalty

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revenue. Sales of Illuccix in the U.S. were the main driver of the 35% increase in revenue from contracts with customers for the Precision Medicine segment.

Adjusted EBITDA increased by $77.0 million to $173.9 million for the year ended December 31, 2024, up from $97.0 million in 2023.

Therapeutics

The Therapeutics segment focuses on the development of our core therapeutic pipeline for commercialization. This segment includes revenue received from license agreements prior to commercialization and research and development services.

The following table sets forth the results of operations for our Therapeutics segment for the years ended December 31, 2025, 2024 and 2023.

	Year ended December 31,			2025 vs. 2024		2024 vs. 2023	
	2025	2024	2023	Change	Change	Change	Change
	US$'000	US$'000 (Recast)	US$'000 (Recast)	US$'000	%	US$'000	%
	(in thousands, except percentage data)						
Revenue from contracts with customers	9,273	6,226	3,496	3,047	49	2,730	44
Cost of sales	(229)	-	-	(229)	*	-	*
Gross profit	**9,044**	**6,226**	**3,496**	**2,818**	**45**	**2,730**	**44**
Research and development costs	(98,039)	(55,877)	(31,258)	(42,162)	75	(24,619)	44
Selling and marketing expenses	(1,434)	(88)	(106)	(1,346)	1,525	18	(20)
Manufacturing and distribution costs	(4,238)	(22)	(69)	(4,216)	*	46	(208)
General and administration costs	(3,606)	(137)	(185)	(3,469)	2,533	49	(35)
Other gains (net)	21	-	-	21	*	-	100
Operating loss	**(98,252)**	**(49,898)**	**(28,122)**	**(48,354)**	**97**	**(21,776)**	**44**
Other gains (net)	(21)	-	-	(21)	*	-	100
Depreciation and amortization	278	-	-	278	*	-	*
Adjusted EBITDA	**(97,995)**	**(49,898)**	**(28,122)**	**(48,097)**	**96**	**(21,776)**	**44**

* Percentage not meaningful

Comparison of Years Ended December 31, 2025 and 2024

For the year ended December 31, 2025, revenue from contracts with customers for our Therapeutics segment consisted of $9.1 million (2024: $6.2 million) in R&D services revenue. The year-over-year change in revenue from contracts with customers for our Therapeutics segment reflected higher investment in our R&D expenditure toward new therapeutic product candidates in the year ended December 31, 2025, which resulted in higher R&D services revenue from the Grand Pharma contract.

Research and development costs were $98.0 million in 2025, compared to $55.9 million in 2024, reflecting the increased R&D investment towards patient recruitment and clinical manufacturing for the Phase 3 ProstACT Global trial, and an increased investment into the development of our late-stage therapeutic assets.

Selling and marketing expenses were $1.4 million in 2025, compared to $0.1 million in 2024. The increase was predominantly due to an increase in global medical affairs activities and investigator-initiated trial costs.

Manufacturing and distribution costs were $4.2 million in 2025 compared to nil in 2024, predominantly due to the increase in CMC activities undertaken by our Manufacturing Solutions business to advance our therapeutics pipeline and logistics costs in delivering clinical doses to patients.

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General and administration costs were $3.6 million in 2025, compared to $0.1 million in 2024, reflecting a higher allocation of corporate services provided to support the growth in activities, including an increase in business development, finance, intellectual property and legal costs.

Adjusted EBITDA for the Therapeutics segment was a loss of $98.0 million in 2025, compared to $49.9 million in 2024, reflecting the increase in activities as our late-stage therapeutics products progress through the clinical stages of development.

Comparison of Years Ended December 31, 2024 and 2023

For the year ended December 31, 2024, revenue from contracts with customers for our Therapeutics segment consisted of $6.2 million (2023: $3.5 million) in R&D services revenue. The year-over-year change in revenue from contracts with customers for our Therapeutics segment reflected higher investment in our R&D expenditure toward new therapeutic product candidates in the year ended December 31, 2024, which resulted in higher R&D services revenue.

Adjusted EBITDA for the Therapeutics segment was a loss of $49.9 million in 2024, compared to $28.1 million in 2023, reflecting the increased R&D investment towards patient recruitment and clinical manufacturing for the Phase 3 ProstACT Global trial.

Manufacturing Solutions

The Manufacturing Solutions segment focuses on the operations of our vertically integrated supply chain and manufacturing business and includes our production TMS facilities at Brussels South, North Melbourne, Sacramento and Yokohama, ARTMS, IsoTherapeutics, and RLS Radiopharmacies. This segment comprises revenue generated from distribution service fee revenue, as well as the sale of PET and SPECT products at RLS. Outside of RLS, revenue is generated by the provision of contract manufacturing services to companies in the radiopharmaceutical industry, as well as the operating expenses associated with our manufacturing solutions business.

The following table sets forth the results of operations for our Manufacturing Solutions segment for the fiscal years ended December 31, 2025, 2024 and 2023.

	Year ended December 31,			2025 vs. 2024		2024 vs. 2023	
	2025	2024	2023	Change	Change	Change	Change
	US$'000	US$'000 (Recast)	US$'000 (Recast)	US$'000	%	US$'000	%
	(in thousands, except percentage data)						
Revenue from contracts with customers	172,591	1,817	277	170,774	9,398	1,540	85
Inter-segment revenue	72,514	-	-	72,514	*	-	*
Cost of sales	(222,853)	(2,125)	-	(220,728)	*	(2,125)	100
Gross profit/(loss)	**22,252**	**(308)**	**277**	**22,560**	**(7,325)**	**(585)**	**190**
Research and development costs	(5,813)	(425)	(388)	(5,388)	1,267	(37)	9
Selling and marketing expenses	(12,973)	(507)	-	(12,467)	2,461	(507)	100
Manufacturing and distribution costs	(30,093)	(11,397)	(1,384)	(18,696)	164	(10,013)	88
General and administration costs	(12,021)	(3,977)	(2,475)	(8,044)	202	(1,502)	38
Other gains (net)	14,711	81	-	14,630	*	82	101
Operating loss	**(23,937)**	**(16,533)**	**(3,970)**	**(7,404)**	**45**	**(12,563)**	**76**
Other gains (net)	(14,711)	(81)	-	(14,630)	*	(82)	101
Depreciation and amortization	16,933	856	157	16,077	1,878	699	82
Adjusted EBITDA	**(21,715)**	**(15,758)**	**(3,813)**	**(5,957)**	**38**	**(11,945)**	**76**

* Percentage not meaningful

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Comparison of Years Ended December 31, 2025 and 2024

For the year ended December 31, 2025, revenue from contracts with customers for our Manufacturing Solutions segment consisted of $172.6 million (2024: $1.8 million) in services revenue, with the year-over-year increase related to operations of the RLS business acquired in late January 2025.

Selling and marketing expenses were $13.0 million in 2025, compared to $0.5 million in 2024 reflecting the 11 months of operations from the newly acquired RLS. These costs comprise predominantly amortization of acquired intangible assets of $4.8 million, employment costs, sales commissions and travel costs related to sales and marketing personnel.

Manufacturing and distribution costs were $30.1 million and general and administration costs were $12.0 million for our Manufacturing Solutions segment for the year ended December 31, 2025 (compared to $11.4 million and $4.0 million for the year ended December 31, 2024, respectively). These increases were predominantly driven by increased personnel and occupancy costs from the newly acquired RLS business, combined with increased activity to prepare the Brussels South facility for GMP commercial production.

Other gains were $14.7 million in 2025, compared to $0.1 million in 2024, comprising the remeasurement of provisions related to contingent consideration liabilities for ARTMS and RLS. The remeasurements were based on revised probabilities applied to the achievement of certain commercial milestones.

For the year ended December 31, 2025, Adjusted EBITDA for the Manufacturing Solutions business was a loss of $21.7 million, compared to $15.8 million in the year ended December 31, 2024. The year-over-year change in Adjusted EBITDA was driven by increased investment in our manufacturing, supply chain and logistics functions and the continued buildout of our Brussels South, Yokohama and North Melbourne facilities.

Comparison of Years Ended December 31, 2024 and 2023

For the year ended December 31, 2024, revenue from contracts with customers for our Manufacturing Solutions segment consisted of $1.8 million in services revenue compared to $0.3 million for the year ended December 31, 2023, with the year-over-year increase related to operations of the IsoTherapeutics business acquired during the year.

Manufacturing and distribution costs were $11.4 million and general and administration costs were $4.0 million for the year ended December 31, 2024 (compared to $1.4 million and $2.5 million for the year ended December 31, 2023, respectively). These increases were predominantly driven by increased personnel and occupancy costs from the newly acquired ARTMS and IsoTherapeutics businesses, combined with increased activity to prepare the Brussels South facility for GMP commercial production.

For the year ended December 31, 2024, Adjusted EBITDA for the Manufacturing Solutions segment was a loss of $15.8 million, compared to $3.8 million in the year ended December 31, 2024. The year-over-year change in Adjusted EBITDA was driven by increased investment in our manufacturing, supply chain and logistics functions and the continued buildout of our Brussels South facility.

For more information on our segment reporting, see note 3 to our audited consolidated financial statements appearing elsewhere in this Annual Report.

Recently Adopted Accounting Pronouncements

Refer to note 2.2 within our Material accounting policy information for a summary of recently adopted or yet to be adopted accounting pronouncements.

Foreign Private Issuer Status

We report under the Exchange Act as a “foreign private issuer” under U.S. securities laws. In our capacity as a foreign private issuer, we are exempt from certain SEC and Nasdaq requirements.

Consequently, we are not subject to all of the disclosure requirements applicable to U.S. domestic public companies. For example, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, at present, our executive officers, the members of our board of directors and our principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and the reporting rules under the Exchange Act with respect to their purchases and sales of our securities. However, absent an exemption from the SEC, following recent legislative changes that become effective on March 18, 2026, our officers and directors will be subject to the insider reporting obligations under Section 16(a) of the Exchange Act, including the requirements to file Forms 3, 4 and 5, pursuant to the Holding Foreign Insiders Accountable Act enacted on December 18, 2025. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies the securities of which are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that 50% or more of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of the members of either our board of directors or

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our global management team are U.S. citizens or residents; (ii) more than 50% of our assets are located in the U.S.; or (iii) our business is administered principally in the U.S.

We have taken advantage of certain reduced reporting and other requirements in this Annual Report. Accordingly, the information contained herein may be different from the information you receive from other public companies.

B. Liquidity and Capital Resources

Prior to the fiscal year ended December 31, 2023, we incurred operating losses in each year since our founding. We anticipate that as we expand through strategic acquisitions, increase our sales and marketing efforts and expand our investment in R&D, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, strategic collaborations and other third-party funding arrangements. Our future liquidity and capital resources will depend on product revenue from the successful continued commercialization of Illuccix and Gozellix, revenue from any future products for which we obtain regulatory approval and the R&D costs and other expenditure necessary to support these initiatives and future products. Our total comprehensive loss was $14.1 million, for the year ended December 31, 2025. Our total comprehensive income was $36.0 million and $1.7 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2025, we had cash and cash equivalents of $141.9 million and accumulated losses of $154.5 million. As of December 31, 2025, we held 52.8% of our cash in Australian dollars, 39.7% in U.S. dollars, 5.5% in Euros, 0.3% in British pounds, 0.5% in Canadian dollars and 1.0% in Swiss Francs.

Sources and Uses of Liquidity

Our operations have been financed primarily through cash generated by our commercial operations and the issuance and sale of new ordinary shares and Convertible Bonds.

We intend to leverage our commercial revenues and the proceeds raised from the issuance of and sale of new ordinary shares and Convertible Bonds as a source of funding for the development of additional therapeutic and diagnostic product candidates in our pipeline, including conducting label-expanding trials across our portfolio of diagnostic imaging agents and advancing clinical trials for our therapeutic product candidates. In the years ended December 31, 2025, 2024 and 2023, we received $774.2 million, $467.7 million and $311.8 million respectively, in receipts from customers, which predominantly consisted of collections from sales from our Precision Medicine and Manufacturing Solutions businesses.

In the first quarter of 2022, we entered into two loan agreements whereby BNP Paribas agreed to lend us $6.8 million and IMBC Group agreed to lend us $4.5 million. Each loan is denominated in Euros, in the amounts of €6.1 million and €4.0 million, respectively, and have been translated to US$ based on the applicable exchange rate as of December 31, 2025. Each loan has a 10-year term and an interest rate of 1.85% per annum, payable monthly, and each is repayable in 96 monthly installments beginning at the end of a two-year grace period. As of December 31, 2025, the outstanding balance of these facilities was $10.4 million (translated based on the applicable exchange rate as of December 31, 2025). In connection with the loan agreement with BNP Paribas, we also entered a roll-over loan agreement whereby BNP Paribas agreed to lend us an additional $2.3 million (€2.0 million, translated based on the applicable exchange rate as of December 31, 2025). The loan has a two-year extendable term and a per annum interest rate calculated by adding the eurozone interbank interest rate as of the determination date to a 1.5% margin, payable based on our choice of interest period ranging from 1 month to 12 months for each advance (with a default interest period of three months if no alternative is chosen), and it is repayable in full upon its expiration date. As of December 31, 2025, we have not drawn down from this facility. We have used the borrowings from these loans in order to fund the renovation and redevelopment of our Brussels South production facility.

On July 30, 2024 the Group completed the issue of $426,140,000 (A$650,000,000) in convertible bonds maturing in 2029. The bonds are convertible into fully paid ordinary shares in Telix Pharmaceuticals Limited. The initial conversion price of the convertible bonds is A$24.78 per share, subject to anti-dilution adjustments set out in the final terms and conditions of the convertible bonds. The net proceeds were $416,324,000, after transaction costs.

The convertible bonds will bear interest at a rate of 2.375 per cent per annum. Interest will be payable quarterly in arrears on October 30, January 30, April 30 and July 30 in each year, beginning on October 30, 2024. The convertible bonds will mature on or about July 30, 2029, unless redeemed, repurchased, or converted in accordance with their terms. The holders have the option to redeem all or some of the convertible bonds on July 30, 2027 at their principal amount together with accrued but unpaid interest accrued to that date. The convertible bonds are listed on the SGX.

Funding Requirements

We believe that our existing cash resources and cash that we expect to generate from sales from the Precision Medicine and Manufacturing Solutions businesses will be sufficient to meet our projected operating expenses and capital expenditure requirements for at least the next 12 months, as well as our anticipated longer-term operating cash requirements and obligations. Our expectations regarding our short-term and long-term funding requirements are based on assumptions that may prove to be wrong, and we may need additional capital resources to fund our operating plans and capital expenditure requirements.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the commercialization of products for which we receive regulatory approval and continue clinical development of our

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therapeutic product candidates. Accordingly, we will need to obtain substantial funding in connection with our continuing operations. Until we can generate a sufficient amount of revenue from the sale of approved products, if ever, we expect to finance our operating activities through cash generated from commercial sales, existing cash and cash equivalents and financing activities, which may include equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise capital through the sale of equity or convertible debt securities, the ownership interest of our investors will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of ADSs. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates. If we are unable to raise funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our present and future funding requirements will depend on many factors, including, among other things:

- The amount of revenue received from commercial sales of products for which we receive marketing approval;
- The initiation, progress, timing, costs and results of our clinical trials for our product candidates;
- The costs associated with in-licensing or acquiring assets to expand our pipeline, acquiring businesses or assets to vertically integrate our supply chain and manufacturing and acquiring complementary business;
- The amount of milestones and royalties that we may be required to pay under existing acquisition and licensing agreements;
- Costs associated with expanding our organization;
- The costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringement raised by third parties;
- The time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates; and
- The costs of operating as a public listed company in both Australia and the U.S.

For more information as to the risks associated with our future funding needs, see “Item 3. Key Information — D. Risk Factors.”

Cash Flows

The following table summarizes our cash flows for the periods presented:

1. Year ended December 31,

	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
	(in thousands)		
Net cash (used in)/from operating activities	(17,293)	27,490	14,273
Net cash used in investing activities	(285,921)	(86,687)	(16,839)
Net cash (used in)/provided by financing activities	(3,719)	416,791	7,091
Net (decrease)/increase in cash and cash equivalents	**(306,933)**	**357,594**	**4,525**

Operating Activities

Net cash used in operating activities was $17.3 million during the year ended December 31, 2025. The primary source of cash from operating activities was $774.2 million in receipts from customers, which predominantly consisted of collections from sales from the Precision Medicine and Manufacturing Solutions businesses. The primary uses of cash in operating activities were payments to suppliers and employees of $710.6 million. Other operating cash outflows included $51.8 million in contingent consideration payments and $21.3 million in income tax payments.

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Net cash from operating activities was $27.5 million during the year ended December 31, 2024. The primary source of cash from operating activities was $467.7 million in receipts from customers, which predominantly consisted of collections from sales of Illuccix. The primary uses of cash in operating activities were payments to suppliers and employees of $418.3 million. Other operating cash outflows included $23.9 million in contingent consideration payments and $2.0 million in income tax payments.

Net cash from operating activities was $14.3 million during the year ended December 31, 2023. The primary sources of cash from operating activities were $311.8 million in receipts from customers, which predominantly consisted of collections from sales of Illuccix. The primary uses of cash in operating activities were payments to suppliers and employees of $280.4 million. Other operating cash outflows included $10.9 million in contingent consideration payments to former ANMI shareholders and $6.9 million in income tax payments.

Investing Activities

Net cash used in investing activities was $285.9 million during the year ended December 31, 2025. The primary uses of cash in investing activities were the acquisition of businesses. We invested $220.7 million in payments toward our acquisitions of RLS and ImaginAb and $18.1 million in payments related to the acquisition of intellectual property associated with FAP targeting candidates, and $25.7 million in property, plant and equipment purchases for the buildout of our manufacturing facilities.

Net cash used in investing activities was $86.7 million during the year ended December 31, 2024. The primary uses of cash in investing activities were $32.9 million in financial assets, which included a $31.0 million cash deposit into a cash security account to establish a working capital facility. We also invested $20.7 million in payments toward our acquisitions of IsoTherapeutics and ARTMS, $13.1 million in payments related to the acquisition of intellectual property associated with QSAM, $8.4 million in payments toward the purchase of isotope raw material purchases and $9.1 million in property, plant and equipment purchases for the buildout of our manufacturing facility in Belgium.

Net cash used in investing activities was $16.8 million during the year ended December 31, 2023. The primary uses of cash in investing activities were $8.7 million in payments toward our acquisition of QSAM and strategic investment in Mauna Kea and $6.3 million in property, plant and equipment purchases for the buildout of our manufacturing facility in Belgium.

Financing Activities

For the year ended December 31, 2025, net cash used in financing activities totaled $3.7 million. Financing activity cash flows included $1.8 million received from the issuance of new ordinary shares on the exercise of options previously granted to employees and $5.2 million paid toward lease liabilities.

For the year ended December 31, 2024, net cash provided by financing activities totaled $416.8 million. Financing activity cash flows included $0.7 million received from the issuance of new ordinary shares on the exercise of options previously granted to employees, net proceeds of $427.9 million received from the issue of convertible bonds and $1.3 million paid toward lease liabilities.

For the year ended December 31, 2023, net cash provided by financing activities was $7.1 million. Financing activity cash flows included $4.2 million received from the issuance of new ordinary shares on the exercise of options previously granted to employees, proceeds of $4.2 million received from borrowings related to the loan facilities provided for the construction of our manufacturing facility in Belgium and $1.3 million paid toward lease liabilities.

Off-Balance Sheet Arrangements

During the periods presented, we did not, and we do not currently, engage in off-balance sheet financing arrangements as defined under SEC rules, such as relationships with other entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our consolidated statement of financial position. In addition, we do not engage in trading activities involving non-exchange traded contracts.

C. Research and Development, Patents and Licenses, etc.

For a discussion of our research and development activities, see "— A. Operating Results" and "Item 4. Information on the Company — B. Business Overview."

D. Trend Information

Our growth strategy and trends affecting our performance are detailed in "— A. Operating Results" and "Item 4. Information on the Company — B. Business Overview." For a discussion of uncertainties and certain factors that could materially affect our business, see "Item 3. Key Information — D. Risk Factors."

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E. Critical Accounting Estimates

We believe that the accounting policies set out in Note 2 to the Consolidated Financial Statements involve a high degree of judgment and complexity. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of our operations. See Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report for a description of our material accounting policies and Note 2.28 to our audited consolidated financial statements appearing elsewhere in this Annual Report for additional information on our key judgments and estimates.

Australian Disclosure Requirements

State of Affairs

There have been no significant changes in the state of affairs of the Group during the financial year ended December 31, 2025 other than as disclosed in this Annual Report.

Events subsequent to the end of the financial year

There were no subsequent events that required adjustment to or disclosure in the Australian Directors' report (as filed with the ASX) or the Financial statements of the Company for the year ended December 31, 2025.

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ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

Start of the Remuneration report for Australian Disclosure Requirements

The Board of Directors ("Board") of Telix presents the Remuneration report, which details the Company's remuneration policy and practice for Key Management Personnel ("KMP") for the financial year ended December 31, 2025. The Board has determined that each KMP is an "executive officer" within the meaning of Rule 3b-7 of the Exchange Act.

KMP are defined as individuals with the authority and responsibility for planning, directing and controlling the activities of the Group, either directly or indirectly. Telix's 2025 Remuneration report covers both the Company's Non-Executive Directors ("NEDs") and executive officers noted below during the year ended December 31, 2025 and up to the date of this Annual Report.

This Remuneration report has been prepared in accordance with the Australian Corporations Act 2001 (Cth) for the Group.

A. Directors and Senior Management

1. Key Management Personnel

The following table sets forth information regarding our directors and executive officers as of the date of this Annual Report. The following table lists the names of our directors and executive officers. The business address for our directors and executive officers is c/o 55 Flemington Road, North Melbourne, Victoria 3051, Australia.

Name	Age	Position	Term during 2025
Non-Executive Directors			
H Kevin McCann AO[1]	N/A	Non-Executive Director and Chairman of the Board	January 1 - May 21
Tiffany Olson[2]	N/A	Non-Executive Director and Chair of the Board	Full year
Marie McDonald	69	Non-Executive Director	March 3 - December 31
Mark Nelson[3]	66	Non-Executive Director	Full year
Jann Skinner	68	Non-Executive Director	Full year
Executive Officers/Executive KMP			
Christian Behrenbruch PhD MBA	51	Managing Director and Group Chief Executive Officer ("MD & CEO")	Full year
Darren Smith FCPA MBA	60	Group Chief Financial Officer ("CFO")	Full year
David Cade MD MBA	57	Group Chief Medical Officer ("CMO")	Full year
Darren Patti PharmD	54	Group Chief Operating Officer (COO)	Full year

[1] Mr. Kevin McCann retired as Non-Executive Director and Chairman of the Board immediately following the Company's Annual General Meeting on May 21, 2025.
[2] Ms. Olson was appointed Chair of the Board on May 21, 2025 following Mr. McCann's retirement, and resigned from the Board effective February 3, 2026.
[3] Mr. Nelson was appointed Interim Chair of the Board following Ms. Olson's resignation as Chair and Non-Executive Director, effective February 3, 2026.

The responsibilities of our Board are described in our Board Charter and Constitution, each of which is filed as an exhibit to this Annual Report. Our executive officers are responsible for making and executing decisions that build value in accordance with Board-approved delegated authorities.

The following is the biographical information of our current directors:

Directors

Mark Nelson has served as a Non-Executive Director since September 2017 and as Interim Chair since February 3, 2026. Dr. Nelson has served as Chairman of the Caledonia Investments Group since January 2012, and as a Director of The Caledonia Foundation since August 2002. He previously served as Chief Executive Officer and Co-Chief Investment Officer of the Caledonia Investments Group from February 1992 to January 2012. He has also served as Director of Kaldor Public Art Projects since October 2005, Governor of the Florey Neurosciences Institute since October 2007, Director of the Mindgardens Neuroscience Network since February 2018 and Chairman of Art Exhibitions Australia since 2019. Dr. Nelson received his B.Sc. from the University of Melbourne, his M.Phil from the University of Cambridge and his Ph.D. from the University of Melbourne. We believe Dr. Nelson's qualifications and experience in capital, equity and investment markets, including in the life sciences industry, qualify him to serve on our board of directors.

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Christian Behrenbruch is one of our Co-Founders, has served as Group Chief Executive Officer since January 2017 and joined our board of directors as Managing Director in January 2017. He has previously served as Chief Executive Officer at Mirada Solutions from July 2001 to December 2002, President at CTI Molecular Imaging (now Siemens Healthcare) from August 2003 to September 2006, Chief Executive Officer at Fibron Technologies, Inc. from June 2008 to December 2011 and Chief Executive Officer at ImaginAb, Inc from October 2007 to February 2015. He served as a Director at Siemens Molecular Imaging Ltd from May 2005 to September 2006, Momentum Biosciences LLC from July 2007 to June 2009, Radius Health Ltd (now Adaptix Ltd) from May 2009 to February 2011, Factor Therapeutics Limited from October 2015 to May 2021 and Amplia Therapeutics Limited from May 2016 to February 2020, and he was the Chairman of Cell Therapies Pty Ltd (a partnership with the Peter MacCallum Cancer Centre) from October 2012 to July 2014. Dr. Behrenbruch holds a Doctor of Philosophy (PhD) in biomedical engineering from the University of Oxford, an executive Master of Business Administration (MBA) jointly awarded from New York University, HEC Paris and the London School of Economics (TRIUM Program) and a Juris Doctor from the University of Melbourne. Dr. Behrenbruch is a Fellow of Engineers Australia in the management and biomedical colleges and a Graduate of the Australian Institute of Company Directors. We believe Dr. Behrenbruch's expertise and over 20 years of experience in healthcare entrepreneurship and executive leadership qualify him to serve on our board of directors.

Marie McDonald has served as a Non-Executive Director since March 2025. Ms. McDonald serves as a Non-Executive Director of Nanosonics Limited (since October 2016), Walter and Eliza Hall Institute of Medical Research (since October 2016) and Nufarm Limited (since March 2017), and served as a Non-Executive Director of CSL Limited between August 2013 and October 2025. Ms McDonald practised as a commercial lawyer, specializing in mergers and acquisitions and corporate governance, at Ashurst Australia (previously Blake Dawson Waldron) from 1984 to 2014. She was a member of the Australian Takeovers Panel from 2001 to 2010, and was also Chair of the Corporations Committee of the Business Law Section of the Law Council of Australia (2012-2013), having previously been a deputy chair. Ms. McDonald received her BSc (Hons) and LLB (Hons) from the University of Melbourne. We believe Ms. McDonald's significant experience in financial markets, M&A, regulatory policy, remuneration, risk management and compliance qualify her to serve on our board of directors.

Jann Skinner has served as a Non-Executive Director since June 2018. Ms. Skinner was a partner at PricewaterhouseCoopers from 1987 to 2004. She has served as Chair of Create Foundation Limited since July 2024 and Director since 2004. She also served as Non-Executive Director of QBE Insurance Group Limited from October 2014 to May 2024 and Director of HSBC Bank Australia Limited from April 2017 to April 2023. Ms. Skinner is a Fellow of both Chartered Accountants Australia & New Zealand and the Australian Institute of Company Directors. She received her Bachelor of Commerce (BCom) from the University of New South Wales. We believe Ms. Skinner's expertise in audit and accounting and prior board experience qualify her to serve on our board of directors.

Group Executive Team

The following is the biographical information of our Group Executive Team ("GET"), which includes executive officers/KMP. Not all members of the GET are executive officers/KMP. The individuals designated as executive officers/KMP are indicated below with an *.

Christian Behrenbruch* is one of our Co-Founders, has served as Group Chief Executive Officer since January 2017 and joined our board of directors as Managing Director in January 2017. Biographical information for Dr. Behrenbruch is included above under "Item 6. Directors, Senior Management and Employees — A. Directors and Senior Management — Directors."

Darren Smith* has served as our Group Chief Financial Officer since August 2022. Previously, he was Global Chief Financial Officer and Company Secretary at Sirtex Medical Ltd from June 2008 to March 2019, and Chief Financial Officer of Waverley Council from April 2019 to August 2021. Mr. Smith has over 20 years of experience in executive finance and general management experience across a broad range of industries, including life-sciences, for publicly listed, private, international, and Australian government organizations. Mr. Smith holds a Master of Business Administration (MBA) from the University of New South Wales in Australia and a Bachelor of Business (Accounting) from Western Sydney University. He has been a Fellow Certified Practicing Accountant for 20 years.

David Cade* has served as our Group Chief Medical Officer since January 2024. Prior to transitioning to this role, he was the Chief Executive Officer of our Asia Pacific operations from May 2021 to December 2023 and our Chief Business Officer and Head of Investor Relations from October 2019 to April 2021. Previously, he served as Chief Medical Officer at Sirtex Medical Limited from January 2007 to September 2017 and Chief Medical Officer at Cochlear Limited from October 2017 to September 2019. Dr. Cade received a Bachelor of Medicine and Bachelor of Surgery (MBBS) from Monash Medical School and a Master of Business Administration (MBA) from Melbourne Business School and ESADE Business and Law School Barcelona. He is also a Graduate of the Australian Institute of Company Directors.

Darren Patti* was appointed as our Group Chief Operating Officer in March 2024. Prior to transitioning to this role, he was the Chief Operating Officer and General Manager of our Americas operations from March 2021 to March 2024. Previously, he served as Vice President of Operations at Sofie Biosciences Inc. from November 2019 to March 2021, and, preceding this role, he served in numerous other leadership capacities over his 15 year tenure at Sofie, including managing high capacity PET manufacturing facilities and directing regional operations over multiple PET manufacturing locations. Prior to joining Sofie, he worked in brachytherapy manufacturing with a small startup which was eventually acquired by CR Bard. Dr. Patti has over 20 years of experience in radiopharmaceutical and device manufacturing with expertise in network management and operations, including new radiopharmaceutical manufacturing, implementation

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and compliance. Dr. Patti holds a Doctor of Pharmacy (Pharm.D.) from the University of Illinois at Chicago and a Bachelor of Arts from Southern Illinois University at Carbondale. He is also an Authorized Nuclear Pharmacist and is a licensed pharmacist in multiple states within the U.S.

Kevin Richardson serves as our Chief Executive Officer, Telix Precision Medicine. Mr. Richardson leads the development of the Company's diagnostics, global marketing and commercial operations in the U.S. and Canada. He has more than 25 years' experience in the healthcare industry, including seven years focused in sales, marketing and business operations in the radiopharmaceutical segment. Immediately prior to joining Telix, Mr. Richardson was the Chief Operating Officer of UroShape Medical, a technology company which has developed and successfully commercialized a medical device for a large, undertreated segment in the women's health market. Prior to this, he spent seven years in the Americas division of Sirtex Medical Ltd.

Mary Jessel serves as our Group Chief of Clinical Affairs. Dr. Jessel has over 15 years of pharmaceutical, biotechnology and drug development experience and has proven expertise in building effective Medical Affairs infrastructure, launch and product lifecycle strategies. She is passionate about innovation that improves unmet medical need and enhancing the accessibility and comprehensibility of complex medical and scientific information. Dr. Jessel has led successful product launches at Ionis Pharmaceuticals and Akcea, drug development at Alcamena Stem Cell Therapeutics, and drug development research at the University of California, San Francisco in leukodystrophies. She holds a PhD in Neuroscience from the University of Michigan and a MBA from Portland State University.

Richard Valeix serves as our Chief Executive Officer, Telix Therapeutics. Mr. Valeix leads the Company's therapeutic pipeline commercialization and business development. He has more than 20 years of pharmaceutical industry experience, including radiopharmaceuticals, gained in senior executive leadership roles across a broad range of therapeutic product areas. Previously, Richard worked at Advanced Accelerator Applications (AAA), a Novartis Company (from January 2014 to April 2021) where he served in the roles of General Manager for France, Switzerland, Belgium, Netherlands and Luxembourg, and Global Head of Marketing and Sales.

Raphaël Ortiz serves as our Chief Executive Officer, Telix International. Mr. Ortiz leads the "rest of world" commercial operations for Europe, Middle East and Africa (EMEA), Asia Pacific (APAC) and Latin America regions. He joined Telix with more than 20 years of pharmaceutical industry experience in a variety of roles, including in finance, business development, marketing and sales, as well as general management in Europe, Latin America and Asia. Prior to joining Telix, he worked at Advanced Accelerator Applications, a Novartis Company, and most recently in the role of Asia-Pacific Cluster Head, setting up the radioligand therapy operations in the region.

Lena Moran-Adams serves as our Group General Counsel.[1] Ms. Moran-Adams has over 25 years' experience driving proactive, results driven legal and compliance solutions worldwide, including more than 20 years' experience in the pharmaceutical industry in various country, regional and global leadership roles. Prior to joining Telix, Ms Moran-Adams was the Head of Legal and Business Conduct, Intercontinental at Gilead Sciences and a Global Head of Legal at Novartis. She is admitted to the bar and entitled to practice law in Australia, the United Kingdom and in New York.

Meredith Crowe serves as our Senior Vice President, People & Culture.[1] Ms. Crowe has been with Telix since October 2021 and has more than 10 years experience driving people strategy in health and biotech, most recently in organizational development at the Peter MacCallum Cancer Centre. Ms. Crowe holds a Masters of Design from Victoria University and is an IECL Certified Executive Coach.

Company Secretary

Genevieve Ryan has served as our Company Secretary since December 2022. Ms. Ryan has over 20 years' experience in legal and governance roles, including with ASX-200 companies. Previously, she was General Counsel – Governance, Corporate and Commercial at Orora Limited. Ms. Ryan was also previously Senior Legal Counsel and Alternate Company Secretary at Australian Pharmaceutical Industries Limited (acquired by Wesfarmers Limited). Ms Ryan began her career as a lawyer with law firm Ashurst. She holds a Bachelor of Laws (Honors) and Bachelor of Science (Honors). Ms Ryan is a fellow of the Governance Institute of Australia and a graduate member of the Australian Institute of Company Directors.

1. Family relationships

There are no family relationships among any of our executive officers and our directors.

2. Arrangements for election of Directors and members of Management

There are no contracts or other arrangements pursuant to which directors have been or must be selected.

[1] Ms. Moran-Adams and Ms. Crowe are advisors to the GET.

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Executive KMP employment

All Executive KMP are employed on ongoing, permanent contracts and have notice period and cascading non-compete and non-solicit clauses in their employment agreements. The maximum non-compete and non-solicit period is detailed below with cascading time periods applicable to the MD & CEO and CFO:

Role	Notice period	Non-compete and non-solicit	Restricted area
Dr. Behrenbruch (MD & CEO)	6 months	6 months	Australia/United Kingdom/European Union or U.S.; Victoria; Melbourne
Mr. Smith (CFO)	4 months	6 months	Australia; Victoria; Melbourne
Dr. Cade (CMO)	4 months	6 months	Australia; Melbourne
Dr. Patti (COO)	4 months	6 months	U.S.; Australia, United Kingdom and European Union; states, provinces or territories within U.S.

Employment may be terminated by either party on the provision of notice in the minimum period stated above. In the event of termination for cause, Telix may terminate an Executive KMP's employment immediately without notice.

B. Compensation

2. Executive KMP remuneration approach

2.1. Remuneration principles

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2.2. Overview of remuneration elements

	Total Fixed Remuneration ("TFR")	Short Term Variable Remuneration ("STVR")	Long Term Variable Remuneration ("LTVR")
Purpose	Attract and retain global talent capable of leading and delivering Telix's strategy.	Reward achievement of annual corporate and business unit ("BU") objectives aligned to the delivery of Telix's strategy.	Align remuneration with shareholder outcomes, rewarding achievement of long-term sustainable performance and shareholder value creation.
Principles	Target 80-120% of the market median (see Peer Group below) considering experience and capability.	Reward achievement against annual corporate objectives	Rewards achievement of long term financial and product milestones. Use of notional exercise price delivers value with share price growth.
Composition and delivery	Base salary and pension contributions paid over the year, and packaged benefits.[1]	Annual performance incentive delivered as: • 50% cash (approx. February the following year), and • 50% deferred share rights ("STVR SRs") which vest approx. 12 months after the cash payment.	Performance Share Appreciation Rights ("PSARs") subject to achievement of 3-year performance and vesting conditions, as well as a service requirement. Stretch target set (maximum 150% of target). Vesting approx. 2 months after the end of the performance period with 2-year exercise period.
Peer Group	Global listed companies in the health care sector with a focus on the biotechnology and pharmaceutical and health care supply industries. Companies are chosen based on market capitalization and revenue with Telix positioned near the median.		
TTR	Total Target Remuneration ("TTR") being the sum of TFR, STVR and LTVR.		

1 Australian Executive KMP can elect to cap their superannuation at the statutory superannuation maximum and receive the additional 11.5% (January 1 to June 30, 2025) and 12% (July 1 to December 31, 2025) over the maximum as base salary. Refer to section x for full details in the 2025 statutory remuneration disclosures.

3. 2025 Executive KMP remuneration

3.1. Executive summary - 2025 KMP remuneration

3.1.1. 2025 target remuneration

The following table summarizes the 2025 target remuneration packages for Executive KMP effective 1 January 2025, as disclosed in the 2024 Remuneration report:

	Dr. Behrenbruch (MD & CEO)	Mr. Smith (CFO)	Dr. Cade (CMO)	Dr. Patti (COO)
Base salary	A$799,092	A$705,600	A$539,000	US$414,000
TFR	A$892,985	A$788,508	A$602,333	US$434,700
TFR compa ratio[1]	0.85	0.99	0.76	0.82
STVR[2] (% of base salary)	110%	65%	65%	65%
STVR target value	A$879,001	A$458,640	A$350,350	US$269,100
LTVR[2, 3] (% of base salary)	150%	100%	100%	100%
LTVR target value	A$1,198,634	A$705,600	A$539,000	US$414,000
TTR	A$2,970,624	A$1,952,748	A$1,491,683	US$1,117,800
TTR compa ratio[1]	0.38	0.52	0.40	0.45

1 Compa ratio is the TFR or TTR for Executive KMP as a proportion of the median (50th percentile) of the 2023 Mercer benchmarking data.
2 2025 variable remuneration as a percentage of base salary increased in line with Mercer's 2023 recommendation.
3 LTVR maximum opportunity is 150% of target (subject to achievement of the stretch financial performance condition).

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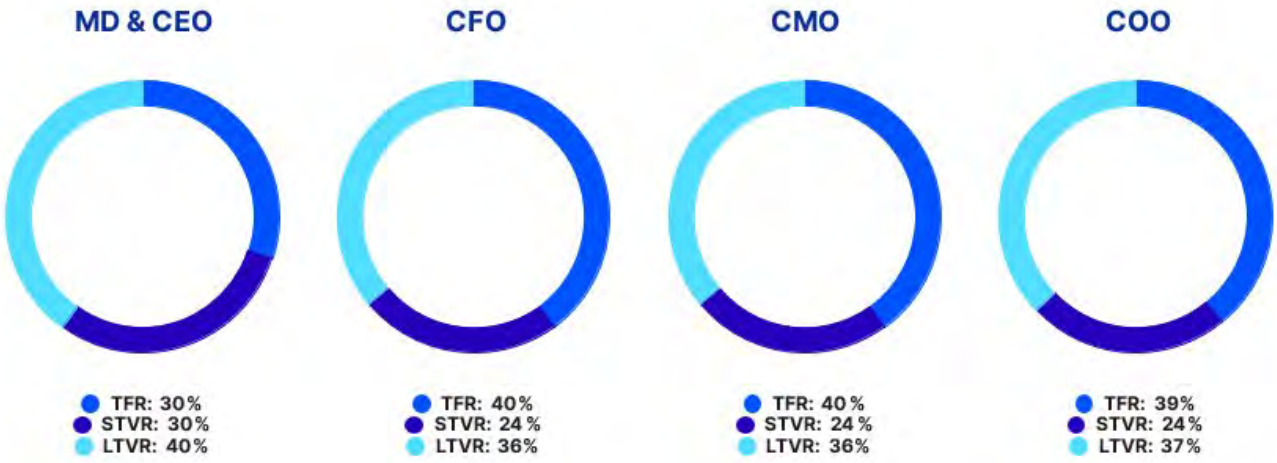
3.1.2. 2025 remuneration delivery

3.1.3. 2025 target remuneration mix

The annualized remuneration elements at target for Executive KMP are as follows, noting that the TFR proportion is lower for the COO role as it is performed in the U.S. where pensions are paid at a lower proportion than in Australia, where the CFO and CMO are based:



3.2. 2025 Executive KMP remuneration framework

3.2.1. Total fixed remuneration ("TFR")

TFR incorporates base salary, pension contributions and packaged benefits. Due to regional variations for pensions and packaged benefits, Telix uses base salary to determine STVR and LTVR targets to minimize regional impacts upon Total Target Remuneration.

The Board's target approach is to pay TFR within 80-120% of the market median, considering each Executive KMP's experience and capability, and relativity to the market benchmark. The market median used to set 2025 remuneration was based on a peer group of 40 companies (peer group) as part of the Mercer 2023 benchmarking review and recommendation.

Executive TFR is set on appointment and reviewed annually in line with Telix's performance review cycle and is subject to Board approval.

Executive KMP receive TFR (base salary, pension contributions and packaged benefits) in equal cash installments paid over the year. Australian Executive KMP can elect to cap their pension (superannuation) at the statutory superannuation maximum and receive any additional amount over the maximum as base salary.

Fixed pay effective January 1, 2025 was disclosed in the 2024 Remuneration report and was aligned with Mercer's 2023 recommendation and the Board's principles for Executive Remuneration. For 2025, TFR reflected 76-99% of the market median (50th percentile) of the 2023 peer group.

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3.2.2. Overview of variable remuneration

Variable remuneration includes STVR and LTVR. Both elements have an equity component which is subject to the following terms:

Feature	Summary of terms common to STVR and LTVR Equity
Treatment of vested equity after departure	The Board will automatically exercise vested unrestricted STVR Share Rights ("STVR SRs") and PSARs into American Depository Shares ("ADSs") or shares for departed Executive KMP who retain their STVR SRs or PSARs after exit. This will generally occur within 90 days of equity becoming unrestricted.
Securities Dealing Policy	Testing and vesting is completed in accordance with the policy. All Executives must operate within local requirements and the Securities Dealing Policy.
Equity Incentive Plan rules	STVR SRs and PSARs are granted in accordance with the Equity Incentive Plan rules (approved by shareholders at the 2024 AGM).
Equity grants to the MD & CEO	Any equity grant to the MD & CEO is subject to shareholder approval.
Dividend and voting rights	Unvested and vested but unexercised STVR SRs and PSARs have no dividend or voting rights and are held subject to Telix's Securities Dealing Policy.
Other activities	Treatment of STVR and LTVR equity is subject to Board discretion in the case of other events, such as (but not limited to) a change of control.
Equity holding	Based on the Executive KMP's location: • U.S. Executives receive equity based on USD values on the Nasdaq (that vests into ADSs) • Executives in all other locations receive equity converted to A$ and on the ASX that vests into ASX:TLX shares

3.2.3. Short Term Variable Remuneration ("STVR")

STVR is designed to reward achievement of annual corporate objectives aligned to the delivery of Telix's strategy.

Feature	Summary of 2025 STVR terms				
Performance period	January 1 to December 31, 2025				
Delivery	Cash: 50% (paid in approx. February 2026), and Equity: 50% granted in STVR SRs after the 2025 full year results announcement and restricted for approximately 12 months from the cash payment (the restricted period).[1]				
Equity exercise price and vesting	STVR SRs have a nil exercise price and at vesting treatment is based on the Executive's location: • U.S STVR SRs are automatically vested into ADSs at the end of the restricted period • All other locations STVR SRs vest with a two-year exercise period.				
Performance measures	Corporate Objectives, including financial and non-financial measures that maintain focus on underlying value creation within business operations, together with objectives relevant to each executive's BU (except for MD & CEO).				
Corporate objectives	Financial: Revenue Earnings Cost control Strategic	Dr. Behrenbruch 40% 15% 15% 30%	Mr. Smith 20% 7.5% 7.5% 15%	Dr. Cade 20% 7.5% 7.5% 15%	Dr. Patti 20% 7.5% 7.5% 15%
BU objectives		-	50%	50%	50%
Modifiers	The Board has the discretion to apply modifiers to either increase or decrease the STVR outcome based upon non-corporate objective obligations: contribution to good corporate governance, company values and market engagement, and driving a performance culture throughout the organization.				
STVR SRs calculations	The number of STVR SRs Executive KMP receive is determined as 50% of their total STVR outcome, divided by the allocation value being the Volume Weighted Average Price (VWAP) for the 5 trading days after the release of the 2025 full year results.				
General treatment to cash component on termination	Where employment is terminated for any reason prior to the payment date, the cash component is forfeited.				

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Feature	Summary of 2025 STVR terms	
General treatment to Equity component on termination (the Board retains discretion to determine a different treatment)	Termination for cause during the performance or restricted period	Forfeited.
	Other circumstances such as death, disability, retirement, redundancy, mutually agreed separation or resignation	Where an Executive's employment is terminated • during the performance period: forfeited • during the restricted period: retained.
Reporting	See section 3.3.1 for 2025 overall outcomes. The 2026 AGM NOM will set out the MD & CEO allocation value and number of STVR SRs to be granted, subject to shareholder approval.	

[1] In certain circumstances the Board may determine that participants receive a cash equivalent value of the vested element after testing.

3.2.4. Long Term Variable Remuneration ("LTVR")

LTVR aligns Executive KMP remuneration with shareholder interests and outcomes, rewarding achievement of long-term, sustainable performance and shareholder value creation.

Feature	Summary of 2025 LTVR terms	
Performance period	Cumulative three-year period: January 1, 2025 to December 31, 2027	
Delivery	Performance Share Appreciation Rights (PSARs) provide the right to acquire Telix shares or ADSs equal in value to the gain above the notional 'exercise' price, subject to the satisfaction of performance conditions set by the Board, and terms and conditions that apply over the Performance Period. PSARs are granted based on Executive location:	
	U.S. in US$ on the Nasdaq; PSARs will vest and upon exercise convert into ADSs	**Other locations**: A$ on the ASX; PSARs will vest and upon exercise convert into shares
Notional exercise price	The volume weighted average price (VWAP) of Telix shares or ADSs over the 20 trading days following the 2024 full year results announcement (February 21 to March 20, 2025):	
	U.S.: US$19.99 on the Nasdaq	**Other locations:** A$28.67 on the ASX
Testing, vesting and exercise	PSAR performance is tested following audited financial results in approx. February 2028. The Board will determine the number of PSARs that vest (between 0 and 150% based on company achievement against the performance measures)[1]. Following vesting, Executive KMP have a two-year exercise period. The value delivered to Executives is the positive gain between the notional exercise price and the share/ADS price at the time of exercise.	
Grant method	Granted at the maximum possible outcome (150% of target). Following testing, PSARs that do not meet the milestones are forfeited and are not subject to retesting.	
Performance measures	Performance measure	Vesting outcome
Financial (Adjusted EBITDAR) milestone[2]	Less than US$1,058 million	-
	US$1,058 million	25%
	Greater than US$1,058 million and up to US$1,284 million	Straight line between 25% and 50%
	Greater than US$1,284 million and up to US$1,450 million	Straight line between 50% and 100%
Product milestones	For details regarding the rationale and the strategic significance of the product milestones, refer to section 8.2.5 of the 2024 Remuneration report	
Precision Medicine	Marketing authorization of an additional urology imaging asset in the U.S.	Achieved 17% Not achieved 0%
Therapeutics	Interim results from 3 pivotal trials across 3 therapeutic compounds	Achieved 17% Not achieved 0%
TMS	Inclusion of a Telix Manufacturing Solutions (TMS) site in a submission of a new commercial product	Achieved 8% Not achieved 0%
	TMS achieves a break-even profit and loss in any financial year within the period	Achieved 8% Not achieved 0%
LTVR calculations	The number of PSARs each Executive KMP receives is based on the concluded value, being the fair value price (independently determined using a Black Scholes valuation), adjusted for the probability of achievement of the non-market vesting conditions:	
	U.S.: on the Nasdaq: US$6.4716 concluded value and US$8.4413 fair value.	**Other locations:** on the ASX: A$10.7997 concluded value and A$14.0866 fair value

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Feature	Summary of 2025 LTVR terms	
Equity grant details	2025 LTVR PSARs were granted to all Executive KMP on May 30, 2025 with the exception of the MD & CEO whose grant was made on June 13, 2025 following shareholder approval at the 2025 Annual General Meeting.	
General treatment on termination (the Board retains discretion to determine a different treatment)	Departure reason	Treatment
	Termination for cause	Forfeited
	Resignation	Generally a pro-rata retain is calculated on the portion of the first year of the measurement period served, remaining on-foot to the usual testing and vesting date.[3]
	Death, disability, retirement, redundancy and mutually agreed separation	
Reporting	The 2025 PSARs testing outcomes will be reported in the 2027 Remuneration report, with equity movements advised to the market via ASX disclosure and reported in the 2028 Remuneration report.	

1 In certain circumstances the Board may determine that participants receive a cash equivalent value of the vested element after testing.
2 Refer to ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS for definition of these non-IFRS measures
3 See section 4.1.4 for changes to the pro rata calculation applicable for PSARs granted on or after January 1, 2026.

3.3. 2025 Executive KMP remuneration outcomes

3.3.1. Short Term Variable Remuneration (STVR) outcomes

Following the objectives, weightings and targets set for STVR performance at the commencement of the financial year, the Corporate Objectives outcomes for 2025 are as follows:

Objective (Target %)	Details	Outcome	% STVR achieved
Financial: Revenue augmentation and diversification (40%)	The 2025 Corporate Objectives were set prior to the acquisition of RLS, and as a result, RLS revenue is not included in either the target or actual revenue achievement disclosed in the STVR outcomes. Telix achieved revenue of US$631 million in 2025, excluding RLS. This outcome exceeded the 2024 result by 22% and was very close to the revenue target (in $) for 2025, but diversification targets were not achieved for 2025.	Below target	20%
Financial: 1) Earnings (15%); and 2) Cost control (15%)	1) EBITDAR: Telix achieved an Earnings Before Interest, Tax, Depreciation, Amortization and Research and Development (EBITDAR) of US$200 million in 2025, below target. 2) Cost control: Telix invested US$171 million in Product Development, in line with plan. The circumstances that contributed to not meeting the revenue target also affected the ability to meet the EBITDAR target, which was not met. Research and development investment was aligned with our strategy to deliver our late stage pipeline and includes Zircaix inventory value (US$14 million) in preparation for launch activities.	Below target	15%
Non-financial: compliance (30%)	Substantial progress was made towards compliance requirements aligned to the Nasdaq listing. On target performance was achieved for a number of elements, but one was only partially achieved.	Below target	25%
Total			**60%**

Executive KMP STVR is determined by achievement against the Corporate Objectives, and the Business Unit Objectives relevant to their position. The following details are provided for Other Executive KMP and performance against their Business Unit objectives in 2025:

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Executive	Business Unit Performance summary	Outcome	% achieved	
			Business Unit (of 100%)	Total (Corporate & BU)
Mr. Smith (CFO)	**Global services:** progress made for commercial launch readiness of Zircaix and Pixclara and RLS services teams integrated into Global Services. Substantial progress on SOX compliance, strategic procurement capability in place, but uplift continues into 2026.	Below target	65.00%	62.50%
Dr. Cade (CMO)	Equal measure between the business unit outcomes for both Precision Medicine and Therapeutics. **Therapeutics:** significant progress has been made across the therapeutic portfolio, however some milestones have experienced delays into 2026. **Precision Medicine:** achieved Illuccix registration in multiple EU countries, US approval of Gozellix, and filing completed in China. Pixclara and Zircaix received complete response letters (CRLs) from the FDA, which impacted market authorization timelines.	Below target	67.50%	63.75%
Dr. Patti (COO)	**Telix Manufacturing Solutions**: significant progress towards reliable clinical dose delivery for late-stage therapies. High on-time delivery for Illuccix and Gozellix. Some delays seen in Therapeutic dose delivery and technology transfers. Significant progress on product quality and Environment, Health and Safety (EHS).	Below target	70.00%	65.00%

In 2025 the Board assessed the STVR Corporate Objectives and Business Unit scorecards as well as the modifiers as detailed in section 3.2.3. Following this assessment, the Board decided not to apply any discretion or modifier to any Executive KMP STVR outcomes:

Executive	Target	Awarded			Performance against target	
		Total	Cash	STVR SRs	Achieved	Forfeited
Dr. Behrenbruch (MD & CEO)	A$879,001	A$527,401	A$263,700	A$263,700	60.00%	40.00%
Mr. Smith (CFO)	A$458,640	A$286,650	A$143,325	A$143,325	62.50%	37.50%
Dr. Cade (CMO)	A$350,350	A$223,348	A$111,674	A$111,674	63.75%	36.25%
Dr. Patti (COO)	US$269,100	US$174,915	US$87,457	US$87,457	65.00%	35.00%

3.3.2. Long Term Variable Remuneration (LTVR) outcomes

All Executive KMP held unvested 2023 PSARs as at December 31, 2025. The outcomes achieved are as follows:

Measure	Target	Performance Period Result (January 1, 2023 to December 31, 2025)	Weight at target	% vesting
Adjusted EBITDAR (Earnings before interest, tax, depreciation, amortization and research and development costs)	Threshold: A$227 million **Target: A$332 million** Stretch: A$403 million	Over the three-year cumulative period, Telix achieved the stretch target with an adjusted EBITDAR of A$760 million, based on: 2023: A$181 million 2024: A$285 million 2025: A$294 million	Threshold 25% Target 50% Stretch 100%	100%
ProstACT Global Phase III interim read-out completed	Achieve milestone	Significant progress has been made toward this target; however, the milestone was not met by the end of the performance period, December 31, 2025.	25%	Nil

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Measure	Target	Performance Period Result (January 1, 2023 to December 31, 2025)	Weight at target	% vesting
Pre-pivotal trial (pre-IND) meeting completed with a major regulator for one of Telix's rare disease therapy programs	Achieve milestone	The pre-pivotal trial (pre-IND) meeting was completed during the performance period for TLX-101, one of Telix's rare disease therapy programs.	25%	25%
Overall vesting				**125%**

No discretion was applied by the Board to either alter the product milestones or adjust the vesting outcomes, the results were endorsed as realized at the testing date (December 31, 2025).

The 2023 PSARs will vest in March 2026, following the audited results release and aligned with the Securities Dealing Policy. The outcome and equity movements for each Executive KMP will be reported in the 2026 Remuneration report.

3.3.3. 2025 equity disclosures

Telix grants equity for retention and alignment of Executive KMP and shareholder interests. During 2025 Executives received 2025 LTVR PSARs under the Equity Incentive plan (see sections 3.2.4 and 6.3).

The following equity vested to Executive KMP during 2025:

Equity type	Grant date	Executive KMP	Grant details		Vesting details		Exercise details		
			Type	# units	Date	Exercise price	Date	Resultant shares	Value exercised
Talent equity[1]	05-Apr-22	COO	Rights	15,000	24-Apr-25	A$0.00	05-May-25	45,000	A$1,274,400
	15-Jun-23			15,000					
	26-Aug-24			15,000					
2022 PSARs	05-Apr-22	MD & CEO	PSARs	139,672	06-Mar-25	A$4.95	n/a	n/a	-
		CMO		78,189			n/a	n/a	-
		COO		15,826			n/a	n/a	-
2022 PSARs	24-Oct-22	CFO	PSARs	77,912		A$6.15	n/a	n/a	-
2021 options	21-Jul-21	COO	Options	100,708	28-Oct-22	A$5.37	10-Mar-25	100,000	A$2,254,000

1. Refer to section 2.4 of the 2024 Remuneration report regarding Talent equity granted to Dr. Patti prior to his appointment to an Executive KMP position.

The following equity was exercised by Executive KMP in 2025:

- As detailed above, Dr. Patti's talent equity was auto-exercised at vesting aligned to the terms of the offer. In addition, Dr. Patti exercised 100,000 options at an exercise price of A$5.37.
- On November 5, 2025, Dr. Behrenbruch exercised 100,708 TLXO009 options with an exercise price of A$4.95. These options vested on October 28, 2022 as detailed in section 12.2.2 and the ASX/SEC disclosure dated November 7, 2025. Dr. Behrenbruch paid the exercise cost of $441,101 to receive the resultant 100,708 shares.

3.3.4. Equity held by Executive KMP during 2025

The following plans remain in the performance (restricted) period as at December 31, 2025 for current Executive KMP:

Equity type	Grant	Restricted period	Vesting date	Performance conditions	Exercise price
Performance rights[1]	19-Jul-21	19-Jul-21 to 18-Jul-26	18-Jul-26	Achievement of cumulative APAC revenue target within the restricted period	A$0.00
PSARs (2023 LTVR & LTI)	02-May-23; 24-May-23	01-Jan-23 to 31-Dec-25	31-Dec-25	Adjusted EBITDAR and product milestones. Refer section 3.3.2	A$6.90

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Equity type	Grant	Restricted period	Vesting date	Performance conditions	Exercise price
Talent equity[2]	31-Oct-23	01-Nov-23 to 31-Dec-26	31-Dec-26	Continued employment and high performance to drive Telix's success	A$0.00
		01-Nov-23 to 31-Dec-27	31-Dec-27		A$0.00
PSIRs	08-Mar-24	01-Jan-24 to 31-Dec-26	31-Dec-26	Adjusted EBITDAR and Revenue Refer section 5.4.2 of the 2024 Remuneration report	A$0.00
		01-Jan-24 to 31-Dec-27	31-Dec-27	Product milestone Refer section 5.4.2 of the 2024 Remuneration report	A$0.00
PSARs (2024 LTVR & LTI)	21-Mar-24; 22-May-24	01-Jan-24 to 31-Dec-26	Thursday, December 31, 2026	Adjusted EBITDAR and product milestones. Refer section 5.3.1 of the 2024 Remuneration report	A$11.94
PSARs (2025 LTVR)	30-May-25	01-Jan-25 to 31-Dec-27	Friday, December 31, 2027	Adjusted EBITDAR and product milestones. Refer section 3.2.4	Non-US KMP on ASX: A$28.67 U.S. KMP on Nasdaq: US$19.99

1 Granted to Dr. Cade in his pre-KMP role as CEO, APAC.
2 Granted to Dr. Patti in his pre-KMP role as COO, Americas, refer to 2024 Remuneration report for full details.

3.3.5. 2025 realized remuneration

The following voluntary disclosure is made on a non-IFRS basis.

Please refer to statutory remuneration disclosures in section 3.5.

Executive KMP	TFR	STVR	Equity	Total
Dr. Behrenbruch (MD & CEO)	A$892,985	A$527,401	A$430,959	A$1,851,345
Mr. Smith (CFO)	A$788,508	A$286,650	A$380,541	A$1,455,699
Dr. Cade (CMO)	A$602,333	A$223,348	A$362,464	A$1,188,145
Dr. Patti (COO)	US$434,700	US$174,915	US$78,226	US$687,841

Disclosures are based on the following assumptions:

- TFR: contractual base salary plus superannuation for Australian Executives and 401k pension contributions for U.S. Executives
- STVR: total STVR (cash and equity components) for the 2025 performance year, as detailed in section 3.3.1. This includes both the amount paid in cash in February 2026 and the amount paid in STVR SRs that are deferred to approximately February 2027.
- Equity: the number of vested 2023 PSARs multiplied by the appreciation per PSAR - being A$11.20 (the closing share price on December 31, 2025), less the exercise price of A$6.90. For Dr. Patti, his equity value in A$ has been converted to US$ to determine the total based on the 12 month average exchange rate for the year.

3.4. 2025 Executive KMP remuneration alignment to shareholder wealth

In line with Telix's remuneration principles and philosophy, performance measures are chosen to align Executive KMP and shareholder interests and ensure variable remuneration is contingent on outcomes that grow and protect long-term shareholder value.

Telix's financial performance for 2021 to 2025 is summarized below, noting that Telix has retrospectively changed its presentation currency from Australian Dollars to United States Dollars (USD or US$). Refer to

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Type	Measure	2025	2024	2023	2022	2021
Short-term measures	Revenue from contracts with customers ($'000)	803,794	516,551	332,978	111,219	5,708
	Net cash (used in)/ from operating activities ($'000)	(17,293)	27,490	14,273	(44,440)	(44,579)
Long-term measures (non-IFRS measures)	Adjusted EBITRD ($'000)[1]	180,017	183,772	116,654	2,627	(26,766)
	Adjusted EBITDAR ($'000)[2]	201,523	188,623	121,139	6,365	(22,879)
Other measures	(Loss)/profit before income tax ($'000)	(5,266)	37,915	2,594	(68,513)	(60,461)
	Basic (loss)/earnings per share (cents)	(2.1)	10.2	1.3	(23.3)	(21.4)
	Net tangible assets per share ($)	(1.00)	0.1600	0.0239	0.0224	(0.1451)
	Dividend per share ($)	-	-	-	-	-
	Closing share price – ASX:TLX ($)	A$11.20	A$24.61	A$10.08	A$7.27	A$7.75
	Increase/(decrease): ASX share price (%)	(54)	144	39	(6)	105
	Closing ADR/ADS price – Nasdaq:TLX (US$)	US$7.49	US$15.40	n/a	n/a	n/a
	Increase/(decrease): Nasdaq ADS price (%)	(51)	n/a	n/a	n/a	n/a
	Market capitalization (US$'000)	2,537,440	5,154,757	2,169,352	1,558,123	1,603,079

1. Adjusted EBITRD (Earnings Before Interest, Taxes and R&D expense) on a 3-year cumulative basis is the 2022 LTVR financial metric.
2. Adjusted EBITDAR (Earnings Before Interest, Taxes, Depreciation and Amortization and R&D expense) is the LTVR financial metric from 2023 onwards.

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3.5. 2025 Executive KMP statutory remuneration

The below table shows details of the remuneration expenses recognized for Executive KMP for 2025 and 2024 prepared in accordance with IFRS and Australian Accounting Standards.

All numbers have been recast for 2024 and provided in 2025 in US$ using the average exchange rate over the 2025 year.

		Fixed remuneration[1]			Variable remuneration		Termination benefit	Total	Variable remuneration	
		Salary	Superannuation /pension	Leave accruals	STVR	Share-based payment				
Name	Year	US$	US$	US$	US$	US$	US$	US$	US$	%
Executive KMP										
Dr. Behrenbruch	**2025**	**556,718**	**19,333**	**(53,987)**	**169,937**	**569,657**	**-**	**1,261,658**	**739,594**	**58.62**
	2024	400,134	18,961	3,325	155,983	350,187	-	928,590	506,171	54.51
Mr. Smith[2]	**2025**	**488,989**	**19,333**	**35,623**	**92,363**	**381,828**	**-**	**1,018,135**	**474,191**	**46.57**
	2024	350,817	18,896	26,345	66,748	341,589	-	804,395	408,337	50.76
Dr. Patti[3]	**2025**	**381,877**	**9,569**	**15,508**	**87,458**	**354,833**	**-**	**849,244**	**442,291**	**52.08**
	2024	288,000	20,270	-	64,920	236,072	-	609,262	300,992	49.40
Dr. Cade	**2025**	**368,899**	**19,333**	**13,898**	**71,966**	**71,103**	**-**	**545,199**	**143,069**	**26.24**
	2024	340,573	18,961	21,643	64,894	259,382	-	705,452	324,275	45.97
Former Executive KMP										
Mr. Valeix[4]	**2025**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
	2024	255,255	27,885	157	52,314	342,669	-	678,280	394,983	58.23
Total	**2025**	**1,796,483**	**67,568**	**11,042**	**421,724**	**1,377,421**	**-**	**3,674,236**	**1,799,145**	**48.97**
	2024	**1,634,779**	**104,973**	**51,470**	**404,859**	**1,529,899**	**-**	**3,725,979**	**1,934,758**	**51.93**

[1] Remuneration includes movement in annual leave and long service leave provisions during the year.
[2] Mr. Smith participated in the 2025 Australian ESPP and received a discount of $2,352 on shares acquired related to salary sacrifice in the period April to May 2025, allocated in September 2025. This discount is reflected in the assessed fair value of the ESPP rights and disclosed in the Share-based payment column above.
[3] Dr. Patti was appointed as Group Chief Operating Officer on March 11, 2024. His remuneration in 2024 is reported to include all amounts associated with his role as KMP from March 11, 2024.
[4] Mr. Valeix moved to the non-KMP role of CEO, Telix Therapeutics, and ceased as KMP on August 18, 2024. His 2024 remuneration is reported to include all amounts associated with his role as KMP up to August 18, 2024. Mr. Valeix was paid in CHF, reported in USD using the respective monthly exchange rates.

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4. 2026 Executive KMP remuneration

Telix's headcount, revenue and market capitalization in early 2025 were significantly higher than the data used by the prior Mercer benchmarking prepared in 2023.

Recognizing Telix's growth and development since the 2023 data was provided, in 2025 the Board engaged Mercer to provide current remuneration benchmarking data for Executive KMP. A global peer group of 40 companies was established with Telix positioned near the median for metrics such as market capitalization and revenue, based on 6 month average data to June 30, 2025. Given the changes in Telix's share price during the year, updated data as to Telix's positioning in the peer groups, as at the end of October 2025, was also obtained.

The June 30 data indicated that current executive KMP remuneration was significantly below the benchmark median. Executive KMP remuneration remained below the market midpoint, with both TFR and TTR midpoints increasing from the 2023 to 2025 benchmarking data. This movement resulted in further decreased compa ratios for remuneration going into 2026 (based on June 2025 data) compared with those in 2025 (based on the 2023 data).

The October 2025 data also confirmed that remuneration remained below Telix's then position in the global peer group.

4.1. 2026 Executive KMP remuneration framework

4.1.1. Approach in 2026

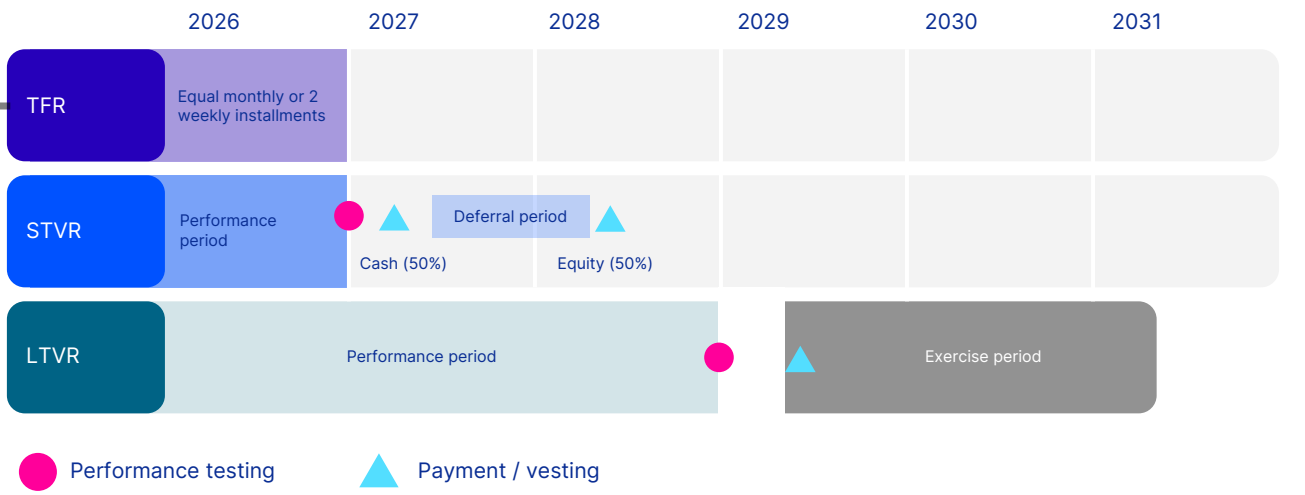
Having regard to the shareholder experience in 2025, the Board decided not to make any material changes to KMP remuneration for 2026, other than as mentioned below.

The Board decided to apply the average Telix employee market adjustment of 3.5% to the base salaries of Executive KMP (including the CEO), with the exception of Dr. Patti who received a 15% uplift. This is in recognition of the significant increase in position scope of his Group COO role to include radiopharmacy site and distribution network management (including responsibility for approximately 500 additional employees) as a result of the RLS acquisition.

See section 4.2 for 2026 remuneration at target for Telix's Executive KMP.

4.1.2. 2026 remuneration delivery

No changes will be made in the delivery of remuneration to Executive KMP in 2026. Despite the positioning against the benchmarking data outlined above, the Board determined that no changes would be made to STVR and LTVR opportunity levels for 2026.



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4.1.3. Short Term Variable Remuneration (STVR)

To promote alignment across the organization, in 2026 we are returning to having the same set of measures for STVR for all GET members, consisting of corporate financial objectives (40%) and shared business unit objectives (60%). This is a move away from the 2025 approach of individual business unit objectives assigned to each Executive KMP (excluding the MD & CEO).

As a result, from January 1, 2026, STVR outcomes for all Executive KMP (including the MD & CEO) will be measured based on achievement of a single Corporate objective scorecard comprising:

- Global revenue augmentation and diversification (20%),
- EBITDAR earnings target (10%),
- Product development (10%), and
- Business Unit priorities of 60%, split equally between Precision Medicine, Therapeutics, TMS and the International Business

The Business Unit priorities are:

- **Precision Medicine**: a combination of revenue diversification and Px program milestones
- **Therapeutics**: patient enrollment into clinical trials, achieving trial approvals from regulators and data readouts
- **TMS:** effective delivery of Telix doses and commercial products, build R&D capability and increase capabilities across global sites
- **International Business**: ex-U.S./Canada revenue and market share targets and trial registration, lodgment of approvals and commercial availability of products within EMEA

The Board will continue to consider modifiers based on non-corporate objective obligations of Executive KMP as detailed in section 3.2.3.

4.1.4. Long Term Variable Remuneration

The 2026 LTVR will replicate the 2025 approach as detailed in section 3.2.4, with elements included below where the terms differ:

Feature	Summary of 2026 LTVR terms	
Performance period	January 1, 2026 to December 31, 2028	
Notional exercise price	The volume weighted average price (VWAP) of Telix shares or ADSs over the 20 trading days following the 2025 full year results announcement (February 23 to March 20, 2026).	
Testing, vesting and exercise	PSAR performance will be tested following the audited financial results in March 2029. The Board will determine the number of PSARs that vest (between 0 and 150% based on the performance measures)[1]. Following vesting, Executive KMP have a two-year exercise period for the vested PSARs. The value received to Executives is the positive gain between the notional exercise price and the share/ADS price at the time of exercise.	
Grant method	Granted at the maximum possible outcome (150%), where the stretch financial target is achieved alongside all product milestones. Following testing, PSARs are forfeited that don't meet the milestones and are not subject to retesting.	
Performance measure	Performance measure	Vesting outcome
Financial (Adjusted EBITDAR) milestones	Less than US$1,365 million	-
	US$1,365 million	25%
	Greater than US$1,365 million and up to US$1,837 million	Straight line between 25 and 50%
	Greater than $1,837 million and up to US$2,042 million	Straight line between 50 and 100%
Product milestones		

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Feature	Summary of 2026 LTVR terms	
Precision Medicine (Px)	Gain FDA approval for a sNDA or a NDA of a new asset or indication expansion of a PSMA targeting imaging agent.	If achieved 12% If not achieved 0%
	Submit for a non-prostate indication expansion (metatastic) in the Precision Medicine business unit	If achieved 4% If not achieved 0%
Therapeutics (Tx)	Submit a marketing authorization for a TLX therapeutic product in a commercially relevant jurisdiction	If achieved 15% If not achieved 0%
	Run an EAP/NPP with government financial support, of one Tx asset in a relevant jurisdiction	If achieved 2% If not achieved 0%
Telix Manufacturing Solutions (TMS)	Have at least five RLS sites manufacturing a commercial Telix Px imaging agent.	If achieved 6% If not achieved 0%
	Delivery of at least four Tx drug product production lines within the US market capable of Phase 3/commercial production	If achieved 6% If not achieved 0%
	Delivery of at least one commercial ready therapeutic isotope supply chain	If achieved 5% If not achieved 0%
Equity grant details	2026 LTVR PSARs will be granted at stretch target (150% outcome) to all Executive KMP, with the MD & CEO grant made after shareholder approval at the 2026 Annual General Meeting.	
Treatment on termination (the Board retains discretion to determine a different treatment)	Departure reason	Treatment
	Termination for cause	Forfeited
	Resignation	Generally the number of PSARs retained is calculated on a pro rata basis with the remaining PSARs staying on foot to the usual testing and vesting date. The pro rata calculation and % retained is as follows: • Up to 12 months: 0% • 12 months and less than 24 months: 25% • 24 months and less than 36 months: 50% • Full three-year period: 100% retained
	Death, disability, retirement, redundancy and mutually agreed separation	A pro-rata portion of the unvested PSARs based on the number of days between the beginning of the Performance Period and the exit date will remain on foot to the usual testing and vesting date.
Reporting	The 2026 PSARs testing outcomes will be reported in the 2028 Remuneration report, with equity movements advised to the market via ASX disclosure and reported in the 2029 Remuneration report.	

1 In certain circumstances the Board may determine that participants receive a cash equivalent value of the vested element after testing.

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Additional information on 2026 LTVR performance measures

Measure	Rationale and strategic significance	Calculation	Measure type
Adjusted EBITDAR	Demonstrates Telix's underlying performance before non-operating expenditure, finance costs, depreciation and amortization, taxation expense and research and development activities.	Refer to Alternative performance measures	Financial
Precision Medicine (Px)	Expansion of the Telix PSMA franchise and non-prostate indication expansion will increase Telix's opportunity for continued sales growth and strengthened market position.	Either achieved or not achieved milestone (hit/ miss).	Strategic delivery
Therapeutics (Tx)	Regulator engagement with Therapeutic assets such as an EAP/NPP and marketing authorization submission shows key progress of Telix's Therapeutic assets.		
TMS	Supply and qualification of both Precision Medicine and Therapeutic production capabilities within RLS demonstrates successful expansion, and the maturation of TMS sites aligning with projected commercial needs.		
Targets	The Board sets targets at the outset of each performance period. Targets are set to be sufficiently challenging for Executive KMP and deliver appropriate returns for shareholders. The product milestones reflect Telix's strategy and focus on the Px, Tx and TMS business units. Including these measures for Executive KMP ensures a cohesive approach across the Executive team, towards sustainable company and shareholder long term value.		

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4.2. 2026 Executive KMP remuneration at target

Executive KMP remuneration from January 1, 2026 is outlined below. No changes were made to STVR and LTVR opportunity levels.

	Dr. Behrenbruch (MD & CEO)	Mr. Smith (CFO)	Dr. Cade (CMO)	Dr. Patti (COO)
Base salary	A$827,060 (3.5% uplift)	A$730,296 (3.5% uplift)	A$557,865 (3.5% uplift)	US$476,100 (15% uplift)
TFR	A$926,307	A$817,932	A$624,809	US$499,905
TFR compa ratio[1]	0.68	0.85	0.70	0.77
STVR[2] (% of base salary)	110%	65%	65%	65%
STVR target value	A$909,766	A$474,692	A$362,612	US$309,465
LTVR[2, 3] (% of base salary)	150%	100%	100%	100%
LTVR target value	A$1,240,590	A$730,296	A$557,865	US$476,100
TTR	A$3,076,664	A$2,022,920	A$1,545,286	US$1,285,470
TTR compa ratio[1]	0.56	0.52	0.42	0.48

1 Compa ratio is the TFR for an Executive KMP as a proportion of the median (50th percentile) of the recent 2025 Mercer benchmarking data.
2 Variable remuneration as a percentage of base salary increased in line with Mercer's recommendation (STVR and LTVR).
3 LTVR maximum opportunity is 150% of target.

5. 2025 NED remuneration

5.1. Remuneration principles

To attract and retain suitably qualified individuals, NED fees are set to reflect the obligations, responsibilities and demands of Telix's NEDs. They are reviewed periodically by the Board, considering market benchmark data and the financial position of the Group.

As detailed in the 2024 Remuneration report, increases were made to NED remuneration effective January 1, 2025 to align with the 80 to 120% of the market median approach, utilizing the data provided by Mercer in 2023 (not a recommendation). Mercer's 2023 benchmarking considered 19 ASX listed companies, with Telix positioned towards the median based on the average six-month market capitalization at August 31, 2023.

NEDs receive fees as Directors of Telix and for membership or chairing of some Board Committees. NEDs do not receive any performance-based remuneration. The Chair is not compensated for Committee memberships but is compensated for Committee Chair roles, where applicable.

The most recent NED Share Appreciation Rights ("NED SARs") grant made to Ms. Olson after shareholder approval at the 2022 Annual General Meeting vested on May 19, 2025.

As disclosed in the 2024 Remuneration report, during 2025 the Board introduced:

- A minimum shareholding policy for NEDs to hold equity equivalent to their annual base NED fee within 3 years of appointment or the introduction of the policy in 2025, and
- NED Rights plans for directors to salary sacrifice up to 40% of their base Board fees into Telix equity

There is no retirement benefit scheme (other than statutory superannuation contributions as required for Australian-based NEDs).

5.2. 2025 NED remuneration

The NED aggregate fee limit of A$1,800,000 was approved by shareholders at the 2025 Annual General Meeting. Total NED remuneration paid during 2025 was A$744,699, within the fee limit (41.4% of the total).

NED remuneration (inclusive of superannuation or other relevant statutory requirements, as applicable) are as follows:

Board and Committee Fees	Chair	Member
Board	A$360,000	A$180,000
Audit and Risk Committee	A$36,000	A$18,000
People Committee	A$36,000	A$18,000

Non-Australian based NEDs continued to be paid in 2025 in line with the exchange rate at the time of their appointment.

5.2.1. 2025 equity disclosures

The following equity vested to NEDs during 2025:

Equity type	Grant details		Vesting details		Exercise details		
	Date	# units	Date	Exercise price	Date	Resultant shares	Value exercised
2022 NED SARs	18-May-22	52,070	18-May-25	A$4.95	n/a	n/a	0

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5.3. 2025 NED statutory remuneration

The table below sets out NED remuneration for 2025 and 2024, prepared in accordance with relevant IFRS and Australian Accounting Standards.

All numbers have been restated for 2024 and provided in 2025 in US$ using the average exchange rate over the 2025 year.

		Directors' Fees	Superannuation	Share-based payment[1]	Non-cash benefits	Total	Options	
Name	**Year**	**US$**	**US$**	**US$**	**US$**	**US$**	**US$**	**%**
NEDs								
Ms. McDonald[2]	2025	104,332	12,314	-	-	116,646	-	-
	2024	-	-	-	-	-	-	-
Mr. Nelson	2025	115,898	13,618	-	-	129,516	-	-
	2024	80,164	9,018	-	-	89,182	-	-
Ms. Skinner	2025	134,971	15,864	-	-	150,835	-	-
	2024	92,071	10,357	-	-	102,428	-	-
Former NEDs								
Ms. Olson[3]	2025	230,380	-	-	-	230,380	-	-
	2024	97,211	-	37,730	-	134,942	37,730	27.96
Mr. McCann[4]	2025	88,296	9,398	-	19,628	117,322	-	-
	2024	148,465	16,701	-	-	165,166	-	-
Dr. Kluge[5]	2025	-	-	-	-	-	-	-
	2024	68,779	-	-	-	68,779	-	-
Total	**2025**	**673,877**	**51,194**	**-**	**19,628**	**744,699**	**-**	**n/a**
	2024	**486,690**	**36,076**	**37,730**	**-**	**560,497**	**37,730**	**n/a**

[1] Following Shareholder approval, premium-priced unlisted share options were issued to Ms. Olson in 2022. The amounts recorded for share based payments (options) for NEDs reflect the fair value of these options expensed each year over the life of the option.
[2] Ms. McDonald joined the Board on March 3, 2025, and her remuneration for 2025 is for the part year worked.
[3] Ms. Olson resigned as Chair and Non-Executive Director, effective February 3, 2026. Ms. Olson was paid in USD with an exchange rate as at the date he joined the Board of 0.7527.
[4] Mr. McCann retired from the Board on May 21, 2025. His remuneration reported for 2025 is for the part year worked. The non-cash benefit provided related to a retirement gift, funded between the Directors and Telix.
[5] No superannuation was applicable for Dr. Kluge in 2024 as he did not provide services in Australia. Ms. Olson has a certificate of coverage, which exempts the Group from paying superannuation.
Dr. Kluge was paid in Euro (€) with an exchange rate as at the date he joined the Board of 0.69326. Dr. Kluge retired from the Board on October 17, 2024, and his remuneration reported for 2024 is for the part year worked

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5.4. 2026 NED remuneration

As previously disclosed, Telix experienced significant growth in market capitalization, revenue and headcount in 2024 and into 2025. As a result of this significant growth, and similar to the position for Executive KMP, Mercer was also requested to provide updated remuneration benchmarking for the NED group. The same global peer group that was used for Executive KMP was also used for NED benchmarking.

In addition, an ASX peer group was used comprising 20 companies in the health care, communication services, information technology and industrials (production/manufacturing only) sectors, with Telix situated in the middle by market capitalization. Regard was also had to a further group of 14 ASX listed companies, with international operations and NEDs resident overseas.

The benchmarking data indicated that NED Board and Committee fees were generally below benchmark, in some cases significantly so. Having regard to the shareholder experience in 2025, the Board does not presently propose to increase NED fees for 2026. However, the Board is undertaking a search for internationally experienced directors and if it is necessary to adjust the fees (including through the addition of equity, subject to shareholder approval) in order to attract high calibre directors, an adjustment to fees may be considered.

6. Remuneration governance

6.1 Governance framework

The governance of Telix's remuneration framework ensures:

- The Board delegates specific responsibilities to the People Committee to provide recommendations to the Board
- Telix's strategic objectives, corporate governance principles, market practice and stakeholder interests are considered, and
- Achievement of pre-determined financial results and strategic objectives is rewarded through sustainable means.

<table>
<tr><th colspan="2">Roles in the Governance framework</th></tr>
<tr><td>THE BOARD has overall responsibility for oversight of Telix's remuneration approach for KMP (NEDs and Executives), including:
evaluating performance, determining remuneration outcomes and succession planning for the MD & CEO
determining remuneration outcomes, monitoring performance and succession planning of NEDs and Other Executive KMP, and
approving the Group's remuneration policies and practices.</td><td>THE PEOPLE COMMITTEE assists the Board in fulfilling its responsibilities to shareholders and regulators in relation to the Group's people and culture, remuneration and workplace health and safety policies and practices, including:
Telix's remuneration framework and policies, including Telix's Equity Incentive Plan rules;
remuneration arrangements and outcomes for KMP (NEDs and Other Executive KMP), including in respect of short term and long term variable remuneration,
remuneration related reporting and disclosures.
The People Committee may engage external advisors to provide information to assist in making remuneration decisions.</td></tr>
<tr><td>MANAGEMENT provides relevant information and analysis required to support effective decision making, including for remuneration related considerations.</td><td rowspan="2">EXTERNAL ADVISORS may be engaged by the People Committee to provide:
information to support effective decision making
an external perspective to assist in analysis with their expertize for remuneration related matters, and
on occasion, to provide remuneration recommendation/s as defined by section 9B of the Australian Corporations Act 2001 (Cth).</td></tr>
<tr><td>AUDIT AND RISK COMMITTEE assists the Board with the Group's risk management framework and risk appetite.</td></tr>
</table>

As detailed in sections 4.2 and 5.6, during 2025, Mercer was engaged to provide market benchmarking data for Executive KMP and NEDs. They provided data only, and did not provide any remuneration recommendations in 2025.

Further information on the Board's role and Telix's corporate governance policies (including the Securities Dealing Policy) is available in Telix's 2025 Corporate Governance Statement and on Telix's website at: ir.telixpharma.com/governance/documents/charters. Telix's Securities Dealing Policy prohibits hedging or margin lending in respect of Telix securities.

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6.2. Malus and clawback

The Board in its sole discretion, may reduce, cancel in full, or seek to clawback any incentive provided to any Executive KMP, including former Executive KMP, if it determines that at any time the Executive KMP:

- Acted dishonestly (including, but not limited to, misappropriating funds or deliberately concealing a transaction)
- Acted or failed to act in a way that contributed to Telix making a material financial misstatement including where Telix is required to prepare an 'Accounting Restatement' for the purposes of Telix's Clawback / Dodd-Frank Compensation Recovery Policy
- Acted or failed to act in a way that contributed to a breach of a significant legal or regulatory requirement
- Acted or failed to act in a way that contributed to Telix incurring significant reputational harm, a significant unexpected financial loss, impairment charge, cost or provision
- Exposed employees, the broader community or environment to excessive risks, including health and safety
- Breached their post-employment restraints (unless otherwise determined by the Board)
- Committed a material breach or non-compliance with Telix's Code of Conduct and/or any other employee or governance related policies, and/or
- Took excessive material risks or contributed to or may benefit from unacceptable cultures within the Group.

During 2025, the Board exercised no malus or clawback.

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6.3. Equity Incentive Plan

The purpose of the EIP is to align employees' and directors' interests with shareholders' interests by providing equity as part of remuneration arrangements.

The EIP enables our Board of Directors to award different types of equity instruments tailored to specific applications. These can include rights to acquire shares contingent on meeting specified performance metrics, options to acquire shares on payment of an exercise price and rights and/or options that are contingent on remaining in employment, among others. We offer three types of securities under the EIP, including share options, share rights (including share appreciation rights) and restricted shares, which we refer to as Incentive Securities.

Feature	Details
Eligibility	The Board determines the full-time or part-time employees (including a Director employed in an executive capacity), NEDs, casual employees or contractors or any other eligible persons (determined at the Board's discretion) that may participate in the EIP, collectively referred to as Eligible Employees. Casual and contractor staff must be employed on at least a 40% Full Time Equivalent (FTE) to participate in line with the EIP rules.
Administration of the EIP	The EIP is administered by our board of directors, who have the power to determine the appropriate procedures for the EIP.
Invitation	The Board of Directors may make an invitation to an Eligible Employee to apply for Incentive Securities on such terms and conditions as the board of directors determines from time-to-time, including with relation to the Incentive Securities: (1) the type and number and/or the method by which the number will be calculated; (2) the amount (if any) payable for the grant; (3) any vesting conditions or other conditions; (4) the procedure for exercising an option or right following vesting; (5) the determination the board of directors has made at its discretion that vesting of share rights and/or exercise of options (as applicable) will be satisfied through an allocation of shares or by cash payment; (6) the circumstances in which rights and/or options will lapse, shares allocated under the EIP may be forfeited or an EIP participant's entitlement may be reduced/extinguished; (7) how the securities may be treated in the event that an Eligible Employee ceases employment; (8) any restrictions on dealing shares; and (9) any other terms and conditions that, in the opinion of our board of directors, are fair and reasonable and not inconsistent with the EIP, and any other information that is required by applicable law.
Grant price	Unless the board of directors determines otherwise, no payment is required for the grant of Incentive Securities under the EIP.
Cap on number of ordinary shares to be issued under the EIP	The number of equity securities offered to participants under the EIP must not, when aggregated with the number of equity securities issued over the prior three years under (i) the EIP; (ii) any other employee share scheme covered by the ASIC Instrument 2022/1021; or (iii) an ASIC-exempt arrangement of a similar kind to an employee incentive scheme, exceed 32,405,821 equity securities, as approved by shareholders at an annual general meeting of shareholders on May 22, 2024. Our board of directors retains the discretion to adjust the cap on the number of the shares to be issued under the EIP, so long as the adjustment complies with applicable law.
Rights attaching to shares (including restricted shares)	*Ranking*. Shares issued under the EIP rank equally with other fully paid ordinary shares at the time of issue, except in relation to any rights attaching to such shares by reference to a record date prior to the date of their issue. *Dividends*. Holders of shares granted under the EIP are entitled to participate in all dividends and other distributions or benefits payable to participants in respect of their shares. *Voting rights*. Holders of shares granted under the EIP are entitled to exercise all voting rights attached to their shares, either generally or in a particular case, in accordance with our Constitution.

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Feature		Details
Options	Exercise price	The board of directors shall advise each Eligible Employee in the offer documentation the procedure for exercising share options, including any exercise price that will become payable with respect to the share options exercised. Subject to ASX listing rules, prior to the exercise of share options, the board of directors will retain the power to adjust the relevant exercise price in order to minimize or eliminate any material advantage or disadvantage to a participant resulting from a corporate action by, or capital reconstruction in relation to, the Company.
	Exercise period	Share options will vest and become exercisable when all vesting conditions and any other conditions advised to the participant by the board of directors have been tested and satisfied (or otherwise waived by the board of directors). If the vesting conditions and all other relevant conditions are satisfied during a period in which the participant is prohibited from dealing in our securities or shares, the board of directors may determine that the vesting of the options held by the affected participant will be delayed until such dealings are permitted.
	Lapse of share options	Share options will lapse upon the earliest to occur of: (1) ten years after the date on which the options were allocated to the participant, or any other date nominated as the expiry date of the offer; (2) the option lapsing in accordance with a provision of the EIP; (3) failure to meet a vesting condition or any other applicable condition within the vesting period; or (4) our receipt of a written notice from the participant that the participant has elected to surrender the option.
	Shares issued	Upon the exercise of a share option, we will issue the number of fully paid ordinary shares allocatable to the share options that have been exercised, ranking equally with, and having the same rights and entitlements as, other ordinary shares on issue at the date of allotment of the share (other than rights and entitlements accrued prior to the date of allotment of the share). Notwithstanding, the board of directors may determine that the exercise of an option will be satisfied in part or in whole by a cash payment in lieu of an allocation of shares.
	Restrictions on transfer of share options	In the case of options held by/on behalf of a participant who is a director, vested options must be satisfied by shares that have been purchased on market, unless (1) no shareholder approval is required under the listing rules in respect of the director's participation in the EIP; or (2) shareholder approval has been obtained for the director's participation in the EIP to the extent required under the listing rules.
Share Rights	Exercise price	No amount is payable with respect to share rights upon vesting and exercise.
	Exercise period	Share rights will vest and become exercisable (or will automatically be exercised, if specified by the board of directors in the terms provided at the time of grant) when all vesting conditions and any other conditions advised to the participant by the board of directors have been satisfied (or otherwise waived by the board of directors). If the vesting conditions and all other relevant conditions are satisfied during a period in which the participant is prohibited from dealing in our securities or shares, the Board may determine that the vesting of the rights held by the affected participant will be delayed until such dealings are permitted.
	Lapse of share rights	The share rights will lapse upon the earliest to occur of: (1) ten years after the date the rights were allocated to the participant, or any other date nominated as the expiry date in the offer; (2) the rights lapsing in accordance with a provision of the EIP; (3) failure to meet a vesting condition or any other applicable condition within the vesting period; or (4) receipt of a written notice from the participant that the participant has elected to surrender the right.
	Shares issued	Upon vesting, the board of directors will issue the number of fully paid ordinary shares allocatable to the share rights that have vested, ranking equally with, and having the same rights and entitlements as, our other ordinary shares on issue at the date of allotment of the share (other than rights and entitlements accrued prior to the date of allotment of the share). Notwithstanding, the board of directors may determine that the exercise of a share right will be satisfied in part or in whole by a cash payment made in lieu of an allocation of shares. In the case of share rights held by a participant who is a director, vested rights must be satisfied by shares that have been purchased on market, unless: (1) no shareholder approval is required under the listing rules in respect of the director's participation in the EIP; or (2) shareholder approval has been obtained for the director's participation in the EIP to the extent required under the listing rules.

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Feature		Details
	Share appreciation rights	At its discretion, the board of directors may determine that share appreciation rights will be granted to Eligible Employees. Share appreciation rights are share rights which only produce value if, at the time of vesting and exercise, the current market price exceeds a notional price specified by the board of directors at the time of the offer of such share appreciation rights. In the event that the calculation of current market price less notional price results in a zero or negative value at the time of exercise, the participant will not be entitled to any issuance of shares or cash payment. In the event that such calculation returns a positive value, the participant will be entitled to shares (or cash payment, as determined by the board of directors under the applicable rules of the EIP) with a value equal to the excess of the current market value over the notional price. Notwithstanding, the remainder of the terms of the EIP applicable to share rights (including exercise period, lapse, and restrictions on transfer) apply equally to share appreciation rights.
	Restrictions on transfer of share rights	Unless the board of directors determines otherwise, share rights may not be registered in any name other than that of the participant and may not be transferred, assigned, or otherwise dealt with by the participant.
Restricted Shares	Cessation of restrictions	A restricted share ceases to be restricted (i.e., vests) where the vesting period and all other relevant conditions have been satisfied or waived by the board of directors and the participant has been notified that the restrictions have ceased or no longer apply. If the vesting conditions and all other relevant conditions are satisfied during a period in which the participant is prohibited from dealing in our securities or shares, the board of directors may determine that the vesting of the restricted shares held by the affected participant will be delayed until such dealings are permitted.
	Forfeiture of restricted shares	A restricted share will be forfeited upon the earliest to occur of: (1) the restricted share being forfeited in accordance with a provision of the EIP; (2) the failure to meet a vesting condition or other applicable condition within the vesting period; or (3) our receipt of a written notice from the participant that the participant has elected to surrender the restricted share.
Vesting conditions		Incentive Securities may be subject to any vesting condition the board of directors determines. Incentive Securities will vest to the participant upon all the vesting conditions and any other applicable conditions that apply to such Incentive Securities being satisfied. The board of directors has discretion to attach individual vesting conditions to the Incentive Securities at the time they are issued. Eligible Employees will be advised of such vesting conditions in connection with their invitation to participate in a grant. The board of directors may in its absolute discretion waive, amend, or replace any or all of the vesting conditions, provided that the interests of the affected participant are not, in the opinion of the Board, materially prejudiced or advantaged relative to the position reasonably anticipated at the time of grant.
Employee Share Purchase Plan Shares ("ESPP Shares")		For Australian participants only, ESPP Shares will be allocated via new issue twice per year: in September and the following March, based on payroll deductions over the calendar year. The September purchase will include salary deductions between January 1 and June 30, and the March purchase based on salary deductions between July 1 and December 31. These will be held as Restricted Shares under the EIP, until they pass an approximately 18-month restricted period, at which point they will be released to the participant (in an open trading window). For US participants, please see the section below "U.S. Employee Stock Purchase Plan."
Amendments, suspensions or termination to/of the EIP		Subject to the exceptions listed below, our board of directors may at any time by resolution amend, suspend or terminate any provision of the EIP without the consent of the participant. However, no amendment, suspension or termination may be made if the amendment, suspension or termination materially prejudices the rights of any participant as they existed before the date of the relevant amendment, suspension or termination. The exceptions are amendments introduced: (1) for complying or conforming with present or future laws or regulations; (2) to correct any manifest error or mistake; or (3) to take into consideration adverse taxation implications in relation to the EIP. Moreover, the board of directors may waive, amend or replace any vesting condition attaching to an Incentive Security if the board of directors determines that the original vesting condition is no longer appropriate or applicable.

6.4. U.S. Employee Stock Purchase Plan

On December 12, 2024, the Board approved and adopted the Telix Pharmaceuticals (US) Inc. Employee Stock Purchase Plan Rules ("U.S. ESPP"), subject to shareholder approval. Shareholders subsequently approved the U.S. ESPP on May 21, 2025 at the 2025 AGM.

The material terms of the U.S. ESPP are summarized below.

General

The U.S. ESPP is comprised of two distinct components in order to provide flexibility to grant options to purchase shares under the U.S. ESPP. Specifically, the U.S. ESPP authorizes (1) the grant of options to U.S. employees that are intended to qualify for favorable U.S. federal tax treatment under Section 423 of the Internal Revenue Code of 1986, as amended ("the Code") referred to as the Section 423 Component, and (2) the grant of options that are not intended to be tax-qualified under Section 423 of the Code to provide flexibility to achieve tax, securities laws or other objectives, which are referred to as the Non-Section 423 Component. Where permitted under local law and custom, we expect that the Non-Section 423 Component will generally be operated and administered on terms and conditions similar to the Section 423 Component. In order for the Section 423 Component to qualify for U.S. federal tax treatment under Section 423 of the Code, shareholders must approve the U.S. ESPP within 12 months of adoption by the Board.

Shares Available for Awards; Administration

A total of 1,351,000 ordinary shares are initially reserved for issuance under the U.S. ESPP. The board of directors, or a committee of the board of directors, will be the administrator of the U.S. ESPP, or the Administrator, and has authority to interpret the terms of the U.S. ESPP and determine eligibility of participants. The People Committee is the initial Administrator of the U.S. ESPP. The ordinary shares purchased under the U.S. ESPP may be authorized but unissued shares or treasury shares, including shares bought on the open market, new issue, recycled, or otherwise acquired for purposes of the U.S. ESPP. The Administrator will have the authority to grant options to purchase ADSs to eligible participants in lieu of ordinary shares.

Eligibility

U.S. employees who have been continuously employed by a participating company within the Group (as determined by the Administrator) for at least six months prior to the enrollment date, and whose customary employment is 20 hours or more per week, are eligible to participate in the U.S. ESPP. However, an employee may not be granted an option to purchase shares under the U.S. ESPP if the employee, immediately after the grant, would own (directly or through attribution) shares possessing 5% or more of the total combined voting power or value of all classes of Telix shares or shares of any of Telix's subsidiaries.

Offering Periods and Purchase Price

Shares will be offered under the U.S. ESPP during offering periods. Eligible participants will be able to enroll in the U.S. ESPP during a specified enrollment period each calendar year, with each plan year commencing on January 1 (other than the first plan year for calendar year 2025, which commenced on April 1, 2025). Starting in calendar year 2026, there will be a series of sequential offering periods, with the first offering period commencing on or around January 1 of each calendar year and ending on or before September 30 of that same year, and with the second offering period commencing on or around July 1 and ending on or before March 15 of the following calendar year. Within each offering period, there will be a six month contribution period, starting on January 1 and July 1 of each calendar year, respectively, within which employee payroll deductions will be collected from participants and accumulated under the plan for the applicable offering period. If permitted by the Administrator to comply with non-U.S. requirements for the Non-423 Component, in lieu of payroll deductions, the Administrator may provide that an eligible employee may elect to participate via cash, check or other means acceptable to the Administrator. Employee contributions will be used to allocate shares (via purchase or new issue of shares) on each exercise date during an offering period. The exercise dates for each offering period will be the final trading day in the offering period. The Administrator may, in its discretion, modify the terms of future offering and contribution periods.

The U.S. ESPP permits participants to have contributions made during the contribution periods to be expressed, at Telix's sole discretion, as a U.S. dollar amount with the minimum and/or maximum U.S. dollar amount to be specified by Telix. These contributions will be used to purchase ordinary shares. The Administrator may establish a minimum or maximum amount of contributions a participant may make, and the minimum or maximum number of shares that may be purchased during any offering period. In addition, no employee will be permitted to accrue an option to purchase shares under the Section 423 Component at a rate in excess of US$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (determined at the fair market value per share of our ordinary shares as of the beginning of each offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase ordinary shares. An option will be exercised automatically at the end of the applicable offering period to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares will be 85% (or such greater percentage, if determined by the Administrator prior to the offering period) of the lower of the fair market value of Telix ordinary shares on the first trading day of the offering period or on the exercise date. The fair market value of Telix's ordinary shares for this purpose will generally be the closing price of our ordinary shares on the ASX (or such other

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exchange as our ordinary shares may be traded at the relevant time, including our ADSs on Nasdaq) on the first trading day of the offering period or on the exercise date, as applicable.

Participant Modification, Withdrawal or Termination

Participants may voluntarily end their participation in the U.S. ESPP at any time during a contribution period prior to the end of the applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase ordinary shares. Participants will not be permitted to modify their plan year contributions following close of the specified enrollment period. Participation ends automatically upon a participant's termination of employment. A participant's contributions will roll over in each new plan year until termination of participation, or modification or discontinuance of contributions consistent with the terms of the U.S. ESPP.

Transfer of Rights

A participant may not transfer, assign, pledge or otherwise dispose of contributions made or rights granted under the U.S. ESPP other than in the event of the death of a participant, in which case such participant's contributions will be delivered to the executor or administrator of the estate of the participant. The Administrator will have the discretion at its election to impose a holding period during which the sale of shares issued under the U.S. ESPP will be restricted. During the initial offering period, the terms of the U.S. ESPP require the Administrator to impose an 18-month holding period from each exercise date, during which the sale of shares issued under the U.S. ESPP will be restricted from transfer. Except for the aforementioned transfer restrictions, once shares have been delivered to participants, such participants will have all of the rights and privileges applicable to other holders of ordinary shares.

Changes to Shares or Capital Structure

Subject to any required shareholder approval, in the event that there is a specified type of change in our capital structure, such as a share split, share dividend, or combination or reclassification of the shares, proportionate adjustments will be made to the number of shares reserved under the U.S. ESPP, the price of shares that any participant has elected to purchase, and any other variables tied to the number of shares or the per share purchase price which we determine should be adjusted.

Amendment and Termination

The Administrator may amend, suspend or terminate the U.S. ESPP at any time without the consent of the participant. However, to the extent that shareholder approval is required under applicable tax, securities, stock exchange or other laws or rules, no amendment may be made without such approval.

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7. Additional statutory disclosures

7.1. Ordinary shareholdings

The relevant interests of KMP in the shares issued by Telix, held directly, indirectly or beneficially either personally or by their related parties are included in this section.

7.1.1. NED ordinary shareholdings

Name	Balance January 1, 2025	Shares issued from Options exercised	Net acquired/ (disposed)	Other changes	Balance December 31, 2025
Mr. McCann[1]	1,150,000	-	(30,000)	(1,120,000)	-
Ms. Olson[2]	95,235	-	11,315	-	106,550
Mr. Nelson	3,628,750	-	-	-	3,628,750
Ms. McDonald	-	-	3,719	-	3,719
Ms. Skinner	595,000	-	-	-	595,000
	5,468,985	**-**	**(14,966)**	**(1,120,000)**	**4,334,019**

1 Mr. McCann's ordinary shareholdings are reflected as Nil at year end as he is no longer a KMP
2 Ms. Olson resigned as Chair and Non-Executive Director, effective February 3, 2026

7.1.2. Executive KMP ordinary shareholdings

Name	Balance January 1, 2025	Shares issued from Options exercised	Net acquired/ (disposed)	Other changes	Balance December 31, 2025	% of base salary held in shares[1]
Dr. Behrenbruch	23,228,298	100,708	(2,000,000)	-	21,329,006	29,895 %
Mr. Smith	6,500	1,096	-	-	7,596	12 %
Dr. Cade	373,133	-	-	-	373,133	775 %
Dr. Patti	-	145,000	(119,442)	-	25,558	45 %
	23,607,931	**246,804**	**(2,119,442)**	**-**	**21,735,293**	

1 As at December 31, 2025, the Executive KMP's shareholding as a percentage of base salary is calculated using the closing share price of A$11.20 on the ASX.

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7.2. KMP option holdings for the year ended December 31, 2025

Equity-based awards granted to our non-executive directors and executive officers consist of options (no longer issued) and PSARs that provide the holder with the right to convert each option or PSAR to a fully paid ordinary share if vesting conditions are met. The following table discloses particulars of all awards outstanding for non-executive directors and executive officers as of December 31, 2025, including awards (as options) granted before fiscal year 2025. All values in A$, except where noted.

7.2.1. NED option holdings

Name	Grant date of options	Number of options granted	Exercise price	Expiry date	Fair value per option at grant date	Vesting date	Vesting number	Vested during the year	Lapsed or forfeited during the year	Exercised in current or prior year	Eligible to exercise at December 31, 2025	Unvested at December 31, 2025	Maximum value yet to vest
Ms. Olson[1]	18-May-22	52,070	A$4.95	18-May-26	A$2.19	31-Dec-24	52,070	52,070	-	-	52,070	-	-
Total		**52,070**					**52,070**	**52,070**	**-**	**-**	**-**	**-**	**-**

[1] Ms. Olson resigned as Chair and Non-Executive Director, effective February 3, 2026

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7.2.2. Executive KMP option holdings

Name	Grant date of options	Number of options granted	Exercise price A$ / US$	Expiry date	Fair value per option at grant date A$ / US$	Vesting date	Vesting number	Vested during the year	Lapsed or forfeited during the year	Exercised in current or prior year	Eligible to exercise at December 31, 2025	Unvested at December 31, 2025	Maximum value yet to vest US$
Dr. Behrenbruch	12-Jan-20	200,000	A$2.23	12-Jan-24	A$0.46	12-Jan-23	200,000	200,000	-	(200,000)	-	-	-
	26-Jan-21	100,708	A$4.38	26-Jan-26	A$2.12	28-Oct-22	100,708	100,708	-	(100,708)	-	-	-
	05-Apr-22	139,672	A$4.95	04-Apr-27	A$2.43	31-Dec-24	139,672	139,672	(46,558)	-	-	93,114	75,645
	30-May-23	120,268	A$6.90	31-Dec-27	A$7.65	31-Dec-25	120,268	-	-	-	-	120,268	102,741
	26-Jun-24	144,037	A$11.94	31-Mar-29	A$8.57	31-Mar-27	144,037	-	-	-	-	144,037	427,881
	21-May-25	166,483	A$28.67	31-Mar-30	A$10.81	31-Mar-28	166,483	-	-	-	-	166,483	1,141,166
	21-May-25	2,595	A$0.00	31-Mar-28	A$25.68	28-Feb-26	2,595	-	-	-	-	2,595	9,310
Mr. Smith	24-Oct-22	45,449	A$6.15	24-Oct-27	A$3.08	24-Oct-25	45,449	45,449	-	-	-	45,449	-
	24-Oct-22	32,463	A$6.15	24-Oct-27	A$3.08	24-Oct-25	32,463	32,463	-	-	-	32,463	-
	25-Apr-23	106,197	A$6.90	31-Dec-27	A$3.79	31-Dec-25	106,197	-	-	-	-	106,197	45,146
	25-Mar-24	35,000	A$0.00	28-Feb-29	A$11.70	31-Mar-27	35,000	-	-	-	-	35,000	198,312
	25-Mar-24	35,000	A$0.00	28-Feb-30	A$11.70	31-Mar-28	35,000	-	-	-	-	35,000	216,259
	13-May-24	76,311	A$11.94	31-Mar-29	A$7.59	31-Mar-27	76,311	-	-	-	-	76,311	263,252
	01-Jan-25	98,003	A$28.67	31-Mar-30	A$14.09	31-Mar-28	98,003	-	-	-	-	98,003	854,148
	01-Jan-25	1,111	A$0.00	31-Mar-28	A$25.56	28-Feb-26	1,111	-	-	-	-	1,111	2,655
	17-Mar-25	1,096	A$12.16	30-Sep-25	A$15.70	01-Sep-25	1,096	1,096	-	(1,096)	-	-	-
	17-Mar-25	893	A$22.40	15-Mar-26	A$7.70	01-Mar-26	893	-	-	-	-	893	795
Dr. Cade	04-Nov-19	500,000	A$2.30	04-Nov-23	A$0.48	04-Nov-22	500,000	500,000	-	(500,000)	-	-	637
	26-Jan-21	85,347	A$4.38	26-Jan-26	A$2.12	28-Oct-22	85,347	85,347	-	(85,347)	-	-	-
	21-Jul-21	100,000	A$0.00	20-Jul-26	A$5.35	20-Jul-26	100,000	-	-	-	-	100,000	358,450
	05-Apr-22	78,189	A$4.95	04-Apr-27	A$2.43	31-Dec-24	78,189	78,189	-	-	-	78,189	-
	25-Apr-23	101,152	A$6.90	31-Dec-27	A$3.79	31-Dec-25	101,152	-	-	-	-	101,152	43,001
	13-May-24	74,191	A$11.94	31-Mar-29	A$7.59	31-Mar-27	74,191	-	-	-	-	74,191	255,937
	01-Jan-25	74,864	A$28.67	31-Mar-30	A$14.09	31-Mar-28	74,864	-	-	-	-	74,864	652,480
	01-Jan-25	1,080	A$0.00	31-Mar-28	A$25.56	28-Feb-26	1,080	-	-	-	-	1,080	2,580

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Name	Grant date of options	Number of options granted	Exercise price A$ / US$	Expiry date	Fair value per option at grant date A$ / US$	Vesting date	Vesting number	Vested during the year	Lapsed or forfeited during the year	Exercised in current or prior year	Eligible to exercise at December 31, 2025	Unvested at December 31, 2025	Maximum value yet to vest US$
Dr. Patti	21-Jul-21	100,000	A$5.37	20-Jul-26	A$2.62	28-Oct-22	100,000	100,000	-	(100,000)	-	-	-
	05-Apr-22	15,826	A$4.95	04-Apr-27	A$2.43	31-Dec-24	15,826	15,826	-	-	-	15,826	-
	05-Apr-22	15,000	A$0.00	04-Apr-27	A$4.53	05-Apr-25	15,000	15,000	-	(15,000)	-	-	-
	02-May-23	32,938	A$6.90	31-Dec-27	A$3.79	31-Dec-25	32,938	-	-	-	-	32,938	14,002
	06-Jul-23	15,000	A$0.00	31-Dec-25	A$10.79	31-Dec-25	15,000	-	-	(15,000)	-	-	-
	01-Nov-23	15,000	A$0.00	01-Nov-28	A$8.99	31-Dec-26	15,000	-	-	-	-	15,000	39,632
	01-Nov-23	15,000	A$0.00	01-Nov-29	A$8.99	31-Dec-27	15,000	-	-	-	-	15,000	51,802
	13-May-24	17,175	A$11.94	31-Mar-29	A$7.59	31-Mar-27	17,175	-	-	-	-	17,175	59,249
	13-May-24	83,082	A$11.94	31-Mar-29	A$7.59	31-Mar-27	83,082	-	-	-	-	83,082	286,609
	26-Aug-24	15,000	A$0.00	04-Apr-25	A$19.86	01-Apr-25	15,000	15,000	-	(15,000)	-	-	-
	01-Jan-25	95,958	US$19.99	31-Mar-30	US$8.44	31-Mar-28	95,958	-	-	-	-	95,958	747,683
	01-Jan-25	1,230	US$0.00	13-Mar-26	US$17.43	27-Feb-26	1,230	-	-	-	-	1,230	2,945
Total		**2,741,318**					**2,741,318**	**1,328,750**	**(46,558)**	**(1,032,151)**	**-**	**1,662,609**	**5,852,317**

End of Remuneration Report

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C. Board Practices

Director Terms

In accordance with the ASX Listing Rules, a director (other than the CEO) must not hold office, without re-election, past the third annual general meeting ("AGM") following the director's appointment or three years, whichever is longer. In addition, under our Constitution, a director appointed by our Board who is not a CEO holds office until the next AGM of the Company following his or her appointment and no director who is not the CEO may hold office without re-election beyond the third AGM of the Company following the meeting at which such director was last elected (or re-elected). Under our Constitution, to the extent that the ASX Listing Rules require an election of directors to be held and no director would otherwise be required to submit for election or re-election, the director to retire is any director who wishes to retire (whether or not he or she intends to stand for re-election), otherwise it is the director who has been longest in office since their last election or appointment (excluding the CEO). As between directors who were last elected or appointed on the same day, the director to retire must be decided by lot (unless they can agree among themselves).

Set forth below is information regarding the terms of service of each of our current directors:

Name	Title	Date of initial appointment	End of current term / Eligible for re-election
Christian Behrenbruch	Managing Director and Group CEO	January 2017	N/A
Marie McDonald	Independent Non-Executive Director	March 2025	2028 AGM
Mark Nelson	Interim Chair and Independent Non-Executive Director	September 2017	2026 AGM
Jann Skinner	Independent Non-Executive Director	June 2018	2028 AGM

Ms. Olson, our former Chair and Non-Executive Director, was appointed to our Board in March 2022, and served as Chair of the Board from May 21, 2025 until her resignation, effective February 3, 2026.

Service Contracts

Other than as disclosed in this section, we do not have any service contracts with directors which provide for benefits upon termination of employment.

Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our Board, except that our Audit and Risk Committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our Board has determined that, under current listing requirements and rules of Nasdaq and taking into account the Board's Charter independence requirements, Mark Nelson, Marie McDonald, and Jann Skinner are "independent directors" under Rule 10A-3 of the Exchange Act, and pursuant to applicable Nasdaq rules. In making such determination, our Board considered the relationships that each non-executive director has with us and all other facts and circumstances our Board deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

The independence criteria under the applicable Nasdaq rules differ from the independence criteria set forth by the ASX in the Corporate Governance Principles and Recommendations, 4th edition. Under the Corporate Governance Principles and Recommendations, 4th edition, Mark Nelson, Marie McDonald, and Jann Skinner are "independent directors."

Board Committees

To assist with the effective discharge of its duties, our Board has established an Audit and Risk Committee ("ARC"), a People Committee, a Nomination Committee and a Disclosure Committee. Each committee (other than the Disclosure Committee which reviews and approves all material announcements to the market, where not approved by the full Board as specified by our Continuous Disclosure Policy and Disclosure Committee Charter) operates under a charter approved by our Board, which sets forth the purposes and responsibilities of the committee as well as qualifications for committee membership, committee structure and operations and committee reporting to our Board. Previously, the responsibilities of the People Committee and the Nomination Committee were vested in the People, Culture, Nomination and Remuneration Committee, which was dissolved effective March 3, 2025 in connection with the establishment of the People Committee and the Nomination Committee. The primary roles of each of the committees, as set forth under their respective Charters, is described below. Copies of the Charters are available under the Investor Centre section of our website at www.telixpharma.com.

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Audit and Risk Committee

The ARC has been established in accordance with our Constitution and operates under a Charter approved by our Board. The ARC's role outlined in the Charter is to review and make recommendations (as appropriate) to our Board in relation to its accounting, auditing, financial reporting, internal control, risk management, legal and regulatory compliance, sustainability responsibilities (including related to climate change), and internal and external audit functions. The ARC has also been delegated primary responsibility for overseeing the Group's risk management processes (see the section titled "Managing Risk - Role of the Board in Risk Oversight" below).

Under the Charter, the ARC is required to be comprised of at least three non-executive directors, all of whom must be independent. In addition, none of the members may have participated in the preparation of the financial statements of Telix or any current subsidiary at any time during the past three years.

The current membership of the ARC is:

- Jann Skinner (Chair);
- Marie McDonald; and
- Mark Nelson.

Ms. Olson, our former Chair and Non-Executive Director, served as a member of the ARC during the year ended December 31, 2025, and until her resignation, effective February 3, 2026. Ms. McDonald was appointed as a member of the ARC effective February 3, 2026.

People Committee

The People Committee has been established in accordance with our Constitution and operates under a Charter approved by our Board. The People Committee's roles outlined in the Charter include assisting our Board in fulfilling its responsibilities relating to our key people and organizational culture strategies and their alignment with our purpose and strategy, reviewing and making recommendations to the Board (as appropriate) with respect to Group remuneration, including the Group's remuneration framework and policies, and the remuneration of Non-Executive Directors, the CEO and other GET members (including KMP), approving the appointment and overseeing the succession planning of the Group CFO and other KMP (other than the CEO), and the general terms of their employment contracts, oversight responsibilities to shareholders with respect to our remuneration policies and practices, and belonging initiatives.

Under the Charter, the People Committee is required to be comprised of at least three non-executive directors, all of whom must be independent.

The current membership of the People Committee is:

- Marie McDonald (Chair);
- Mark Nelson; and
- Jann Skinner.

Ms. Olson, our former Chair and Non-Executive Director, served as a member of the People Committee during the year ended December 31, 2025, and until her resignation, effective February 3, 2026. Dr. Nelson was appointed as a member of the People Committee effective February 3, 2026.

Nomination Committee

The Nomination Committee has been established in accordance with our Constitution and operates under a Charter approved by our Board. The Nomination Committee's role outlined in the Charter is to assist the Board in the discharge of its responsibilities related to, among other things, the size, composition and organization of the Board and its committees, Board succession planning, including non-executive director appointments and appointment of the Group CEO, assessing the independence of non-executive directors, the process for evaluating the performance of the Board and its committees, the approval of the appointment and removal of the Group Company Secretary, and induction and ongoing development for directors.

Under the Charter, the Nomination Committee is required to be comprised of at least three non-executive directors, all of whom must be independent.

The current membership of the Nomination Committee is:

- Mark Nelson (Chair);
- Marie McDonald; and

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- Jann Skinner.

Ms. Olson, our former Chair and Non-Executive Director, served as Chair of the Nomination Committee during the year ended December 31, 2025, and until her resignation, effective February 3, 2026. Dr. Nelson was appointed Chair of the Nomination Committee, and Ms. Skinner was appointed as a member of the Nomination Committee, effective February 3, 2026.

Managing Risk

Role of the Board in Risk Oversight

The ARC assists the Board in overseeing and reviewing the integrity of financial and corporate reporting, risk appetite and the effectiveness of the enterprise risk management framework ("ERMF"), compliance systems and internal control framework, the legality, propriety and materiality of related party transactions, and the external and internal audit functions. In addition, the ARC has oversight of Telix's sustainability strategy and reporting framework, including in respect of climate change, healthcare and environmental governance and performance. The ARC receives reports from management at least quarterly regarding our assessment of risks, having regard to the risk appetite approved by the Board.

GET and other senior executives and internal and external auditors attend Committee meetings on invitation by the ARC. The ARC holds regular meetings with the internal auditor, and separately with the external auditor without the management team or MD & CEO present. Any Director who is not a member of the ARC may attend any meeting of the Committee in an ex-officio capacity.

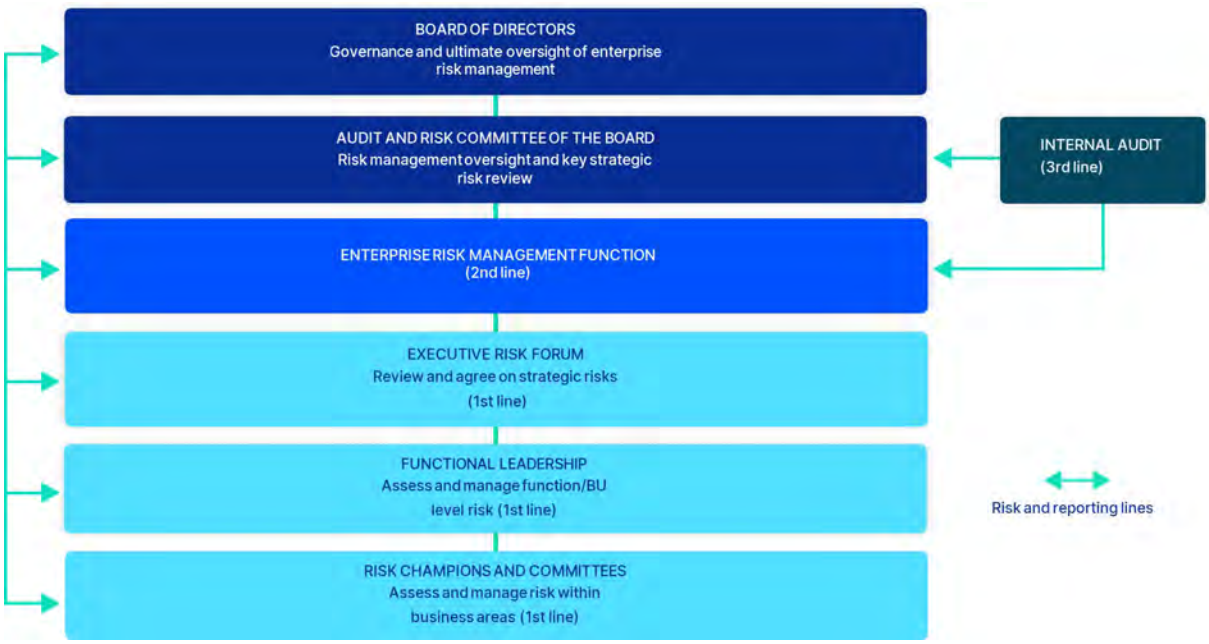
Risk Governance

The Company has adopted and follows an ERMF that incorporates the principles of effective risk management, as set out in the Global Risk Management Standard ISO 31000, to identify, evaluate, monitor and manage risks in the Telix Group - to improve business performance, remain innovative and establish competitive advantage, anticipate and communicate uncertainties, reduce operational losses and surprises, and protect Telix's reputation. Our ERMF data informs leaders in their decision making from prioritizing activities, to resourcing, to escalation.

Risk and opportunity is managed through objective and consistent identification, assessment, monitoring, measurement and reporting across the Telix Group. Management executes daily risk management activities, including by making decisions within stated Board-delegated authority, ensuring employees understand their responsibilities for managing risk through a "three lines" model, and establishing internal controls and guidance for the implementation of the ERMF.

In the "three lines" model, the first line, consisting of the business units and expert teams, executes core processes and controls. The second line, comprising the Enterprise Risk Management function, sets policies, establishes frameworks to manage risks, and delivers training and guidance to the first line. The third line, which constitutes internal and external audit, provides independent review of the first and second lines.

Ultimate risk management oversight sits with the Board. The Board, with assistance from the ARC, sets the risk appetite, within which it expects management to operate, and considers Telix's risk profile on a regular basis to ensure it supports the achievement of Telix's strategic and corporate goals.



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Foreign Private Issuer Exemption

We qualify as a "foreign private issuer" as defined in Rule 3b-4 of the Exchange Act. As a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our executive officers and directors are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. They are, however, subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules, to the extent applicable. Furthermore, absent an exemption from the SEC, and effective March 18, 2026, our officers and directors will be subject to the insider reporting obligations under Section 16(a) of the Exchange Act, including the requirements to file Forms 3, 4 and 5, pursuant to the Holding Foreign Insiders Accountable Act enacted on December 18, 2025. The foreign private issuer exemption also permits us to follow home country corporate governance practices or requirements instead of certain Nasdaq listing requirements, including the following:

- We rely on an exemption from the requirement that our independent directors meet regularly in executive sessions. In contrast to Nasdaq requirements, the ASX Listing Rules and the Australian Corporations Act 2001 (Cth) do not require the independent directors of an Australian company to have executive sessions.

- We rely on an exemption from the quorum requirements applicable to meetings of shareholders under Nasdaq rules. While Nasdaq requires that an issuer provide for a quorum as specified in its bylaws for any meeting of the holders of ordinary shares, which quorum may not be less than 33 1/3% of the outstanding shares of an issuer's voting ordinary shares, our Constitution provides that two shareholders present and entitled to vote on a resolution at the meeting shall constitute a quorum for a general meeting.

- We rely on an exemption from the requirement that the responsibility for the appointment of the independent registered public accounting firm be made by the audit committee. While the ARC is directly responsible for remuneration and oversight of the independent registered public accounting firm, the ultimate responsibility for the appointment of the independent registered public accounting firm rests with our shareholders in accordance with Australian law and our Constitution. In accordance with Rule 10A-3 of the Exchange Act, the ARC is responsible for the annual auditor engagement and if there is any proposed change to the independent registered public accounting firm, the committee will make a recommendation to our board of directors, which would then be considered by our shareholders at an annual meeting of shareholders.

- We rely on an exemption from the requirement prescribed by Nasdaq that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, changes of control or private placements of securities, or the establishment or amendment of certain stock option, purchase or other compensation plans. Applicable Australian law and rules differ from Nasdaq requirements, with the ASX Listing Rules providing generally for the ability to seek prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% of our issued share capital in any 12 month period (but, in determining the available issue limit, securities issued under an exception to the rule or with shareholder approval are not counted), (ii) issuance of equity securities to related parties, certain substantial shareholders and their respective associates (as defined in the ASX Listing Rules) and (iii) directors or their associates acquiring securities under an employee incentive plan.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and the listing rules of Nasdaq.

Australian Disclosure Requirements

Meetings and attendance

The Board meets as often as required. During the financial year ended December 31, 2025, the Board met 13 times. Members of the Group Executive Team and other members of senior management attend meetings of the Board by invitation. Each Board Committee provides a standing invitation for any Non-Executive Director to attend Committee meetings (rather than just limiting attendance to Committee members). Committee agendas and papers are provided to all Directors concerning matters to be considered. The table below excludes the attendance of Directors at Committee meetings where they were not a Committee member.

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	Board of Directors		Audit and Risk Committee		People Committee[1]		Disclosure Committee		Nomination Committee	
	Eligible to attend	Meetings attended	Eligible to attend	Meetings attended	Eligible to attend	Meetings attended	Eligible to attend	Meetings attended	Eligible to attend	Meetings attended
H K McCann[2]	5	5	3	3	2	2	2	2	1	1
T Olson	13	13	5	5	4	4	3	3	3	3
C Behrenbruch[3]	13	13					3	3		
M Nelson	13	13	5	5	1	1			3	3
J Skinner	13	12	5	5	4	4	2	2		
M McDonald[4]	11	11			3	3			3	3
A Whitaker[5]	1	1								

1. The People, Culture, Nomination and Remuneration Committee was dissolved and a separate People Committee of the Board and Nomination Committee of the Board was established effective March 3, 2025. Attendance noted combines the People, Culture, Nomination and Remuneration Committee and People Committee
2. H K McCann retired from the Board effective May 21, 2025
3. C Behrenbruch attends Audit and Risk Committee, People Committee and Nomination Committee meetings by invitation
4. M McDonald was appointed Non-Executive Director, Chair of the People Committee and member of the Nomination Committee effective March 3, 2025
5. A Whitaker was appointed Non-Executive Director effective April 7, 2025 and resigned April 29, 2025

Directors' interests in the securities of Telix

The relevant interests[1] of each Director in the share capital of Telix as at the date of this report are included in Item 6 section 7.1.1.

Issue of unlisted equity securities

Unlisted ordinary shares under options or rights issued during the year were as follows:

Options/Rights granted	ASX code	Expiry date	Exercise price	Number under option
TLXO030	TLXAO	March 31, 2030	A$28.67	1,700,510
TLXO031	TLXAU	March 31, 2028	nil	10,561
TLXO032	TLXAO	March 31, 2028	A$14.90	742,992
TLXO033	Not applicable	September 30, 2025	A$ 12.16	14,353
TLXO034	Not applicable	March 15, 2026	A$22.40	11,815
TLXO030-ADS	TLXAW	March 31, 2030	US$19.99	2,881,250
TLXO031-ADS	TLXAV	March 13, 2026	nil	10,342
TLXO032-ADS	TLXAW	March 31, 2028	US$9.98	1,758,187
TLXO033-ADS	Not applicable	September 30, 2025	US$8.02	26,361
TLXO034-ADS	Not applicable	March 15, 2026	US$13.61	28,776
Performance rights	TLXAR	January 31, 2030	nil	3,914,631

Shares issued for acquisitions, on exercise of rights or options and lapse of options

Acquisition share issues and exercise of rights

The Company completed the following acquisitions during the period, which resulted in the respective issue of fully paid ordinary shares and rights outlined below.

On January 31, 2025, Telix completed the acquisition of ImaginAb, Inc. The purchase price was paid to shareholders in equity through the issue of 2,053,311 fully paid ordinary Telix shares and the balance paid in cash.

[1] The number of shares held refers to shares held either directly, indirectly or beneficially by Directors as at February 20, 2026. Where applicable, the information includes shares held indirectly, including by nominee and/or other controlled entities

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In addition to the above, milestone rights have been issued to ImaginAb shareholders. Each milestone has a fixed dollar amount which can be settled, at Telix's election, either in cash or shares.

On January 31, 2025, March 17, 2025 and 6 May 2025, a total of 94,512, 83,395 and 91,168 shares were issued respectively following the satisfaction and exercise of Lightpoint performance rights.

On March 17, 2025 13,356 and on October 29, 2025 24,219 shares were issued following the satisfaction and exercise of Dedicaid performance rights.

Employee exercise or lapse of options

Ordinary shares of Telix issued during the financial year ended December 31, 2025 on the exercise of options granted over unissued shares and lapse of options were as follows:

- a total of 1,692,603 fully paid ordinary shares were issued upon exercise of 2,272,000 unlisted share options or PSARs, and
- a total of 1,850,000 share options lapsed unexercised. These options lapsed in accordance with the terms of their grant.

Since December 31, 2025 to the date of this Annual Report, no shares were issued from the exercise of options under Telix's Equity Incentive Plan.

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Indemnification

Indemnification of officers

Under Telix's Constitution, Telix has entered into agreements with each person who is, or has been, an officer of the Company. This includes the Directors in office at the date of this report, the Company Secretary and other executive officers, indemnifying them against any liability to any person other than Telix, or a related body corporate, that may arise from their acting as officers of the Company, notwithstanding that they may have ceased to hold office. There is an exception where the liability arises out of conduct involving a lack of good faith or is otherwise prohibited by law. During and since the end of the financial year ended December 31, 2024, Telix has paid or agreed to pay the premiums for an insurance policy to insure current and previous Directors and other executive officers against certain liabilities incurred in that capacity. Due to the confidentiality obligations and undertakings set out in these agreements, no further details regarding premiums paid, or the terms of the agreements, can be disclosed. No indemnity payment has been made under any document referred to above during or since the financial year ended December 31, 2025.

Auditor independence and non-audit services

Telix may decide to employ its auditor on assignments additional to statutory audit duties where the auditor's expertise and experience with the Group are important.

Details of amounts paid or payable to Telix's auditor, PricewaterhouseCoopers, for non-audit services provided during the year are set out in note 37 of the Financial report. The Directors, in accordance with advice received from the Audit and Risk Committee, are satisfied that the provision of non-audit services is compatible with the general standard of independence for auditors imposed by the Australian Corporations Act 2001 (Cth) for the following reasons:

- the Audit and Risk Committee has reviewed, or if required pre-approved, all non-audit services to confirm they do not affect the impartiality and objectivity of the auditor, and
- none of the services undermine the general principles relating to auditor independence as set out in APES 110 Code of Ethics for Professional Accountants, including reviewing or auditing the auditor's work, acting in a management or decision-making capacity for Telix, acting as an advocate for Telix, or jointly sharing the economic risks and rewards.

A copy of the auditor's independence declaration, as required under section 307C of the Australian Corporations Act 2001 (Cth), is included in this Annual Report as Exhibit 15.2.

Rounding

The Company is of a kind referred to in ASIC Legislative Instrument 2016/191, relating to the "rounding off" of amounts in the Australian Directors' report. Amounts in this report are rounded off in accordance with the instrument to the nearest thousand dollars or, in certain cases, to the nearest dollar.

Corporate governance

Throughout 2025, Telix's governance arrangements were consistent with the 4th edition of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations. This year, Telix was unable to fully comply with the ASX Corporate Governance Council's Corporate Governance Recommendation 1.5 due to new legal requirements introduced in the U.S. Instead, Telix has provided a summary of its approach to belonging at Telix in the 2025 Corporate Governance Statement, which has been approved by the Board and available at ir.telixpharma.com/governance/documents-charters. Telix is also subject to governance requirements related to our convertible bonds listing on the SGX, and our Nasdaq listing and registration with the SEC outlined in Item 16G within this Annual Report.

Related party transactions with KMP

Remuneration: Remuneration to KMP is recorded in the tables above.

Loans: There were no loans between the Group and any KMP in the years ended December 31, 2025 and 2024.

Other transactions: Refer to note 36 of the Financial report for further details.

Other than those noted above, there were no related party transactions with any KMP in the year ended December 31, 2025.

The components of our Directors' report are incorporated in various places within this Annual Report. Refer Contents page for this Annual Report and table charting these components is included within Appendix 4E, which is included as Exhibit 99.1 to this Annual Report.

Directors' Resolution

This report is approved in accordance with a resolution of the Directors.

Mark Nelson	Christian Behrenbruch
Interim Chair	Managing Director and Group CEO
February 20, 2026	February 20, 2026

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D. Employees

As of December 31, 2025, we had 1,184 employees based in 12 countries, as shown in the chart below.

	Employees
United States	886
Australia	95
Belgium	78
Canada	48
Switzerland	27
United Kingdom	25
Japan	10
France	5
Spain	6
The Netherlands	2
Sweden	1
New Zealand	1
Total	1,184

None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see “Item 7. Major Shareholders and Related Party Transactions — A. Major Shareholders.”

F. Disclosure of a Registrant’s Action to Recover Erroneously Awarded Compensation

None.

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ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The below table sets forth information with respect to the beneficial ownership of our ordinary shares as of December 31, 2025, for:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our ordinary shares;
- each of our executive officers;
- each of our directors; and
- all of our directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own.

Applicable percentage ownership is based on 338,777,049 ordinary shares outstanding as of December 31, 2025, which includes 4,730,676 ADSs. As of December 31, 2025, we had 84 holders of record of our ordinary shares in the United States, holding, in the aggregate 3,112,361 ordinary shares, or 0.92% of our outstanding ordinary shares, and 1 holder of record of our ADSs in the United States, holding, in the aggregate, 4,330,676 ADSs, or 91.5% of our outstanding ADSs. In computing the number of shares beneficially owned by a person or entity and the percentage ownership of such person or entity, we deemed to be outstanding all shares subject to options held by the person or entity that are currently exercisable, or exercisable within 60 days of December 31, 2025. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person or entity. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares. Each of our shareholders is entitled to one vote per ordinary share. None of the holders of our ordinary have different voting rights from other holders of our ordinary shares. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company. For further information regarding options to purchase ordinary shares held by our directors and executive officers, see “Item 6. Directors, Senior Management and Employees — B. Compensation.”

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Unless otherwise indicated, the address of each beneficial owner listed below is c/o Telix Pharmaceuticals Limited, 55 Flemington Road, North Melbourne, Victoria, 3051, Australia.

Name of Beneficial Owner	Number of Ordinary Shares Beneficially Owned	Percentage (%)
5% or greater shareholders		
JPMorgan Chase & Co.[1]	17,663,335	5.21
State Street Corporation[2]	24,734,225	7.30
Challenger Limited[3]	18,096,417	5.34
Gnosis Verwaltungsgesellschaft m.b.H[4]	20,675,000	6.10
Directors and Executive officers		
Dr. Behrenbruch[5]	21,329,006	6.30
Mr. Nelson[6]	3,628,750	1.07
Ms. Olson[7]	158,620	*
Ms. Skinner[8]	595,000	*
Ms. McDonald[9]	3,719	*
Mr. Smith[10]	7,596	*
Dr. Patti[11]	25,558	*
Dr. Cade[12]	373,133	*
All directors and executive officers as a group (eight persons)	**26,121,382**	**7.71**

* Less than one percent.

[1] Based on information filed with the ASX by JPMorgan Chase & Co., and its affiliates on November 17, 2025. The address for JPMorgan Chase & Co. is 270 Park Avenue, New York, NY, 10017.
[2] Based on information filed with the ASX by State Street Corporation and subsidiaries on October 8, 2025. The address for State Street Corporation is State Street Financial Center, 1 Lincoln Street, Boston, MA 02111.
[3] Based on information filed with the ASX by Challenger Limited and its associated entities on September 25, 2025. The address for Challenger Limited is Level 2, 5 Martin Place, Sydney NSW 2000, Australia.
[4] Dr. Kluge, a former Non-Executive Director who retired in October 2024, is the Managing Director of Gnosis Verwaltungsgesellschaft m.b.H. ("Gnosis") and has discretionary authority to vote and dispose of the ordinary shares held by Gnosis. The address for Gnosis is Veilchenweg 38, 01326 Dresden, Germany.
[5] Consists of (i) 21,329,006 ordinary shares beneficially owned (including 400,000 ADSs, each representing one of our ordinary shares) and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2025.
[6] Consists of (i) 3,628,750 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2025.
[7] Consists of (i) 106,550 ordinary shares beneficially owned and (ii) 52,070 ordinary shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2025. Ms. Olson resigned as Chair and Non-Executive Director effective February 3, 2026.
[8] Consists of (i) 595,000 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2025.
[9] Consists of (i) 3,719 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2025.
[10] Consists of (i) 7,596 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2025.
[11] Consists of (i) 25,558 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2025.
[12] Consists of (i) 373,133 ordinary shares beneficially owned and (ii) no ordinary shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2025.

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Australian Disclosure Requirements

Directors' interests in the securities of Telix

The relevant interests of each director in the share capital of Telix as at the date of this report are as follows:

	Ordinary Shares	Options/PSARs
Dr. Behrenbruch[1]	21,329,006	526,497
Mr. McCann[2]	-	-
Mr. Nelson	3,628,750	-
Ms. McDonald	3,719	-
Ms. Olson[3]	106,550	52,070
Ms. Skinner	595,000	-

B. Related Party Transactions

Since January 1, 2023, we have engaged in the following transactions with our directors, executive officers or holders of more than 5% of our voting securities, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest.

Director and Executive Officer Compensation

See "Item 6. Directors, Senior Management and Employees — B. Compensation" for information regarding compensation of our executive officers and directors.

Master Services Agreement with ABX-CRO

ABX-CRO is a clinical research organization that specializes in radiopharmaceutical product development. We have entered into a master services agreement with ABX-CRO for the provision of clinical and analytical services for its programs. Dr. Andreas Kluge, a former non-executive director who retired from our board of directors on October 17, 2024, is the principal owner and Managing Director of ABX-CRO. In the year ended December 31, 2023, ABX-CRO was engaged to perform close-out activities relating to the ZIRCON trial, and the total amount paid to ABX-CRO was $835,315. During the year ended December 31, 2024, ABX-CRO continued to perform close out activities relating to the ZIRCON trial, including delivery of dosimetry, PK evaluation, and the imaging report, and the total amount paid to ABX-CRO was $513,809. The transactions with Andreas Kluge and ABX-CRO do not meet the criteria of a related party transaction following Andreas Kluge's retirement as a non-executive director. Related party transactions were reviewed on an ongoing basis by the Audit and Risk Committee in accordance with Australian law.

Consultancy Agreement with Dr. Andreas Kluge

Following Dr. Kluge's retirement from our board of directors on October 17, 2024, Dr. Kluge was engaged by us on a consultancy basis and will continue to provide the board of directors strategic advice alongside clinical input into key development programs.

QDOSE Platform Partnership with ABX-CRO

In March 2024, we entered into an agreement to commercially partner the QDOSE dosimetry software platform with ABX-CRO and its development partner, Quantinm AB. QDOSE is a software platform designed to enable reliable estimation of patient-specific dosimetry for both therapeutic and diagnostic radiopharmaceuticals. We paid ABX-CRO upfront cash consideration of €1.2 million, and agreed to pay a share of profits generated from QDOSE sales and a referral fee on deals referred from or initiated by ABX-CRO for two years, expiring in 2026. During the year ended December 31, 2024, no other payments were made to ABX-CRO pursuant to this agreement other than the initial upfront cash consideration.

Indemnification Agreements

Our Constitution provides that, except to the extent prohibited by law including under the Australian Corporations Act 2001 (Cth), we must indemnify every person who is or has been a director, alternate director or executive officer of the Company and such other officers or former officers of the Company or of its related bodies corporate as the board of directors in each case determines against all losses, liabilities, costs, charges and expenses incurred by that person as a director or officer.

[1] Total interest includes 400,000 ADSs.
[2] H Kevin McCann retired as Non-Executive Director and Chairman of the Board on May 21, 2025.
[3] Tiffany Olson resigned as Chair and Non-Executive Director effective February 3, 2026.

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We have entered into Deeds of Indemnity, Insurance and Access ("Indemnity Deeds") with Christian Behrenbruch, Marie McDonald, Mark Nelson, Tiffany Olson, and Jann Skinner, and Deeds of Indemnity and Insurance with David Cade, Darren Patti, and Darren Smith. Under the Indemnity Deeds, we have agreed to indemnify (to the maximum extent permitted under Australian law and our Constitution, subject to certain specified exceptions) each director and executive officer against all liabilities incurred in their capacity as our or our subsidiaries' director or officer and any and all costs and expenses relating to such a claim or to any notified event incurred by such director or executive officer, including costs and expenses reasonably and necessarily incurred to mitigate any liability for such a claim or any claim which may arise from such a notified event. The Indemnity Deeds provide that the indemnities are unlimited as to amount, continuous and irrevocable.

Separately, we have obtained insurance for our directors and executive officers, as required by the Indemnity Deeds. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Related Party Transaction Policy

We comply with Australian law and the ASX Listing Rules regarding approval of transactions with related parties. Our Audit and Risk Committee is responsible for reviewing and monitoring the propriety of related party transactions, as set out in the Audit and Risk Committee Charter.

Effective upon the listing of our ADSs on Nasdaq, we amended our related party transaction policy to set forth our procedures for the identification, review, consideration and approval or ratification of related party transactions to comply with Nasdaq requirements. For purposes of our policy, a related party transaction is a transaction, arrangement or similar contractual relationship, or any series of similar transactions, arrangements or relationships, in which we and any related party are, were or will be participants and the amount involved in the transaction exceeds US$120,000, with the exception of usual transactions concluded under normal conditions. A related party is any member of our board of directors, our executive officers or any beneficial owner of more than 10% of any class of our ordinary shares, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related party transaction, including any transaction that was not a related party transaction when originally consummated or any transaction that was not initially identified as a related party transaction prior to consummation, our executive officers must present information regarding the related party transaction to the chief financial officer and the transaction will be subject to review, consideration and approval by the Audit and Risk Committee or, if required, the Board. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related party, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third-party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each member of our board of directors and executive officers to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy.

All of the transactions described above were entered into prior to the effective date of the amended written policy, but our Board evaluated and approved all transactions that were considered to be related party transactions under Australian law and the ASX Listing Rules at the time at which they were consummated.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See "Item 18. Financial Statements" for our consolidated financial statements filed as part of this Annual Report.

Legal Proceedings

As previously disclosed, Telix has received a subpoena from the SEC seeking various documents and information primarily relating to the Company's disclosures regarding the development of the Company's prostate cancer therapeutic candidates[1]. This matter remains a fact-finding request. Telix is cooperating with the subpoena including responding to the SEC's requests. The SEC has not asserted any charges against the Group or any of it's personnel, and no conclusions have been reached, or that the SEC has a negative opinion of any person, entity or security. At this stage, the Group cannot predict the duration, scope or outcome of this matter. The Group will continue to monitor the inquiry and update its disclosures as appropriate.

On November 10, 2025, a putative securities class action complaint was filed in the United States District Court for the Southern District of Indiana seeking, among other relief, class certification, designation of a lead plaintiff, damages and a

[1] Telix ASX disclosure July 22, 2025

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jury trial. On January 20, 2026, the Group was formally served the complaint on behalf of a purposed U.S. shareholder. This case is in its earliest stages; no class has been certified and the court has not ruled on any dispositive motions. At this stage, the Group cannot predict the duration, scope or outcome of this matter. The Group will continue to monitor this matter and update its disclosures as appropriate.

Other than as set forth above, we are not currently a party to any material legal proceedings or investigations. From time to time, we may become involved in other litigation or legal proceedings, particularly relevant to defending our IP rights or in response to or relating to claims arising from the ordinary course of business.

Australian Disclosure Requirements

Dividends

No dividend was declared or paid, and Telix did not return capital to any of its shareholders, during the year ended December 31, 2025.

Due to the stage of our company and the corporate objective of building and investing in our pipeline for the future, we have not declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our operations and pipeline development activities and build the capabilities of our business to drive growth and value accretion. Future dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our Board, and subject to applicable Australian law.

While we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, any dividend that we may declare will be paid to the holders of ADSs, subject to the terms of the deposit agreement, to the same extent as holders of our ordinary shares, to the extent permitted by applicable law and regulations, less the fees and expenses payable under the deposit agreement. Any dividend we declare will be distributed by the depositary bank to the holders of the ADSs, subject to the terms of the deposit agreement. See "Item 12. Description of Securities Other Than Equity Securities — D. American Depositary Shares."

B. Significant Changes

Except as otherwise disclosed in this Annual Report, no significant change has occurred since the date of the most recent financial statements included in this Annual Report.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

The principal trading market for our ordinary shares is the ASX in Australia, where our ordinary shares have been listed since 2017. Our ordinary shares trade under the symbol "TLX."

Since November 13, 2024, our ADSs have been listed on the Nasdaq Global Select Market, where they trade under the symbol "TLX." Each ADS represents one of our ordinary shares. JPMorgan Chase Bank, N.A., is the depositary for the ADSs.

B. Plan of Distribution

Not applicable.

C. Markets

See "Item 9. The Offer and Listing — A. Offer and Listing Details."

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issuer

Not applicable.

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ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

For Items 10.B.1 – 10.B.10, please refer to Item 10.B of our Registration Statement on Form 20-F, filed with the SEC on October 29, 2024, which is incorporated into this Annual Report by reference.

C. Material Contracts

Please see “Item 4. Information on the Company — B. Business Overview — Collaboration and License Agreements” and “Item 5. Operating and Financial Review and Prospects — B. Liquidity and Capital Resources” for a discussion of material contracts. Except as otherwise disclosed in this Annual Report (including the exhibits) or the annual report for the year ended December 31, 2024 that we filed with the SEC on February 24, 2025, we are not currently, and have not been in the preceding two years, party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

Australia has largely abolished exchange controls on investment transactions. The Australian dollar is freely convertible into U.S. dollars or other currencies. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Transaction Reports and Analysis Centre ("AUSTRAC"), which monitors such transactions, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply and under such there are either exemptions or limitations on the level of tax to be withheld.

E. Taxation

The following is a summary of material U.S. federal and Australian income tax considerations to U.S. Holders, as defined below, of the acquisition, ownership and disposition of our ADSs and ordinary shares. This discussion is based on the laws in force as of the date of this Annual Report, and is subject to changes in the relevant tax law, including changes that could have retroactive effect. The following summary is not a comprehensive description of all U.S. federal or Australian tax considerations that may be relevant to a decision to acquire or dispose of ADSs or ordinary shares and does not take into account or discuss the tax laws of any country or other taxing jurisdiction other than the U.S. and Australia. Holders are advised to consult their tax advisors concerning the overall tax consequences of the acquisition, ownership and disposition of ADSs and ordinary shares in their particular circumstances. This discussion is not intended, and should not be construed, as legal or professional tax advice.

Material U.S. Federal Income Tax Considerations

The following summary describes the material U.S. federal income tax consequences to a U.S. Holder (as defined below) of the acquisition, ownership and disposition of the ADSs and ordinary shares as of the date hereof. This summary is limited to U.S. Holders that hold the ADSs or ordinary shares as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended ("the Code").

This summary does not address the Medicare tax on net investment income, the effects of U.S. federal estate and gift tax laws, alternative minimum taxes, or any state and local tax considerations. In addition, this section does not discuss the tax consequences to any particular holder or any tax considerations that may apply to U.S. Holders subject to special tax rules, such as:

- insurance companies;
- banks or other financial institutions;
- tax-exempt entities including pension plans, “individual retirement accounts” or “Roth IRAs”;
- regulated investment companies;
- real estate investment trusts;
- individuals who are former U.S. citizens or former long-term U.S. residents;
- brokers, dealers or traders in securities, commodities or currencies;

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- traders that elect to use a mark-to-market method of accounting;
- except as specifically described below, persons holding the ADSs or ordinary shares through a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) or S corporation;
- persons that received ADSs or ordinary shares as compensation for the performance of services;
- persons that hold ADSs or ordinary shares as a position in a straddle or as part of a hedging, constructive sale, conversion or other integrated transaction for U.S. federal income tax purposes;
- persons that have a functional currency other than the U.S. dollar;
- corporations that accumulate earnings to avoid U.S. federal income tax; or
- persons that own (directly, indirectly or constructively) 10% or more of our equity (by vote or value).

In this section, a "U.S. Holder" means a beneficial owner of our ADSs or ordinary shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the U.S.;
- a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the U.S. or any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust (i) the administration of which is subject to the primary supervision of a court in the U.S. and for which one or more U.S. persons has the authority to control all substantial decisions or (ii) that has an election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person for U.S. federal income tax purposes.

We have not received, nor do we expect to seek, a ruling from the U.S. Internal Revenue Service ("IRS") regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of those set forth below. Each prospective investor should consult its own tax advisors with respect to the U.S. federal, state and local and non-U.S. tax consequences of acquiring, owning and disposing of the ADSs and ordinary shares.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes acquires, owns or disposes of ADSs or ordinary shares, the U.S. federal income tax treatment of a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its own tax advisor as to the U.S. federal income tax consequences of acquiring, owning and disposing of the ADSs or ordinary shares.

The discussion below is based upon the provisions of the Code, existing and proposed U.S. Treasury regulations, published rulings and judicial decisions, all as of the date hereof. Such authorities may be replaced, revoked or modified, possibly with retroactive effect, so as to result in U.S. federal income tax consequences different from those discussed below. In addition, this summary is based, in part, upon representations made by the depositary to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

YOU ARE URGED TO CONSULT YOUR OWN TAX ADVISOR WITH RESPECT TO THE U.S. FEDERAL, AS WELL AS STATE, LOCAL AND NON-U.S. TAX CONSEQUENCES TO YOU OF ACQUIRING, OWNING AND DISPOSING OF ADSs OR ORDINARY SHARES IN LIGHT OF YOUR PARTICULAR CIRCUMSTANCES, INCLUDING THE POSSIBLE EFFECTS OF CHANGES IN U.S. FEDERAL AND OTHER TAX LAWS.

ADSs

Assuming that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement will be complied with in accordance with their terms, a U.S. Holder of ADSs generally will be treated for U.S. federal income tax purposes as the owner of the underlying ordinary shares that are represented by such ADSs. Accordingly, no gain or loss will be recognized for U.S. federal income tax purposes if a U.S. Holder exchanges ADSs for the underlying ordinary shares represented by those ADSs.

Distributions

As described below in "– F. Dividends and Paying Agents," we do not currently anticipate paying any distributions on the ADSs or ordinary shares in the foreseeable future. However, to the extent there are any distributions made with respect to the ADSs or ordinary shares, and subject to the PFIC rules discussed below, the gross amount of any such distributions made out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) will generally be taxable to a U.S. Holder as ordinary dividend income on the date such distribution is actually

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or constructively received. Distributions in excess of our current and accumulated earnings and profits, as so determined, will be treated first as a tax-free return of capital to the extent of the U.S. Holder's adjusted tax basis in the ADSs or ordinary shares, as applicable, and thereafter, as capital gain. However, because we do not intend to calculate our earnings and profits under U.S. federal income tax principles, it is expected, and U.S. Holders should assume, that any distribution will be reported as a dividend and will constitute ordinary dividend income to a U.S. Holder. Any dividends will generally be treated as foreign-source and will not be eligible for the dividends-received deduction generally allowed to corporate U.S. Holders.

Subject to the discussion under "—Passive Foreign Investment Company Considerations," below, dividends paid to non-corporate U.S. Holders may qualify as "qualified dividend income" eligible for the preferential rates of taxation applicable to long-term capital gains if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. We generally will be considered to be a qualified foreign corporation (i) if we are eligible for the benefits of the Convention between the Government of the United States of America and the Government of Australia for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, signed on August 6, 1982, as amended and currently in force ("the U.S.-Australia Tax Treaty") or (ii) the ADSs or our ordinary shares are readily tradable on an established securities market in the U.S. In addition, we believe that we qualify as a resident of Australia for purposes of, and are eligible for the benefits of, the U.S.-Australia Tax Treaty, although there can be no assurance in this regard. Therefore, subject to the discussion under "— Passive Foreign Investment Company Considerations," below, any dividends on the ADSs or our ordinary shares generally will be "qualified dividend income" in the hands of individual U.S. Holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met.

Distributions paid in Australian dollars, including any Australian taxes withheld, will be included in a U.S. Holder's gross income in a U.S. dollar amount calculated by reference to the spot exchange rate in effect on the date of actual or constructive receipt, regardless of whether the Australian dollars are converted into U.S. dollars at that time. A U.S. Holder will have a tax basis in the Australian dollars equal to their U.S. dollar value on the date of receipt. As a result, if a U.S. Holder converts the Australian dollars into U.S. dollars on the date of receipt, such U.S. Holder generally should not be required to recognize any foreign exchange gain or loss. If Australian dollars so received are not converted into U.S. dollars on the date of receipt, any gain or loss on a subsequent conversion or other disposition of the Australian dollars generally will be treated as ordinary income or loss and generally will be income or loss from sources within the U.S. for foreign tax credit limitation purposes.

Subject to certain limitations, a U.S. Holder may be able to claim as a credit against its U.S. federal income tax liability the amount of any Australian tax withheld from any dividends at a rate not exceeding an applicable rate under the U.S.-Australia Tax Treaty. Alternatively, a U.S. Holder may be able to deduct such Australian taxes from its U.S. federal taxable income, provided that the U.S. Holder elects to deduct rather than credit all foreign income taxes paid or accrued for the relevant taxable year. The rules governing U.S. foreign tax credits are complex and U.S. Treasury Regulations may further restrict the availability of any such credit based on the nature of the withholding tax imposed by the foreign jurisdiction. A notice from the IRS indicates that the IRS is considering proposing amendments to such foreign tax credit regulations. Each U.S. Holder should consult its tax advisors regarding the foreign tax credit rules, including regarding the availability of such credit or deductions.

Sale, Exchange or Other Disposition of ADSs or Ordinary Shares

A U.S. Holder generally will recognize gain or loss for U.S. federal income tax purposes upon the sale or other taxable disposition of the ADSs or the ordinary shares in an amount equal to the difference between the U.S. dollar value of the amount realized from such disposition and the U.S. Holder's adjusted tax basis in those ADSs or ordinary shares, determined in U.S. dollars. Subject to the discussion under "—Passive Foreign Investment Company Considerations" below, any such gain or loss generally will be a capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder's holding period for such ADSs or ordinary shares is more than one year at the time of such disposition. A U.S. Holder's adjusted tax basis in the ADSs or ordinary shares generally will be equal to the amount paid for such ADSs or ordinary shares. Any long-term capital gain from the disposition of the ADSs or our ordinary shares by a non-corporate U.S. Holder generally is eligible for a preferential rate of taxation. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. Holder recognizes generally will be treated as U.S.-source gain or loss for foreign tax credit limitation purposes. U.S. Holders should consult their tax advisors regarding the tax consequences if Australian taxes are imposed on or in connection with a sale, exchange or other disposition of the ADSs or the ordinary shares and their ability to credit any Australian tax against their U.S. federal income tax liability.

In the case of a U.S. Holder that is a cash basis taxpayer, any units of foreign currency received on a disposition of the ADSs or our ordinary shares are translated into U.S. dollars at the spot exchange rate on the settlement date of the disposition if the ADSs or ordinary shares disposed of are treated as traded on an established securities market. In such case, no foreign currency exchange gain or loss will result for a cash basis taxpayer from currency fluctuations between the trade date and the settlement date of such a disposition. An accrual basis taxpayer may elect the same treatment required of cash basis taxpayers with respect to dispositions of the ADSs or our ordinary shares that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. If an accrual basis taxpayer does not make such election, or if the ADSs or our ordinary shares are not treated as traded on an established securities market, any units of foreign currency received on a disposition of the ADSs or our ordinary shares are translated into U.S. dollars at the spot exchange rate on the trade date

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of the disposition. In such case, the taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. Holder recognizes will be U.S.-source ordinary income or loss.

Passive Foreign Investment Company Considerations

If we are classified as a PFIC in any taxable year, certain adverse tax consequences could apply to U.S. Holders as a result of that classification. We generally will be classified as a PFIC for any taxable year if (i) at least 75% of our gross income for the taxable year consists of certain types of passive income, or (ii) at least 50% of our gross assets during the taxable year, based on a quarterly average and generally determined by value, produce or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions and gains from the disposition of assets that produce or are held for the production of passive income. Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. In determining whether we are a PFIC, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of each corporation in which we own, directly or indirectly, at least a 25% interest (by value).

Based on the expected nature and amount of our estimated gross income, the anticipated nature and estimated average value of our gross assets, the anticipated cash needs of our group's operations and the nature and extent of the active businesses conducted by our "25% or greater" owned subsidiaries, we do not expect that we will be classified as a PFIC in the current taxable year or for the foreseeable future. However, the determination of our PFIC status for any taxable year will not be determinable until after the end of the taxable year, and will depend on, among other things, the composition of our income and assets (which could change significantly during the course of a taxable year) and the market value of our assets for such taxable year, which may be, in part, based on the market price of the ADSs or ordinary shares (which could be volatile). Accordingly, there can be no assurance that we will not be a PFIC for our current or any future taxable year. U.S. Holders should consult their own tax advisors regarding our PFIC status.

If we are a PFIC for any taxable year during which a U.S. Holder holds ADSs or ordinary shares, absent certain elections (including the mark-to-market election or qualified electing fund election described below), such U.S. Holder generally will be subject to adverse rules (regardless of whether we continue to be classified as a PFIC) with respect to (i) any "excess distribution" that we make to such U.S. Holder (generally, any distributions on the ADSs or ordinary shares in a taxable year that are greater than 125% of the average annual distributions received by such U.S. Holder in the three preceding taxable years or, if shorter, the U.S. Holder's holding period) and (ii) any gain recognized from a sale or other disposition (including a pledge) of such ADSs or ordinary shares. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period for the ADSs or ordinary shares;
- the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which we were classified as a PFIC will be treated as ordinary income arising in the current taxable year (and would not be subject to the interest charge discussed below); and
- the amount allocated to each other taxable year will be subject to income tax at the highest marginal tax rate in effect for individuals or corporations, as applicable, for such year, and the interest charge generally applicable to underpayments of tax will be imposed with respect to the resulting tax attributable to each such year.

In addition, non-corporate U.S. Holders will not be eligible for reduced rates of taxation applicable to "qualified dividend income" on any dividends that we pay if we are a PFIC for either the taxable year in which the dividend is paid or the preceding year.

If we are classified as a PFIC in any taxable year with respect to which a U.S. Holder owns ADSs or ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding taxable years, regardless of whether we continue to be classified as a PFIC under the tests described above, unless we cease to be classified as a PFIC and such U.S. Holder makes a "deemed sale" election. If we cease to be classified as a PFIC and a U.S. Holder makes the "deemed sale" election, such U.S. Holder will be deemed to have sold our ADSs or ordinary shares at their fair market value on the last day of the last taxable year in which we were classified as a PFIC, and any gain recognized from such deemed sale would be taxed under the PFIC excess distribution regime described above. After the "deemed sale" election, a U.S. Holder's ADSs or ordinary shares would not be treated as shares of a PFIC unless we subsequently become a PFIC.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares, and one of our non-U.S. subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the PFIC excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions.

If a U.S. Holder owns ADSs or our ordinary shares during any taxable year in which we are a PFIC, such U.S. Holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment

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Company or Qualified Electing Fund) with respect to us, generally with its U.S. federal income tax return for that year. U.S. Holders should consult their tax advisors regarding any annual filing requirements.

If we are a PFIC, a U.S. Holder will not be subject to tax under the PFIC excess distribution regime on distributions or gain recognized on our ADSs or ordinary shares if a valid "mark-to-market" election is made by the U.S. Holder for our ADSs or ordinary shares, provided that the ADSs or ordinary shares held by such U.S. Holder are "marketable."

If a U.S. Holder makes a mark-to-market election, it must include in gross income, as ordinary income, for each taxable year that we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs or ordinary shares that are "marketable stock" at the close of the taxable year over such U.S. Holder's adjusted tax basis in such ADSs or ordinary shares. If a U.S. Holder makes such election, it may also claim a deduction as an ordinary loss in each such year for the excess, if any, of such U.S. Holder's adjusted tax basis in such ADSs or ordinary shares over their fair market value at the end of the year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. The U.S. Holder's adjusted tax basis in the ADSs or ordinary shares with respect to which the mark-to-market election applies would be adjusted to reflect amounts included in gross income or allowed as a deduction because of such election. If a U.S. Holder makes an effective mark-to-market election, any gain recognized upon the sale or other disposition of the ADSs or ordinary shares in a year that we are a PFIC will be treated as ordinary income and any loss will be treated first as ordinary loss (to the extent of any net mark-to-market gains for prior years) and thereafter as capital loss. However, a mark-to-market election will generally not be available with respect to a lower-tier PFIC unless the shares of such lower-tier PFIC are themselves treated as "marketable stock."

If a U.S. Holder makes a mark-to-market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs or ordinary shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election. U.S. Holders are urged to consult their tax advisors about the availability of the mark-to-market election.

Alternatively, in certain cases, a U.S. Holder may be able to avoid the interest charge and the other adverse PFIC tax consequences described above by electing to treat the PFIC as a "qualified electing fund," or QEF, under Section 1295 of the Code. If a U.S. Holder makes a valid and timely QEF election and we provide certain required information to such U.S. Holder, then for each taxable year to which such an election applies, the U.S. Holder will be subject to U.S. federal income tax on its pro rata share of our net capital gain and ordinary earnings, regardless of whether such amounts are actually distributed to the U.S. Holder in that year or any later year. However, we do not anticipate that this election will be available to U.S. Holders because we do not expect to provide U.S. Holders with the information that would be necessary to make a valid QEF election.

Backup Withholding Tax and Information Reporting Requirements

U.S. Holders generally will be subject to information reporting requirements with respect to distributions paid on the ADSs or our ordinary shares, and on the proceeds from the sale, exchange or other disposition of the ADSs or our ordinary shares that are paid within the U.S. or through U.S.-related financial intermediaries, unless the U.S. Holder is an "exempt recipient." In addition, U.S. Holders may be subject to backup withholding on such payments, unless the U.S. Holder provides a correct taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. Holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Certain U.S. Holders are required to report information relating to an interest in the ADSs and our ordinary shares, subject to certain exceptions (including an exception for ADSs and ordinary shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their U.S. federal income tax return. Substantial penalties may be imposed upon a U.S. Holder that fails to comply. U.S. Holders should consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ADSs or our ordinary shares.

THE DISCUSSION ABOVE IS A SUMMARY OF THE MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF AN INVESTMENT IN THE ADSs AND ORDINARY SHARES AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT, ALL OF WHICH ARE SUBJECT TO CHANGE OR DIFFERING INTERPRETATION, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN THE ADSs AND ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

Material Australian Tax Considerations

In this section, we discuss the material Australian income tax, stamp duty and goods and services tax considerations related to the acquisition, ownership and disposal by the absolute beneficial owners of the ADSs or ordinary shares. It is based upon existing Australian tax law as of the date of this Annual Report, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian tax law which may be important to particular investors in light of their individual investment circumstances, such as ADSs or shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax-exempt organizations). In addition, this summary does not discuss any non-Australian or state tax considerations, other than stamp duty.

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Prospective investors are urged to consult their tax advisors regarding the Australian and non-Australian income and other tax considerations of the acquisition, ownership and disposition of the ADSs or shares. This summary is based upon the premise that the holder is not an Australian tax resident and is not carrying on business in Australia through a permanent establishment (referred to as a "Non-Australian Holder" in this summary).

Nature of ADSs for Australian Taxation Purposes

Non-Australian Holders of ADSs should obtain specialist Australian tax advice regarding their rights and obligations under the deposit agreement with the depositary, including whether the deposit arrangement constitutes a 'bare trust' for Australian taxation purposes. Specialist Australian tax advice should also be obtained before a Non-Australian Holder surrenders ADSs to the depository for cancellation to receive the ordinary shares underlying those ADSs. Apart from certain aspects of the Australian tax legislation (for example, the Australian capital gains tax and withholding tax provisions, which are discussed below), there is no express legislative basis for disregarding "bare trusts" for Australian tax purposes generally. This summary proceeds on the assumption that the deposit arrangement constitutes a bare trust such that a Holder of an ADS is absolutely entitled (as against the depository) to the underlying share and presently entitled to dividends paid on the underlying shares.

Holders of ADSs can be treated as the owners of the underlying ordinary shares for Australian capital gains tax purposes provided that they are 'absolutely entitled' to those shares. Dividends paid on the underlying ordinary shares will also be treated as dividends derived by the holders of ADSs as the persons presently entitled to those dividends.

Taxation of Dividends

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent they are paid out of company profits that have been subject to income tax. Fully franked dividends are not subject to dividend withholding tax. To the extent that they are unfranked, dividends payable to Non-Australian Holders will be subject to dividend withholding tax except to the extent they are declared to be conduit foreign income ("CFI"). Dividend withholding tax will be imposed at 30%, unless a shareholder is a resident of a country with which Australia has a double taxation treaty and qualifies for the benefits of the treaty. Under the provisions of the current Double Taxation Convention between Australia and the U.S., the Australian tax withheld on unfranked dividends that are not declared to be CFI to which a resident of the U.S. is beneficially entitled is limited to 15% where that resident is a qualified person for the purposes of the Double Taxation Convention.

Under the Double Taxation Convention between Australia and the U.S., if a company that is a resident of the U.S. and qualifies for the benefits of the Convention directly owns a 10% or greater interest in us, the Australian tax withheld on unfranked dividends that are not declared to be CFI paid by us to which the company is beneficially entitled is limited to 5%.

Character of ADSs for Australian Taxation Purposes

The Australian tax treatment of a sale or disposal of the ADSs will depend on whether they are held on revenue or capital account. ADSs may be held on revenue rather than capital account, for example, where they are held by share traders or where the shares are acquired for the purposes of sale by the holder at a profit. Non-Australian Holders of ADSs should obtain specialist Australian tax advice regarding the characterization of any gain or loss on a sale or disposal of the ADSs as revenue or capital in nature.

Tax on Sales or other Dispositions of Shares—Capital Gains Tax

A Non-Australian Holder who is treated as the owner of the underlying shares on the basis that they are absolutely entitled to those shares will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of ordinary shares unless the shares are "taxable Australian property." The shares will be "taxable Australian property" under current law where:

- the Non-Australian Holder, together with associates, holds 10% or more of our issued capital, at the time of disposal or for a 12-month period during the two years prior to disposal; and
- more than 50% of our assets held directly or indirectly, determined by reference to market value, consist of Australian real property (which includes land and leasehold interests) or Australian mining, quarrying or prospecting rights at the time of disposal.

However, the Australian government announced that the capital gains tax rules for non-residents will be clarified and broadened with effect from July 1, 2025 so that they apply to assets with 'a close economic connection to Australian land' (in addition to 'real property'), and to apply the 50% value test throughout a 12 month period prior to disposal rather than at the time of disposal. Non-Australian Holders should monitor developments in this regard.

Australian capital gains tax applies to net capital gains at a taxpayer's marginal tax rates. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains. The 50% capital gains tax discount is not available to Non-Australian Holders on gains from assets acquired or accrued after May 8, 2012 where they were non-Australian residents during the entire holding period. Companies are not entitled to a capital gains tax discount.

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Broadly, where there is a disposal of certain taxable Australian property, the purchaser will be required to withhold and remit to the Australian Taxation Office ("ATO") 12.5% of the proceeds from the sale. On December 13, 2023, the Australian government announced that the withholding rate will be increased from 12.5% to 15% of the proceeds of sale for disposals occurring from January 1, 2025. While draft legislation has been released, this announced increase is yet to be legislated and may be subject to change. A transaction is excluded from the withholding requirements in certain circumstances, including where the transaction is an on-market transaction conducted on an approved stock exchange, a securities lending transaction, or the transaction is conducted using a broker operated crossing system. There may also be an exception to the requirement to withhold where a Non-Australian Holder provides a declaration that their ordinary shares are not 'indirect Australian real property interests,' although the Australian government is currently running a consultation process to consider whether the Australian Taxation Office should be notified in advance of such a declaration being made for transactions with a value in excess of A$20 million. The Non-Australian Holder may be entitled to receive a tax credit for the tax withheld by the purchaser which they may claim in their Australian income tax return.

Tax on Sales or other Dispositions of ADSs or Shares—Revenue Account

Non-Australian Holders who hold their ADSs on revenue account may have the gains made on the sale or other disposal of the ADSs included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia. There are no express provisions which treat holders of ADSs as the owners of the underlying shares where there is a bare trust.

Non-Australian Holders assessable under these ordinary income provisions in respect of gains made on ADSs held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 30% for individuals, and would be required to file an Australian tax return. Relief from Australian income tax may be available to a Non-Australian Holder who is resident of a country with which Australia has a double taxation treaty, qualifies for the benefits of the treaty and does not, for example, derive the gain in carrying on business through a permanent establishment in Australia. To the extent an amount would be included in a Non-Australian Holder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount may be reduced, so that the holder may not be subject to double Australian tax on any part of the gain.

The statements under "— Tax on Sales or Other Dispositions of Shares—Capital Gains Tax" regarding a purchaser being required to withhold 12.5% tax (proposed to increase to 15% from January 1, 2025) on the acquisition of certain taxable Australian property are also relevant where the disposal of the ADSs by a Non-Australian Holder is likely to generate gains on revenue account, rather than a capital gain.

The same consequences apply for Non-Australian Holders who hold ordinary shares on revenue account.

Dual Residency

If a holder of ADSs is a resident of both Australia and the U.S. under those countries' domestic taxation laws, that holder may be subject to tax as an Australian resident. If, however, the holder is an individual and is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the U.S. and Australia, the Australian tax would be subject to limitation by the Double Taxation Convention. Holders should obtain specialist taxation advice in these circumstances.

Stamp Duty

No Australian stamp duty is payable by Australian residents or non-Australian residents on the issue, transfer and/or surrender of the ADSs or ordinary shares while we continue to satisfy the requirements of a listed company for the purposes of Australian duties legislation, provided that the securities issued, transferred and/or surrendered do not represent 90% or more of our issued shares.

Australian Death Duty

Australia does not have estate or death duties. As a general rule, no capital gains tax liability is realized upon the inheritance of a deceased person's shares. The disposal of inherited shares by beneficiaries may, however, give rise to a capital gains tax liability if the gain falls within the scope of Australia's jurisdiction to tax.

Goods and Services Tax

No Australian goods and services tax will be payable on the supply of the ADSs or ordinary shares.

THE DISCUSSION ABOVE IS A SUMMARY OF THE AUSTRALIAN TAX CONSEQUENCES OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT, ALL OF WHICH ARE SUBJECT TO CHANGE, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

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F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the reporting requirements of the Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 under the Exchange Act. See "Item 6. Directors, Senior Management and Employees — C. Board Practices — Foreign Private Issuer Exemption" for information on reporting exemptions applicable to us as a foreign private issuer. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act. However, we file with the SEC an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and submit reports to the SEC on Form 6-K to disclose other material information, as required. We also submit reports to the SEC on Form 6-K containing unaudited financial information for the first six months of each fiscal year.

The SEC maintains a website at www.sec.gov from which our filings may be accessed.

In addition, since our ordinary shares are traded on the ASX, we have filed periodic corporate reports, including annual and semi-annual reports with, and furnish information to, the ASX, as required under the ASX Listing Rules and the Australian Corporations Act 2001 (Cth). Copies of our filings with the ASX can be retrieved electronically at www.asx.com.au under our symbol "TLX". We also maintain a website at www.telixpharma.com.

I. Subsidiary Information

For information about our subsidiaries, see "Item 4. Information on the Company — C. Organizational Structure."

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily attributable to foreign currency exchange rate risk.

Interest Rate Risk

As of December 31, 2025, we had cash and cash equivalents of $141.9 million. We have limited exposure to interest rate risk. Our cash and cash equivalents are not locked into long-term deposits at fixed rates so as to mitigate the risk of earning interest below the current floating rate.

Our exposure to market interest rates relates primarily to short-term deposits. The roll-over loan facility totaling $9.5 million (translated from Euros based on the exchange currency rate as of December 31, 2025) carries an interest rate that is calculated using the eurozone interbank interest rate as of each interest determination date. However, all of our borrowings that have been drawn down as of December 31, 2025 bear a fixed interest rate. Therefore, we are not exposed to any significant interest rate risk under these borrowings. An immediate 10% change in current market interest rates would not have a material impact on our borrowings, financial position or results of operations.

We do not believe that inflation has had a material effect on our business, financial condition, or results of operations. Nonetheless, if our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs. Our inability or failure to do so could harm our business, results of operations, or financial condition.

Foreign Currency Exchange Rate Risk

Foreign currency risk is the risk of fluctuation in fair value or future cash flows of a financial instrument as a result of changes in foreign exchange rates. We operate internationally and are exposed to foreign exchange risk, primarily related to the Australian dollar and Euro.

Our treasury risk management policy is to settle all U.S. dollar denominated expenditures with U.S. dollar denominated receipts from sales of Commercial Products in the U.S. We also manage currency risk by making decisions as to the levels of cash to hold in each currency by assessing future activities which will likely be incurred in those currencies. Any remaining foreign currency exposure has therefore not been hedged.

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We have both foreign currency receivables and payables, predominantly denominated in Australian dollar and Euro. We had a surplus of foreign currency receivables and financial assets over payables of $67.4 million as of December 31, 2025.

Our exposure to the risk of changes in foreign exchange rates also relates to the net investments in foreign subsidiaries, which predominantly include denominations in Euro and Australian dollar, however given the level of current investments in non US dollar denominated subsidiaries, the impact is limited

As of December 31, 2025, we held 39.7% of our cash in U.S. dollars, 52.8% in Australian dollars, 5.5% in Euros, 0.3% in British pounds, 0.5% in Canadian dollars and 1.0% in Swiss Francs. The following table sets forth the balances of our cash and cash equivalents, trade receivables and financial assets as of December 31, 2025 that give rise to currency risk exposure, as presented in US$:

	USD	AUD	EUR	CHF	JPY	GBP	CAD
	U.S. Dollars	Australian Dollars	Euros	Swiss Francs	Japanese Yen	British Pounds	Canadian Dollars
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
Cash and cash equivalents	56,371	74,891	7,850	1,445	134	413	762
Trade receivables	126,056	540	2,606	-	-	-	-
Financial assets	-	33,749	3,345	-	-	-	-

We are primarily exposed to foreign exchange risk inherent in Australian dollar-denominated cash and cash equivalents, trade receivables, trade payables and financial assets and in Euro-denominated cash and cash equivalents, trade payables and contingent consideration liability. We also have exposure to exchange rate risk from the Euro attributable to our Euro-denominated loans from BNP Paribas and IMBC Group. For the year ended December 31, 2025, an increase or decrease of the US dollar to Australian dollar exchange rate by +10% would decrease our profit after tax by $nil or decrease our profit after tax by $nil , respectively, and an increase or decrease of the US$ to Euro exchange rate by +10% would decrease our profit after tax by US$0.2 million or increase our profit after tax by US$2.0 million, respectively. For the year ended December 31, 2024, an increase or decrease of the U.S. dollar to Australian dollar exchange rate by +10% would decrease our profit after tax by $nil or increase our profit after tax by $nil , respectively, and an increase or decrease of the US dollar to Euro exchange rate by +10% would increase our profit after tax by US$1.2 million or decrease our profit after tax by US$1.5 million, respectively. For more information on our currency risk exposure and sensitivity analysis, see Note 33.3 to our audited consolidated financial statements included elsewhere in this Annual Report.

Liquidity Risk

We are exposed to liquidity and funding risk from operations and from external borrowings, where the risk is that we may not be able to refinance debt obligations or meet other cash outflow obligations when required. Vigilant liquidity risk management requires that we maintain sufficient liquid assets (mainly cash and cash equivalents). We manage liquidity risk by maintaining adequate cash reserves by continuously monitoring actual and forecast cash flows and matching the maturity profiles of financial assets and liabilities.

Credit Risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to us. Credit risk arises from cash and cash equivalents and credit exposures to customers, including outstanding receivables.

Credit risk is managed on a group basis. If customers are independently rated, these ratings are used. Otherwise, if there is no independent rating, we assess the credit quality of the customer, taking into account its financial position, past experience and other factors. Individual risk limits are set based on internal or external ratings. The compliance with credit limits by customers is regularly monitored. We obtain guarantees where appropriate to mitigate credit risk.

We apply the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables.

To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. The expected loss rates are based on historical payment profiles of sales and the corresponding historical credit losses experienced. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

Trade receivables are written off where there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with us, and the failure to make contractual payments for a period of greater than 120 days past due.

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Impairment losses on trade receivables are presented within sales and marketing costs within profit or loss. Subsequent recoveries of amounts previously written off are credited against the same line item. The expected credit losses were $2.4 million and $0.1 million as of December 31, 2025 and 2024 respectively.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Fees and Expenses

Our ADS depositary, JPMorgan Chase Bank, N.A. ("JPMorgan") may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of ordinary shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADSs are cancelled or reduced for any other reason, a fee of up to US$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, or upon which a share distribution or elective distribution is made or offered, as the case may be.

The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional fees, charges and expenses shall also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing ordinary shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of up to US$0.05 per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of up to US$0.05 per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- an amount for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian, as well as charges and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law, rule or regulation relating to foreign investment) in connection with the servicing of the ordinary shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge from one or more cash dividends or other cash distributions);
- a fee of up to US$0.05 per ADS held for the direct or indirect distribution of securities (other than ADSs or rights to purchase additional ADSs) or the net cash proceeds from the public or private sale of such securities, regardless of whether any such distribution and/or sale is made by, for, or received from, or (in each case) on behalf of, the depositary, us and/or any third-party (which fee may be assessed against ADR holders as of a record date set by the depositary);
- stock transfer or other taxes and other governmental charges;
- a transaction fee per cancellation request (including any cancellation request made through SWIFT, facsimile transmission or any other method of communication) as disclosed on the "Disclosures" page (or successor page) of www.adr.com (as updated by the depositary from time to time, "ADR.com") and any applicable delivery expenses (which are payable by such persons or ADR holders);

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- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and

- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within the banking division of JPMorgan ("the Bank") and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third-party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to a foreign exchange transaction will be either (i) a published benchmark rate, or (ii) a rate determined by a third-party local liquidity provider, in each case plus or minus a spread, as applicable. The depositary will disclose which foreign exchange rate and spread, if any, apply to such currency on the “Disclosures” page (or successor page) of ADR.com. Such applicable foreign exchange rate and spread may (and neither the depositary, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of a foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depositary, us, ADR holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.*

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depositary, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depositary will distribute the U.S. dollars received from us.

Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depositary on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.

We will pay all other fees, charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary.

The right of the depositary to charge and receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depositary.

The fees and charges described above may be amended from time to time by agreement between us and the depositary.

Depositary Reimbursements

The depositary anticipates reimbursing us for certain expenses incurred by us that are related to the establishment and maintenance of the ADR program upon such terms and conditions as we and the depositary may agree from time to time. The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary may also agree to reduce or waive certain fees that would normally be charged on ADSs issued to or at the direction of, or otherwise held by, us and/or certain holders and beneficial owners and holders and beneficial owners of shares of ours. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

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Payment of Taxes

ADR holders and/or beneficial owners must pay any tax or other governmental charge payable by the custodian or the depositary on any ADS or ADR, deposited security or distribution. If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon such tax or other governmental charge shall be paid by the ADR holder thereof to the depositary and by holding or owning, or having held or owned, an ADR or any ADSs evidenced thereby, the ADR holder and all beneficial owners thereof, and all prior ADR holders and beneficial owners thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect of such tax or other governmental charge. Notwithstanding the depositary's right to seek payment from current or former ADR holders and beneficial owners, each ADR holder and beneficial owner, and each prior ADR holder and beneficial owner, by holding or owning, or having held or owned, an ADR or an interest in ADSs acknowledges and agrees that the depositary has no obligation to seek payment of amounts owing from any current or prior beneficial owner. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case, the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split up or combination of ADRs or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto. Neither we nor the depositary nor any of our or its respective agents, shall be liable to ADR holders or beneficial owners of the ADSs for failure of any of them to comply with applicable tax laws, rules and/or regulations.

As an ADR holder or beneficial owner, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained, which obligations shall survive any transfer or surrender of ADSs or the termination of the deposit agreement.

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PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Group Chief Executive Officer and Group Chief Financial Officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2025 and concluded that our disclosure controls and procedures were not effective because of the material weakness in internal control over financial reporting described below.

Notwithstanding management's assessment that our disclosure controls and procedures were ineffective as of December 31, 2025, our Group Chief Executive Officer and Group Chief Financial Officer have concluded that the consolidated financial statements included in this Annual Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting as such term is defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatement. Also, projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of the Group Chief Executive Officer and Group Chief Financial Officer, has evaluated the effectiveness of our internal controls over financial reporting as of December 31, 2025 based on the criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

Management has excluded RLS (USA) Inc. ("RLS") from its assessment of internal control over financial reporting as of December 31, 2025, because it was acquired in a purchase business combination during 2025. RLS is a wholly-owned subsidiary of the Company whose total assets and total sales excluded from management's assessment represent 34% and 21% respectively, of each of the related consolidated financial statement amounts as of and for the year ended December 31, 2025.

Based on this evaluation, our management, with the participation of our Group Chief Executive Officer and Group Chief Financial Officer, has concluded that, as of December 31, 2025, our internal control over financial reporting was not effective because of the material weakness described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of its financial statements will not be prevented or detected on a timely basis.

As previously disclosed in Item 15 of our Annual Report on Form 20-F for the year ended December 31, 2024, we identified a material weakness arising from segregation of duties, which have not been sufficiently established across the key business and financial processes to maintain appropriate segregation of duties over certain manual and information technology business controls. This material weakness did not result in a misstatement of our annual consolidated financial statements. However, the material weakness could result in a misstatement of our financial statement accounts or disclosures that would result in a material misstatement to our annual consolidated financial statements that would not be prevented or detected on a timely basis.

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The effectiveness of the Company's internal control over financial reporting as of December 31, 2025, has been audited by PricewaterhouseCoopers, an independent registered public accounting firm as stated in their report, which appears in the Consolidated financial statements on Form 20-F.

Plan for Remediation of Material Weakness in Internal Control over Financial Reporting

Management has initiated remediation actions, including redesigning roles and access rights to enforce segregation of duties, implementing system-based workflow approvals, and enhancing documentation of review controls. We expect these actions to be completed and tested for effectiveness during 2026.

Although we have made considerable progress and intend to complete these remediation activities, we will not be able to fully remediate the material weakness until these steps have been completed, the enhanced processes have been operating effectively for a sufficient period of time and appropriate testing has been performed. We provide no assurances with respect to the timeline for implementing effective remedial measures, and our initiatives may not prove to be successful in remediating the material weakness or preventing additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future.

Remediation of Previously Reported Material Weakness in Internal Control Over Financial Reporting

As previously disclosed in Item 15 of our Annual Report on Form 20-F for the year ended December 31, 2024, we identified a material weakness related to a lack of appropriately designed, implemented and documented procedures and controls at both the entity-level and process-level to allow us to achieve complete, accurate and timely financial reporting.

Since the material weakness has been identified, we have enhanced risk and control documentation practices related to internal control over financial reporting, strengthened the monitoring and management testing of controls and oversight mechanisms to promote ongoing compliance with internal control policies and procedures, continued the annual Sarbanes-Oxley training program, and developed and implemented additional controls and procedures, including compensating controls where necessary. These enhanced processes, including the implementation of new mitigating controls, have now operated for a sufficient period of time and we have concluded, through testing, that they are designed and are operating effectively. As a result, we have concluded the material weakness has been remediated as of December 31, 2025.

Changes in Internal Control over Financial Reporting

Except as described above, there were no changes in our internal control over financial reporting during the period covered by this Annual Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. RESERVED

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Jann Skinner is a member of our board of directors and serves on our Audit and Risk Committee as Chair. Our board of directors has determined that Ms. Skinner is an audit committee financial expert and satisfies the "independence" requirements of the rules and regulations of the SEC, the Nasdaq Listing Rules and the ASX Listing Rules.

ITEM 16B. CODE OF ETHICS

We have adopted a Code of Conduct applicable to all of our directors, officers, employees, consultants and contractors to the Telix Group. Our Code of Conduct is publicly available on our website at www.telixpharma.com. We post on our website all disclosures that are required by law, the ASX Listing Rules or the Nasdaq Listing Rules concerning any amendments to, or waivers from, any provision of the Code of Conduct.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

For the years ended December 31, 2025 and 2024, PricewaterhouseCoopers served as our independent registered public accounting firm. The address for PricewaterhouseCoopers is 2 Riverside Quay, Southbank, Victoria 3006, Australia.

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The table below sets out the total amount of fees for services rendered to us by PricewaterhouseCoopers in the years ended December 31, 2025 and 2024, and breaks down these amounts by category of service:

	2025	2024
	US$	US$
	(in thousands)	
Audit fees[1]	2,299	2,884
Audit-related fees[2]	86	–
Tax fees[3]	–	83
All other fees[4]	60	–
Total	**2,446**	**2,967**

1. "Audit fees" include fees for services performed by our external auditor in connection with our annual audit for 2025 and 2024, fees related to the review of semi-annual financial statements, fees related to the pro forma financial information, comfort letters, consents, and services that are normally provided in connection with statutory and regulatory filings.

2. "Audit-related fees" relate to assurance and associated services that are traditionally performed by an independent auditor, including accounting consultation and consultation concerning financial accounting, reporting standards and due diligence.

3. "Tax fees" include fees for professional services rendered by our independent registered public accounting firm for tax compliance, transfer pricing and tax advice on actual or contemplated transactions.

4. "All other fees" include fees for services rendered by our independent registered public accounting firm with respect to any other advisory matters.

Pre-Approval Policies and Procedures

The Audit and Risk Committee has adopted a pre-approval policy for the engagement of our external auditor to perform certain audit and non-audit services. Pursuant to this policy, which is designed to ensure that such engagements do not impair the independence of our external auditor, pre-approval by the Audit and Risk Committee is required for all audit and non-audit services to be performed by our external auditor, subject to the de minimis exceptions for non-audit services described in Section 10A(i)(1)(B) of the Exchange Act which are approved by the Audit and Risk Committee prior to the completion of the services.

All engagements by us of our external auditor for 2025 and 2024 were pre-approved by our Audit and Risk Committee.

ITEM 16D. EXEMPTIONS FROM LISTING STANDARDS FOR AUDIT COMMITTEES

None.

ITEM 16E. PURCHASE OF EQUITY SECURITIES BY ISSUER AND AFFILIATED PURCHASERS

None.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

None.

ITEM 16G. CORPORATE GOVERNANCE

Under Nasdaq Rule 5615(a)(3), foreign private issuers, such as our company, are permitted to follow certain home country corporate governance practices instead of certain provisions of the Nasdaq rules. A foreign private issuer that elects to follow a home country practice instead of any such Nasdaq rules must submit to Nasdaq, in advance, a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws. We submitted such a written statement to Nasdaq. See "Item 6. Directors, Senior Management and Employees—C. Board Practices— Foreign Private Issuer Exemption" for a summary of such differences.

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ITEM 16H. MINE SAFETY DISCLOSURE

None.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

ITEM 16J. INSIDER TRADING POLICIES

We have a comprehensive Securities Dealing Policy ("SDP"), which applies to all directors, officers and employees as well as contractors and consultants whose terms of engagement apply the SDP to them. The SDP is reviewed and updated by our board of directors on an as needed basis, and at least annually, for currency of practice. The purpose of the SDP is to inform all persons to whom the SDP applies of the laws relating to insider trading, including pursuant to ASX Listing Rules, the rules and regulations of the SEC, and the Nasdaq Listing Rules, and to provide them with practical guidance for avoiding unlawful transactions in Telix securities and to protect our reputation.

Our SDP also prohibits short-term or speculative dealing in Telix securities by directors and employees. In addition, directors and employees are not permitted to enter into any hedging arrangements that operate to limit the economic risk associated with holding Telix securities or margin loan arrangements in relation to Telix securities. This includes securities awarded under Telix's equity incentive schemes.

A copy of the current SDP is available in the Corporate Governance section of our website at www.telixpharma.com, and is included as an exhibit to this Annual Report.

ITEM 16K. CYBERSECURITY

Risk Management and Strategy

We have implemented processes to identify, assess and manage material cyber security risks. Those processes include frameworks to respond to and assess internal and external threats to the confidentiality, availability and integrity of our data and information systems. Our cybersecurity policies, standards, processes, and practices are part of our information security management system ("ISMS") program, which is aligned to ISO 27001:2022, an international standard for information security management.

Our cybersecurity management team, led by our Chief Information Officer and Cyber Security Manager, are responsible for assessing and managing our material risks from cybersecurity threats. The team is primarily responsible for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our external cybersecurity partners. Our cybersecurity management team has relevant academic backgrounds and possesses extensive knowledge in cybersecurity risk management.

We rely on third parties, including cloud vendors and consultants, for various business functions. We oversee third-party service providers by conducting vendor diligence. Vendors are generally assessed for risk based on the nature of their service, access to data and systems and supply chain risk

As of the date of this Annual Report, we have not experienced any cybersecurity incidents or risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us, our business strategy, results of operations, or financial condition.

Governance

Our Board of Directors has established oversight mechanisms with respect to risks from cybersecurity threats. Our Audit and Risk Committee has responsibility for the oversight of cybersecurity, including the responsibility to review and discuss with management and the Company's auditors, as appropriate, management risks relating to data privacy, technology and information security. The Audit and Risk Committee, or the Board of Directors as a whole, is briefed on any material cybersecurity incidents that may adversely affect the Company and on cybersecurity risks in general.

At the management level, our cybersecurity program is managed by our Chief Information Officer, who reports to our Group Chief Financial Officer. Our Chief Information Officer reports regularly to the Audit and Risk Committee and such reporting includes topics such as risk assessments, risk management and control decisions, service provider arrangements, test results, security incidents and responses and recommendations for changes and updates to policies and procedures.

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PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to include financial statements and related information specified in Item 18.

ITEM 18. FINANCIAL STATEMENTS

Financial statements are filed as part of this Annual Report, beginning on page F-1.

ITEM 19. EXHIBITS

The following documents are filed as part of this Annual Report.

Exhibit Number	Description of Exhibit
1.1	Certificate of Registration of the Company (incorporated by reference to Exhibit 1.1 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
1.2	Constitution of the Company (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
2.1	Deposit Agreement (incorporated by reference to Exhibit 2.1 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
2.2	Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 2.1).
2.3	Description of Securities Registered under Section 12 of the Exchange Act (incorporated by reference to Exhibit 2.3 to the Company's Annual Report on Form 20-F filed February 24, 2025).
4.1†	License Agreement between Telix International Pty Ltd. and Eli Lilly Kinsale Limited, dated as of April 8, 2022, as amended (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.2†	License Agreement between Telix International Pty Ltd. and Wilex AG, dated as of January 16, 2017, as amended (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.3	Form of Deed of Indemnity, Insurance and Access (filed herewith).
4.4	Lease Agreement, dated November 30, 2022, by and between Collan Investment Limited and Telix International Pty Ltd (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.5	Loan Agreement, dated March 3, 2022, by and between Telix Pharmaceuticals (Belgium) SPRL and BNP Paribas Fortis (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.6	Loan Agreement, dated March 3, 2022, by and between Telix Pharmaceuticals (Belgium) SPRL and IMBC (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.7+	Equity Incentive Plan Rules (incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 20-F filed February 24, 2025).
4.8+†	Employment Agreement, dated January 16, 2017, by and between Telix Pharmaceuticals Limited and Christian Behrenbruch (filed herewith).
4.9+†	Employment Agreement, dated August 1, 2022, by and between Telix Pharmaceuticals Limited and Darren Smith (filed herewith).
4.10+†	Employment Agreement, dated December 20, 2023, by and between Telix Pharmaceuticals Limited and David Cade (filed herewith).
4.11+†	Employment Agreement, dated March 5, 2024, by and between Telix Pharmaceuticals (US) Inc. and Darren Patti (filed herewith).
4.12+	Form of Non-Executive Director Agreement (incorporated by reference to Exhibit 4.13 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).

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4.13	Agreement and Plan of Merger, dated as of February 7, 2024, by and among Telix Pharmaceuticals Limited, QSAM Biosciences, Inc., Cyclone Merger Sub I, Inc., Cyclone Merger Sub II, Inc. and David H. Clarke (incorporated by reference to Exhibit 4.14 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.14†	Share Purchase Agreement, dated as of March 4, 2024, between ARTMS Inc. and Telix Pharmaceuticals Limited (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.15	Trust Deed, dated as of July 30, 2024, between Telix Pharmaceuticals Limited and The Hongkong and Shanghai Banking Corporation Limited (incorporated by reference to Exhibit 4.16 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.16	Stock Purchase Agreement, dated as of September 20, 2024, by and among Telix Pharmaceuticals (US) Inc., RLS Group Ltd., RLS (USA) Inc. and Perceptive Credit Holdings III, LP (incorporated by reference to Exhibit 4.17 to the Company's Registration Statement on Form 20-F (001-42128) filed October 30, 2024).
4.17	Amendment No. 1 to the Stock Purchase Agreement, dated as of January 26, 2025, by and among Telix Pharmaceuticals (US) Inc., RLS Group Ltd., RLS (USA) Inc. and Perceptive Credit Holdings III, LP (incorporated by reference to Exhibit 4.18 to the Company's Annual Report on Form 20-F filed February 24, 2025).
4.18	US Employee Stock Purchase Program (incorporated by reference to Exhibit 4.19 to the Company's Annual Report on Form 20-F filed February 24, 2025).
4.19	Form of Deed of Indemnity and Insurance (filed herewith).
8.1	List of subsidiaries (filed herewith).
11.1	Securities Dealing Policy (filed herewith).
12.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
12.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
13.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
13.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
15.1	Consent of PricewaterhouseCoopers, independent registered public accounting firm (filed herewith).
15.2	Auditor's Independence Declaration
15.3	Independent Auditor's Report
18.1	Clawback / Dodd-Frank Compensation Recovery Policy (included as an Annexure to Exhibit 4.7 herein).
99.1	Appendix 4E
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover page Interactive Data File (embedded within the Inline XBRL document)

+ Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

TELIX PHARMACEUTICALS LIMITED

By: _____

Name: Dr. Christian Behrenbruch

Title: Managing Director and Group Chief Executive Officer

Date: February 20, 2026

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Consolidated statement of comprehensive income or loss for the year ended December 31, 2025

	Note	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Continuing operations				
Revenue from contracts with customers	4	803,794	516,551	332,978
Cost of sales		(377,356)	(180,388)	(123,445)
Gross profit		**426,438**	**336,163**	**209,533**
Research and development costs	5	(171,249)	(127,930)	(85,315)
Selling and marketing expenses		(96,766)	(55,953)	(33,464)
Manufacturing and distribution costs	6	(44,593)	(16,670)	(6,251)
General and administration costs	7	(95,789)	(85,318)	(49,668)
Other gains/(losses)(net)	10	11,735	4,885	(23,827)
Operating profit		**29,776**	**55,177**	**11,008**
Finance income		5,826	7,180	671
Finance costs	11	(40,868)	(24,442)	(9,085)
(Loss)/profit before income tax		**(5,266)**	**37,915**	**2,594**
Income tax (expense)/benefit	12	(1,859)	(4,230)	1,614
(Loss)/profit for the year		**(7,125)**	**33,685**	**4,208**
(Loss)/profit for the year attributable to:				
Owners of Telix Pharmaceuticals Limited		(7,125)	33,685	4,208
Other comprehensive (loss)/income:				
Items that will not be reclassified to profit or loss in subsequent periods:				
Changes in the fair value of investments at fair value through other comprehensive income		(1,242)	(3,287)	(612)
Items to be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations		(5,757)	5,568	(1,863)
Total comprehensive (loss)/income for the year		**(14,124)**	**35,966**	**1,733**
Total comprehensive (loss)/income for the year attributable to:				
Owners of Telix Pharmaceuticals Limited		(14,124)	35,966	1,733

	Note	2025 Cents	2024 Cents	2023 Cents
Basic (loss)/earnings per share from continuing operations after income tax attributable to the ordinary equity holders of the Company	13.1	(2.11)	10.17	1.32
Diluted (loss)/earnings per share from continuing operations after income tax attributable to the ordinary equity holders of the Company	13.2	(2.11)	9.76	1.30

The above consolidated statement of comprehensive income or loss should be read in conjunction with the accompanying notes.

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Consolidated statement of financial position as at December 31, 2025

	Note	2025 US$'000	2024 US$'000 (Recast)	1 January 2024 US$'000 (Recast)
Current assets				
Cash and cash equivalents		141,866	439,999	84,295
Trade and other receivables	14	129,202	86,928	44,041
Inventories	15	37,080	23,620	12,738
Current tax asset		6,043	5,912	5,237
Other current assets	16	16,089	13,658	12,380
Total current assets		**330,280**	**570,117**	**158,691**
Non-current assets				
Financial assets	17	37,094	34,746	8,387
Deferred tax assets	18.1	59,353	28,920	13,991
Property, plant and equipment	19	58,661	27,841	15,848
Right-of-use assets	20	56,950	5,805	5,010
Intangible assets	21	592,823	257,858	75,054
Other non-current assets	22	28,825	15,092	277
Total non-current assets		**833,706**	**370,262**	**118,567**
Total assets		**1,163,986**	**940,379**	**277,258**
Current liabilities				
Trade and other payables	24	150,349	86,790	54,334
Borrowings	25	13,110	11,763	660
Current tax payable		30,742	30,087	13,110
Contract liabilities		402	6,967	7,522
Lease liabilities	26	5,548	1,546	407
Provisions	27	562	576	395
Contingent consideration	28	11,540	53,215	25,417
Employee benefit obligations	29	19,371	14,144	9,528
Total current liabilities		**231,624**	**205,088**	**111,373**
Non-current liabilities				
Borrowings	25	391,914	341,811	5,945
Contract liabilities		-	2,036	8,320
Lease liabilities	26	56,534	5,042	5,252
Deferred tax liabilities	18.2	44,706	5,796	-
Other non-current liabilities		3,517	-	-
Provisions	27	9,177	8,530	5,475
Contingent consideration	28	10,694	18,834	38,036
Employee benefit obligations	29	444	305	212
Total non-current liabilities		**516,986**	**382,354**	**63,240**
Total liabilities		**748,610**	**587,442**	**174,613**
Net assets		**415,376**	**352,937**	**102,645**

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	Note	2025 US$'000	2024 US$'000 (Recast)	1 January 2024 US$'000 (Recast)
Equity				
Share capital	30.1	479,962	414,012	315,178
Share capital reserve	30.2	(11,612)	15,945	(41,742)
Other reserves	30.3	101,564	75,894	16,328
Accumulated losses		(154,538)	(152,914)	(187,119)
Total equity		**415,376**	**352,937**	**102,645**

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

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Consolidated statement of changes in equity for the year ended December 31, 2025

	Note	Share capital	Share capital reserve	Other reserves	Accumulated losses	Total equity
		US$'000	US$'000	US$'000	US$'000	US$'000
Balance as at January 1, 2025		**414,012**	**15,945**	**75,894**	**(152,914)**	**352,937**
Loss for the year		-	-	-	(7,125)	(7,125)
Other comprehensive loss		-	-	(6,999)	-	(6,999)
Total comprehensive loss		**-**	**-**	**(6,999)**	**(7,125)**	**(14,124)**
Issue of shares on acquisitions	30.1	31,761	-	-	-	31,761
Issue of shares on exercise of options	30.1, 30.2	29,722	(27,557)	-	-	2,165
Share-based payments to employees	30.3	-	-	19,350	-	19,350
Share-based payments associated with acquisitions	30.3	-	-	23,287	-	23,287
Transfer on satisfaction of acquisition performance rights	30.1, 30.3	4,467	-	(4,467)	-	-
Transfer on exercise of options	30.3	-	-	(5,501)	5,501	-
		65,950	**(27,557)**	**32,669**	**5,501**	**76,563**
Balance as at December 31, 2025		**479,962**	**(11,612)**	**101,564**	**(154,538)**	**415,376**
		(Recast)	(Recast)	(Recast)	(Recast)	(Recast)
Balance as at January 1, 2024		**315,178**	**(41,742)**	**16,328**	**(187,119)**	**102,645**
Profit for the year		-	-	-	33,685	33,685
Other comprehensive income		-	-	2,281	-	2,281
Total comprehensive income		**-**	**-**	**2,281**	**33,685**	**35,966**
Issue of shares on acquisitions	30.1	93,477	-	-	-	93,477
Issue of shares on exercise of options	30.1, 30.2	5,357	(4,697)	-	-	660
Issue of convertible bonds			63,849			63,849
Transaction costs arising on convertible bonds issue			(1,465)			(1,465)
Share-based payments to employees	30.3	-	-	12,928	-	12,928
Share-based payments associated with acquisitions	30.3	-	-	44,877	-	44,877
Transfer on exercise of options	30.3	-	-	(520)	520	-
		98,834	**57,687**	**57,285**	**520**	**214,326**
Balance as at December 31, 2024		**414,012**	**15,945**	**75,894**	**(152,914)**	**352,937**

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	Note	Share capital	Share capital reserve	Other reserves	Accumulated losses	Total equity
		US$'000	US$'000	US$'000	US$'000	US$'000
		(Recast)	(Recast)	(Recast)	(Recast)	(Recast)
Balance as at January 1, 2023		**265,551**	**(18,231)**	**1,140**	**(193,670)**	**54,790**
Profit for the year		-	-	-	4,208	4,208
Other comprehensive loss		-	-	(2,475)	-	(2,475)
Total comprehensive income		**-**	**-**	**(2,475)**	**4,208**	**1,733**
Issue of shares on acquisitions	30.1	21,770	-	-	-	21,770
Issue of shares on exercise of options	30.1, 30.2	27,857	(23,511)	-	-	4,346
Share-based payments to employees	30.3	-	-	5,848	-	5,848
Share-based payments associated with acquisitions	30.3	-	-	14,158	-	14,158
Transfer on exercise of options	30.3	-	-	(2,343)	2,343	-
		49,627	**(23,511)**	**17,663**	**2,343**	**46,122**
Balance as at December 31, 2023		**315,178**	**(41,742)**	**16,328**	**(187,119)**	**102,645**

The above consolidated statement of changes of equity should be read in conjunction with the accompanying notes.

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Consolidated statement of cash flows for the year ended December 31, 2025

	Note	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Cash flows from operating activities				
Receipts from customers		774,199	467,660	311,754
Payments to suppliers and employees		(710,551)	(418,328)	(280,388)
Payments for contingent consideration		(51,786)	(23,902)	(10,917)
Income taxes paid		(21,298)	(2,033)	(6,859)
Interest received		5,843	7,180	1,068
Interest paid		(13,700)	(3,087)	(385)
Net cash (used in)/from operating activities	**32.1**	**(17,293)**	**27,490**	**14,273**
Cash flows from investing activities				
Payments for investments in financial assets		(892)	(32,913)	(8,698)
Payments for acquisition of subsidiaries, net of cash acquired		(220,662)	(20,662)	-
Purchases of intangible assets		(18,084)	(13,067)	(802)
Purchases of other non-current assets		(12,224)	(8,395)	-
Purchases of property, plant and equipment		(25,692)	(9,117)	(6,307)
Payments for contingent consideration		(7,667)	(2,533)	(995)
Payments for deferred consideration		(700)	-	-
Payments for decommissioning liability		-	-	(37)
Net cash used in investing activities		**(285,921)**	**(86,687)**	**(16,839)**
Cash flows from financing activities				
Proceeds from borrowings		529	427,904	4,188
Repayment of borrowings		(819)	(745)	-
Principal element of lease payments		(5,237)	(1,317)	(1,266)
Proceeds from issue of shares and other equity		1,808	662	4,169
Transaction costs of borrowings or capital raising		-	(9,713)	-
Net cash (used in)/provided by financing activities		**(3,719)**	**416,791**	**7,091**
Net (decrease)/increase in cash held		**(306,933)**	**357,594**	**4,525**
Net foreign exchange differences		8,800	(1,890)	992
Cash and cash equivalents at the beginning of the financial year		439,999	84,295	78,778
Cash and cash equivalents at the end of the financial year		**141,866**	**439,999**	**84,295**

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

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1. Corporate information

Telix Pharmaceuticals Limited ("Telix" or "the Company") is a for-profit company incorporated and domiciled in Australia. It is limited by shares that are publicly traded on the Australian Securities Exchange (ASX: TLX) and on the Nasdaq Global Select Market (NASDAQ: TLX). These consolidated financial statements comprise the results of Telix and its subsidiaries (together referred to as "the Group"). The consolidated financial statements were authorized for issue in accordance with a resolution of the Directors on February 20, 2026.

2. Material accounting policy information

The material accounting policies that have been used in the preparation of these financial statements are summarized below.

2.1. Going concern

The Directors are satisfied that the Group continues to be a going concern as at the date of these financial statements. Further, the Directors are of the opinion that no asset is likely to be realized for an amount less than the amount at which it is recorded in the consolidated statement of financial position as at December 31, 2025.

As such, no adjustment has been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or the classification of liabilities that might be necessary should the Group not continue as a going concern.

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2.2. Basis of preparation

Telix Pharmaceuticals Limited is a for-profit entity for the purpose of preparing the financial statements.

These general purpose financial statements have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS Accounting Standards") and Australian Accounting Standards and Interpretations as issued by the Australian Accounting Standards Board and the Australian Corporations Act 2001 (Cth).

The financial statements have been prepared on a historical cost basis, except for certain financial instruments, which have been measured at fair value.

1. Comparatives

Where necessary, comparative information has been re-classified to achieve consistency in disclosure with current financial amounts and other disclosures.

2. New and amended standards adopted by the Group

The Group has adopted all relevant new and amended standards and interpretations issued by the International Accounting Standards Board which are effective for annual reporting periods beginning on January 1, 2025.

3. New standards and interpretations not yet adopted

Certain new accounting standards and interpretations have been published that are not mandatory for December 31, 2025 reporting periods and have not been early adopted by the Group.

4. IFRS 18 Presentation and Disclosure in Financial Statements (effective for annual periods beginning on or after January 1, 2027)

IFRS 18 will replace IAS 1 Presentation of financial statements, introducing new requirements that will help to achieve comparability of the financial performance of similar entities and provide more relevant information and transparency to users. Even though IFRS 18 will not impact the recognition or measurement of items in the financial statements, its impacts on presentation and disclosure are expected to be pervasive, in particular those related to the statement of comprehensive income or loss and providing management-defined performance measures within the financial statements.

Management is currently assessing the detailed implications of applying the new standard on the Group's consolidated financial statements.

2.3. Significant changes in the current reporting period

2.3.1 Change in presentation currency

The Group has retrospectively changed its presentation currency from Australian Dollars to United States Dollars (USD or US$). The change in presentation currency, in the opinion of the Directors, will provide investors and other stakeholders

with a clearer and more reliable understanding of the Group's business performance and is more comparable to the Group's peers, most of which are presented in U.S. Dollars.

The voluntary change in presentational currency is effective from 1 January 2025 and has been accounted for retrospectively in the consolidated financial statements.

The financial report has been recast to USD using the procedures outlined below:

1. Consolidated statement of comprehensive income or loss and consolidated statement of cash flows have been translated into USD using foreign currency rates at the dates of transactions prevailing for the relevant period;

2. Assets and liabilities in the consolidated statement of financial position have been translated into USD at the closing foreign currency rates on the relevant reporting dates;

3. The equity section of the consolidated statement of financial position has been translated into USD as follows:

    a. Foreign currency translation reserve, share based payment reserve and accumulated losses have been translated to USD using foreign currency rates at the dates of transactions prevailing for the relevant period.

    b. Share capital and share capital reserves have been translated into USD using historical rates;

4. Earnings per share has been translated into USD based on the translated USD net income, translated as described above.

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2.4. Principles of consolidation

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. If the Group loses control of a subsidiary, the Group derecognizes the assets and liabilities of the former subsidiary from the consolidated statement of financial position and recognizes the gain or loss associated with the loss of control attributable to the former controlling interest.

Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated on consolidation. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

2.5. Foreign currency translation

1. Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in U.S. Dollars.

2. Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are generally recognized in profit or loss. Foreign exchange gains and losses that relate to borrowings are presented in the consolidated statement of comprehensive income or loss, within finance costs. All other foreign exchange gains and losses are presented in the consolidated statement of comprehensive income or loss on a net basis within other income or other expenses.

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss.

3. Group companies

The results and financial position of foreign operations (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each consolidated statement of financial position presented are translated at the closing rate at the date of that consolidated statement of financial position

- income and expenses for each consolidated statement of comprehensive income or loss are translated at actual exchange rates at the dates of the transactions, and
- all resulting exchange differences are recognized in other comprehensive income.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognized in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to profit or loss, as part of the gain or loss on sale. Goodwill and fair value adjustments arising on the acquisition of a foreign operation are treated as assets and liabilities of the foreign operation and translated at the closing rate.

2.6. Business combinations

The acquisition method of accounting is used to account for all business combinations, regardless of whether equity instruments or other assets are acquired. The consideration transferred for the acquisition of a subsidiary comprises the:

- fair values of the assets transferred
- liabilities incurred to the former owners of the acquired business
- equity interests issued by the Group
- fair value of any asset or liability resulting from a contingent consideration arrangement, and
- fair value of any pre-existing equity interest in the subsidiary.

Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are, with limited exceptions, measured initially at their fair values at the acquisition date. Acquisition-related costs are expensed as incurred. The excess of the consideration transferred, amount of any non-controlling interest in the acquired entity, and acquisition-date fair value of any previous equity interest in the acquired entity over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the subsidiary acquired, the difference is recognized directly in profit or loss as a bargain purchase.

Where settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value as at the date of exchange. The post-tax discount rate used is the entity's incremental borrowing rate, being the rate at which a similar borrowing could be obtained from an independent financier under comparable terms and conditions. Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognized in profit or loss.

The acquisition date carrying value of the Group's previously held equity interest in the acquiree is remeasured to fair value at the acquisition date. Any gains or losses arising from such remeasurement are recognized in profit or loss. If the initial accounting for a business combination is incomplete by the end of the reporting period in which the combination occurs, the Group reports provisional amounts for the items for which the accounting is incomplete. Those provisional amounts are adjusted during the measurement period (see below), or additional assets or liabilities are recognized, to reflect new information obtained about facts and circumstances that existed as of the acquisition date that, if known, would have affected the amounts recognized as of that date. The measurement period is the period from the date of acquisition to the date the Group obtains complete information about facts and circumstances that existed as of the acquisition date and is subject to a maximum of one year.

2.7. Current and non-current classification

Assets and liabilities are presented in the consolidated statement of financial position based on current and non- current classification.

An asset is current when it is expected to be realized or intended to be sold or consumed in the Group's normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realized within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is current when it is expected to be settled in the Group's normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current. For instances where a liability is based on sales volumes, the payment expected to be realized within 12 months is current based on the underlying estimate of the timing of sales.

Deferred tax assets and liabilities are always classified as non-current.

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2.8. Cash and cash equivalents

For the purpose of presentation in the consolidated statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the consolidated statement of financial position.

2.9. Trade and other receivables

Trade receivables and other receivables are all classified as financial assets held at amortized cost. Trade receivables are recognized initially at the amount of consideration that is unconditional, unless they contain significant financing components when they are recognized at fair value.

Impairment of trade and other receivables

The collectability of trade and other receivables is reviewed on an ongoing basis. Individual debts which are known to be uncollectible are written off when identified. The Group recognizes an impairment provision based upon anticipated lifetime losses of trade receivables.

The anticipated losses are determined with reference to historical loss experience (when it is available) and are regularly reviewed and updated. They are subsequently measured at amortized cost using the effective interest method, less loss allowance. See note 33.4 for further information about the Group's accounting for trade receivables and description of the Group's impairment policies.

2.10. Inventories

Raw materials and stores, work in progress and finished goods

Raw materials and stores, work in progress and finished goods are stated at the lower of cost and net realizable value. Cost comprises direct materials, direct labor and an appropriate proportion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Cost includes the reclassification from equity of any gains or losses on qualifying cash flow hedges relating to purchases of raw material but excludes borrowing costs. Costs are assigned to individual items of inventory on the basis of weighted average costs. Costs of purchased inventory are determined after deducting rebates and discounts. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale. Clinical and pre-launch inventory with no alternative use is expensed as produced and recorded as research and development expense.

2.11. Property, plant and equipment

All property, plant and equipment is stated at historical cost less accumulated depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Cost may also include transfer from equity of any gains or losses on qualifying cash flow hedges of foreign currency purchases of property, plant and equipment. Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably.

The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate the cost, net of the residual values, over the estimated useful lives. The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

The useful lives of assets are as follows:

- Buildings: 18 years
- Plant and equipment: 3-15 years
- Furniture, fittings and equipment: 3-5 years
- Leased plant and equipment: 3-5 years

Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in profit or loss. When revalued assets are sold, it is Group policy to transfer any amounts included in other reserves in respect of those assets to accumulated losses.

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2.12. Lease liabilities

Liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable
- variable lease payments that are based on an index or a rate, initially measured using the index or rate as at the commencement date
- amounts expected to be payable by the Group under residual value guarantees
- the exercise price of a purchase option if the Group is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the Group exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

Leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

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2.13. Right-of-use assets

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability
- any lease payments made at or before the commencement date less any lease incentives received
- any initial direct costs, and
- restoration costs.

Right-of-use assets are depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

2.14. Non-current financial assets

Non-current financial assets held for long-term strategic purposes are classified within non-current assets on the consolidated statement of financial position. The financial impacts related to these financial assets are recorded in other comprehensive income.

Non-current financial assets are initially recorded at fair value on their trade date, which is different from the settlement date when the transaction is ultimately effected. Quoted securities are remeasured at each reporting date to fair value based on current market prices. If the market for a financial asset is not active or no market is available, fair values are established using valuation techniques.

Equity securities held as strategic investments are generally designated at the date of acquisition as financial assets valued at fair value through other comprehensive income with no subsequent recycling through profit or loss. Unrealized gains and losses, including exchange gains and losses, are recorded as a fair value adjustment in the consolidated statement of comprehensive income. They are reclassified to retained earnings when the equity security is sold.

2.15. Intangible assets

1. Goodwill

Goodwill on acquisitions of subsidiaries is included in intangible assets. Goodwill is not amortized, but is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold. Goodwill is allocated to cash-generating units for the purpose of impairment testing. The allocation is made to those cash-generating units or group of cash-generating units that are expected to benefit from the business combination in which the goodwill arose.

2. Patents, trademarks, licenses and customer contracts

Separately acquired trademarks and licenses are shown at historical cost. Trademarks, licenses and customer contracts acquired in a business combination are recognized at fair value at the acquisition date. They have a finite useful life and

are subsequently carried at cost less accumulated amortization and impairment losses. The useful life of these intangibles assets is 5 to 20 years.

3. Intellectual property

Intellectual property arising from business combinations is recognized at fair value when separately identifiable from goodwill. Intellectual property is recorded as an indefinite life asset when it is not yet ready for use. At the point the asset is ready for use, the useful life is reassessed as a definite life asset and amortized over a period of 5 to 20 years. Amortization and impairment charges related to currently marketed products are recognized in cost of goods sold.

Assets not available for use are tested annually for impairment. Assets are carried at cost less accumulated impairment losses and/or accumulated amortization. An impairment trigger assessment is performed annually for assets available for use.

4. Research and development

Research expenditure on internal projects is recognized as an expense as incurred. Costs incurred on development projects (relating to the design and testing of new or improved products) are recognized as intangible assets when it is probable that the project will, after considering its commercial and technical feasibility, be completed and generate future economic benefits and its costs can be measured reliably. The expenditure that could be recognized comprises all directly attributable costs, including costs of materials, services, direct labor and an appropriate proportion of overheads.

Other expenditures that do not meet these criteria are recognized as an expense as incurred. As the Group has not met the requirement under the standard to recognize costs in relation to development as intangible assets, these amounts have been expensed within the financial statements.

2.16. Impairment of assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or Groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

2.17. Trade and other payables

These amounts represent liabilities for goods and services provided to the Group prior to the reporting date which are unpaid. The amounts are unsecured and are usually paid within 30 days of recognition. Trade and other payables are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

2.18. Provisions

Provisions are recognized when the Group has a present (legal or constructive) obligation as a result of a past event, it is probable the Group will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation. The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at the reporting date, taking into account the risks and uncertainties surrounding the obligation. If the time value of money is material, provisions are discounted using a current pre-tax rate specific to the liability. The increase in the provision resulting from the passage of time is recognized as a finance cost.

Decommissioning liability

The Group has recognized a provision for its obligation to decommission its radiopharmaceutical production facility at the end of its operating life. At the end of a facility's life, costs are incurred in safely removing certain assets involved in the production of radioactive isotopes. The Group recognizes the full discounted cost of decommissioning as an asset and liability when the obligation to restore sites arises. The decommissioning asset is included within property, plant and equipment with the cost of the related installation. The liability is included within provisions. Revisions to the estimated costs of decommissioning which alter the level of the provisions required are also reflected in adjustments to the decommissioning asset. The amortization of the asset is included in the consolidated statement of comprehensive income or loss and the unwinding of discount of the provision is included within Finance costs. Further detail has been provided in note 27.2.

2.19. Contingent consideration

The contingent consideration liabilities associated with business combinations are measured at fair value which has been calculated with reference to our judgment of the expected probability and timing of the potential future milestone payments, which is then discounted to a present value using appropriate discount rates with reference to the Group's

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weighted average cost of capital. Subsequent changes in estimates for contingent consideration liabilities are recognized in Other gains/(losses) (net). The effect of unwinding the discount over time is recognized in Finance costs.

Contingent consideration in connection with the purchase of individual assets outside of business combinations is recognized as a liability only when a non-contingent obligation arises (i.e. when milestone is met). Where the contingent consideration is payable in shares, or the group has an election to pay in shares, it is accounted for as an equity settled share-based payment. Equity settled share-based payments are recognized at their fair value at the date control of the asset is obtained. The determination of whether the payment should be capitalized or expensed is usually based on the reason for the contingent payment. If the contingent payment is based on regulatory approvals received (i.e. development milestone), it will generally be capitalized as the payment is incidental to the acquisition so the asset may be made available for its intended use. If the contingent payment is based on period volumes sold (i.e. sales related milestone), it will generally be expensed.

Changes in the fair value of liabilities from contingent consideration will be capitalized or expensed based on the nature of the asset acquired (refer above), except for the effect from unwinding discounts. Interest rate effects from unwinding of discounts are recognized as finance costs. The fair value of equity-settled share-based payments is not re-assessed once the asset has been recognized.

2.20. Employee benefits

Employee benefits are recognized as an expense, unless the cost qualifies to be capitalized as an asset.

1. Short-term obligations

Liabilities for wages and salaries, including non-monetary benefits and annual leave that is expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognized in respect of employees' services up to the end of the reporting period. These liabilities are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the consolidated statement of financial position.

2. Other long-term employee benefit obligations

The liabilities for long service leave are not expected to be settled wholly within 12 months after the end of the period in which the employees render the related service. They are therefore measured as the present value of expected future payments to be made in respect of services provided by employees up to the end of the reporting period using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the end of the reporting period of high-quality corporate bonds with terms and currencies that match, as closely as possible, the estimated future cash outflows. Remeasurements as a result of experience adjustments and changes in actuarial assumptions are recognized in profit or loss.

The obligations are presented as current liabilities in the consolidated statement of financial position if the entity does not have an unconditional right to defer settlement for at least 12 months after the reporting period, regardless of when the actual settlement is expected to occur.

3. Share-based payments

Equity-settled share-based compensation benefits are provided to certain employees. Equity-settled transactions are awards of shares, options or performance rights over shares, that are provided to employees. The cost of equity-settled transactions is measured at fair value on grant date. Fair value is determined using the Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option and volatility. No account is taken of any other vesting conditions.

If the non-vesting condition is within the control of the consolidated entity or employee, the failure to satisfy the condition is treated as a cancellation. If the condition is not within the control of the consolidated entity or employee and is not satisfied during the vesting period, any remaining expense for the award is recognized over the remaining vesting period, unless the award is forfeited. If equity-settled awards are cancelled, it is treated as if it has vested on the date of cancellation, and any remaining expense is recognized immediately. If a new replacement award is substituted for the cancelled award, the cancelled and new awards are treated as if they were a modification.

4. Termination benefits

Termination benefits are payable when employment is terminated by the Group before the normal retirement date, or when an employee accepts voluntary redundancy in exchange for these benefits. The Group recognizes termination benefits at the earlier of the following dates:

- when the Group can no longer withdraw the offer of those benefits, and
- when the entity recognizes costs for a restructuring that is within the scope of IAS 37 *Provisions, Contingent Liabilities and Contingent Assets* and involves the payment of termination benefits. In the case of an offer made to

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encourage voluntary redundancy, the termination benefits are measured based on the number of employees expected to accept the offer. Benefits falling due more than 12 months after the end of the reporting period are discounted to present value.

2.21. Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw- down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalized as a prepayment for liquidity services and amortized over the period of the facility to which it relates.

The fair value of the liability portion of a convertible bond is determined using a market interest rate for an equivalent non-convertible bond. This amount is recorded as a liability on an amortized cost basis until extinguished on conversion or maturity of the bonds. The remainder of the proceeds is allocated to the conversion option. This is recognized and included in share capital reserve within equity.

Borrowing costs that are directly attributable to the construction of qualifying assets are capitalized as part of the cost of the relevant asset.

Borrowings are removed from the consolidated statement of financial position when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognized in profit or loss as other income or finance costs.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the reporting period.

2.22. Revenue

Revenue is measured at the fair value of the consideration received or receivable. Amounts disclosed as revenue are net of returns, trade allowances, rebates and amounts collected on behalf of third parties.

Revenue is recognized using a five step approach in accordance with IFRS 15 *Revenue from Contracts with Customers* to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

Distinct promises within the contract are identified as performance obligations. The transaction price of the contract is measured based on the amount of consideration the Group expects to be entitled to from the customer in exchange for goods or services. Factors such as requirements around variable consideration, significant financing components, non-cash consideration, or amounts payable to customers also determine the transaction price. The transaction is then allocated to separate performance obligations in the contract based on relative standalone selling prices.

Revenue is recognized when, or as, performance obligations are satisfied, which is when control of the promised good or service is transferred to the customer.

Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities. Amounts expected to be recognized as revenue within the 12 months following the consolidated statement of financial position date are classified within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the consolidated statement of financial position date are classified within non-current liabilities.

1. Sales of goods

The Group's revenue recognition policy has been updated below to reflect the impact of the acquisition of RLS.

Sales are recognized at a point-in-time when control of the products has transferred, being when the products are delivered to the customer. Further, in determining whether control has transferred, Telix considers if there is a present right to payment and legal title, along with risks and rewards of ownership having transferred to the customer. Revenue from sales is recognized based on the price specified in the contract, net of the estimated volume discounts and rebates.

Accumulated experience is used to estimate and provide for discounts, using the expected value method, and revenue is recognized to the extent that it is highly probable that a significant reversal will not occur. No element of financing is deemed present as the sales are made with credit terms ranging from 30 to 45 days, which is consistent with market practice.

Where the Group uses third-party distributors to facilitate the supply of a product, a fee is charged for the radiolabeling process, with control transferring to the customer once the radiolabeling process is completed. This fee is expensed within Cost of sales in the Consolidated statement of comprehensive income or loss.

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With the acquisition of RLS, the Group has the ability to perform the radiolabeling process for existing Telix products. The cost of radiolabeling for Telix products is recognized within Cost of sales in the Consolidated statement of comprehensive income or loss.

2. Licenses of intellectual property

When licenses of intellectual property are distinct from other goods or services promised in the contract, the transaction price is allocated to the license as revenue upon transfer of control of the license to the customer. All other promised goods or services in the license agreement are evaluated to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services.

The transaction price allocated to the license performance obligation is recognized based on the nature of the license arrangement. The transaction price is recognized over time if the nature of the license is a 'right to access' license. This is where the Group performs activities that significantly affect the intellectual property to which the customer has rights, the rights granted by the license directly expose the customer to any positive or negative effects of the Group's activities, and those activities do not result in the transfer of a good or service to the customer as those activities occur. When licenses do not meet the criteria to be a right to access license, the license is a 'right to use' license, and the transaction price is recognized at the point in time when the customer obtains control over the license.

3. Research and development services

Where research and development ("R&D") services do not significantly modify or customize the license nor are the license and development services significantly interrelated or interdependent, the provision of R&D services is considered to be distinct. The transaction price is allocated to the R&D services based on a cost-plus margin approach. Revenue is recognized over time based on the costs incurred to date as a percentage of total forecast costs. Reforecasting of total costs is performed at the end of each reporting period to ensure that costs recognized represent the goods or services transferred.

4. Manufacturing services

Revenue from providing contract manufacturing services is recognized in the period in which the services are rendered. For fixed-price contracts, revenue is recognized based on the actual service provided to the end of the reporting period as a proportion of the total services to be provided, because the customer receives and uses the benefits simultaneously. This is determined based on the actual time spent to deliver the service relative to the total expected hours.

For instances where contracts include multiple deliverables, such as the sale of consumables and irradiation systems, each deliverable is therefore accounted for as a separate performance obligation. Where the contracts include multiple performance obligations, the transaction price is allocated to each performance obligation based on the stand-alone selling prices. Where these are not directly observable, they are estimated based on expected cost plus margin. If contracts include the installation of systems, revenue for the system is recognized at a point in time when control is transferred to the customer. The customer obtains control at the point in time when the system is delivered to the customer in accordance with the agreed terms and the customer accepted the system.

5. Financing component

The existence of a significant financing component in the contract is considered under the five-step method under IFRS 15 *Revenue from Contracts with Customers*.

If the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer or the Group with a significant benefit of financing the transfer of goods or services to the customer, the promised amount of consideration will be adjusted for the effects of the time value of money when determining the transaction price.

6. Milestone revenue

The five-step method under IFRS 15 *Revenue from Contracts with Customers* is applied to measure and recognize milestone revenue.

The receipt of milestone payments is often contingent on meeting certain clinical, regulatory or commercial targets, and is therefore considered variable consideration.

The transaction price of the contingent milestone is estimated using the most likely amount method. Within the transaction price, some or all of the amount of the contingent milestone is included only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the contingent milestone is subsequently resolved. Milestone payments that are not within the control of the Group, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received.

Any changes in the transaction price are allocated to all performance obligations in the contract unless the variable consideration relates only to one or more, but not all, of the performance obligations. When consideration for milestones is a sale-based or usage-based royalty that arises from licenses of intellectual property (such as cumulative net sales

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targets), revenue is recognized at the later of when (or as) the subsequent sale or usage occurs, or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

7. Sales-based or usage-based royalties

Licenses of intellectual property can include royalties that are based on the customer's usage of the intellectual property or sale of products that contain the intellectual property. The specific exception to the general requirements of variable consideration and the constraint on variable consideration for sales-based or usage-based royalties promised in a license of intellectual property is applied. The exception requires such revenue to be recognized at the later of when (or as) the subsequent sale or usage occurs and the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

8. Distribution services

Where RLS is a distributor for third-party customers, revenue is recognized via a service fee when it satisfies the performance obligation of the radiolabeling process. On completion of the radiolabeling process, control of the product transfers to RLS, which also recognizes revenue from the sale of goods once all performance obligations have been satisfied with the customer. These patient specific doses are transported and delivered to imaging clinics within specific time frames. Revenue is recognized in Revenue from contracts with customers within the Consolidated statement of comprehensive income and loss.

Distribution services contracts are generally fixed-price per dose and as such revenue is recognized on successful delivery of a ready-to-inject dose, as the customer receives and uses the benefits simultaneously.

2.23. Government grants

Income from government grants is recognized at fair value where there is a reasonable assurance that the grant will be received, and the Group will comply with all attached conditions. Income from government grants is recognized in the consolidated statement of comprehensive income or loss on a systematic basis over the periods in which the Group recognizes as an expense the related costs for which the grants are intended to compensate.

2.24. Income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled. Deferred tax assets are recognized only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses.

Included in income tax expense for the period is the effect of Australian R&D tax credits which may only be offset against Australian taxable income. As such, they are recognized as a component of income tax expense.

Tax consolidation regime

Telix Pharmaceuticals Limited and its wholly owned Australian resident entities have formed a tax-consolidated group and are therefore taxed as a single entity. The head entity within the tax-consolidated group is Telix Pharmaceuticals Limited. As a consequence, the deferred tax assets and deferred tax liabilities of these entities have been offset in the consolidated financial statements.

2.25. Sales taxes and Goods and Services Tax (GST)

Revenues, expenses and assets are recognized net of the amount of associated sales taxes and GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognized as part of the cost of acquisition of the asset or as part of the expense.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the taxation authority, are presented as operating cash flows.

2.26. Earnings per share

1. Basic earnings per share

Basic earnings per share is calculated by dividing: the profit attributable to owners of the Company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during

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the financial period, adjusted for bonus elements in ordinary shares issued during the period and excluding treasury shares.

2. Diluted earnings per share

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account: the after-income tax effect of interest and other financing costs associated with dilutive potential ordinary shares, and the weighted average number of additional ordinary shares that would have been outstanding assuming the conversion of all dilutive potential ordinary shares.

2.27. Fair value measurement

Certain judgments and estimates are made in determining the fair values of the financial instruments that are recognized and measured at fair value in the financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards. The different levels have been defined as follows:

- **Level 1:** fair value of financial instruments traded in active markets is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets is the current bid price.
- **Level 2:** fair value of financial instruments that are not traded in an active market is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.
- **Level 3:** if one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

There were no transfers between level 1, 2 and 3 for recurring fair value measurements during the year. The Group's policy is to recognize transfers into and transfers out of fair value hierarchy levels at the end of the reporting period. Certain judgments and estimates are made in determining the fair values of the financial instruments that are recognized and measured at fair value in the financial statements.

2.28. Key judgments and estimates

In the process of applying the Group's accounting policies, a number of judgments and estimates of future events are required.

1. Impairment assessment – carrying value of goodwill and intangible assets

The assessment of impairment of the goodwill and intangible assets has required estimates and judgments to be made. The inputs for these have been outlined in note 21.

2. Contingent consideration and decommissioning liabilities

The Group has identified the contingent consideration and decommissioning liabilities as balances requiring estimates and significant judgments. These estimates and judgments have been outlined in note 27 and note 28.

3. Segment reporting

The Group has operations in the Americas, Asia Pacific, and Europe, Middle East and Africa regions.

Reportable segments

The Group's operating segments are based on the reports reviewed by the Group Chief Executive Officer who is considered to be the chief operating decision maker.

Segment performance is evaluated based on Adjusted earnings before interest, tax, depreciation and amortization ("Adjusted EBITDA"). Adjusted EBITDA excludes the effects of the remeasurement of contingent consideration and government grant liabilities and other income and expenses which may have an impact on the quality of earnings such as impairments where the impairment is the result of an isolated, non-recurring event. Interest income and treasury related finance costs are not allocated to segments as this activity is managed by a central treasury function, which manages the cash position of the Group.

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Segment assets and liabilities are measured in the same way as in the financial statements. The assets and liabilities are allocated based on the operations of the segment.

Reportable segment	Principal activities
Precision Medicine	Commercial sales of Illuccix, Gozellix and other diagnostic products subsequent to obtaining regulatory approvals. This segment includes the development activities of the Group's diagnostic pipeline. The Group's International and Medical Technologies businesses are operating segments that are included within the Precision Medicine reportable segment due to the similar nature of the diagnostic products being sold or developed for commercialization.
Therapeutics	Developing the Group's core therapeutic pipeline for commercialization. This segment includes revenue received from license agreements prior to commercialization and research and development services. This segment includes the development activities of the Group's therapeutic pipeline.
Manufacturing Solutions	Telix Manufacturing Solutions business. This segment comprises costs to operate our facilities and assets associated with the Group's vertically integrated manufacturing and supply chain. This business includes facilities at Brussels South, IsoTherapeutics, TMS Sacramento, North Melbourne, ARTMS and RLS Radiopharmacies.

Reconciling items includes head office and centrally managed costs.

3.1. Segment performance

	Precision Medicine	Therapeutics	Manufacturing Solutions	Inter-segment eliminations	Total segment
2025	**US$'000**	**US$'000**	**US$'000**	**US$'000**	**US$'000**
Revenue from contracts with customers	621,930	9,273	172,591	-	803,794
Inter-segment revenue	-	-	72,514	(72,514)	-
Cost of sales	(222,750)	(229)	(222,853)	68,476	(377,356)
Gross profit	**399,180**	**9,044**	**22,252**	**(4,038)**	**426,438**
Research and development costs	(71,156)	(98,039)	(5,813)	3,759	(171,249)
Selling and marketing expenses	(82,359)	(1,434)	(12,973)	-	(96,766)
Manufacturing and distribution costs	(10,262)	(4,238)	(30,093)	-	(44,593)
General and administration costs	(22,303)	(3,606)	(12,021)	-	(37,930)
Other (losses)/gains (net)	(3,552)	21	14,711	-	11,180
Operating profit	**209,548**	**(98,252)**	**(23,937)**	**(279)**	**87,080**
Other losses/(gains) (net)	3,552	(21)	(14,711)	-	(11,180)
Depreciation and amortization	3,333	278	16,933	-	20,544
Adjusted earnings/ (loss) before interest, tax, depreciation and amortization	**216,433**	**(97,995)**	**(21,715)**	**(279)**	**96,444**

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2024	Precision Medicine US$'000 (Recast)	Therapeutics US$'000 (Recast)	Manufacturing Solutions US$'000 (Recast)	Total segment US$'000 (Recast)
Revenue from contracts with customers	508,508	6,226	1,817	516,551
Cost of sales	(178,263)	-	(2,125)	(180,388)
Gross profit	**330,245**	**6,226**	**(308)**	**336,163**
Research and development costs	(71,628)	(55,877)	(425)	(127,930)
Selling and marketing expenses	(55,358)	(88)	(507)	(55,953)
Manufacturing and distribution costs	(5,251)	(22)	(11,397)	(16,670)
General and administration costs	(27,777)	(137)	(3,977)	(31,891)
Other (losses)/gains (net)	(5,976)	-	81	(5,895)
Operating profit/(loss)	**164,255**	**(49,898)**	**(16,533)**	**97,824**
Other losses/(gains) (net)	5,976	-	(81)	5,895
Depreciation and amortization	3,679	-	856	4,535
Adjusted earnings/(loss) before interest, tax, depreciation and amortization	**173,910**	**(49,898)**	**(15,758)**	**108,254**

2023	Precision Medicine US$'000 (Recast)	Therapeutics US$'000 (Recast)	Manufacturing Solutions US$'000 (Recast)	Total segment US$'000 (Recast)
Revenue from contracts with customers	329,205	3,496	277	332,978
Cost of sales	(123,445)	-	-	(123,445)
Gross profit	**205,760**	**3,496**	**277**	**209,533**
Research and development costs	(53,669)	(31,258)	(388)	(85,315)
Selling and marketing expenses	(33,358)	(106)	-	(33,464)
Manufacturing and distribution costs	(4,798)	(69)	(1,384)	(6,251)
General and administration costs	(20,707)	(185)	(2,475)	(23,367)
Other losses (net)	(24,497)	-	-	(24,497)
Operating profit/(loss)	**68,731**	**(28,122)**	**(3,970)**	**36,639**
Other losses (net)	24,497	-	-	24,497
Depreciation and amortization	3,729	-	157	3,886
Adjusted earnings/(loss) before interest, tax, depreciation and amortization	**96,957**	**(28,122)**	**(3,813)**	**65,022**

Activities between segments are eliminated on consolidation. The amounts presented are measured consistently with the group's external reporting. Segment assets are allocated based on the operations of the segment and the physical location of the asset.

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3.2. Reconciliation of total segment adjusted EBITDA to profit/(loss) before income tax

	Note	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Total segment adjusted EBITDA		**96,444**	**108,254**	**65,022**
Unallocated income, expenses and eliminations:				
General and administration costs		(56,897)	(53,111)	(25,702)
Other gains/(losses) (net)	10	11,735	4,885	(23,827)
Finance income		5,826	7,180	671
Finance costs	11	(40,868)	(24,442)	(9,085)
Depreciation and amortization	9	(21,506)	(4,851)	(4,485)
(Loss)/profit before income tax		**(5,266)**	**37,915**	**2,594**

General and administration costs predominantly comprise employment costs of $31,950,000 (2024: $30,264,000 2023: $18,420,000) and other centrally managed IT, legal and other corporate costs.

3.3. Operating segment assets and liabilities

December 31, 2025	Precision Medicine US$'000	Therapeutics US$'000	Manufacturing Solutions US$'000	Total segment US$'000	Reconciling items US$'000	Group US$'000
Total assets	233,252	228,110	515,429	**976,791**	187,195	**1,163,986**
Total liabilities	159,523	17,099	156,599	**333,221**	415,389	**748,610**
Additions to non-current assets	19,503	67,715	324,472	**411,690**	7,840	**419,530**

December 31, 2024	Precision Medicine US$'000 (Recast)	Therapeutics US$'000 (Recast)	Manufacturing Solutions US$'000 (Recast)	Total segment US$'000 (Recast)	Reconciling items US$'000 (Recast)	Group US$'000 (Recast)
Total assets	300,731	134,440	137,223	**572,394**	367,985	**940,379**
Total liabilities	149,745	9,414	53,962	**213,121**	374,321	**587,442**
Additions to non-current assets	1,590	92,867	110,828	**205,285**	308	**205,593**

Reconciling items primarily comprise cash and cash equivalents held centrally $82,833,000 (2024: $326,421,000), investments in financial assets $37,094,000 (2024: $34,746,000), property, plant and equipment $6,915,000 (2024: $1,084,000), borrowings (convertible bonds) $383,023,000 (2024: $333,378,000) which are managed centrally.

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3.4. *Geographical information*

	2025	2024	2023
	Revenue by location of customer	Revenue by location of customer	Revenue by location of customer
	US$'000	US$'000 (Recast)	US$'000 (Recast)
China	9,834	382	863
United States	784,905	502,760	324,474
Other countries	9,055	13,409	7,641
Total	**803,794**	**516,551**	**332,978**

	2025	2024
	Non-current assets by location of asset	Non-current assets by location of asset
	US$'000	US$'000 (Recast)
Australia	101,753	81,242
Belgium	59,460	36,324
Canada	86,643	78,292
United Kingdom	37,071	34,020
United States	481,181	107,904
Other countries	8,245	3,560
Total	**774,353**	**341,342**

The total non-current assets figure above excludes deferred tax assets.

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4. Revenue from contracts with customers

Disaggregation of revenue from contracts with customers.

The Group derives revenue from the sale and transfer of goods and services over time and at a point in time under the following major business activities:

	Recognition	Operating segment	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Sale of goods	At a point in time	Precision Medicine	621,612	508,401	328,921
Sale of goods	At a point in time	Manufacturing Solutions	164,048	-	-
Royalty income	At a point in time	Precision Medicine	318	100	260
Royalty income	At a point in time	Therapeutics	55	-	-
Provision of services	Over time	Manufacturing Solutions	8,543	1,817	277
Licenses of intellectual property	Over time	Therapeutics	88	-	64
Research and development services	Over time	Precision Medicine	-	7	24
Research and development services	Over time	Therapeutics	9,130	6,226	3,432
Total revenue from continuing operations			**803,794**	**516,551**	**332,978**

5. Research and development costs

Therapeutics	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Phase 3	49,209	36,378	17,585
Phase 2	19,332	8,376	7,937
Early stage clinical candidates	16,995	4,914	4,553
Pre-clinical research and innovation	12,503	6,209	1,183
Total Therapeutics R&D	**98,039**	**55,877**	**31,258**
Precision Medicine			
Commercial	18,806	7,139	3,883
Pre-commercial[1]	46,403	61,831	45,117
Pre-clinical research and innovation	5,947	2,658	4,669
Total Precision Medicine R&D	**71,156**	**71,628**	**53,669**
Total product development R&D	**169,195**	**127,505**	**84,927**
Manufacturing Solutions			
Other research and development projects	5,813	425	388
Total Manufacturing Solutions R&D	**5,813**	**425**	**388**
Inter-segment R&D	**(3,759)**	**-**	**-**
Total research and development costs	**171,249**	**127,930**	**85,315**

[1] Pre-commercial R&D costs includes $14,103,000 (2024 $2,779,000) of Zircaix inventory that is included within research and development costs, refer to note 15 for further details.

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Other research and development projects includes research and innovation costs and other early-stage development projects

6. Manufacturing and distribution costs

The following costs are included within manufacturing and distribution costs:

	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Radiopharmacy operations	9,696	-	-
Quality costs	9,329	6,422	3,603
Supply chain costs	4,335	1,484	-
Technical services	3,433	1,539	-
Global manufacturing costs	3,631	806	2,644

The increase in manufacturing and distribution costs was driven by the impact of RLS results for 11 months and higher costs associated with preparing the Brussels South manufacturing facility for GMP commercial production.

7. General and administration costs

The significant components of general and administration costs are summarized below:

	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Professional fees	16,541	9,794	6,651
Acquisition transaction costs	-	5,750	-
U.S. listing costs	-	6,026	-
IT infrastructure, hosting and support	8,406	5,967	4,691
Travel, conferences and entertainment	2,935	4,732	3,920
Rent and insurance	4,550	2,835	2,509

The increase in general and administration costs was driven by the impact of RLS results for 11 months, costs incurred to implement a Sarbanes-Oxley program, and professional fees in connection with the legal matters outlined in note 34 of this report. Other material general and administration costs are employment related as included within note 8 below.

8. Employment costs

	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Salaries and wages	174,066	87,116	56,168
Short term incentives	13,269	5,801	4,750
Sales commissions	8,753	5,604	4,746
Share-based payment charge	19,146	12,928	5,848
Superannuation	3,542	1,711	1,236
Non-Executive Directors' fees	752	563	383
	219,528	**113,723**	**73,131**

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Salaries and wages of $2,235,000 (2024: $3,984,000, 2023: $983,000) are included within the cost of sales in the Consolidated statement of comprehensive income/(loss). The increase in employment costs was predominantly due to the impact of RLS results for 11 months, and additional employees hired to drive higher commercial sales and support our global manufacturing facilities.

9. Depreciation and amortization

	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
Amortization of intangible assets	9,882	2,545	2,883
Depreciation	11,624	2,306	1,602
	21,506	**4,851**	**4,485**

10. Other (gains)/losses (net)

	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
Remeasurement of contingent consideration[1]	(11,618)	7,326	22,687
Remeasurement of provisions	(12)	458	(130)
Realized currency gain	(193)	(76)	(1,636)
Impairments/(impairment reversals) of intangible assets	566	(475)	550
Other income	(1,234)	(299)	(14)
Unrealized currency gain/(loss)	756	(11,819)	2,370
	(11,735)	**(4,885)**	**23,827**

11. Finance costs

	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
Unwind of discount	26,653	19,356	8,423
Interest expense on lease liabilities	3,637	491	423
Convertible bond interest expense	9,945	4,239	-
Interest expense	181	64	97
Bank fees	452	292	142
Finance costs	**40,868**	**24,442**	**9,085**

The Group recognized an unwind of discount on convertible bonds of $22,502,000 (2024: $9,088,000, 2023: Nil), unwind of working capital facility costs of $49,000 (2024: Nil, 2023: Nil), contingent consideration liabilities of $2,201,000 (2024: $9,546,000, 2023: $7,575,000), provisions of $445,000 (2024: $256,000, 2023: $279,000) and contract liabilities of $137,000 (2024: $469,000, 2023: $644,000).

[1] Refer to note 28 for further information of remeasurements associated with contingent consideration.

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12. Income tax expense/(benefit)

12.1. Income tax expense/(benefit)

	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
Current tax expense[1]	13,994	18,566	10,924
Deferred tax benefit	(12,135)	(14,336)	(12,538)
Income tax expense/(benefit)	**1,859**	**4,230**	**(1,614)**

1. The current tax expense is attributable to Telix Innovations SA and Telix Pharmaceuticals US Inc and is driven by the individual entity's taxable profits.

12.2. Numerical reconciliation of prima facie tax payable to income tax expense/(benefit)

	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
(Loss)/profit before income tax	(5,266)	37,915	2,594
Prima-facie tax at a rate of 30.0% (2024: 30.0%, 2023: 30.0%)	(1,580)	11,375	778
Tax effect of amounts which are not deductible (taxable) in calculating taxable income:			
Net R&D tax incentive credit	(1,425)	(13,818)	(4,889)
Remeasurement of provisions	589	4,910	9,183
Share-based payments expense & Employee Share Trust payments	(8,442)	(1,301)	(5,372)
Sundry items	81	371	375
Foreign exchange translation gains	360	-	678
	(10,417)	**1,537**	**753**
Current year tax losses not recognized	17,765	40,522	23,197
Difference in overseas tax rates	(5,489)	(37,829)	(25,564)
Income tax expense/(benefit)	**1,859**	**4,230**	**(1,614)**

13. Earnings per share

13.1. Basic earnings per share

	2025	2024	2023
	Cents	Cents (Recast)	Cents (Recast)
Basic (loss)/earnings per share from continuing operations attributable to the ordinary equity holders of the Company	(2.11)	10.17	1.32
Total basic (loss)/earnings per share attributable to the ordinary equity holders of the Company	(2.11)	10.17	1.32

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13.2. Diluted earnings per share

	2025	2024	2023
	Cents	Cents (Recast)	Cents (Recast)
Diluted (loss)/earnings per share from continuing operations attributable to the ordinary equity holders of the Company	(2.11)	9.76	1.30
Total diluted (loss)/earnings per share attributable to the ordinary equity holders of the Company	(2.11)	9.76	1.30

13.3. Weighted average number of shares used as the denominator

	2025	2024	2023
	Number '000	Number '000	Number '000
Weighted average number of ordinary shares used as the denominator in calculating basic earnings/loss per share	337,880	331,226	319,181
Weighted average number of ordinary shares used as the denominator in calculating diluted earnings/loss per share[1]	337,880	345,188	323,710

13.3.1. Options and rights

Equity instruments (options, PSARs, PSIRs and rights) granted to employees under the Group's EIP scheme (refer to note 31 for further details) and rights issued as part of acquisitions are considered to be potential ordinary shares. They have been included in the determination of diluted earnings per share based on achieving the required performance hurdles, and to the extent to which they are dilutive.

13.3.2. Convertible bonds

Convertible bonds issued during the year are not included in the calculation of diluted earnings per share, because they are antidilutive for the year ended December 31, 2025. These options could potentially dilute basic earnings per share in the future. Refer to note 25.3 for further details relating to the convertible bonds.

14. Trade and other receivables

	2025	2024
	US$'000	US$'000 (Recast)
Trade receivables	131,579	87,059
Allowance for impairment losses[2]	(2,377)	(131)
	129,202	**86,928**

[1] For the year ended December 31, 2025 there were 14,057,626 options that were not included in the calculation of diluted earnings as they were antidilutive.
[2] In conjunction with acquisition of RLS, allowance for impairment losses increased as a result of the shift in customer base post-acquisition. Refer to Note 2.9 for further information on our accounting policies with respect to trade receivables.

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15. Inventories

	2025 US$'000	2024 US$'000 (Recast)
Raw materials and stores	18,734	8,915
Work in progress	9,789	8,598
Finished goods	25,413	8,686
Provision for obsolescence	(16,856)	(2,579)
Total inventories	**37,080**	**23,620**

The amount of inventory recognized as an expense during the year was $142,002,000 (2024: $23,875,000, 2023: $13,939,000).

Clinical inventory and inventory manufactured as part of the TLX250-Px (Zircaix)[1] commercial manufacturing process qualification and validation has been capitalized as work in progress, with a corresponding provision for obsolescence recognized. This is on the basis that, prior to regulatory approval, the Group has not demonstrated that the batches produced can be sold commercially.

16. Other current assets

	2025 US$'000	2024 US$'000 (Recast)
Other receivables	1,286	1,767
GST receivables	1,840	5,047
Prepayments	12,963	6,844
Total other current assets	**16,089**	**13,658**

17. Financial assets

	2025 US$'000	2024 US$'000 (Recast)
Investment in Mauna Kea Technologies	1,023	2,104
Investment in Atonco SAS	2,321	1,670
Investment in IRMA Surgical Pty Ltd	334	-
Restricted cash[2]	33,416	30,972
Total financial assets	**37,094**	**34,746**

[1] Brand name subject to final regulatory approval
[2] The Group has paid a cash security deposit as part of the working capital facility agreement with HSBC Bank Australia Limited, the deposit is for a term longer than 90 days and as such it has been excluded from cash and cash equivalents (refer to note 25.2 for further details of this facility)

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18. Deferred tax assets and liabilities

18.1. Deferred tax assets

	2025	2024
	US$'000	US$'000 (Recast)
The balance comprises temporary differences attributable to:		
Tax losses	22,568	1,162
Intangible assets	-	-
Employee benefit obligations	16,160	4,005
Lease liabilities	14,532	1,258
Inventories	22,283	22,643
Other	1,931	5,279
Total deferred tax assets	**77,474**	**34,347**
Set-off of deferred tax liabilities pursuant to set-off provisions	(18,121)	(5,427)
Net deferred tax assets	**59,353**	**28,920**

Deferred tax assets movements	Tax losses	Intangible assets	Employee benefit obligations	Lease liabilities	Inventories	Other	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
Balance at January 1, 2025	**1,162**	**-**	**4,005**	**1,258**	**22,643**	**5,279**	**34,347**
Credited/(charged):							
on acquisition	10,867	-	-	13,670	-	-	**24,537**
to profit and loss	10,539	-	12,155	(396)	(360)	(3,348)	**18,590**
Balance at December 31, 2025	**22,568**	**-**	**16,160**	**14,532**	**22,283**	**1,931**	**77,474**
	(Recast)	(Recast)	(Recast)	(Recast)	(Recast)	(Recast)	(Recast)
Balance at January 1, 2024	**-**	**5,675**	**1,909**	**1,218**	**7,507**	**364**	**16,673**
Credited/(charged):							-
to profit and loss	1,162	(5,675)	2,096	40	15,136	4,915	**17,674**
Balance at December 31, 2024	**1,162**	**-**	**4,005**	**1,258**	**22,643**	**5,279**	**34,347**

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18.2. Deferred tax liabilities

	2025	2024
	US$'000	US$'000 (Recast)
The balance comprises temporary differences attributable to:		
Intangible assets	44,706	5,796
Right-of-use assets	14,315	1,621
Unrealized foreign exchange gains	3,806	3,806
Total deferred tax liabilities	**62,827**	**11,223**
Set-off of deferred tax assets pursuant to set-off provisions	(18,121)	(5,427)
Net deferred tax liabilities	**44,706**	**5,796**

Deferred tax liabilities movements	Intangible assets	Right-of-use assets	Unrealized foreign exchange gains	Total
	US$'000	US$'000	US$'000	US$'000
Balance at January 1, 2025	**5,796**	**1,621**	**3,806**	**11,223**
Charged/(credited):				
on acquisition	32,079	13,070	-	45,149
to profit and loss	6,831	(376)	-	6,455
Balance at December 31, 2025	**44,706**	**14,315**	**3,806**	**62,827**
	(Recast)	(Recast)	(Recast)	(Recast)
Balance at January 1, 2024	**1,625**	**1,057**	**-**	**2,682**
Charged/(credited):				
on acquisition	5,203	-	-	5,203
to profit and loss	(1,032)	564	3,806	3,338
Balance at December 31, 2024	**5,796**	**1,621**	**3,806**	**11,223**

18.3. Unrecognized deferred tax assets

The composition of the Group's unrecognized deferred tax assets is as follows:

Unrecognized deferred tax assets	2025	2024
	US$'000	US$'000 (Recast)
Tax losses and tax credits	112,725	90,426
Temporary differences in relation to provisions	-	2
Temporary differences in relation to employee benefit obligations	1,363	1,213
Temporary differences in relation to intangible assets	-	678
Temporary differences in relation to inventories	-	332
Temporary differences in relation to lease liabilities	1,819	419
Temporary differences in relation to share-based payments	9,500	19,777
Total unrecognized deferred tax assets	**125,407**	**112,847**

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18.4. Carried forward tax losses and credits

Unused tax losses and carried forward tax credits for which no deferred tax asset has been recognized	2025 US$'000	2024 US$'000 (Recast)	2023 US$'000 (Recast)
Australia	112,633	83,326	56,717
Other countries	92	7,100	1,029
Unrecognized income tax benefit	**112,725**	**90,426**	**57,746**
Unused tax losses and carried forward tax credits for which a deferred tax asset has been recognized			
Other countries	3,431	1,162	-
Recognized income tax benefit	**3,431**	**1,162**	**-**

19. Property, plant and equipment

	Land and buildings	Plant, equipment and vehicles	Furniture, fittings and equipment	Leasehold improvements	Construction in progress	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
Balance at January 1, 2025	**11,733**	**3,311**	**1,764**	**1,572**	**9,461**	**27,841**
Additions	-	10,840	1,826	2,110	11,246	26,022
Acquisition of businesses	-	3,286	738	224	803	5,051
Reclassifications	6,287	4,657	(1,469)	(173)	(9,302)	-
Changes in provisions	(775)	(22)	21	-	-	(776)
Depreciation charge	(308)	(1,995)	(988)	(402)	-	(3,693)
Exchange differences	1,397	2,256	258	71	234	4,216
Balance at December 31, 2025	**18,334**	**22,333**	**2,150**	**3,402**	**12,442**	**58,661**
Cost	18,854	24,757	4,080	4,279	12,442	64,412
Accumulated depreciation	(520)	(2,424)	(1,930)	(877)	-	(5,751)
Net book amount	**18,334**	**22,333**	**2,150**	**3,402**	**12,442**	**58,661**
	(Recast)	(Recast)	(Recast)	(Recast)	(Recast)	(Recast)
Balance as at January 1, 2024	**8,133**	**317**	**466**	**1,061**	**5,871**	**15,848**
Additions	26	3,099	1,470	428	4,416	9,439
Acquisition of businesses	-	933	173	424	-	1,530
Reclassifications	(53)	(73)	77	49	-	-
Changes in provisions	3,564	-	-	-	-	3,564
Depreciation charge	-	(234)	(312)	(228)	-	(774)
Exchange differences	63	(731)	(110)	(162)	(826)	(1,766)
Balance at December 31, 2024	**11,733**	**3,311**	**1,764**	**1,572**	**9,461**	**27,841**
Cost	11,945	3,740	2,706	2,047	9,461	29,899
Accumulated depreciation	(212)	(429)	(942)	(475)	-	(2,058)
Net book amount	**11,733**	**3,311**	**1,764**	**1,572**	**9,461**	**27,841**

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20. Right-of-use assets

	Properties	Motor vehicles	Total
	US$'000	US$'000	US$'000
Balance at January 1, 2025	**4,072**	**1,733**	**5,805**
Additions	8,373	415	8,788
Acquisition of businesses	46,930	2,769	49,699
Depreciation charge	(6,696)	(1,080)	(7,776)
Exchange differences	391	43	434
Balance at December 31, 2025	**53,070**	**3,880**	**56,950**
Cost	62,876	6,239	69,115
Accumulated depreciation	(9,806)	(2,359)	(12,165)
Net book amount	**53,070**	**3,880**	**56,950**
	(Recast)	(Recast)	(Recast)
Balance at January 1, 2024	**4,197**	**813**	**5,010**
Additions	-	1,482	1,482
Reclassifications	1,129	-	1,129
Depreciation charge	(1,118)	(414)	(1,532)
Exchange differences	(136)	(148)	(284)
Balance at December 31, 2024	**4,072**	**1,733**	**5,805**
Cost	7,573	3,055	10,628
Accumulated depreciation	(3,501)	(1,322)	(4,823)
Net book amount	**4,072**	**1,733**	**5,805**

The consolidated statement of comprehensive income or loss shows the following amounts relating to right-of-use assets:

Depreciation charge on right-of-use assets	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
Properties	6,696	1,118	669
Motor vehicles	1,080	414	300
	7,776	**1,532**	**969**

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21. Intangible assets

	Goodwill	Intellectual property	Customer relationships and brands	Software	Patents	Licenses	Total
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
Balance at January 1, 2025	**66,586**	**176,426**	**741**	**2,284**	**318**	**11,503**	**257,858**
Acquisition of businesses	143,660	-	90,200	806	-	15,400	250,066
Additions	-	32,410	127	1,291	46	46,030	79,904
Measurement period adjustments	4,731	-	-	-	-	-	4,731
Reclassifications	(18,759)	18,759	-	-	-	-	-
Amortization charge	-	(2,026)	(5,871)	(460)	(17)	(1,508)	(9,882)
Impairments	-	-	-	-	-	(566)	(566)
Changes in provisions	6	(565)	-	-	-	-	(559)
Exchange differences	2,764	6,395	-	403	25	1,684	11,271
Balance at December 31, 2025	**198,988**	**231,399**	**85,197**	**4,324**	**372**	**72,543**	**592,823**
Cost	198,988	250,952	91,230	4,805	715	75,095	621,785
Accumulated amortization	-	(19,553)	(6,033)	(481)	(343)	(2,552)	(28,962)
Net book amount	**198,988**	**231,399**	**85,197**	**4,324**	**372**	**72,543**	**592,823**
	(Recast)	(Recast)	(Recast)	(Recast)	(Recast)	(Recast)	(Recast)
Balance as at January 1, 2024	**3,940**	**62,495**	**-**	**1,109**	**362**	**7,148**	**75,054**
Acquisition of businesses	65,452	26,232	902	-	-	-	92,586
Additions	-	92,867	-	1,303	-	5,257	99,427
Reclassifications	52	-	-	-	-	(52)	-
Amortization charge	-	(2,589)	(142)	-	(30)	(300)	(3,061)
Impairments	-	475	-	-	-	-	475
Changes in provisions	-	993	-	-	-	-	993
Exchange differences	(2,858)	(4,047)	(19)	(128)	(14)	(550)	(7,616)
Balance at December 31, 2024	**66,586**	**176,426**	**741**	**2,284**	**318**	**11,503**	**257,858**
Cost	66,586	192,448	902	2,284	609	12,434	275,263
Accumulated amortization	-	(16,022)	(161)	-	(291)	(931)	(17,405)
Net book amount	**66,586**	**176,426**	**741**	**2,284**	**318**	**11,503**	**257,858**

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Cash generating units

The allocation of intangible assets to each cash-generating unit ("CGU") is summarized below:

Operating segment	Useful life	Product or business unit	2025 US$'000	2024 US$'000 (Recast)
Precision Medicine	Definite and indefinite	TLX591-Px (Illuccix®)	2,511	4,304
Precision Medicine	Definite	TLX66-Px	513	475
Precision Medicine	Indefinite	TLX300-Px	134	-
Precision Medicine	Definite	Patents	372	318
Precision Medicine	Definite and indefinite	SENSEI	36,641	33,826
Precision Medicine	Indefinite	Dedicaid, QDOSE	3,091	2,300
Therapeutics	Indefinite	TLX101-Tx	1,356	1,209
Therapeutics	Indefinite	TLX090-Tx	92,762	92,762
Therapeutics	Indefinite	TLX591-Tx	12,079	11,195
Therapeutics	Indefinite	TLX66-Tx	10,902	10,629
Therapeutics	Indefinite	TLX300-Tx	4,560	4,226
Therapeutics	Indefinite	TLX400-Tx	11,771	-
Therapeutics	Indefinite	Telix Targeting Technology	66,970	-
Manufacturing Solutions	Indefinite	ARTMS	85,209	76,554
Manufacturing Solutions	Indefinite	RLS	143,660	-
Manufacturing Solutions	Definite	RLS	99,741	-
Manufacturing Solutions	Definite and indefinite	IsoTherapeutics	12,027	12,271
Manufacturing Solutions	Definite	Brussels South and Sacramento	8,524	7,789
			592,823	**257,858**

Goodwill is allocated to the CGUs outlined below.

CGU	2025 US$'000	2024 US$'000 (Recast)
Brussels South and Sacramento	511	511
RLS	143,660	-
IsoTherapeutics	11,530	11,530
ARTMS	39,927	51,502
TLX101-Tx	849	716
TLX591-Px (Illuccix®)	2,511	2,327
Total goodwill allocated to CGUs	**198,988**	**66,586**

For the purposes of the annual impairment test outlined below, each RLS radiopharmacy is considered a separate CGU on the basis that each site incurs site-specific costs and generates independent cash flows.

Impairment test for goodwill and indefinite life intangible assets

Goodwill and indefinite life intangible assets are tested annually for impairment or more frequently if events or changes in circumstances indicate that the carrying value of cash-generating units containing indefinite-lived intangible assets and goodwill may be impaired. Potential impairment is identified by comparing the fair value of a cash-generating unit to its carrying value, including goodwill. At December 31, 2025, the Directors used a fair value less costs to sell approach to assess the carrying value of goodwill and indefinite life intangible assets. No impairment was recognized by the Group.

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Key assumptions used for the fair value less costs to sell approach

The Group has identified the estimate of the recoverable amount as a significant judgment for the year ended December 31, 2025. In determining the recoverable amount of goodwill and indefinite life intangible assets, the Group has used discounted cash flow forecasts and the following key assumptions (classified as level 3 inputs in the fair value hierarchy):

- discounted expected future cash flows for assets under development comprise of remaining costs to be incurred to marketing authorization and then span a further 10 years from marketing authorization. A terminal value with a declining growth rate, where appropriate, based on our view of the longer term growth profile of the asset is applied. This reflects the anticipated product life cycle, and includes cash inflows and outflows determined using further assumptions below
- discounted expected future cash flows for operating business within Manufacturing Solutions span 10 years after which a terminal value using a long term growth rate of 5% (2024: 5%) is applied, and cash inflows and outflows determined using further assumptions below
- asset specific risk adjusted post-tax discount rates which range from – 11.7% to 15.0% (2024: 12.5%)
- regulatory/marketing authorization approval dates, these are re-assessed in conjunction with Senior Management and Commercial teams
- expected sales volumes, these are determined by applying a target market share to cancer incidence rates across various countries, sourced from data provided by the World Health Organization's International Agency for Research on Cancer
- net sales price per unit, for commercialized products forecast average selling price is used and for products in development a target sales price is used
- approval for marketing authorization probability success factor, this varies depending on the clinical trial stage of each program and is generally based on internal or external clinical research or publically available industry data
- in relation to cash outflows consideration has been given to cost of sales, selling and marketing expenses, general and administration costs and the anticipated research and development costs to reach commercialization. Associated expenses such as royalties, milestone payments and license fees are included, and
- costs of disposal were assumed to be immaterial at December 31, 2025.

Impact of possible changes in key assumptions

The Group has considered reasonable possible changes in the key assumptions as outlined below and has not identified any instances that could cause the carrying amounts of the intangible assets at December 31, 2025 to exceed their recoverable amounts.

Outlined below are impacts of possible changes in key assumptions for material CGUs that were recently acquired. The group would have to recognize an impairment against the carrying value of the intangible assets of each respective CGU.

Asset	An increase of 2.5% in post-tax discount rate	A 10% decrease in probability of success	A one year delay in commercialization	A 50% reduction in terminal growth rate	A 10% reduction in future cash inflows
	US$'000	US$'000	US$'000	US$'000	US$'000
Telix Targeting Technology	(21,500)	(37,400)	(10,000)	Not applicable	Not applicable
RLS	(70,300)	Not applicable	Not applicable	(46,000)	(45,200)

The key sensitivities in the valuation remain the continued successful development and commercialization of core assets. If the Group is unable to successfully develop each asset, this may result in an impairment of the carrying amount of our intangible assets.

There were no other internal or external factors identified that could result in an impairment of definite life intangible assets at December 31, 2025.

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22. Other non-current assets

	2025 US$'000	2024 US$'000 (Recast)
Isotope raw materials	26,621	14,765
Investment in sub-leases	1,340	-
Other deposits and assets	864	327
Total other non-current assets	**28,825**	**15,092**

23. Acquisitions

23.1 Acquisition of RLS (USA) Inc.

On January 28, 2025 Telix completed the acquisition of RLS (USA) Inc. (RLS), a radiopharmacy network distributing PET, SPECT and therapeutic radiopharmaceuticals. The acquisition of RLS is aligned to Telix's investment strategy around vertically integrated supply chain, manufacturing, and distribution, further enabling the delivery of future clinical and commercial radiopharmaceutical products.

The total consideration is $240,921,000 of which $225,171,000 was paid in cash. A further $15,750,000 is payable in cash, contingent on achievement of certain milestones related to demonstration of accretive financial and operational performance during the four-quarters following closing.

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The following table summarizes the consideration paid for RLS, the fair value of assets acquired and liabilities assumed at the acquisition date.

Consideration	Fair value US$'000
Cash paid	225,171
Contingent consideration	15,750
Total consideration	**240,921**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Cash and cash equivalents	4,509
Trade and other receivables	22,848
Other current assets	12,063
Inventories	3,676
Property, plant and equipment	5,051
Intangible assets	806
Investment in sub-lease	1,635
Right-of-use assets	49,699
Trade and other payables	(32,339)
Contingent or deferred consideration	(8,124)
Lease liabilities	(52,008)
Total identifiable assets and liabilities	**7,816**
Fair value adjustments	
Customer relationships	60,400
Brand name	29,800
Radiopharmacy licenses	15,400
Deferred tax liabilities	(27,456)
Deferred tax asset	11,301
Total fair value adjustments	**89,445**
Goodwill	143,660
Total	**240,921**

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Following the finalization of the purchase price accounting, goodwill increased by $13,173,000 from the provisional fair value reported as at June 30, 2025 for the reasons below:

- post acquisition net working capital changes of $2,816,000, and
- reduction of deferred tax asset by $10,357,000 following the completion of the formal tax analysis assessing the recoverability of the acquired carried forward tax tax losses.

The goodwill arising is attributable to the acquired workforce, anticipated future cost savings from utilizing RLS' radiopharmaceutical distribution capabilities and synergies of integrating the business within the Group. The goodwill arising from the acquisition has been allocated to each radiopharmacy which operate as separate CGUs (refer to note 21 for further details).

Fair value adjustments have been recognized for acquisition-related intangible assets and related deferred tax.

The useful economic lives of each of these acquisition-related intangible assets is as follows:

Acquired intangible asset	Useful economic life
Customer relationships	20 years
Brand name	10 years
Licenses	10 years

Significant estimates used in purchase price accounting

The Group has used the multi-period excess earnings method and the relief from royalty method, which are a form of the income approach, in estimating the fair value of customer relationships and the brand name acquired, respectively when allocating the purchase consideration paid for the acquisition.

The estimates of the customer relationships and the brand name involve significant judgment by management in making cash flow projections for the intangible assets acquired and include significant assumptions with measurement uncertainty, such as:

- the revenue growth rates, earnings before interest and taxes ("EBIT") margin, and discount rate for customer relationships, and
- revenue growth rates, royalty rate, and discount rate for the brand name.

RLS contributed $170,088,000 in revenue and a net loss of $8,767,000 towards the Group's loss before tax attributable to equity holders of the parent for the period after the date of acquisition.

Had the acquisition of RLS been completed on the first day of the 2025 financial year, Group revenues would have been approximately $13,607,000 higher and Group loss before tax attributable to equity holders of the parent would have been approximately $1,484,000 higher.

23.2 Acquisition of ImaginAb, Inc.

On January 30, 2025 Telix completed the acquisition of a pipeline of next generation therapeutic candidates, proprietary novel biologics technology platform, and a protein engineering and discovery research facility to enhance existing innovation capabilities from antibody engineering company ImaginAb, Inc.

The upfront purchase price for the transaction was $67,116,000 which comprised $10,000,000 in cash and 29,895,000 in equity through the issue of 2,053,311 fully paid ordinary Telix shares in January 2025 at a share price of $14.56 per share. A further $60,000,000 in Milestone Rights, or performance rights, is payable in cash and/or in ordinary shares, upon achievement of certain clinical milestones. The purchase price also includes a deferred amount payable of $3,472,000 (up to a maximum of $4,000,000 in equity) at the conclusion of a 15-month indemnity period.

Upon achievement of specific key development and commercial milestones, Telix will pay up to a total of $185 million, a portion of which may be paid in cash or equity at Telix's election. Royalties are also payable on net sales in the low single digits on a limited number of platform and early-stage products after the first four products have been developed, as well as single-digit sublicense fees, as applicable. The acquisition has been allocated to the Therapeutics operating segment.

The Group has assessed that the acquisition does not meet the definition of a business in IFRS 3/AASB 3 Business Combinations as the Group concluded that the acquisition does not include a self-sustaining substantive process capable of generating outputs. The assets acquired are discovery stage assets and the process of transforming them into commercially available products remains undeveloped and incomplete at the acquisition date. On this basis, the Group has concluded that the components acquired will be treated as an asset acquisition.

The performance rights associated with the development milestones have been recognized as an equity settled share-based payment at a fair value of $23,160,000 which has been included in the fair value of intellectual property. Each milestone associated with the rights has a fixed dollar amount which can be settled either in cash or shares. The fair value of the performance rights was determined based on management's assessment of the likelihood of each milestone being reached against the fixed dollar amount for that milestone. The likelihood of the milestones being attained are considered non-vesting conditions as there are no further services or obligations of the counterparty, thus being reflected in the fair value.

The following table summarizes the consideration paid for ImaginAb, the fair value of assets acquired and liabilities assumed at the acquisition date.

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Consideration	Fair value US$'000
Cash paid	10,000
Performance rights issued	23,160
Equity issued	29,895
Acquisition related costs	589
Deferred payment	3,472
Total consideration	**67,116**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Property, plant and equipment	105
Right-of-use assets	629
Intellectual property	25,866
Licenses	41,145
Lease liabilities	(629)
Total identifiable assets and liabilities	**67,116**

Acquisition-related intangible assets of $25,866,000 relate to the valuation of the acquired ImaginAb therapeutic candidate intellectual property and $41,145,000 associated with a perpetual license for the targeting technology platform. The useful economic life of the intellectual property has not been assessed at the acquisition date, as the intellectual property is not available for commercial use until regulatory approval has been obtained.

23.3 Acquisition of FAP targeting candidates

On March 12, 2025 Telix entered into an asset purchase and exclusive worldwide in-license agreements for a suite of clinically validated FAP-targeting therapeutic and precision medicine (diagnostic) radiopharmaceutical candidates.

At closing Telix entered into an exclusive worldwide license agreement with a German company controlled by Professor Frank Roesch, SCV GmbH, and a concurrently-signed asset purchase agreement with German company Medianezia GmbH, which collectively hold the intellectual property rights to the FAP assets.

Telix paid €5,300,000 (US$5,774,000) in cash (in addition to €700,000 (US$747,000) paid upfront at agreement signing); and will pay a further €4,000,000 (US$4,354,000) in cash in the 12 months following entry into the agreements, subject to potential indemnity set-off. Telix will pay up to a further €132,000,000 (US$154,651,200) contingent upon achievement of certain clinical development and regulatory milestones related to both the diagnostic and therapeutic candidates under both agreements. An additional €20,000,000 (US$23,432,000) will be payable under the license agreement on achievement of certain commercial milestones related to the diagnostic product; as well as royalties on net sales in the low to mid-single digits on the diagnostic product and an earlier formulation of the therapeutic product, if used.

The Group has assessed that the acquisition does not meet the definition of a business in IFRS 3/AASB 3 Business Combinations as the Group concluded that the acquisition does not include a self-sustaining substantive process capable of generating outputs. On this basis, the Group has concluded that the components acquired will be treated as an asset acquisition.

Contingent consideration in connection with the purchase of individual assets outside of business combinations is recognized as a financial liability only when the non-contingent obligation arises (i.e. when milestone is met). The determination of whether the payment should be capitalized or expensed is usually based on the reason for the contingent payment.

For the acquisition of the FAP targeting candidates, contingent payments based on regulatory approvals received (i.e. development milestones) will be capitalized as the payments are incidental to the acquisition and making the asset available for its intended use. Contingent payments associated with sales related milestones will be expensed.

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The fair values of identifiable assets on acquisition are outlined below:

Consideration	Fair value US$'000
Cash paid	6,521
Acquisition related costs	31
Deferred payment	4,354
Total consideration	**10,906**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Intellectual property	6,544
License agreement	4,362
Total identifiable assets and liabilities	**10,906**

23.4 Acquisition of ARTMS, Inc.

On 11 April 2024 Telix completed the acquisition of radioisotope production technology firm ARTMS, Inc. (ARTMS). During the period the Group finalised the purchase price allocation associated with the ARTMS acquisition. The adjustments to the acquired assets and liabilities and resultant goodwill were as follows:

Identifiable assets and liabilities	Increase or decrease	Fair value US$'000
Intellectual property	Increase	18,759
Deferred tax liabilities	Increase	(4,731)
Goodwill	Decrease	14,028

24. Trade and other payables

	2025 US$'000	2024 US$'000 (Recast)
Trade creditors	71,661	42,227
Accruals	27,275	29,578
Deferred consideration	11,068	-
Customer rebates payable	17,148	7,450
Other creditors	17,215	3,322
Accrued royalties	604	1,617
Payroll liabilities	4,729	1,857
Government rebates payable	649	739
Total trade and other payables	**150,349**	**86,790**

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25. Borrowings

	2025		2024	
	Current	Non-current	Current	Non-current
	US$'000	US$'000	US$'000 (Recast)	US$'000 (Recast)
Secured				
Bank loans	1,418	8,989	923	8,526
Working capital facility	-	(98)	-	(93)
Total secured borrowings	**1,418**	**8,891**	**923**	**8,433**
Unsecured				
Convertible bonds	11,692	383,023	10,840	333,378
Total unsecured borrowings	**11,692**	**383,023**	**10,840**	**333,378**
Total borrowings	**13,110**	**391,914**	**11,763**	**341,811**

December 31, 2025

Lenders	Loan balance US$'000	Due < 1 year US$'000	Due > 1 year US$'000	Facility limit US$'000	Maturity date
The Hongkong and Shanghai Banking Corporation Limited As The Trustee For Convertible Bond Holders	394,715	11,692	383,023	434,395	30-Jul-29
IMBC Group	3,921	550	3,371	4,686	31-Mar-33
BNP Paribas	6,486	868	5,618	9,490	29-Feb-32
HSBC Bank Australia Ltd	(98)	-	(98)	33,415	3 years from first utilization
Total	**405,024**	**13,110**	**391,914**	**481,986**	

December 31, 2024

Lenders	Loan balance US$'000 (Recast)	Due < 1 year US$'000 (Recast)	Due > 1 year US$'000 (Recast)	Facility limit US$'000 (Recast)	Maturity date
The Hongkong and Shanghai Banking Corporation Limited As The Trustee For Convertible Bond Holders	344,218	10,840	333,378	402,610	30-Jul-29
IMBC Group	3,727	63	3,664	4,147	31-Mar-33
BNP Paribas	5,722	860	4,862	8,398	29-Feb-32
HSBC Bank Australia Ltd	(93)	-	(93)	30,970	3 years from first utilization
Total	**353,574**	**11,763**	**341,811**	**446,125**	

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25.1. Bank loans

The bank loans outstanding at December 31, 2025 are in relation to the build-out of the Brussels South radiopharmaceutical production facility. Telix Pharmaceuticals (Belgium) SPRL (a wholly owned subsidiary of Telix) entered into two loan agreements, one with BNP Paribas and IMBC Group totaling €10,100,000 on a 10-year term, and a second loan with BNP Paribas totaling €2,000,000 on a two-year extendable term. All loans have a two-year repayment holiday period, with repayments due to commence from March 2024. The loans are secured by a fixed charge over the facility.

The loan agreements entitle BNP Paribas and IMBC Group to suspend or terminate all or part of the undrawn portion of the loan facilities with immediate effect and without prior notice. At December 31, 2025, the undrawn portion under the agreements was €1,989,000 ($2,330,000). As at the reporting date Telix has not received any notice to this effect.

The loan agreements require Telix Pharmaceuticals (Belgium) SRL to comply with various covenants relating to the conduct of the business, including non-payment of required repayments, specified cross-defaults (in the event of the use of trade bills) and ensuring cumulative losses of Telix Pharmaceuticals (Belgium) SPRL do not exceed 25% of its capital and reserves. Upon the occurrence of an event of default and in the event of a change of control, BNP Paribas and IMBC Group may accelerate payments due under the loan agreements or terminate the loan agreements. There were no events of default or changes of control during the year.

25.2. Working capital facility

On December 17, 2024, the Group entered into an agreement with HSBC Bank Australia Limited ("HSBC") to obtain a working capital facility of up to $33,415,000 (A$50,000,000). To date, the Group has not utilized this facility and has incurred establishment fee costs of $99,000 (A$150,000) associated with the facility.

The working capital facility is secured by a cash security deposit on an interest-bearing term deposit of $33,415,000 (A$50,000,000) held by HSBC with a maturity date equivalent to the term of the facility. There are no financial covenants associated with the facility. Refer to note 17 for further details.

25.3. Convertible bonds

On July 30, 2024 the Group completed the issue of $426,140,000 (A$650,000,000) in convertible bonds maturing in 2029. The bonds are convertible into fully paid ordinary shares in Telix Pharmaceuticals Limited. The initial conversion price of the convertible bonds is A$24.78 per share, subject to anti-dilution adjustments set out in the final terms and conditions of the convertible bonds. The net proceeds were $416,324,000, after transaction costs.

The convertible bonds will bear interest at a rate of 2.375 per cent per annum. Interest will be payable quarterly in arrears on October 30, January 30, April 30 and July 30 in each year, beginning on October 30, 2024. The convertible bonds will mature on or about July 30, 2029, unless redeemed, repurchased, or converted in accordance with their terms. The holders have the option to redeem all or some of the convertible bonds on July 30, 2027 at their principal amount together with accrued but unpaid interest accrued to that date. The convertible bonds are listed on the SGX.

The convertible bonds are presented in the Group's consolidated statement of financial position as follows:

	2025 US$'000	2024 US$'000 (Recast)
Opening balance	344,218	-
Face value of convertible bonds issued	-	426,140
Transaction costs	-	(9,816)
Other equity securities - value of conversion rights	-	(62,711)
Unwind of discount	22,502	9,088
Interest expense	9,945	4,239
Interest paid	(9,871)	(2,549)
Exchange differences	27,921	(20,173)
Closing balance	**394,715**	**344,218**
Current	11,692	10,840
Non-current	383,023	333,378
Total convertible bond liability	**394,715**	**344,218**

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The initial fair value of the liability portion of the bond was determined using a market interest rate for an equivalent non-convertible bond at the issue date. This fair value has been reduced by directly attributable transaction costs associated with the issue of the convertible bonds. The liability is subsequently recognized on an amortized cost basis until extinguished on conversion or maturity of the bonds. The remainder of the proceeds is allocated to the conversion option and recognized as part of the share capital reserve, net of income tax and a proportion of transaction costs, and is not subsequently remeasured. Refer to note 30.2.2 for further details.

25.4. Reconciliation of liabilities arising from financing activities

	Opening balance	Net cash inflow/ (outflow)	Other non-cash movements	Closing balance
	US$'000	US$'000	US$'000	US$'000
For the year ended December 31, 2025				
Bank loans	9,449	(524)	1,482	10,407
Working capital facility	(93)	-	(5)	(98)
Convertible bonds	344,218	(9,871)	60,368	394,715
Lease liabilities	6,588	(8,874)	64,368	62,082
	360,162	**(19,269)**	**126,213**	**467,106**
	(Recast)	(Recast)	(Recast)	(Recast)
For the year ended December 31, 2024				
Bank loans	6,275	3,592	(418)	9,449
Working capital facility	-	(99)	6	(93)
Convertible bonds	-	413,775	(69,557)	344,218
Lease liabilities	5,659	(1,821)	2,750	6,588
	11,934	**415,447**	**(67,219)**	**360,162**

Other non-cash movements include recognition of the conversion option as part of the share capital reserve, new leases entered into during the year, leases acquired via acquisitions of a business, disposal of leases and exchange differences.

25.5. Fair value

For bank loans, the fair values are not materially different to their carrying amounts, since the interest payable on those borrowings is either close to current market rates or the borrowings are of a short-term nature.

For the convertible bonds, the fair value is outlined below. The fair value is based on discounted cash flows using a current borrowing rate. They are classified as level 3 fair values in the fair value hierarchy (refer to note 33.6) due to the use of unobservable inputs, including own credit risk.

	2025		2024	
	Carrying amount	Fair value	Carrying amount	Fair value
	US$'000	US$'000	US$'000 (Recast)	US$'000 (Recast)
Bank loans	10,309	10,309	9,356	9,356
Convertible bonds	394,715	399,348	344,218	344,412

25.6. Risk exposures

Capital risk management: Capital is defined as the combination of shareholders' equity, reserves and net debt. The key objective of the Group when managing its capital is to safeguard its ability to continue as a going concern, so that the Group can continue to provide benefits for stakeholders and maintain an optimal capital and funding structure. The aim of the Group's capital management framework is to maintain, monitor and secure access to future funding arrangements to finance the necessary research and development activities being performed by the Group.

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26. Lease liabilities

The consolidated statement of financial position shows the following amounts relating to leases:

	2025	2024
	US$'000	US$'000 (Recast)
Balance at January 1,	6,588	5,659
Additions	8,281	1,837
Acquisition of businesses	52,008	1,104
Interest expense	3,637	491
Lease payments (principal and interest)	(8,874)	(1,821)
Exchange differences	442	(682)
Balance at December 31,	**62,082**	**6,588**

Lease liabilities	2025	2024
	US$'000	US$'000 (Recast)
Current	5,548	1,546
Non-current	56,534	5,042
Total lease liabilities	**62,082**	**6,588**

The consolidated statement of comprehensive income shows the following amounts relating to leases:

Interest expense relating to leases	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
Properties	3,476	428	402
Motor vehicles	161	63	21
Total lease interest	**3,637**	**491**	**423**

The total cash outflow for leases in 2025 comprises $5,237,000 (2024: $1,317,000, 2023: $1,266,000) principal and $3,637,000 (2024: $491,000, 2023: $423,000) interest payments.

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27. Provisions

	Government grant liability	Decommissioning liability	Total
	US$'000	US$'000	US$'000
Balance at January 1, 2025	**1,858**	**7,248**	**9,106**
Remeasurement of provisions	(12)	-	(12)
Unwind of discount	169	276	445
Charged to profit or loss	**157**	**276**	**433**
Exchange differences	254	953	1,207
Amounts adjusted to property, plant and equipment	-	(780)	(780)
Provision utilized	(223)	(4)	(227)
Balance at December 31, 2025	**2,046**	**7,693**	**9,739**
Current	562	-	562
Non-current	1,484	7,693	9,177
Total provisions	**2,046**	**7,693**	**9,739**
	(Recast)	(Recast)	(Recast)
Balance at January 1, 2024	**1,822**	**4,048**	**5,870**
Remeasurement of provisions	458	-	458
Unwind of discount	133	123	256
Charged to profit or loss	**591**	**123**	**714**
Exchange differences	(111)	(409)	(520)
Amounts adjusted to property, plant and equipment	117	3,656	3,773
Provision utilized	(561)	(170)	(731)
Balance at December 31, 2024	**1,858**	**7,248**	**9,106**
Current	576	-	576
Non-current	1,282	7,248	8,530
Total provisions	**1,858**	**7,248**	**9,106**

27.1. Government grant liability

Telix Innovations has received grants from the Walloon regional government in Belgium. These grants meet the definition of a financial liability as defined in IFRS 9 *Financial Instruments* and were designated to be measured at fair value through profit and loss.

The grants are repayable to the Walloon government based on a split between fixed and variable repayments. The fixed proportion is based on contractual cash flows agreed with the Walloon government. The variable cash flows are based on a fixed percentage of future sales and are capped at an agreed upon level.

The Group has estimated that the full variable repayments will be made up to the pre-agreed capped amount. The key inputs into this calculation are the risk adjusted discount rate of 3.9% (2024: 3.3%), the expected sales volumes and the net sales price per unit. The expected sales volumes and net sales price per unit assumptions are consistent with those utilized by the Group in the calculation of the contingent consideration liability and intellectual property valuation.

27.2. Decommissioning liability

Telix owns and operates a radiopharmaceutical production facility in Belgium. The site has cyclotrons installed in concrete shielded vaults which also contain some nuclear contamination associated with past manufacturing activities. Telix has an obligation to remove the cyclotrons and restore the site.

In 2024, new cyclotrons were installed in the facility, which will be decommissioned at the end of the operating life of the facility. A provision for dismantling and removal of $3,656,000 has been recognized with respect to these cyclotrons, in addition to existing remediation costs to remove nuclear contamination in the vaults.

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The total decommissioning costs expected to be incurred in 2041 of €12,451,000 (2024: €12,451,000) have been discounted using the Belgium risk-free rate of 3.9% (2024: 3.3%) and translated to US$ at the exchange rate at December 31, 2025.

The provision represents the best estimate of the expenditures required to settle the present obligation at December 31, 2025. While the Group has made its best estimate in establishing its decommissioning liability, because of potential changes in technology as well as safety and environmental requirements, plus the actual timescale to complete decommissioning, the ultimate provision requirements could vary from the Group's current estimates. Any subsequent changes in estimate which alter the level of the provision required are also reflected in adjustments to the intangible license asset. Each year, the provision is increased to reflect the unwind of discount and to accrue an estimate for the effects of inflation, with the charges being presented in the consolidated statement of comprehensive income or loss. Actual payments for commencement of decommissioning activity are disclosed as provision utilized in the above table.

28. Contingent consideration

	US$'000
Balance at January 1, 2025	**72,049**
Remeasurement of contingent consideration	(11,618)
Unwind of discount	2,201
Charged to profit or loss	**(9,417)**
Exchange differences	1,946
Acquisition of businesses	17,492
Amounts adjusted to intangible assets	(383)
Payments for contingent consideration (Operating)	(51,786)
Payments for contingent consideration (Investing)	(7,667)
Balance at December 31, 2025	**22,234**
Current	11,540
Non-current	10,694
Total contingent consideration	**22,234**

	(Recast)
Balance at January 1, 2024	**63,453**
Remeasurement of contingent consideration	7,326
Unwind of discount	9,546
Charged to profit or loss	**16,872**
Exchange differences	(2,783)
Acquisition of businesses	19,783
Amounts adjusted to intangible assets	1,159
Payments for contingent consideration (Operating)	(23,902)
Payments for contingent consideration (Investing)	(2,533)
Balance at December 31, 2024	**72,049**
Current	53,215
Non-current	18,834
Total contingent consideration	**72,049**

28.1. Telix Innovations (formerly ANMI)

The Group acquired ANMI on December 24, 2018. The Group is liable for future variable payments which are calculated based on the percentage of net sales for five years following the achievement of marketing authorization of the product.

The percentage of net sales varies depending on the net sales achieved in the U.S. and the rest of the world. The Group also held and exercised an option to buy-out the remaining future variable payments during the year, as the specified sales thresholds were met.

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As at consolidated statement of financial position date, the Group remeasured the contingent consideration by $1,973,000 as a result of actual sales volumes and fully settled the outstanding balance of $51,657,000.

28.2. Telix Switzerland (formerly TheraPharm)

Telix acquired TheraPharm on December 14, 2020. Part of the consideration for the acquisition was in the form of future payments contingent on certain milestones. These are:

- €5,000,000 cash payment upon successful completion of a Phase 3 pivotal registration trial
- €5,000,000 cash payment upon achievement of marketing authorization in Europe or the U.S., whichever approval comes first, and
- 5% of net sales for the first three years following marketing authorization in Europe or the U.S., whichever approval comes first.

The valuation of the contingent consideration has been performed utilizing a discounted cash flow model that uses certain unobservable assumptions. These key assumptions include risk adjusted post-tax discount rate of 13.2% (2024: 12.5%), marketing authorization date, expected sales volumes over the forecast period, net sales price per unit and approval for marketing authorization probability success factor.

The following table summarizes the quantitative information about these assumptions, including the impact of sensitivities from reasonably possible changes where applicable:

Contingent consideration valuation

Unobservable input	Methodology	December 31, 2025
Risk adjusted post-tax discount rate	The post-tax discount rate used in the valuation has been determined based on required rates of returns of listed companies in the biotechnology industry (having regards to their stage of development, size and risk adjustments).	A 0.5% increase / decrease in the post-tax discount rate would decrease / increase the contingent consideration by $68,000.
Expected sales volumes	This is determined through assumptions on target market population, penetration and growth rates in the United States and Europe.	A 10% increase / decrease in the sales volumes would increase / decrease the contingent consideration by $95,000.
Net sales price per unit	The net sales price per unit is estimated based on comparable products currently in the market.	A 10% increase / decrease in the net sales price per unit would increase / decrease the contingent consideration by $95,000.
Approval for marketing authorization probability success factor	This assumption is based on management's estimate for achieving regulatory approval and is determined through benchmarking of historic approval rates.	An increase / decrease in the probability of success factor by 10% would increase / decrease the contingent consideration by $1,033,000.

28.3. IsoTherapeutics

The Group acquired IsoTherapeutics on April 9, 2024. The Group is liable for $5,000,000 which is payable in cash for performance-related milestone payments that are subject to meeting milestone conditions within twelve months of closing. During the year ended December 31, 2025, the milestone conditions were satisfied and the associated liability was settled.

28.4. ARTMS

Telix acquired ARTMS on April 11, 2024. Part of the consideration for the acquisition included US$24.5 million in contingent future earn-out payments which is payable in cash following achievement of certain clinical or commercial milestones. All earn-outs which have not otherwise expired will terminate on the 10 year anniversary of completion.

In addition to the above, the contingent consideration includes future royalty payments for a low single to low double-digit percentage of net sales of ARTMS products or Telix products.

The contingent consideration liability has been valued using a discounted cash flow model that utilizes certain unobservable level 3 inputs. These key assumptions include risk adjusted post-tax discount rate of 14.3% (2024: 15.0%), FDA approval dates, expected sales volume over the forecast period and net sales price per unit and a probability success factor in relation to ARTMS achieving its clinical or commercial milestones.

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The following table summarizes the quantitative information about these assumptions, including the impact of sensitivities from reasonably possible changes where applicable:

Contingent consideration valuation

Unobservable input	Methodology	December 31, 2025
Risk adjusted post-tax discount rate	The post-tax discount rate used in the valuation has been determined based on required rates of returns of listed companies in the biotechnology industry (having regards to their stage of development, size and risk adjustments).	A 0.5% increase / decrease in the post-tax discount rate would decrease / increase the contingent consideration by $90,000.
Expected sales volumes - ARTMS and Telix products	This is determined through assumptions on target market population, penetration and growth rates in the United States and Europe.	A 10.0% increase / decrease in the sales volumes would increase / decrease the contingent consideration by $145,000.
Net sales price per unit	The net sales price per unit is estimated based on comparable products currently in the market.	A 10.0% increase / decrease in the net sales price per unit would increase / decrease the contingent consideration by $180,000 across the different royalties.
Milestone achievement probability of success factor	This assumption is based on management's estimate for achieving the clinical or commercial milestones.	An increase / decrease in the probability of success factor by 10.0% would increase / decrease the contingent consideration by $1,339,000.

29. Employee benefit obligations

	2025	2024
	US$'000	US$'000 (Recast)
Bonuses	15,255	11,238
Annual leave	4,116	2,906
Long service leave	444	305
Balance at December 31,	**19,815**	**14,449**
Current	19,371	14,144
Non-current	444	305
Total employee benefit obligations	**19,815**	**14,449**

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30. Equity

30.1. Share capital

	2025	2024	2023	2025	2024	2023
	Number '000	Number '000	Number '000	US$'000	US$'000 (Recast)	US$'000 (Recast)
Balance at January 1,	**334,725**	**323,727**	**316,343**	**414,012**	**315,178**	**265,551**
Shares issued through the exercise of share options and warrants[1]	1,693	525	3,879	29,722	5,357	27,857
Shares issued for Dedicaid[2]	38	-	207	467	-	1,213
Shares issued for Lightpoint[3]	269	-	3,298	4,467	-	20,557
Shares issued for IsoTherapeutics[4]	-	718	-	-	5,816	-
Shares issued for ARTMS[5]	-	5,675	-	-	46,733	-
Shares issued for QSAM[6]	-	4,080	-	-	40,928	-
Shares issued for Imaginab[7]	2,053	-	-	31,294	-	-
Transaction costs arising on new share issues	-	-	-	-	-	-
Balance at December 31,	**338,778**	**334,725**	**323,727**	**479,962**	**414,012**	**315,178**

1. Options exercised during the year through the employee Equity Incentive Plan resulted in 1,693,000 (2024: 525,000, 2023: 3,879,000) shares being issued of total value of $29,722,000 (2024: $5,357,000, 2023: $27,857,000).

2. On April 27, 2023, the Group completed the acquisition of Dedicaid GmbH. The consideration for the acquisition comprised 207,000 in Telix shares at a 10-day volume weighted average price of shares on the execution date of A$8.73 per share. During the year, the Group issued 37,575 fully paid ordinary shares upon satisfaction of certain milestones.

3. On November 1, 2023, the Group completed the acquisition of Lightpoint through the issue of 3,298,000 fully paid ordinary Telix shares at A$9.37 per share. During the year, the Group issued 269,075 fully paid ordinary shares in satisfaction of Lightpoint milestone rights.

4. On April 9, 2024, the Group completed the acquisition of IsoTherapeutics. The consideration included the issue of 717,587 fully paid ordinary Telix shares at A$12.42 per share.

5. On April 11, 2024, the Group completed the acquisition of ARTMS. The consideration included the issue of 5,674,365 fully paid ordinary Telix shares at A$12.62 per share.

6. On May 3, 2024, the Group completed the acquisition of QSAM. The purchase price included the issue of 3,671,120 fully paid ordinary Telix shares at $14.80 per share and a further 409,026 fully paid ordinary Telix shares at $18.05 per share.

7. On January 30, 2025, the Group completed the acquisition of ImaginAb. The consideration included the issue of 2,053,311 fully paid ordinary Telix shares at A$24.37 per share.

The weighted average ordinary shares for the period January 1, 2025 to December 31, 2025 is 337,879,901 (2024: 331,226,491, 2023: 319,180,783). The Company does not have a limited amount of authorized capital under Australian law.

Rights applying to securities:

1. *Ordinary shares:* Ordinary shares entitle the holder to participate in dividends, and to share in the proceeds of winding up the Company in proportion to the number of and amounts paid on the shares held.

2. *Options and rights:* Holders of Options and rights have no voting rights. Information relating to the Company's Employee Incentive Plan ("EIP"), including details of Options issued, exercised and lapsed during the financial year, is set out in note 31.

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30.2. Share capital reserve

	2025	2024	2023	2025	2024	2023
	Number '000	Number '000	Number '000	US$'000	US$'000 (Recast)	US$'000 (Recast)
Balance at January 1	**-**	**-**	**-**	**15,945**	**(41,742)**	**(18,231)**
Treasury shares acquired	1,693	525	3,877	(27,557)	(4,697)	(23,511)
Issue of convertible bonds	-	-	-	-	63,849	-
Transaction costs arising on convertible bonds issue	-	-	-	-	(1,465)	-
Shares allocated to employees	(1,693)	(525)	(3,877)	-	-	-
Balance at December 31	**-**	**-**	**-**	**(11,612)**	**15,945**	**(41,742)**

30.2.1. Treasury shares

Ordinary shares in the Company were purchased by the Telix Pharmaceuticals Employee Share Trust for the purpose of issuing shares under the Equity Incentive Plan. These shares are allocated to employees and are not held within the Employee Share Trust (see note 31 for further information).

30.2.2. Conversion right of convertible bonds

The amount shown for the issue of convertible bonds is the initial value of the conversion rights relating to the convertible bonds.

30.3. Other reserves

	Foreign currency translation reserve	Share-based payments reserve	Financial assets at FVOCI reserve	Total
	US$'000	US$'000	US$'000	US$'000
Balance as at January 1, 2025	**(1,611)**	**81,404**	**(3899)**	**75,894**
Other comprehensive (loss)/income	(5,757)	-	(1,242)	(6,999)
Total comprehensive (loss)/income	**(5,757)**	**-**	**(1,242)**	**(6,999)**
Share-based payments to employees	-	19,350	-	19,350
Share-based payments associated with acquisitions	-	23,287	-	23,287
Transfer on satisfaction of acquisition performance rights	-	(4,467)	-	(4,467)
Transfer on exercise of options	-	(5,501)	-	(5,501)
	-	**32,669**	**-**	**32,669**
Balance as at December 31, 2025	**(7,368)**	**114,073**	**(5,141)**	**101,564**

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	Foreign currency translation reserve	Share-based payments reserve	Financial assets at FVOCI reserve	Total
	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)
Balance as at January 1, 2024	**(7,179)**	**24,119**	**(612)**	**16,328**
Other comprehensive	5,568	-	(3,287)	2,281
Total comprehensive income/(loss)	**5,568**	**-**	**(3,287)**	**2,281**
Share-based payments to employees	-	12,928	-	12,928
Share-based payments associated with acquisitions	-	44,877	-	44,877
Transfer on exercise of options	-	(520)	-	(520)
	-	**57,285**	**-**	**57,285**
Balance as at December 31, 2024	**(1,611)**	**81,404**	**(3,899)**	**75,894**

	Foreign currency translation reserve	Share-based payments reserve	Financial assets at FVOCI reserve	Total
	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)
Balance as at January 1, 2023	**(5,316)**	**6,456**	**-**	**1,140**
Other comprehensive (loss)/income	(1,863)	-	(612)	(2,475)
Total comprehensive (loss)/income	**(1,863)**	**-**	**(612)**	**(2,475)**
Share-based payments to employees	-	5,848	-	5,848
Share-based payments associated with acquisitions	-	14,158	-	14,158
Transfer on exercise of options	-	(2,343)	-	(2,343)
	-	**17,663**	**-**	**17,663**
Balance as at December 31, 2023	**(7,179)**	**24,119**	**(612)**	**16,328**

30.4. Share-based payments reserve

	2025	2024	2023
	Number '000	Number '000	Number '000
Balance at January 1	**25,522**	**14,601**	**11,736**
EIP options issued	7,185	9,877	6,689
Options exercised	(2,272)	(619)	(4,524)
Options lapsed	(1,850)	(2,621)	(1,824)
Performance Rights issued[1]	3,915	4,284	2,524
Performance Rights exercised	(269)	-	-
Performance Rights lapsed	(488)	-	-
Balance at December 31	**31,743**	**25,522**	**14,601**

1. Relates to the acquisition of ImaginAb in 2025, QSAM in 2024 and Lightpoint in 2023.

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30.5. Financial assets at FVOCI reserve

The group has elected to recognize changes in the fair value of certain investments in equity securities in Other comprehensive income (OCI), as explained in note 17. These changes are accumulated within the FVOCI reserve within equity.

The table below shows how the FVOCI reserve relates to equity securities:

	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
Balance at January 1	(3,899)	(612)	-
Revaluation - gross	(1,242)	(3,287)	(612)
Deferred tax	-	-	-
Balance at December 31	**(5,141)**	**(3,899)**	**(612)**

31. Share-based payments

Equity Incentive Plan and Options

The Equity Incentive Plan ("EIP") was established to allow the Board of Telix to make offers to Eligible Employees to acquire securities in the Company and to otherwise incentivize employees. 'Eligible Employees' includes full time, part time or casual employees of a Group Company, a Non-Executive Director of a Group Company, a Contractor, or any other person who is declared by the Board to be eligible.

The Board may, from time to time and in its absolute discretion, invite Eligible Employees to participate in a grant of Incentive Securities, which may comprise Rights (including Performance Share Appreciation Rights), Options, and/or Restricted Shares. Vesting of Incentive Securities under the EIP is subject to any vesting or performance conditions determined by the Board. Incentive Securities are normally granted under the EIP for no consideration and carry no dividend or voting rights. When exercised, each Incentive Security is convertible into one ASX or ADS-backed Share.

Non-Executive Directors are able to participate in the Equity Incentive Plan, under which equity may be issued subject to Shareholder approval. Options were issued to Non-Executive Directors not as an 'incentive' under the EIP but as a means of cost-effective consideration for agreeing to join the Board. The details of Incentive Securities on issue to individual Directors can be found in the Remuneration report for the year ended December 31, 2025. For the purposes of this table and to illustrate the total number of Incentive Securities on issue under the rules of the EIP, all Incentive Securities issued to Non-Executive Directors, Executive Directors, employees and contractors are included.

Incentive Securities contain a cashless exercise clause that allows employees to exercise the securities for a cash exercise price of $nil in exchange for forfeiting a portion of their vested securities.

ASX securities

	2025	2025	2024	2024
	Number '000	WAEP1[1] AU$	Number '000	WAEP1 AU$
Balance at January 1,	**18,715**	**8.58**	**12,077**	**5.59**
Granted during the year	2,481	24.30	9,878	11.19
Exercised during the year	(2,248)	4.48	(619)	3.34
Lapsed/forfeited during the year	(1,558)	11.67	(2,621)	5.88
Balance at December 31,	**17,390**	**11.06**	**18,715**	**8.58**
Vested and exercisable at December 31,	**1,648**	**5.30**	**754**	**4.91**

[1] WAEP - weighted average exercise price

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ADS-backed securities

	2025 Number '000	2025 WAEP[1] US$	2024 Number '000	2024 WAEP[1] US$
Balance at January 1,	**-**	**-**	**-**	**-**
Granted during the year	**4,704**	16.10	-	**-**
Exercised during the year	**(24)**	8.02	-	**-**
Lapsed/forfeited during the year	**(292)**	19.84	-	**-**
Balance at December 31,	**4,388**	**15.90**	**-**	**-**
Vested and exercisable at December 31,	**-**	**-**	**-**	**-**

Expense arising from share-based payments transactions:

	2025 US$	2024 US$ (Recast)	2023 US$ (Recast)
Options issued under EIP	19,146,002	12,927,880	5,847,731
Total	**19,146,002**	**12,927,880**	**5,847,731**

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Equity Incentive Plan and Options

Details of the number of options convertible to ASX shares issued under the EIP outstanding at the end of the year:

Grant date	Vesting date	Expiry date	Exercise price	Options on issue at January 1, 2025	Issued during the year	Vested during the year	Exercised during the year	Lapsed during the year	Options on issue at December 31, 2025
			A$	'000	'000	'000	'000	'000	'000
01-27-2021	10-28-2022	01-26-2026	4.38	349	-		(320)	-	29
07-27-2021	10-28-2022	07-27-2026	5.37	405	-		(197)	-	208
07-27-2021	07-27-2025	07-27-2026	0.00	100	-		-	-	100
04-05-2022	12-31-2024	04-04-2027	4.95	1,920	-	1,920	(1,040)	(40)	840
04-05-2022	12-31-2024	04-04-2027	0.00	150	-	150	(120)	-	30
10-24-2022	12-31-2024	10-24-2027	6.15	913	-	913	(372)	-	541
05-02-2023	12-31-2025	03-27-2028	6.90	3,905	-		-	(145)	3,760
21-Mar-24. 22-May-24	12-31-2025	05-16-2028	10.04	990	-		-	(195)	795
07-06-2023	31-Mar-25 or 31-Dec-25	15-Jun-25, 15-Jun-28	0.00	215	-		(100)	-	115
10-18-2023	06-30-2026	09-20-2028	11.37	610	-		-	(130)	480
10-31-2023	12-31-2026	10-31-2028	0.00	406	-		-	(64)	342
10-31-2023	12-31-2027	10-31-2029	0.00	406	-		-	(64)	342
11-30-2023	06-30-2026	11-14-2028	8.72	884	-		-	(47)	837
03-08-2024	12-31-2026	03-31-2029	0.00	220	-		-	-	220
03-08-2024	12-31-2027	03-31-2030	0.00	220	-		-	-	220
21-Mar-24, 22-May-24	03-31-2027	03-31-2029	11.94	4,447	-		-	(428)	4,019
04-26-2024	03-31-2027	03-31-2029	0.00	35	-		-	-	35
08-26-2024	04-01-2025	03-31-2027	0.00	130	-		(85)	-	45
08-26-2024	03-31-2027	04-04-2027	0.00	100	-		-	-	100
09-19-2024	03-31-2028	03-31-2029	18.45	1,696	-		-	(315)	1,381
09-19-2024	03-31-2028	03-31-2030	18.45	300	-		-	-	300
10-17-2024	11-01-2027	11-01-2029	0.00	157	-		-	(19)	138
10-17-2024	11-01-2028	11-01-2030	0.00	157	-		-	(19)	138
01-01-2025	03-31-2028	03-31-2030	28.67	—	1,701		-	(61)	1,640
01-01-2025	02-28-2026	03-31-2028	0.00	—	11		-	-	11
10-24-2025	03-31-2028	03-31-2028	14.90	—	743		-	(30)	713
03-17-2025	09-01-2025	09-30-2025	12.16	—	14		(14)	-	-
03-17-2025	03-01-2026	03-15-2026	22.40	—	12		-	(1)	11
				18,715	**2,481**	**2,983**	**(2,248)**	**(1,558)**	**17,390**

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Details of the number of options convertible to ADS-backed shares issued under the EIP outstanding at the end of the year:

Grant date	Vesting date	Expiry date	Exercise price	Options on issue at January 1, 2025	Issued during the year	Vested during the year	Exercised during the year	Lapsed during the year	Options on issue at December 31, 2025
			US$	'000	'000	'000	'000	'000	'000
01-01-2025	03-31-2028	03-31-2030	19.99	-	2,881		-	(287)	2,594
01-01-2025	02-27-2026	03-13-2026	0.00	-	10		-	-	10
10-24-2025	03-31-2028	03-31-2028	9.98	-	1,758		-	-	1,758
03-17-2025	09-01-2025	09-30-2025	8.02	-	26		(24)	(2)	-
03-17-2025	03-01-2026	03-15-2026	13.61	-	29		-	(3)	26
				-	**4,704**	**-**	**(24)**	**(292)**	**4,388**

The assessed fair value of recent tranches of options granted are outlined below. The fair value at grant date is independently determined using the Black Scholes Model. The model inputs for options granted during the year ended December 31, 2025 are included below:

ASX securities

	January 2025	January 2025	May 2025	October 2025	March 2025	March 2025
Fair value	A$14.09	A$25.56	A$25.68	A$6.31	A$15.70	A$7.70
Consideration	Nil	Nil	Nil	Nil	Nil	Nil
Exercise price	A$28.67	A$0.00	A$0.00	A$14.90	A$12.16	A$22.40
Grant date	01-01-2025	01-01-2025	05-21-2025	10-24-2025	03-17-2025	03-17-2025
Expiry date	03-31-2030	03-31-2028	03-31-2028	03-31-2028	09-30-2025	03-15-2026
Term	5 years	3 years	3 years	2 years	1 years	1 years
Share price at grant date	A$ 27.80	A$ 25.56	A$ 25.68	A$ 13.66	A$ 27.36	A$ 27.36
Volatility	55%	47%	47%	55%	44%	44%
Dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Risk-free rate	3.88%	3.56%	3.56%	3.51%	3.56%	3.56%

ADS-backed securities

	January 2025	January 2025	October 2025	March 2025	March 2025
Fair value	US$8.44	US$17.43	US$4.25	US$10.10	US$5.83
Consideration	Nil	Nil	Nil	Nil	Nil
Exercise price	US$19.99	US$0.00	US$9.98	US$8.02	US$13.61
Grant date	01-01-2025	01-01-2025	10-24-2025	03-17-2025	03-17-2025
Expiry date	03-31-2030	03-13-2026	03-31-2028	09-30-2025	03-15-2026
Term	5 years	1 years	2 years	1 years	1 years
Share price at grant date	A$ 17.53	A$ 17.43	A$ 9.16	A$ 17.60	A$ 17.60
Volatility	55%	50%	55%	56%	51%
Dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%
Risk-free rate	4.01%	4.01%	3.64%	4.01%	4.01%

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32. Cash flow information

32.1. Reconciliation of (loss)/profit after income tax to net cash (used in)/from operating activities

	2025	2024	2023
	US$'000	US$'000 (Recast)	US$'000 (Recast)
(Loss)/profit before income tax	(5,266)	37,915	2,594
Adjustments for			
Depreciation and amortization	21,409	5,284	4,155
Impairments/(impairment reversals) of intangible assets	566	(475)	550
Fair value remeasurement of contingent consideration	(11,618)	7,326	22,686
Fair value remeasurement of provisions	(12)	510	(129)
Unwind of discount	40,418	24,118	8,848
Share-based payments	19,350	12,928	5,848
Foreign exchange (losses)/gains	(1,926)	(11,984)	1,478
Interest paid	(13,700)	(3,087)	(385)
Income taxes paid	(21,298)	(2,033)	(6,859)
Change in assets and liabilities			
Increase in trade and other receivables	(20,465)	(37,491)	(18,620)
Increase in inventory	(7,639)	(2,127)	(6,553)
Decrease/(increase) in other current assets	10,241	(7,136)	(7,107)
Decrease/(increase) in other non-current assets	-	365	(176)
Increase in trade creditors	28,976	28,837	21,059
Deduct trade and other payables capitalized to intangible assets	-	-	(2,973)
Contingent consideration payments classified as operating	(51,786)	(23,902)	(10,917)
Increase in employee benefit obligations	4,814	5,206	4,205
(Decrease)/Increase in provisions	(227)	(538)	-
Decrease in contract liabilities	(9,130)	(6,226)	(3,431)
Net cash (used in)/from operating activities	**(17,293)**	**27,490**	**14,273**

33. Financial risk management

The Group's activities expose it to a variety of financial risks: market risk, credit risk and liquidity risk. The overall risk management program focuses on the unpredictability of markets and seeks to minimize potential adverse effects on the financial performance of the Group. The Group uses different methods to measure different types of risk to which it is exposed.

33.1. Interest rate risk

The Group's borrowings that have been drawn down at December 31, 2025 have fixed interest rates, and therefore the Group is not exposed to any significant interest rate risk.

33.2. Price risk

The Group's exposure to equity securities price risk arises from investments held by the Group and classified in the consolidated statement of financial position at fair value through other comprehensive income ("FVOCI") (note 17).

The amounts recognized in other comprehensive income in relation to investments held by the Group are disclosed in note 30.5.

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33.3. Foreign currency risk

The Group operates internationally and is exposed to foreign exchange risk, primarily the Australian dollar and Euro. Foreign exchange risk arises from commercial activities outside the U.S. and research and development activities in Europe.

The Group's treasury risk management policy is to settle all US dollar denominated expenditure with US dollar denominated receipts from sales of Illuccix in the U.S. The Group also manages currency risk by making decisions as to the levels of cash to hold in each currency by assessing its future activities which will likely be incurred in those currencies. Any remaining foreign currency exposure has therefore not been hedged.

We have both foreign currency receivables and payables, predominantly denominated in Australian dollars and Euros. We had a surplus of foreign currency receivables and financial assets over payables of $67.4 million as of December 31, 2025 (December 31, 2024: $49.6 million).

The Group's exposure to the risk of changes in foreign exchange rates also relates to the Group's net investments in foreign subsidiaries, which predominantly include denominations in Euro and Australian dollar, however given the level of current investments in non US dollar denominated subsidiaries, the impact is limited.

As at December 31, 2025, the Group held 52.8% (2024: 32.0%) of its cash in Australian dollars, 39.7% (2024: 64.9%) in US dollars, 5.5% (2024: 2.8%) in Euros (EUR), 0.1% (2024: nil) in Japanese Yen (JPY), 0.3% (2024: 0.1%) in British pounds, 0.5% (2024: 0.1%) in Canadian dollars and 1.0% (2024: 0.1%) in Swiss Francs (CHF).

Exposure

The balances held at December 31, 2025 that give rise to currency risk exposure are presented in US dollars below:

As at December 31, 2025

	USD	AUD	EUR	CHF	JPY	GBP	CAD
	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000	US$'000
Cash and cash equivalents	56,371	74,891	7,850	1,445	134	413	762
Trade receivables	126,056	540	2,606	-	-	-	-
Financial assets	-	33,749	3,345	-	-	-	-
Trade payables	(80,802)	(3,254)	(13,328)	(642)	(93)	(546)	(223)
Other current liabilities	(6,955)	-	(4,700)	-	-	-	-
Other non-current liabilities	(3,517)	-	-	-	-	-	-
Government grant	-	-	(2,046)	-	-	-	-
Decommissioning liability	-	-	(7,694)	-	-	-	-
Contingent consideration	(19,544)	-	(2,686)	-	-	-	-
Borrowings	-	(394,617)	(10,407)	-	-	-	-

The balances held at December 31, 2024 that give rise to currency risk exposure are presented in US dollars below:

	USD	AUD	EUR	CHF	JPY	GBP	CAD
	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)
Cash and cash equivalents	285,345	140,797	12,493	356	129	626	253
Trade receivables	84,564	455	1,466	-	-	-	-
Financial assets	-	30,972	3,774	-	-	-	
Trade payables	(47,620)	(7,658)	(13,659)	(462)	(17)	(996)	(1,171)
Government grant liability	-	-	(1,858)	-	-	-	-
Decommissioning liability	-	-	(7,248)	-	-	-	-
Contingent consideration liability	(56,627)	(519)	(14,903)	-	-	-	-
Borrowings	-	(333,272)	(9,449)	-	-	-	-

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Sensitivity

Outlined below is a sensitivity analysis which assesses the impact that a change of +/- 10% in the exchange rates as at each reporting date would have on the Group's reported profit/(loss) after income tax and/or equity balance.

Impact on post-tax profit/(loss)

	2025	2025	2025	2025	2024	2024	2024	2024
	+10% Profit/ (loss)	-10% Profit/ (loss)	+10% Equity	-10% Equity	+10% Profit/ (loss)	-10% Profit/ (loss)	+10% Equity	-10% Equity
	US$'000	US$'000	US$'000	US$'000	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)	US$'000 (Recast)
AUD	-	-	26,140	(31,949)	-	-	17,449	(21,326)
EUR	(224)	1,983	951	(3,704)	1,248	(1,525)	1,620	(1,980)
CHF	-	-	(73)	89	-	-	(29)	36
JPY	-	-	-	-	1	(1)	(11)	13
GBP	19	(24)	9	(11)	1	(2)	33	(40)
CAD	-	-	39	48	1	(1)	80	(98)
Total	**(205)**	**1,959**	**27,066**	**(35,527)**	**1,251**	**(1,529)**	**19,142**	**(23,395)**

33.4. Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Group. Credit risk arises from cash and cash equivalents and credit exposures to customers, including outstanding receivables.

Credit risk is managed on a group basis. If customers are independently rated, these ratings are used. Otherwise, if there is no independent rating, the Group assesses the credit quality of the customer, taking into account its financial position, past experience and other factors. Individual risk limits are set based on internal or external ratings. The compliance with credit limits by customers is regularly monitored. The Group obtains guarantees where appropriate to mitigate credit risk.

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables.

To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the days past due. The expected loss rates are based on historical payment profiles of sales and the corresponding historical credit losses experienced. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

Trade receivables are written off where there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the Group, and the failure to make contractual payments for a period of greater than 120 days past due.

Impairment losses on trade receivables are presented within selling, general and administration costs within profit or loss. Subsequent recoveries of amounts previously written off are credited against the same line item.

As at December 31, 2025, the expected credit losses are $2,377,000 (2024: $131,000). The following tables sets out the aging of trade receivables, according to their due date:

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Aged trade receivables

	Expected credit losses		Gross carrying amount	
	2025	2024	2025	2024
	US$'000	US$'000 (Recast)	US$'000	US$'000 (Recast)
Not past due:	-	-	122,644	80,900
Past due:				
30 days	(2)	(19)	3,129	3,689
60 days	(5)	(6)	455	548
90 days	(41)	(19)	518	621
120 days	(2,329)	(87)	4,833	1,301
Total	**(2,377)**	**(131)**	**131,579**	**87,059**

Credit risk concentration profile

The Group has a significant credit risk exposure to three distributors of 71% (2024: 87% to three distributors). The Group defines major credit risk as exposure to a concentration exceeding 10% of a total class of such asset.

33.5. Liquidity risk

The Group is exposed to liquidity and funding risk from operations and from external borrowings, where the risk is that the Group may not be able to refinance debt obligations or meet other cash outflow obligations when required. Vigilant liquidity risk management requires the Group to maintain sufficient liquid assets (mainly cash and cash equivalents). The Group manages liquidity risk by maintaining adequate cash reserves by continuously monitoring actual and forecast cash flows and matching the maturity profiles of financial assets and liabilities.

Remaining contractual maturities:

The following tables detail the Group's remaining contractual maturity for its financial instrument liabilities. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the financial liabilities are required to be paid. The tables include both interest and principal cash flows disclosed as remaining contractual maturities and therefore these totals may differ from their carrying amount in the Consolidated statement of financial position.

As at December 31, 2025	1-6 months US$'000	6-12 months US$'000	1-5 years US$'000	Over 5 years US$'000	Total contractual cash flows US$'000	Carrying amount of liabilities US$'000
Non-derivatives						
Trade and other payables	114,261	36,088	-	-	150,349	150,349
Other non-current liabilities	-	-	3,673	-	3,673	3,517
Borrowings	5,860	5,958	469,257	3,024	484,099	405,024
Lease liabilities	3,051	3,969	44,409	34,994	86,423	62,082
Government grant liability	837	564	1,236	169	2,806	2,046
Contingent consideration	8,755	3,545	11,737	665	24,702	22,234
Total financial liabilities	**132,764**	**50,124**	**530,312**	**38,852**	**752,052**	**645,252**

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As at December 31, 2024	1-6 months US$'000 (Recast)	6-12 months US$'000 (Recast)	1-5 years US$'000 (Recast)	Over 5 years US$'000 (Recast)	Total contractual cash flows US$'000 (Recast)	Carrying amount of liabilities US$'000 (Recast)
Non-derivatives						
Trade and other payables	86,790	-	-	-	86,790	86,790
Borrowings	5,236	5,243	444,047	3,161	457,687	353,574
Lease liabilities	915	906	4,923	84	6,828	6,588
Government grant liability	749	304	823	113	1,989	1,858
Contingent consideration	53,042	-	23,652	1,232	77,926	72,049
Total financial liabilities	**146,732**	**6,453**	**473,445**	**4,590**	**631,220**	**520,859**

33.6. Fair value

This section explains the judgments and estimates made in determining the fair values of the financial instruments that are recognized and measured at fair value in the financial statements.

33.6.1. Financial assets

Financial assets are categorized as either level 1 or level 3 financial assets and remeasured at each reporting date with movements recognized in other comprehensive income. The inputs used in the level 1 fair value calculations are with reference to published price quotations for the associated equity instruments in an active market.

Level 3 financial assets are subject to key assumptions and unobservable inputs which include risk adjusted post-tax discount rates and forecasted discounted cashflows. These inputs significantly impact the underlying value of these assets.

Sensitivity of level 1 financial assets

An increase/(decrease) of 10% in the share price of each financial asset while holding all other variables constant will increase/(decrease) other comprehensive income by $102,000 (2024: $234,000).

Sensitivity of level 3 financial assets

An increase/(decrease) of 10% in the discounted cashflows of each financial asset while holding all other variables constant will increase/(decrease) other comprehensive income by $266,000 (2024: $167,000).

33.6.2. Financial liabilities

Contingent consideration liabilities are categorized as level 3 financial liabilities and remeasured at each reporting date with movements recognized in profit or loss, except in instances where changes are permitted to be added to/reduce an associated asset. The inputs used in fair value calculations are determined by Management.

The carrying amount of financial liabilities measured at fair value is principally calculated based on inputs other than quoted prices that are observable for these financial liabilities, either directly (i.e. as unquoted prices) or indirectly (i.e. derived from prices). Where no price information is available from a quoted market source, alternative market mechanisms or recent comparable transactions, fair value is estimated based on Management's views on relevant future prices, net of valuation allowances to accommodate liquidity, modelling and other risks implicit in such estimates.

Sensitivity of level 3 financial liabilities

The potential effect of using reasonably possible alternative assumptions in valuation models, based on a change in the most significant input, such as sales volumes, by an increase/(decrease) of 10% while holding all other variables constant will increase/(decrease) profit before tax by $275,000 (2024: $1,863,000).

Valuation processes

The finance team of the Group performs the valuation of contingent consideration liabilities required for financial reporting purposes, including level 3 fair values. This team reports directly to the Chief Financial Officer ("CFO"). Discussions of valuation processes and results are held between the CFO and Board at least once every six months, in line with the Group's half-yearly reporting periods.

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The main level 3 inputs used by the Group in measuring the fair value of contingent consideration liabilities are derived and evaluated as follows:

- discount rates are determined by an independent third-party using a weighted average cost of capital model to calculate a post-tax rate that reflects current market assessments of the time value of money and the risk specific to the asset
- regulatory/marketing authorization approval dates and approval for marketing authorization probability risk factors are derived in consultation with the Group's regulatory team
- expected sales volumes and net sales price per unit are estimated based on market information on annual incidence rates and information for similar products and expected market penetration, and
- contingent consideration cash flows are estimated based on the terms of the sale contract. Changes in fair values are analyzed at the end of each reporting period during the half-yearly valuation discussion between the CFO and Board. As part of this discussion the CFO presents a report that explains the reason for the fair value movement.

34. Contingent liabilities

The Group has entered into collaboration arrangements, including in-licensing arrangements with various companies. Such collaboration agreements may require the Group to make payments on achievement of stages of development, launch or revenue milestones and may include variable payments that are based on unit sales or profit (e.g. royalty and profit share payments). The amount of variable payments under the arrangements are inherently uncertain and difficult to predict, given the direct link to future sales, profit levels and the range of outcomes.

The Group also has certain take or pay arrangements with contract manufacturers or service providers which serve as commercial manufacturers and suppliers for certain products. To the extent a commitment is determined to be onerous, these are provided for within provisions in the Consolidated statement of financial position.

The Group has received a subpoena from the U.S. Securities and Exchange Commission ("SEC") seeking various documents and information primarily relating to the Company's disclosures regarding the development of the Company's prostate cancer therapeutic candidates. This matter remains a fact-finding request. Telix is cooperating with the subpoena including responding to the SEC's requests. The SEC has not asserted any charges against the Group or any of it's personnel, and no conclusions have been reached, or that the SEC has a negative opinion of any person, entity or security. At this stage, the Group cannot predict the duration, scope or outcome of this matter. The Group will continue to monitor the inquiry and update its disclosures as appropriate.

On November 10, 2025, a putative securities class action complaint was filed in the United States District Court for the Southern District of Indiana seeking, among other relief, class certification, designation of a lead plaintiff, damages and a jury trial. On January 20, 2026, the Group was formally served the complaint on behalf of a purposed U.S. shareholder. The Group intends to seek dismissal on this matter through early motion practice and will rigorously defend itself. This case is in its earliest stages; no class has been certified and the court has not ruled on any dispositive motions. At this stage, the Group cannot predict the duration, scope or outcome of this matter. The Group cannot predict the timing or outcome of this litigation or estimate a possible loss or range of loss, if any, at this time. The Group will continue to monitor this matter.

Legal fees and other costs associated with contingent matters, including litigation, regulatory inquiries and investigations, are expensed as incurred.

35. Commitments

We have commitments against existing development activities and capital commitments relating to the purchase of isotope raw materials from a vendor over a three year period. R&D commitments are estimated based on the contractual obligations included within agreements entered into by us, to the extent that a work order has been executed with the vendor.

Certain of our supply agreements contain minimum purchase commitments in certain situations, the amount and timing of which are not known. Additionally, we enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies and clinical trials, research supplies and other services and drugs for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancellable contracts.

We have entered into collaboration arrangements, including in-licensing arrangements with various companies. Such collaboration agreements may require us to make payments on achievement of stages of development, launch or revenue milestones and may include variable payments that are based on unit sales or profit (e.g., royalty and profit share payments). The amount of variable payments under the arrangements are inherently uncertain and difficult to predict, given the direct link to future sales, profit levels and the range of outcomes. These payments are not included in this table of contractual obligations.

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At December 31, 2025 and at the date of these financial statements, the Group had capital commitments relating to the construction of the Brussels South manufacturing facility and the purchase of isotope raw materials from a vendor over a three year period.

	Due < 1 year	Due > 1 year
	US$'000	US$'000
As at December 31, 2025		
Capital commitments	35,822	11,367
R&D commitments	30,402	7,601
	66,224	**18,968**
	(Recast)	(Recast)
As at December 31, 2024		
Capital commitments	26,435	13,938
R&D commitments	18,676	4,720
	45,111	**18,658**

36. Related party transactions

36.1. Key management personnel compensation

	2025	2024	2023
	US$	US$ (Recast)	US$ (Recast)
Short-term employee benefits	2,922,754	2,577,798	2,056,147
Superannuation entitlements	118,762	141,049	105,715
Share-based payments	1,377,421	1,567,629	776,254
	4,418,937	**4,286,476**	**2,938,116**

36.2. Transactions with other related parties

	2025	2024	2023
	US$	US$ (Recast)	US$ (Recast)
Purchases of various goods and services from entities controlled by key management personnel[1]	-	513,809	835,315

1. Non-Executive Director, Dr. Andreas Kluge (previously a non-executive director, retired from the Board on October 17, 2024), is the principal owner and Geschäftsführer (Managing Director) of ABX-CRO, a clinical research organization (CRO) that specializes in radiopharmaceutical product development. Following retirement as a Non-Executive Director, Dr. Kluge has been engaged by Telix on a consultancy basis and will continue to provide the Board of Directors strategic advice alongside clinical input into key development programs, reflective of his ongoing importance as a founder of the Company.

Transactions with Andreas Kluge and ABX-CRO do not meet the criteria of a related party transaction following Andreas Kluge's retirement as a non-executive director on October 17, 2024.

In March 2024, the Group entered into an agreement to purchase the QDOSE dosimetry software platform from ABX-CRO. QDOSE is a software platform designed to enable reliable estimation of patient-specific dosimetry for both therapeutic and diagnostic radiopharmaceuticals. We agreed to pay ABX-CRO upfront cash consideration of €1,200,000, a share of profits generated from QDOSE sales and a referral fee on deals referred from or initiated by ABX-CRO over a 2-year period from acquisition.

During the year ended December 31, 2024 the total amount paid was $513,809, (2023: $835,315) and the amount payable to ABX-CRO at December 31, 2024 was $nil (2023: $nil) respectively.

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Transactions with related parties are undertaken on an arm's length basis and competitive with quotes obtained from other suppliers for similar services.

36.3. Interests in other entities

The Group's principal subsidiaries at December 31, 2025 are set out below. Unless otherwise stated, they have share capital consisting solely of ordinary shares that are held directly by the Group, and the proportion of ownership interests held equals the voting rights held by the Group. The country of incorporation or registration is also the principal place of business.

Name of entity	Country of incorporation	Ownership interest held by the Group (%)
Telix Pharmaceuticals Ltd	Australia	N/A
Telix Pharmaceuticals (Innovations) Pty Ltd[1]	Australia	100
Telix Pharmaceuticals Holdings Pty Limited[1]	Australia	100
Telix Pharmaceuticals International Holdings Pty Ltd[1]	Australia	100
Telix Pharmaceuticals Australia Holdings Pty Ltd[1]	Australia	100
Telix Pharmaceuticals (ANZ) Pty Ltd[1]	Australia	100
Telix Pharmaceuticals (Corporate) Pty Ltd[1]	Australia	100
Telix Pharmaceuticals (Belgium) SRL	Belgium	100
Telix Innovations SA	Belgium	100
Telix Innovations Rph Participacoes Ltda	Brazil	51
Telix Pharmaceuticals (Canada) Inc.	Canada	100
Telix ARTMS Inc.	Canada	100
Telix Pharmaceuticals (France) SAS	France	100
Telix Pharmaceuticals (Germany) GmbH	Germany	100
Rhine Pharma GmbH[2]	Germany	100
Therapeia GmbH & Co. KG	Germany	100
Therapeia Verwaltungs-GmbH	Germany	100
Telix Pharma Japan KK	Japan	100
Telix Pharmaceuticals (NZ) Limited	New Zealand	100
Telix Pharmaceuticals (Singapore) Pte Ltd	Singapore	100
Telix Pharmaceuticals (Switzerland) GmbH	Switzerland	100
Telix Pharmaceuticals (UK) Ltd	United Kingdom	100
Lightpoint Surgical Ltd	United Kingdom	100
Lightpoint Surgical Spain S.L. (Lightpoint Medical Espana SLU)	Spain	100
Telix Pharmaceuticals (US) Inc.	USA	100
Telix Optimal Tracers, LLC	USA	100
Telix IsoTherapeutics Group, Inc.	USA	100
Telix QSAM, Inc.	USA	100
QSAM Therapeutics Inc.	USA	100
RLS (USA), Inc.	USA	100
Las Vegas Radiopharmacy, Inc.	USA	100
Telix Targeting Technologies, Inc.	USA	100
ARTMS US, Inc.	USA	100

1. Denotes an entity that is a party to a deed of cross guarantee, refer to note 39 for further information.

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2. The Group plans to spin off this entity and has granted options to certain third parties to acquire an economic interest in the entity once key milestones are achieved.

37. Remuneration of auditor

Auditors of the Group - PricewaterhouseCoopers Australia and related network firms	2025 US$	2024 US$ (Recast)	2023 US$ (Recast)
Audit or review of financial statements	2,299,162	1,363,435	917,424
Other assurance services	86,410	1,520,146	113,016
Other advisory services	60,324	83,081	194,029
	2,445,896	**2,966,662**	**1,224,469**

Other assurance services relate to assurance and associated services that are traditionally performed by an independent auditor, including accounting consultation and consultation concerning financial accounting, reporting standards and due diligence. Other assurance services in 2024 includes comfort letter assurance services performed as part of the Group's U.S. listing.

Other auditors and their related network firms	2025 US$	2024 US$ (Recast)	2023 US$ (Recast)
Audit or review of financial statements	96,792	30,367	34,927
Other advisory services	-	-	-
	96,792	**30,367**	**34,927**

38. Parent entity financial information

Australian Disclosure Requirements

The financial information for the parent entity has been prepared on the same basis as the consolidated financial statements. The individual financial statements for the parent entity show the following aggregate amounts:

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Statement of financial position	2025	2024
	$'000	$'000 (Recast)
Assets		
Current assets	967,961	979,858
Non-current assets	650	1,589
Total assets	**968,611**	**981,447**
Liabilities		
Current liabilities	12,286	113,869
Non-current liabilities	383,754	333,418
Total liabilities	**396,040**	**447,287**
Net assets	**572,571**	**534,160**
Equity		
Share capital	479,962	414,012
Share capital reserve	(11,612)	15,945
Other reserves	123,383	41,445
Retained earnings/(accumulated losses)	(19,162)	62,758
Total equity	**572,571**	**534,160**
Statement of comprehensive income		
Loss for the year	**(80,753)**	**(72,526)**
Total comprehensive loss for the year	**(80,753)**	**(72,526)**

39. Deed of cross guarantee

Australian Disclosure Requirements

The Company and certain Australian subsidiaries of the Group have entered into a deed of cross guarantee. By entering into the deed, the subsidiaries which are party to the deed have been relieved from the requirement to prepare and lodge audited financial statements under ASIC Corporations (Wholly-owned Companies) Instrument 2016/785. The subsidiaries identified with a '1' in note 35.3 are parties to a deed of cross guarantee under which each Company guarantees to each creditor payment in full of any debt in accordance with the deed of cross guarantee.

For the year ended December 31, 2025 the parties to the deed of cross guarantee generated a loss of $99,349,000 (2024: profit of $16,291,000) and as at December 31, 2025 were in an asset position of $176,579,000 (2024: net asset position $189,036,000), with cash and cash equivalents of $84,572,000 (2024: $326,514,000).

Cash on hand and the repatriation of future cash inflows from commercial activities undertaken by wholly-owned foreign subsidiaries is considered sufficient to meet forecast cash outflows, research and development activities currently underway and other committed business activities for at least 12 months from the date of these financial statements. Further, current liabilities include loans with other subsidiaries in the Group of $47,190,000 (2024: $29,965,953) which will be settled when sufficient funds are available.

On this basis, the Directors are satisfied that the parties to the deed of cross guarantee continue to be a going concern as at the date of these financial statements.

The consolidated statement of comprehensive income and statement of financial position of the entities party to the deed of cross guarantee are provided as follows:

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Consolidated statement of comprehensive income or loss	2025 US$'000	2024 US$'000 (Recast)
Revenue from contracts with customers	135,699	139,813
Cost of sales	(4,616)	(11,740)
Gross profit	**131,083**	**128,073**
Research and development costs	(98,102)	(84,019)
Selling and marketing expenses	(3,887)	(2,217)
Manufacturing and distribution costs	(8,695)	(5,400)
General and administration costs	(86,819)	(93,479)
Other (losses)/gains (net)	(2,045)	97,506
Operating profit/(loss)	**(68,465)**	**40,464**
Finance income	5,157	5,751
Finance costs	(35,140)	(29,239)
(Loss)/profit before income tax	**(98,448)**	**16,976**
Income tax expense	(901)	(685)
(Loss)/profit from continuing operations after income tax	**(99,349)**	**16,291**
Changes in the fair value of equity investments at fair value through other comprehensive income	(5,113)	(3,870)
Total comprehensive (loss)/income for the year	**(104,462)**	**12,421**

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Consolidated statement of financial position	2025 US$'000	2024 US$'000 (Recast)
Current assets		
Cash and cash equivalents	84,572	326,514
Trade and other receivables	128,528	103,113
Inventories	1,986	714
Other current assets	3,459	5,178
Total current assets	**218,545**	**435,519**
Non-current assets		
Net investment in subsidiaries	342,428	189,361
Intangible assets	29,100	29,480
Property, plant and equipment	6,915	1,084
Right-of-use assets	1,826	1,084
Financial assets	37,094	34,746
Deferred tax assets	7,359	1,108
Other non-current assets	26,817	13,667
Total non-current assets	**451,539**	**270,530**
Total assets	**670,084**	**706,049**
Current liabilities		
Trade and other payables	72,450	86,253
Contract liabilities	-	6,612
Lease liabilities	737	399
Borrowings	11,692	10,840
Contingent consideration	2,500	53,176
Employee benefit obligations	3,946	3,156
Total current liabilities	**91,325**	**160,436**
Non-current liabilities		
Contract liabilities	-	2,036
Lease liabilities	1,394	998
Borrowings	382,926	333,285
Contingent consideration	9,734	18,844
Deferred tax liabilities	7,680	1,108
Employee benefit obligations	446	306
Total non-current liabilities	**402,180**	**356,577**
Total liabilities	**493,505**	**517,013**
Net assets	**176,579**	**189,036**
Equity		
Share capital	476,564	412,245
Share capital reserve	(11,612)	15,945
Other reserve	115,908	65,778
Accumulated losses	(404,280)	(304,931)
Total equity	**176,579**	**189,036**

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40. Events occurring after the reporting period

There were no subsequent events that required adjustment to or disclosure in the financial statements of the Group for the year ended December 31, 2025.

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Australian Disclosure Requirements

Consolidated entity disclosure statement

Basis of preparation

This consolidated entity disclosure statement ("CEDS") has been prepared in accordance with the Australian *Corporations Act 2001 (Cth)* and includes information for each entity that was part of the consolidated entity as at the end of the financial year in accordance with AASB 10 C*onsolidated Financial Statement*s.

Name of entity[1]			Tax residency	
	Country of incorporation	Ownership interest held by the Group (%)	Australian or foreign	Foreign jurisdiction(s)
Telix Pharmaceuticals Ltd	Australia	N/A	Australian	N/A
Telix Pharmaceuticals (Innovations) Pty Ltd	Australia	100	Australian	N/A
Telix Pharmaceuticals Holdings Pty Limited	Australia	100	Australian	N/A
Telix Pharmaceuticals International Holdings Pty Ltd	Australia	100	Australian	N/A
Telix Pharmaceuticals Australia Holdings Pty Ltd	Australia	100	Australian	N/A
Telix Pharmaceuticals (ANZ) Pty Ltd	Australia	100	Australian	N/A
Telix Pharmaceuticals (Corporate) Pty Ltd	Australia	100	Australian	N/A
Telix Pharmaceuticals (Belgium) SRL	Belgium	100	Foreign	Belgium
Telix Innovations SA	Belgium	100	Foreign	Belgium
Telix Innovations Rph Participacoes Ltda	Brazil	51	Foreign	Brazil
Telix Pharmaceuticals (Canada) Inc.	Canada	100	Foreign	Canada
Telix ARTMS Inc.	Canada	100	Foreign	Canada
Telix Pharmaceuticals (France) SAS	France	100	Foreign	France
Telix Pharmaceuticals (Germany) GmbH	Germany	100	Foreign	Germany
Rhine Pharma GmbH3	Germany	100	Foreign	Germany
Therapeia GmbH & Co. KG	Germany	100	Foreign	Germany
Therapeia Verwaltungs-GmbH	Germany	100	Foreign	Germany
Telix Pharma Japan KK	Japan	100	Foreign	Japan
Telix Pharmaceuticals (NZ) Limited	New Zealand	100	Australian	New Zealand
Telix Pharmaceuticals (Singapore) Pte Ltd	Singapore	100	Australian	Singapore
Telix Pharmaceuticals (Switzerland) GmbH	Switzerland	100	Foreign	Switzerland
Telix Pharmaceuticals (UK) Ltd	United Kingdom	100	Australian	United Kingdom
Lightpoint Surgical Ltd	United Kingdom	100	Foreign	United Kingdom
Lightpoint Surgical Spain S.L. (Lightpoint Medical Espana SLU)	Spain	100	Foreign	Spain
Telix Pharmaceuticals (US) Inc.	USA	100	Foreign	USA
Telix Optimal Tracers, LLC	USA	100	Foreign	USA
Telix IsoTherapeutics Group, Inc.	USA	100	Foreign	USA
Telix QSAM, Inc.	USA	100	Foreign	USA
QSAM Therapeutics Inc.	USA	100	Foreign	USA
RLS (USA), Inc.	USA	100	Foreign	USA

[1] All entities are corporate entities.

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Name of entity[1]			Tax residency	
	Country of incorporation	Ownership interest held by the Group (%)	Australian or foreign	Foreign jurisdiction(s)
Las Vegas Radiopharmacy, Inc.	USA	100	Foreign	USA
Telix Targeting Technologies, Inc.	USA	100	Foreign	USA
ARTMS US, Inc.	USA	100	Foreign	USA

Australian Disclosure Requirements

Determination of tax residency

Section 295 (3A)(vi) of the Australian *Corporations Act 2001 (Cth)* defines tax residency as having the meaning in the Income Tax Assessment Act 1997. The determination of tax residency involves judgment as it can be fact dependent and subject to interpretation, requiring consideration of matters such as location of central management and control or place of effective management.

The rules and guidance in respect of tax residency have been applied in good faith. In determining tax residency, the consolidated entity has applied the following interpretations:

- Australian tax residency: The consolidated entity has applied current legislation and judicial precedent, including having regard to the Tax Commissioner's public guidance in Tax Ruling TR 2018/5.
- Foreign tax residency: The consolidated entity has applied current legislation, judicial precedent and practice in the determination of foreign tax residency.

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Directors' declaration

1. In the opinion of the Directors:
   a. the financial statements and notes of the Company and Group are in accordance with the Australian Corporations Act 2001 (Cth), including:
      i. complying with applicable Accounting Standards, the Corporations Regulation 2001 and other mandatory professional reporting requirements; and
      ii. giving a true and fair view of the Company's and Group's financial position as at December 31, 2025 and of their performance for the year ended on that date.
   b. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.
2. Within the notes to the financial statements it is confirmed that the financial statements also comply with the International Financial Reporting Standards as issued by the International Accounting Standards Board and as disclosed in note 2.2.
3. In the opinion of the Directors, as at the date of this declaration, there are reasonable grounds to believe that the Company and entities identified in note 39 will be able to meet any obligations or liabilities to which they are or may become subject by virtue of the Deed of Cross Guarantee between the Company and those entities pursuant to ASIC Corporations (Wholly-Owned Companies) Instrument 2016/785.
4. In the opinion of the Directors the consolidated entity disclosure statement required by subsection 295(3A) of the Australian Corporations Act 2001 (Cth), as disclosed in the Consolidated entity disclosure statement on pages F-69 to F-70, is true and correct.
5. This declaration has been made after receiving the declarations required to be made to the Directors in accordance with section 295A of the Australian Corporations Act 2001 (Cth) for the financial year ended December 31, 2025.
6. Signed in accordance with a resolution of the Directors.

Mark Nelson	Christian Behrenbruch
Interim Chair	Managing Director and Group CEO
February 20, 2026	February 20, 2026

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Independent auditor's report

To the members of Telix Pharmaceuticals Limited

Report on the audit of the financial report

Our opinion

In our opinion:

The accompanying financial report of Telix Pharmaceuticals Limited (the Company) and its controlled entities (together the Group) is in accordance with the *Corporations Act 2001*, including:

a) giving a true and fair view of the Group's financial position as at December 31, 2025, and of its financial performance for the year then ended;

b) complying with Australian Accounting Standards and the Corporations Regulations 2001.

What we have audited

The financial report comprises:

- the consolidated statement of financial position as at December 31, 2025;
- the consolidated statement of comprehensive income or loss for the year then ended;
- the consolidated statement of changes in equity for the year then ended;
- the consolidated statement of cash flows for the year then ended;
- the notes to the consolidated financial statements, including material accounting policy information and other explanatory information;
- the consolidated entity disclosure statement as at December 31, 2025;
- the directors' declaration.

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PricewaterhouseCoopers, ABN 52 780 433 757
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GPO Box 1331 MELBOURNE VIC 3001
T: +61 3 8603 1000, F: +61 3 8603 1999, www.pwc.com.au

Liability limited by a scheme approved under Professional Standards Legislation.

Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the financial report* section of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional & Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to audits of the financial report of public interest entities in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Our audit approach

An audit is designed to provide reasonable assurance about whether the financial report is free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial report.

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial report as a whole, taking into account the geographic and management structure of the Group, its accounting processes and controls and the industry in which it operates.

Audit Scope

Our audit focused on where the Group made subjective judgements; for example, significant accounting estimates involving assumptions and inherently uncertain future events.

In establishing the overall approach to the group audit, we determined the type of work that needed to be performed by us, as the group auditor, or component auditors from other PwC network firms operating under our instruction. Where the work was performed by component auditors, we determined the level of involvement we needed to have in the audit work at those components to be able to conclude whether sufficient appropriate audit evidence had been obtained as a basis for our opinion on the Group financial report as a whole.

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Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report for the current period. The key audit matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. Further, any commentary on the outcomes of a particular audit procedure is made in that context. We communicated the key audit matters to the Audit and Risk Committee.

Key audit matter	*How our audit addressed the key audit matter*
Acquisition of RLS (USA) Inc. – Valuation of Customer Relationships and Brand Name As described in Note 23.1 to the financial report, on January 28, 2025, the Group completed the acquisition of RLS (USA) Inc. ("RLS") for consideration of $240.9 million. Of the acquired intangible assets, $60.4 million of customer relationships and $29.8 million of a brand name were recorded. Fair value is estimated by the Group using a multi-period excess earnings method for customer relationships and a relief from royalty method for the brand name. The Group's cash flow projections for the intangible assets acquired included significant judgements and assumptions relating to revenue growth rates, earnings before interest and taxes ("EBIT") margins, and discount rate for customer relationships and revenue growth rates, royalty rate, and discount rate for the brand name. The principal considerations for our determination that performing procedures relating to the valuation of customer relationships and brand name acquired in the acquisition of RLS is a key audit matter are (i) the significant judgement by the Group when developing the fair value estimate of the customer relationships and brand name acquired; (ii) a high degree of auditor judgement, subjectivity, and effort in performing procedures and evaluating the Group's significant assumptions related to revenue growth rates, EBIT margins, and discount rate for customer relationships and revenue growth rates, royalty rate, and discount rate for the brand name; and (iii) the audit effort involved the use of professionals with specialised skill and knowledge.	Our audit procedures included, among others: • testing the effectiveness of controls related to the acquisition accounting, including controls over the Group's valuation of the customer relationships and brand name acquired; • reading the share purchase agreement; • testing the Group's process for developing the fair value estimate of the customer relationships and brand name acquired; • evaluating the appropriateness of the multi-period excess earnings and relief from royalty methods used by the Group; • testing the completeness and accuracy of the underlying data used in the multi-period excess earnings and relief from royalty methods; and • evaluating the appropriateness of the significant assumptions used by the Group related to revenue growth rates, EBIT margins, and discount rate for customer relationships and revenue growth rates, royalty rate, and discount rate for the brand name. Evaluating the Group's assumptions related to revenue growth rates and EBIT margins for customer relationships and revenue growth rates for the brand name involved considering: • the performance of the RLS business; • the consistency with external market and industry data; and • whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialised skill and knowledge were used to assist in evaluating (i) the appropriateness of the multi-period excess earnings and relief from royalty methods and (ii) the appropriateness of the revenue growth rates, EBIT margins, and discount rate for customer relationships and revenue growth rates, royalty rate, and discount rate for the brand name.

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Key audit matter	*How our audit addressed the key audit matter*
Impairment Assessment of Indefinite-Lived Intangible Assets and Goodwill – TLX090-Tx and ARTMS Cash-Generating Units As described in Note 21 to the financial report, the Group's intangible assets balance including goodwill was $592.8 million as of December 31, 2025. The carrying amount associated with the TLX090-Tx and ARTMS cash-generating units, which includes indefinite-lived intangible assets and goodwill, was $92.8 million and $85.2 million as of December 31, 2025, respectively. The Group conducts an impairment test as of December 31 of each year, or more frequently if events or circumstances indicate the carrying value of cash-generating units containing indefinite-lived intangible assets and goodwill may be impaired. Potential impairment is identified by comparing the fair value of a cash-generating unit to its carrying value, including goodwill. Fair value is estimated by the Group using a discounted cash flow model. The Group's cash flow projections for the TLX090-Tx and ARTMS cash-generating units included significant judgments and assumptions relating to expected sales volumes, net sales prices, probability of success, terminal value, and discount rates. The principal considerations for our determination that performing procedures relating to the indefinite-lived intangible assets and goodwill impairment assessments of the TLX090-Tx and ARTMS cash-generating units is a key audit matter are (i) the significant judgement by the Group when developing the fair value estimate of the TLX090-Tx and ARTMS cash-generating units; (ii) a high degree of auditor judgement, subjectivity, and effort in performing procedures and evaluating the Group's significant assumptions related to expected sales volumes, net sales prices, probability of success, terminal value, and discount rates; and (iii) the audit effort involved the use of professionals with specialised skill and knowledge.	Our audit procedures included, among others: • testing the effectiveness of controls relating to the Group's indefinite-lived intangible assets and goodwill impairment assessments, including controls over the valuation of the Group's TLX090-Tx and ARTMS cash-generating units; • testing the Group's process for developing the fair value estimate of the TLX090-Tx and ARTMS cash-generating units; • evaluating the appropriateness of the discounted cash flow model used by the Group; • testing the completeness and accuracy of underlying data used in the discounted cash flow model; and • evaluating the appropriateness of the significant assumptions used by the Group related to expected sales volumes, net sales prices, probability of success, terminal value, and discount rates. Evaluating the Group's assumptions related to expected sales volumes, net sales prices, probability of success, and terminal value involved evaluating whether the assumptions used by the Group were appropriate considering: • the performance of the TLX090-Tx and ARTMS cash-generating units; • the consistency with external market and industry data; and • whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialised skill and knowledge were used to assist in evaluating (i) the appropriateness of the discounted cash flow model and (ii) the appropriateness of the discount rates assumptions.

Other information

The directors are responsible for the other information. The other information comprises the information included in the annual report for the year ended December 31, 2025, but does not include the financial report and our auditor's report thereon.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon through our opinion on the financial report. We have issued a separate opinion on the remuneration report and we have issued a separate review conclusion on specified Sustainability Disclosures within the Sustainability Report, in accordance with the scope of Australian Standard on Sustainability Assurance ASSA 5010 *Timeline for Audits and Reviews of Information in Sustainability Reports under the Corporations Act 2001*.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, based on the work we have performed on the other information that we obtained prior to the date of this auditor's report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the directors for the financial report

The directors of the Company are responsible for the preparation of the financial report in accordance with Australian Accounting Standards and the *Corporations Act 2001*, including giving a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of the financial report that is free from material misstatement, whether due to fraud or error.

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In preparing the financial report, the directors are responsible for assessing the ability of the Group to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: https://auasb.gov.au/media/bwvjcgre/ar1_2024.pdf. This description forms part of our auditor's report.

Report on the remuneration report

Our opinion on the remuneration report

We have audited the remuneration report included in Item 6 (Directors, Senior Management and Employees) of the Form 20-F for the year ended December 31, 2025, identified by the title 'Start of the Remuneration Report for Australian Disclosure Requirements' to 'End of Remuneration Report'.

In our opinion, the remuneration report of Telix Pharmaceuticals Limited for the year ended December 31, 2025, complies with section 300A of the *Corporations Act 2001*.

Responsibilities

The directors of the Company are responsible for the preparation and presentation of the remuneration report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the remuneration report, based on our audit conducted in accordance with Australian Auditing Standards.

PricewaterhouseCoopers

Brad Peake
Partner

Melbourne
February 20, 2026

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Shareholder information

Telix Pharmaceuticals Limited

ACN 616 620 369

Registered Office

55 Flemington Road North Melbourne, VIC 3051
www.telixpharma.com

Share Registry

Shareholder information in relation to shareholding or share transfer can be obtained by contacting the Company's share registry:

MUFG Corporate Markets (AU) Limited
A division of MUFG Pension & Market Services
(Formerly Link Market Services)
Locked Bag A14
Sydney South NSW 1235
Australia
P: 1300 554 474
F: (02) 9287 0303
E: support@cm.mpms.mufg.com
www.mpms.mufg.com

For all correspondence to the share registry, please provide your Security-holder Reference Number ("SRN") or Holder Identification Number ("HIN").

Change of address

Changes to your address can be updated online at www.linkmarketservices.com.au or by obtaining a Change of Address Form from the Company's share registry. CHESS sponsored investors must change their address details via their broker.

Annual General Meeting

The Annual General Meeting will be held on Wednesday 21 May 2026. Details of how to participate will be included in the Notice of Meeting lodged with the ASX and distributed to shareholders.

Annual report mailing list

All shareholders are entitled to receive the Annual Report. In addition, shareholders may nominate not to receive an annual report by advising the share registry in writing, by fax, or by email, quoting their SRN/HIN.

Securities exchange listing

Telix Pharmaceuticals Limited's shares are listed on the Australian Securities Exchange and trade under the ASX code TLX. The securities of the Company are traded on the ASX under CHESS (Clearing House Electronic Sub-register System).

Telix Pharmaceuticals Limited's American Depository Shares (ADSs) trade on the Nasdaq Global Select Market (NASDAQ) under the ticker symbol 'TLX'. JPMorgan Chase Bank. N.A. is the depositary, custodian and registrar for the ADS program.

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ASX shareholder disclosures

The following additional information is required by the Australian Securities Exchange in respect of listed public companies. The information is current as at 6 February 2026.

Total securities on issue

	Securities (Listed)	Securities (Unlisted)
Fully paid ordinary shares	338,777,319	
Options to acquire shares		31,744,502

Distribution of equity securities – ordinary shares

Range	Securities	%	No. of holders	%
100,001 and Over	255,924,543	75.5	156	0.4
10,001 to 100,000	38,096,643	11.3	1,465	4.1
5,001 to 10,000	13,023,119	3.8	1,757	4.9
1,001 to 5,000	23,716,898	7.0	9,981	27.8
1 to 1,000	8,016,116	2.4	22,560	62.8
Total	**338,777,319**	**100.0**	**35,919**	**100.0**
Unmarketable Parcels	—	—	—	—

Voting rights

Shareholders in Telix Pharmaceuticals Limited have a right to attend and vote at general meetings. At a general meeting, individual shareholders may vote in person or by proxy. A copy of the Constitution is available at ir.telixpharma.com/governance/documents-charters.

Shareholders who have a voting right percentage of greater than 5% are outlined below:

Name	February 6, 2026	%
JPMORGAN CHASE & CO.	22,419,015	6.6
STATE STREET CORPORATION	28,187,775	8.3
ELK RIVER HOLDINGS PTY LTD	20,675,000	6.1
GNOSIS VERWALTUNGSGESELLSCHAFT MBH	20,675,000	6.1

Share buy-back

There is no current or planned buy-back of the Company's shares.

Statement in accordance with ASX Listing Rule 4.10.19

The Company confirms that it has used the cash and assets in a form readily convertible to cash at the time of admission in a way consistent with its business objectives.

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Twenty largest shareholders of record - ordinary shares

Rank	Name	February 6, 2026	%
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	53,462,930	15.8
2	CITICORP NOMINEES PTY LIMITED	31,693,330	9.4
3	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	24,921,869	7.4
4	ELK RIVER HOLDINGS PTY LTD	20,675,000	6.1
4	GNOSIS VERWALTUNGSGESELLSCHAFT MBH	20,675,000	6.1
5	BNP PARIBAS NOMINEES PTY LTD	15,376,442	4.5
6	BNP PARIBAS NOMS PTY LTD	10,433,812	3.1
7	GRAND DECADE DEVELOPMENTS LIMITED	6,000,000	1.8
8	BNP PARIBAS NOMINEES PTY LTD	5,643,043	1.7
9	UV-CAP GMBH & CO KG	4,878,261	1.4
10	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	3,294,701	1.0
11	MAN HOLDINGS PTY LTD	3,228,750	1.0
12	BNP PARIBAS NOMINEES PTY LTD	2,923,857	0.9
13	BNP PARIBAS NOMS (NZ) LTD	2,714,023	0.8
14	NETWEALTH INVESTMENTS LIMITED	2,406,576	0.7
15	LIGHTPOINT MEDICAL LTD	1,918,112	0.6
16	THE ONCIDIUM FOUNDATION	1,846,582	0.6
17	PACIFIC CUSTODIANS PTY LIMITED	1,618,200	0.5
18	UBS NOMINEES PTY LTD	1,191,214	0.4
19	WHSP HOLDINGS PTY LIMITED	1,136,783	0.3
20	BNP PARIBAS NOMINEES PTY LTD	1,120,510	0.3
	Total	**217,158,995**	**64.1**
	Balance of register	**121,618,324**	**35.9**
	Grand total	**338,777,319**	**100.0**

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Company directory

Directors

Mark Nelson (Chairman)
Christian Behrenbruch (MD & CEO)
Marie McDonald
Jann Skinner

Company Secretary

Genevieve Ryan

Investor Relations and Corporate Communications

Kyahn Williamson

Registered Office

Telix Pharmaceuticals Limited
55 Flemington Road
North Melbourne VIC 3051
info@telixpharma.com
www.telixpharma.com

Australian Business Number

85 616 620 369

Securities Exchange Listing

Australian Securities Exchange
ASX: TLX

Nasdaq Global Select Market
NASDAQ: TLX

Auditor

PricewaterhouseCoopers
2 Riverside Quay
Southbank VIC 3006

Share Registry

MUFG Corporate Markets (AU) Limited
A division of MUFG Pension & Market Services
(Formerly Link Market Services)
Locked Bag A14 Sydney South NSW 1235
Australia

P: 1300 554 474
F: (02) 9287 0303
www.mpms.mufg.com

Depository Registry

JP Morgan Chase Bank N.A.Shareowner Services
P.O. Box 64504
St. Paul, MN 55164-0854

General (within U.S.) +1 800 990 1135
From outside the U.S. +1 651 453 2128
www.shareowneronline.com

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Glossary of terms and abbreviations

Abbreviation	Term	Abbreviation	Term
AASB	Australian Accounting Standards Board	IFRS	International Financial Reporting Standard
ACA	Affordable Care Act	IIT	Investigator-initiated trial
ADR	American Depositary Receipts	IND	Investigational new drug
ADS	American Depositary Shares	IPO	Initial Public Offering
AGM	Annual General Meeting	IRA	Inflation Reduction Act
AI	Artificial intelligence	IRB	Institutional Review Board
AML	Acute myeloid leukemia	IRM	Indeterminate renal mass
ANDA	Abbreviated New Drug Application	ISMS	Information Security Management System

Abbreviation	Term	Abbreviation	Term
ARC	Audit and Risk Committee	ISSB	International Sustainability Standards Board
ASIC	Australian Securities and Investments Commission	KMP	Key management personnel
ASX	Australian Securities Exchange	LAT1 & 2	L-type amino acid transporters 1 & 2
AUASB	Auditing and Assurance Standards Board	LTVR	Long Term Variable Remuneration
BBB	Blood-brain barrier	MAA	Marketing Authorization Application
BLA	Biologics License Application	MBS	Medicare Benefits Schedule
BMC	Bone marrow conditioning	mCRPC	Metastatic castration-resistant prostate cancer
CAIX	Carbonic anhydrase IX	MDR	Medical Devices Regulation
CCPA	California Consumer Privacy Act	MHRA	Medicines and Healthcare Products Regulatory Agency
ccRCC	Clear cell renal cell carcinoma	MM	Multiple myeloma
CD66	Cluster of differentiation 66	MOA	Mechanism of action
CE	Conformité Européenne Mark	MRI	Magnetic resonance imaging
CHMP	Committee for Medicinal Products for Human Use	NDA	New Drug Application
CMC	Chemistry, Manufacturing and Controls	NED	Non-Executive Director
CMO	Contract Manufacturing Organization	NPP	Named patient program
CMS	Centers for Medicare & Medicaid Services	NRC	Nuclear Regulatory Commission
CNS	Central nervous system	ODD	Orphan drug designation
COSO	Committee of Sponsoring Organizations of the Treadway Commission	PARP	Poly (ADP-ribose) polymerase
CPRA	California Privacy Rights Act	PCNRC	People, Culture, Nomination and Remuneration Committee
CRL	Complete Response Letter	PCT	Patent Cooperation Treaty
CT	Computed tomography	PDUFA	Prescription Drug User Fee Act
DMA	Double Materiality Assessment	PDGFRα	Platelet-derived growth factor receptor alpha
DNA-PK	DNA-dependent protein kinase	PET	Positron emission tomography
EAP	Early or expanded access program	PMA	Premarket Approval Application
EBIT	Earnings before interest and taxes	PoC	Proof-of-concept
EBITDA	Earnings before interest, taxes, depreciation and amortisation	PRIME	Priority Medicines
EBRT	External beam radiation therapy	PSA	Prostate-specific antigen
EEA	European Economic Area	PSARs	Performance Share Appreciation Rights
EIP	Equity Incentive Plan	PSMA	Prostate-specific membrane antigen
EMA	European Medicines Agency	PSMA-PET	Prostate-specific membrane antigen imaging with positron emission tomography
ERMF	Enterprise Risk Management Framework	QMS	Quality Management System
ESG	Environment, Social and Governance	QSEB	Quality and Safety Evaluation Board

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Abbreviation	Term	Abbreviation	Term
ESPP	Employee Stock Purchase Plan	QSR	Quality System Regulation
FANC	Belgian Federal Agency for Nuclear Control	R&D	Research and development
FAP	Fibroblast activation protein	R&I	Research and Innovation
FCPA	Foreign Corrupt Practices Act	rADC	Radio antibody-drug conjugate
FDA	United States Food and Drug Administration	REACH	Registration, Evaluation and Authorisation of Chemicals
FDCA	Federal Food, Drug, and Cosmetic Act	REMS	Risk Evaluation and Mitigation Strategy
FDORA	Food and Drug Omnibus Reform Act	RGS	Radio-guided surgery
FIH	First-in-human	RLD	Reference Listed Drug
FTC	Federal Trade Commission	rPFS	Radiographic progression-free survival
GAAP	Generally Accepted Accounting Principles	RTF	Refuse to File
GBM	Glioblastoma	SALA	Systemic amyloid light chain amyloidosis
GCP	Good Clinical Practice	SDP	Securities Dealing Policy
GDP	Good Distribution Practice	SEC	Securities and Exchange Commission
GDPR	General Data Protection Regulation	SGX	Securities Trading Limited
GET	Group Executive Team	SoC	Standard of care
GHG	Greenhouse gas	SOP	Standard operating procedure
GLF	Global Leadership Forum	SOX	Sarbanes-Oxley Act
GLP	Good Laboratories Practice	SPECT	Single photon emission computed tomography
GMP	Good Manufacturing Practice	STS	Soft tissue sarcoma
GSRC	Global Safety Review Committee	STVR	Short Term Variable Remuneration
HHS	Department of Health and Human Services	TAT	Targeted alpha therapy
HIPAA	Health Insurance Portability and Accountability Act	TFR	Total Fixed Remuneration
HSCT	Hematopoietic stem cell transplant	TGA	Therapeutic Goods Administration (Australia)
HSWE	Health, safety, wellbeing and environment	TMS	Telix Manufacturing Solutions
HTA	Health Technology Assessment	TNBC	Triple-negative breast cancer
IASB	International Accounting Standards Board	UPC	Unified Patent Court
IDE	Investigational Device Exemption	USPTO	United States Patent and Trademark Office

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