Pacific Edge CANCER DIAGNOSTICS

29 MAY 2025

#### PACIFIC EDGE LAUNCHES NZ\$20 MILLION CAPITAL RAISE

**DUNEDIN, New Zealand** – Cancer diagnostics company Pacific Edge (NZX, ASX: PEB) today announces an offer to raise NZ\$20 million. The offer is to consist of a placement of NZ\$15 million of new ordinary shares to be offered to selected investors and an offer of NZ\$5 million of new shares to retail investors, by way of a share purchase plan, with an ability to accept over subscriptions in both the placement and retail offer at Pacific Edge's sole discretion.

The share issue is priced at NZ\$0.10 per share, which is at a premium to the 20-day volume average weighted price (VWAP) and is expected to be well supported by key existing institutional shareholders. It is aimed at ensuring Pacific Edge has the cash reserves to capitalize on its recent clinical and commercial milestones, grow in non-Medicare channels and regain Medicare coverage of its tests. Medicare coverage of the company's tests ceased after the 'Genetic testing for Oncology; Specific Tests' (L39365) Local Coverage Determination became effective on 24 April 2025.

The capital raising comes as the company announces a resilient financial performance for the year to the end of March 2025 (FY 25). The details of the FY 25 financial results are covered in a separate announcement to NZX and ASX today.

CASH RESERVES NECESSARY FOR RECOVERAGE AND COMMERCIAL MILESTONES Pacific Edge's capital raising is aimed at providing it with the cash reserves to:

- Extend cash runway to support operations for over 12 months without Medicare coverage and reimbursement, or reductions in its cost base, while pursuing recoverage<sup>1</sup>
- Accelerate adoption of Triage in the US with AUA Guidelines as a tailwind for sales, marketing and reimbursement
- Continue clinical evidence generation in an AV, CV and CU framework for coverage, guidelines and medical policy for Triage Plus and Monitor Plus
- Invest in innovation and product development for IVD kits to support entry into international markets in a decentralized deployment model

Chairman Chris Gallaher said: "Inclusion in the AUA guideline has allowed the company to view the non-coverage determination differently and we have a strong desire to use those guidelines to build on the commercial momentum we've already established. The robust evidence emerging from our clinical evidence program is shifting clinical sentiment towards the broader adoption of our tests in the US and further afield. We are determined not to lose that momentum, and it is for this reason we have today launched a NZ\$20 million offer of new shares.

"The new capital will support the company and its operations for over 12 months, giving Pacific Edge the ability to grow testing volume as we work to regain coverage through planned

<sup>&</sup>lt;sup>1</sup> Assuming at least NZ\$20 million is raised in the capital raising to add to net cash of NZ\$22.6 million at 31 March 2025 and an average monthly cash burn of less than NZ\$2.6 million.

Medicare reconsideration requests and challenging the non-coverage of Cxbladder Triage through the Medicare appeals process.

"All of Pacific Edge's Directors and senior management intend to participate in the equity raising. We encourage you to support this offer."

Pacific Edge Chief Executive Dr Peter Meintjes said: "Pacific Edge has an opportunity to entrench its first-mover advantage and the moat we have created around Cxbladder Triage given its inclusion in the AUA microhematuria guideline.

"We are already rapidly migrating clinicians from Detect to Triage and are seeking to appeal all Triage tests through either the Medical Appeals Process or through "external review" for commercial payers. The capital we are seeking today will make this possible, while we work ceaselessly to regain Medicare coverage and reimbursement for our tests.

"Additionally, this capital will enable Pacific Edge to sustain our planned investments in the clinical evidence generation for Triage Plus and Monitor Plus – the future product portfolio of the company. Lastly, it will also support product innovation to simplify Cxbladder into IVD kits as part of a decentralized strategy for international markets. We encourage shareholders to support us to take advantage of these opportunities."

Further details of the capital raise have been included in a capital raising presentation also released to the NZX and ASX today.

#### **OFFER DETAILS:**

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Offer size and	An equity raising, comprising:		
structure	A NZ\$15 million Placement		
	A NZ\$5 million Retail Offer		
Placement offer	The Placement Price will be NZ\$0.100 per share representing:		
details	<ul> <li>22% premium to the last closing price on NZX of NZ\$0.082 per share on 29 May 2025</li> </ul>		
	<ul> <li>18% premium to the 20-day VWAP on NZX of NZ\$0.085 per share<sup>2</sup></li> </ul>		
	<ul> <li>Shareholder approval is required to complete the Placement given the Placement exceeds Pacific Edge's placement capacity (15% of Pacific Edge's current shares on issue) and due to the expected presence of Related Party participation<sup>3</sup></li> </ul>		
	The Placement offer to selected investors will be conducted under a trading halt		
	Pacific Edge reserves the right to vary the size of the Placement based on the size and quality of investor demand		
Commitments	All Pacific Edge directors intend to participate in the equity raising		
Retail Offer details	<ul> <li>Pacific Edge is offering up to NZ\$5 million of shares (with the ability to scale applications or accept oversubscriptions at the Board's discretion) to Pacific</li> </ul>		

<sup>&</sup>lt;sup>2</sup> Volume weighted average price on the NZX for the period 2 May 2025 to 29 May 2025

<sup>&</sup>lt;sup>3</sup> The Placement will also be conditional on all necessary regulatory approvals. In this regard, the company intends to seek a waiver from NZX Listing Rule 4.19.1 to permit the allotment of shares under the Placement after shareholder approval is obtained.

	Edge's eligible existing shareholders resident in New Zealand (up to a maximum of NZ\$50,000 per shareholder) under a Retail Offer, structured as a share purchase plan <sup>4</sup> The Retail Offer will be priced at the Placement Price of NZ\$0.100 per share
	<ul> <li>Allotment of shares under the Retail Offer will be conditional on the Placement becoming unconditional</li> </ul>
Ranking	The new shares to be issued under both the Placement and Retail Offer will be fully paid ordinary shares which, on allotment, will rank equally in all respects with Pacific Edge's existing ordinary shares then on issue
Financial adviser	<ul> <li>Cameron Partners Limited is acting as financial adviser to Pacific Edge</li> <li>Neither the Placement nor the Retail Offer are underwritten</li> </ul>

#### **TIMETABLE**

Placement conducted under trading halt	Friday, 30 May 2025
Announcement of the Placement results (subject to shareholder approval) and trading halt lifted on the NZX and ASX	Tuesday, 3 June 2025
Retail Offer	July/August 2025
Shareholder meeting to seek approval for the Placement	By Early August 2025
Settlement, allotment and trading of Placement and Retail Offer shares on NZX and ASX commence	By Mid August 2025

This timetable is indicative only and subject to change. The company will, in due course, send shareholders formal notice of the meeting at which shareholder approval to the Placement will be sought. The company will provide details of the record date, and offer period, for the Retail Offer on or before sending the notice of meeting to shareholders.

Released for and on behalf of Pacific Edge by Grant Gibson Chief Financial Officer.

For more information:

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Richard Inder The Project P: +64 21 645 643

#### **OVERVIEW**

Pacific Edge: www.pacificedgedx.com

Pacific Edge Limited (NZX/ ASX: PEB) is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in

<sup>&</sup>lt;sup>4</sup> The Board reserves the right to extend the Retail Offer to Australian resident shareholders, subject to obtaining any necessary Australian regulatory relief.

Dunedin, New Zealand, the company provides its suite of Cxbladder tests globally through its wholly owned, and CLIA certified, laboratories in New Zealand and the USA.

#### Cxbladder: www.cxbladder.com

Cxbladder is a suite of non-invasive genomic urine tests optimized for the risk stratification of urothelial cancer in patients presenting with microhematuria and those being monitored for recurrent disease. The tests help improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency.

Supported by over 20 years of research, Cxbladder's evidence portfolio extends to more than 25 peer reviewed publications, and Cxbladder Triage is now included in the American Urological Association's Microhematuria Guideline. To drive increased adoption and improved patient health outcomes, Cxbladder is the focal point of numerous ongoing and planned studies designed to generate further clinical utility evidence.

Cxbladder is available in the US, Australasia, and Israel and in markets throughout Asia and South America. In the US, the test has been used by over 5,000 urologists who have ordered more than 130,000 tests. In New Zealand, Cxbladder is accessible to around 70% of the population via public healthcare and all residents have the option of buying the test online.



# **Capital raising presentation**

Dr Peter Meintjes

Chief Executive Officer

Grant Gibson
Chief Financial Officer

29 May 2025



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- 2. CAPITAL RAISING OVERVIEW
- 3. KEY RISKS AND FOREIGN SELLING RESTRICTIONS







# persona

## SUMMARY: PACIFIC EDGE IS THE FIRST MOVER IN BLADDER CANCER DIAGNOSIS

NON-COVERED FOR MEDICARE; STRATEGY AND EXECUTION STRENGTHENED BY GUIDELINE INCLUSION

>					
	<b>2001-2011</b> Research and development	2011-2020 Commercialisation	2020-2023 Growth acceleration	2023-2025 Temporary uncertainty	2025+ Growth continuation
use c	Establishment and NZX listing     Clinical research and development of Cxbladder prototypes	Cxbladder commercial launch     Labs opened in New Zealand     and the US	Medicare, Kaiser Permanente and the New Zealand (majority) coverage     NZ\$103.5m raised and ASX dual listing     Quarter-on-Quarter	<ul> <li>Uncertainty around ongoing Medicare coverage</li> <li>Focus on clinical evidence, new products, growth in non- Medicare channels and growth in average sales price</li> </ul>	AUA microhematuria guideline inclusion     Medicare non-coverage determination on stale evidence providing clear re-coverage process     Triage Plus priced at US\$1,018/test (draft)

compound growth of 10% for

12 quarters to September 24

Kaiser EMR integration

- We have navigated the last three years through:
  - Refocusing clinical evidence development in a robust AV, CV, CU<sup>1</sup> framework in defined patient populations in appropriately powered studies;
  - Cementing relationships with key customer partners (e.g. Kaiser Permanente);
  - Digitalizing our operations to increase electronic ordering and to improve rates of patient enrollment in clinical studies;
  - Disciplined focus on revenue cycle management and reimbursement to improve sales team efficiency and average sales price; and
  - Investing in product development (e.g. Cxbladder Triage Plus and Monitor Plus) and innovating with future kitted-IVD<sup>2</sup> products for international markets.
- The American Urological Association's (AUA) February 2025 guideline inclusion of Cxbladder Triage as the only urine-based biomarker test with 'Grade A' evidence is a company defining milestone that improves sales, marketing and reimbursement
  - 1. AV is analytical validation, CV is clinical validation and CU is clinical utility
  - 2. IVD is an in-vitro diagnostic, typically sold as a kitted product not a testing service



Triage Plus in early access

Improved average sales price (ASP)

#### CLINICALLY VALIDATED AND GUIDELINE-RECOMMENDED GENOMIC TESTS

- Cxbladder is a suite of clinically-validated, urine-sampled, RNA-based diagnostic tests for hematuria evaluation and surveillance of NMIBC1 recurrence
- Triage Plus and Monitor Plus tests are 'multi-modal' diagnostic tests (DNA and RNA) offering superior performance and greater penetration of existing ~US\$8.5b TAM
- Cxbladder Triage recommended in the AUA 2025 microhematuria guideline as the only urine-based biomarker test that has 'Grade A' evidence
- Commercial sales in the US, New Zealand, Australia and Southeast Asia

#### **CXBLADDER RNA TESTS IN MARKET**

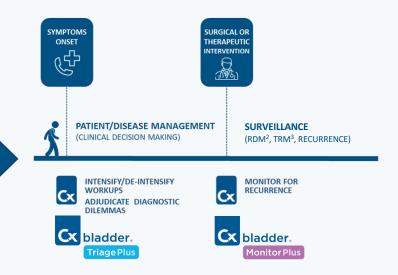
#### SYMPTOMS ONSET THERAPEUTIC INTERVENTION CF. **AND** PATIENT/DISEASE MANAGEMENT SURVEILLANCE (CLINICAL DECISION MAKING) (RDM2, TRM3, RECURRENCE) INTENSIFY/DE-INTENSIFY MONITOR FOR WORKUPS RECURRENCE ADJUDICATE DIAGNOSTIC





# **OUR FUTURE**

#### CXBLADDER RNA+DNA TESTS COMING TO MARKET





- NMIBC is non-muscle invasive bladder cancer
- 2. RDM: Residual Disease Monitoring

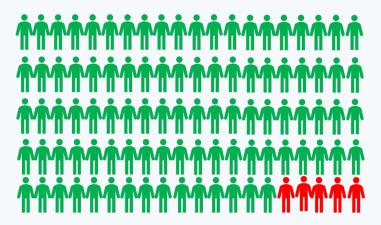
Cx bladder.

TRM: Therapeutic Response Monitoring

CXBLADDER DELIVERS CLINICAL UTILITY, PATIENT SATISFACTION AND ECONOMIC VALUE

Cxbladder offers improvement over the standard of care, avoids unnecessary procedures and streamlines workflow when used to intensify or de-intensify hematuria evaluation or in the surveillance for the recurrence of bladder cancer. For healthcare payers Cxbladder offers substantial total cost savings per patient<sup>1</sup>

**CANCER INCIDENCE IN MICROHEMATURIA PATIENTS** 



Incidence of bladder cancer in microhematuria populations is 5%

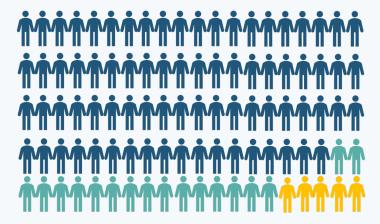


Microhematuria patient with no cancer



Microhematuria patient with cancer

CYSTOSCOPIES SAFELY AVOIDED USING CXBLADDER



With Cxbladder, 78% of patients can avoid cystoscopy, 22% receive cystoscopy, 5 cancers found



undertaken and

cancer found

Cxbladder can spare up to 1.5 million patients in the US per year from cystoscopy

#### MEDICARE REPRESENTS THE LARGEST SINGLE OPPORTUNITY GLOBALLY

#### **COMPELLING GROWTH OPPORTUNITY**

- Total addressable market for Cxbladder in the US estimated to be more than US\$4.4b¹ and US\$8.5b globally
- Laboratory infrastructure in place in New Zealand and the US with lab scalability plan to handle more than 300k tests per annum
- First mover advantage with a "moat" from compelling clinical evidence and guidelines

#### PORTFOLIO OF INTELLECTUAL PROPERTY

- Novel methods for bladder cancer diagnostics are protected by patents
- Unique selling points are underpinned by clinical utility evidence for novel applications
- Potential to leverage existing frameworks for evidence generation and selling for expansion within urology and international markets





<sup>1.</sup> Pacific Edge estimate using US\$1,018 price for hematuria testing and US\$760 for NMIBC surveillance in the US and have estimated appropriate prices for APAC and Europe. See slide 38 of this presentation for the sources and assumptions for the calculation of TAM

CXBLADDER OFFERS A SIGNIFICANT ADDRESSABLE GLOBAL MARKET ANNUALLY

#### THE PATIENT CARE PATHWAY

















340m **Population** 

#### ~7m Present with

~3.5m Referred for clinical workup

## ~1.1m

Receive cystoscopy

#### ~90k

Annual cases of bladder cancer

#### ~750k

Living with bladder cancer ~1.5 Cxb Monitor / year

#### US\$4.4b TAM

Focus of our growth efforts

830m Population

#### ~17m

hematuria

Present with hematuria

#### ~50%

Referred for clinical workup

#### ~3.3m

Receive cystoscopy

#### ~58k

Annual cases of bladder cancer

#### ~300k

Living with bladder cancer ~1.5 Cxb Monitor / year

US\$2.1b

NZ market mature. Australia and SE Asia in business development

600m **Population** 

#### ~12m

Present with hematuria

#### ~50%

Referred for clinical workup

#### >4.0m

Receive cystoscopy

#### ~180k

Annual cases of bladder cancer

#### ~1m

Living with bladder cancer ~1.5 Cxb Monitor / year

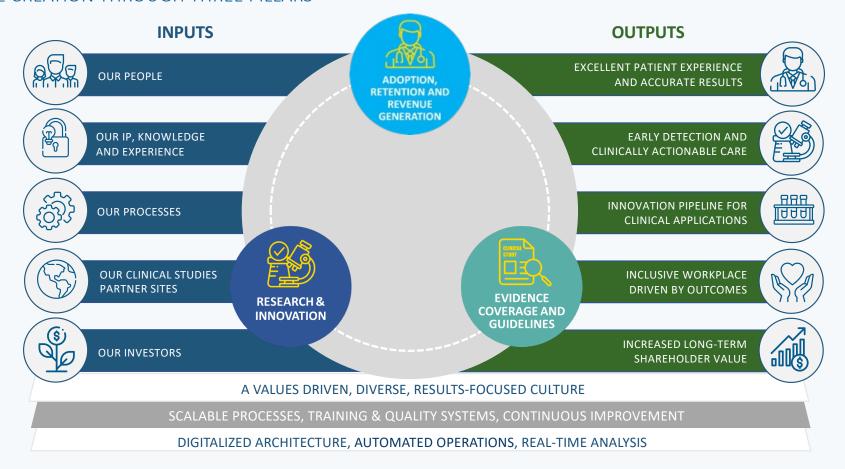
US\$2.0b

New market accessed via IVD / kitted tests



Pacific Edge estimate using US\$1,018 price for hematuria testing in the US and US\$760 for NMIBC surveillance and other market assumptions for APAC and Europe. See slide 38 of this presentation for the sources and assumptions for the calculation of TAM

VALUE CREATION THROUGH THREE PILLARS





## **AUA MICROHEMATURIA GUIDELINE INCLUSION**

#### A COMPANY-DEFINING STRATEGIC MILESTONE ACHIEVED IN FEBRUARY 2025



The 2025 amendment to the AUA microhematuria guideline supports the use of urine-based biomarkers for intermediate-risk patients as an alternative to a cystoscopy

- Primary driver for the change in the guidelines was clinical utility evidence for Cxbladder Triage from a randomized controlled trial, i.e. the STRATA Study<sup>1</sup>
- Cxbladder Triage specifically mentioned as the only urine-based biomarker test that has 'Grade A'<sup>2</sup> evidence cementing first-mover advantage and building a moat vs competitors
- The change was significant:
  - The 2020 guideline expressly prohibited the use of urine-based biomarkers in lieu of a cystoscopy
  - The 2025 guideline brings genomic testing to hematuria evaluation for bladder cancer as already established for prostate, breast, colon and other cancers
- Intermediate-risk patients represent a large cohort (~70%)<sup>3</sup> of microhematuria patients (up to 3.5 million patients annual in the US)
- Offers significant benefits to patients, reduces the burden of unnecessary cystoscopies, improves access to care at a lower cost and reduces legal liability for using biomarker alternatives

AUA guideline inclusion provides significant global clinical validation for Cxbladder which is expected to pave the way for further wider global adoption by healthcare providers and payers – we have already noticed increased interest from physicians



"... [for] intermediate-risk

patients who want to avoid cystoscopy and
accept the risk of forgoing direct visual
inspection of the bladder urothelium, clinicians
may offer urine cytology or validated urine-based
tumor markers to facilitate the decision
regarding utility of cystoscopy."

- 2025 AUA Microhematuria Guideline Amendment



- 1. Lotan et al. (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.
- 2. The AUA defines 'Grade A' evidence as evidence with a high certainty rating and notes evidence of this grade makes it "very confident that the true effect lies close to that of the estimate of the effect"
- 3. Pacific Edge estimate based on the new risk categories created with the 2025 microhematuria guidelines

## MEDICARE NON-COVERAGE FOR CXBLADDER EFFECTIVE IN APRIL 2025

NON-COVERAGE LIKELY TO IMPACT TEST VOLUMES AND REIMBURSEMENT<sup>1</sup>



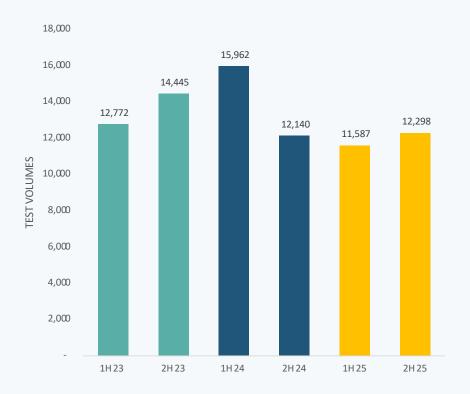
#### MEDICARE COVERAGE COMMENCED IN 2020 BUT CEASED IN 2025

- Medicare reimbursed Cxbladder tests >98% since 2020 at U\$\$760 per test these tests have accounted for the majority of US volumes and ~61% of revenue in FY25
- Novitas the Medicare Administrative Contractor that determines Medicare coverage for our tests – proposed non-coverage for Cxbladder in July 2022 (2H 23).
- We challenged this determination with more recent evidence and support from the AUA<sup>1</sup>, but Novitas finalized its non-coverage determination in January 2025 without considering the most-current evidence available. Litigation has ceased.
- This decision was a poor outcome for Medicare patients and urologists. It removed coverage for AUA guideline-recommended testing, after following a process that failed to review the most-current evidence
- ~47% of US volumes are from other contracted payers (e.g. Kaiser Permanente, the US Veterans Administration and various Blue Cross Blue Shield plans) and non-contracted private payers these volumes are expected to continue to grow without interruption
- We will continue to supply tests to existing US users and will attempt to get reimbursed on all Triage tests based on the 2025 AUA microhematuria guideline through the Medicare appeal process



Medicare is the US national insurance payer for all US citizens over 65 years of age – the most at risk age demographic for bladder cancer

#### US TOTAL TEST VOLUME<sup>2</sup>



- 1. See "Medicare coverage uncertainty" and "Ongoing Financial Viability" risks on slide 28.
- 2. Total Laboratory Throughput (TLT) including commercial, pre-commercial and clinical studies testing
- . AUA: American Urological Association



## SEEKING RE-COVERAGE VIA LCD RECONSIDERATION AND MEDICARE APPEALS

RECONSIDERATION REQUESTS FOR TRIAGE AND MONITOR; APPEALS TO RELY ON GUIDELINE INCLUSION



#### RESTORING MEDICARE COVERAGE FOR TRIAGE AND MONITOR

- **Cxbladder Triage:** A reconsideration request was submitted to Novitas in March 2025 consisting of STRATA<sup>1</sup> and the AUA Microhematuria guideline and is under review
- **Cxbladder Monitor:** A reconsideration request was submitted to Novitas in May 2025 consisting of two new real-world studies from Australia and is under review
- **Cxbladder Detect:** Detect users are being migrated to Triage, accelerating a plan previously intended to coincide with the commercial launch of Triage Plus
- Industry experts typically estimate it is likely to take 6-9 months for Novitas to consider a valid submission of a single product with only a small number of new supporting publications to be reviewed.
- We will attempt to get reimbursed on all Triage tests based on the 2025 AUA microhematuria guideline through the
  Medicare appeal process; the guideline supports our claim for reimbursement on the grounds of being "medically
  reasonable and necessary" despite a non-coverage determination

#### **ESTABLISHING MEDICARE COVERAGE FOR TRIAGE PLUS**

- The analytical validation (AV) and clinical validation (CV) publications for Triage Plus have been submitted for peer review in appropriate scientific journals seeking publication in FY26 Q1
- Pacific Edge will submit a reconsideration request for Triage Plus when the AV and CV is published
- Inclusion of Triage in the AUA microhematuria guideline provides medical policy for Medicare coverage of Triage Plus, meaning AV and CV should be sufficient for coverage
- Further evidence for Triage published by Kaiser Permanente as a presentation at AUA and in peer review by FY26 Q3 further confirms Triage and Triage Plus clinical utility and health economics
- Draft Triage Plus pricing at US\$1,018 is expected to become effective from January 2026



Lotan et al. (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.

## **MEDICARE RE-COVERAGE: ESTIMATED TIMELINES**



COVERAGE DECISIONS, PRIOTIZATION AND TIMELINES ARE AT THE DISCRETION OF NOVITAS  $^{\mathrm{1}}$ 

MEDICARE RECONSIDERATION REQUEST	CATALYST	2025*		2026*					
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Reconsideration request for Triage	STRATA Study (May 2024) AUA Macrohematuria guideline (Feb 2025)								
Reconsideration request for Monitor	AV of Triage, Detect & Monitor (Sept 2024) 2x RWE of Monitor (March 2025)								
Reconsideration request Triage Plus	AV of Triage Plus (Q2E 25)** CV of Triage Plus – DRIVE Study (Q2 25)**								

<sup>\*</sup>Calendar year

**Expected Novitas determination window** 

#### FUTURE CATALYSTS FOR GUIDELINES INCLUSION AND MEDICARE COVERAGE

Publication	Test and evidence standard <sup>2</sup>	Expected date <sup>3</sup>
1. STRATA Concordance	<ul> <li>CU of Triage Plus (concordance)</li> </ul>	Q4 2025
2. Kaiser Permanente Triage RWE <sup>4</sup>	<ul> <li>CU of Triage (RWE)</li> </ul>	Q3 2025 <sup>5</sup>
2. Kaiser Permanente Monitor RWE <sup>4</sup>	- CU of Monitor	Q1 2026 <sup>5</sup>
4. AUSSIE	<ul> <li>CV of Triage Plus</li> </ul>	Q1 2026
5. microDRIVE	<ul> <li>CV of Triage Plus</li> </ul>	Q2 2026
6. Monitor Plus Analytical Validation	<ul> <li>AV of Monitor Plus</li> </ul>	Q2 2026
7. Pooled Analysis <sup>6</sup>	<ul> <li>CV of Triage Plus</li> </ul>	Q2 2026
8. LOBSTER interim analysis	<ul> <li>CV of Monitor/Monitor Plus</li> </ul>	Q1 2027
9. CREDIBLE	<ul> <li>CU of Triage Plus</li> </ul>	Q1 2028

<sup>&</sup>lt;sup>1</sup> Novitas is the Medicare Administrative Contractor (MAC) that covers Pacific Edge Diagnostics USA's lab in Pennsylvania



<sup>\*\*</sup> Estimated publication quarter

<sup>&</sup>lt;sup>2</sup> AV, CV, CU, respectively Analytical Validity, Clinical Validity, Clinical Utility

<sup>&</sup>lt;sup>3</sup> Calendar year

<sup>&</sup>lt;sup>4</sup> RWE is Real World Evidence

<sup>&</sup>lt;sup>5</sup> Timeline determined by Kaiser Permanente

<sup>&</sup>lt;sup>6</sup> The pooled analysis uses data from DRIVE, AUSSIE and microDRIVE studies

## DEMONSTRATED RESILIENCE DURING MEDICARE UNCERTAINTY





#### SALES TEAM FOCUSED ON KEY PERFORMANCE INDICATORS

- Sales FTE down to an average of 16.0 in Q4 25 from 32.7 in Q4 23 as we focused on cash conservation
- Sales force efficiency (total tests/average FTE) up 69% from 239 in Q4
   23 to 405.6 in Q4 25:
  - More effective core sales team
  - Focus on the most profitable territories/accounts
- Tests/US ordering clinician stable, ordering clinicians steady on Q4 24:
  - Change in clinical mix in favor of clinicians that understand the clinical utility of Cxbladder
- Average US Sales Price increases with improved cash collection

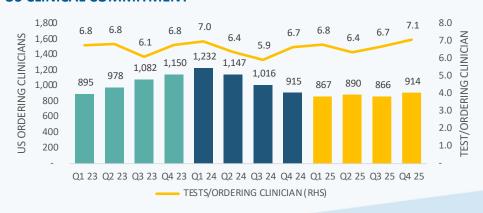
#### **US AVERAGE SALES PRICE**



#### **US SALES FORCE EFFICIENCY**



#### **US CLINICAL COMMITMENT**



## MEDICARE PRICE FOR TRIAGE PLUS ACCELERATES PATH TO PROFITABILITY

DRAFT PRICE FOR TRIAGE PLUS OF US\$1,018.44 PER TEST PUBLISHED APRIL 2025



#### MEDICARE COVERAGE NEEDED BEFORE FULL-SCALE COMMERCIAL LAUNCH

- The Centers for Medicare & Medicaid Services (CMS) price of US\$1,018 for Triage Plus materially lifts margin per test from the previous pricing at US\$760
- Lowers the profitability threshold for number of tests per Account Executive facilitating more rapid scaling and a faster path to profitability
- A reconsideration request will be made to Novitas for coverage of Triage Plus as soon as the analytical validation (AV) and clinical validation (CV) studies have been published (estimated in June 2025)

#### **ACCELERATING THE PATH TO PROFITABILITY**

- Adding digital capabilities and FTE<sup>1</sup> capacity to PEDUSA laboratory
- Simplifying laboratory workflow for improved efficiency
- Optimizing sales team structure for expanded product adoption
- Sales and marketing materials to reflect AUA Guideline messaging
- Enhancing medical education with a speaker bureau, podium presentations, and evidence development







PATIENT/DISEASE MANAGEMENT (CLINICAL DECISION MAKING)

SURVEILLANCE (RDM<sup>1</sup>, TRM<sup>2</sup>, RECURRENCE)











## **SUCCESS IN OTHER CHANNELS CONTINUES**

#### NON-MEDICARE TESTS IN ASIA PACIFIC CONTINUE TO GROW



#### **NON-MEDICARE TESTING**

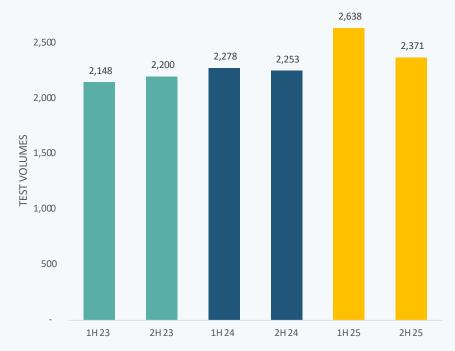
- Non-Medicare testing was primarily from New Zealand and Kaiser Permanente during FY25, but also smaller volumes from Australia, Southeast Asia and the Veterans Administration
- Non-Medicare testing has grown by 22% of the testing mix to 57% since focusing on it after reducing sales headcount in September 2023<sup>1</sup>

#### DRIVING GROWTH IN SOUTHEST ASIA AND CONSOLIDATING NZ

- New Zealand continues to lead the global adoption of Cxbladder by primary care.
   The market is now mature with Cxbladder utilized regions covering >75% of the population
- STRATA<sup>2</sup> and AUA Microhematuria Guideline are well understood in Te Whatu Ora/Health New Zealand; Pacific Edge is focused on a National Pathway for hematuria evaluation
- Southeast Asia is still in business development, and we are extending our reach into the market through a distributor network which has seen testing volumes grow
- While our primary near-term focus remains on the US, Southeast Asia has large population centers, private healthcare systems, and favorable cultural and demographic considerations to be a high-volume market for an IVD-kitted product



#### **APAC TOTAL TEST VOLUME\***



<sup>\*</sup> Total Laboratory Throughput (TLT) including commercial, pre-commercial and clinical studies testing



- . As a result of right-sizing of US Sales force in response to Novitas LCD as we focused on cash conservation
- Lotan et al. (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria
  The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.

## **SUCCESS IN OTHER CHANNELS CONTINUES**

#### NON-MEDICARE TESTS AT KAISER PERMANENTE CONTINUE TO GROW



#### KAISER PERMANENTE PROVIDING SIGNIFICANT VALIDATION

- Kaiser Permanente is the largest non-profit healthcare provider in the US with over 12 million members and has been commercially using Cxbladder since 2020
- In November 2023, we launched our EMR integration with the Southern California Permanente Medical Group, streamlining sample collection, test ordering, and results for Triage and Monitor. Test volumes are steadily increasing and longer term we are targeting other Kaiser Permanente Medical Groups
- Kaiser Permanente's Real World Evidence<sup>1</sup> further demonstrates the clinical utility evidence of Cxbladder Triage and will be used with Medicare reconsideration requests
- Kaiser Permanente's Southern California Region is ~35% of the total Kaiser Permanente Group, and opportunities to expand to other regions continue to be prioritized

#### AUA GUIDLINE OFFERS NEW OPPORTUNITIES FOR CLIENT BILLING

- With AUA guideline inclusion, a new opportunity exists to get paid per test by hospitals and large urology group practices (LUGPAs) and let them handle the commercial reimbursement
- This provides a revenue incentive to hospitals/LUGPAs and has the potential to drive volume, since they are commonly "in-network" with commercial payers and have sophisticated billing teams







Real World Clinical Utility of a Urinary Biomarker (Cxbladder Triage) for Hematuria Referrals in an Integrated Managed Care Health System. Abstract accepted for presentation to the Western Section of the American Urological Association annual conference.

## **CUSTOMER EXPERIENCE INTIATIVES DELIVERING VALUE**

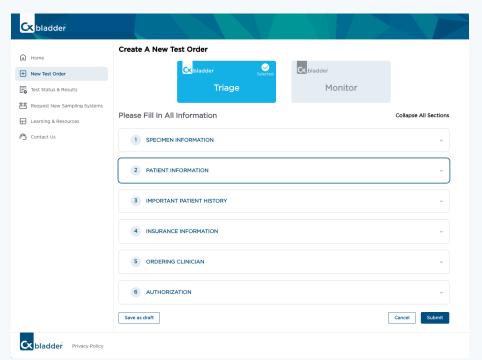
#### DIGITALIZING CUSTOMER EXPERIENCE EMBEDS CXBLADDER IN CLINICAL PRACTICE



#### **ENHANCING CXBLADDER'S EASE OF USE**

- We give customers options to connect with Pacific Edge to fit their needs with easy-to-use digital integrations
- Digital channels for test ordering and results delivery
  - 1-to-1 EMR Integration, e.g. Kaiser interface
  - 1-to-many Integration, e.g. Lumea Digital Pathology, Awanui
  - Customer portal available to any Customer Account
- Improves the end-to-end experience for physicians
  - Easier ordering in-clinic or for in-home sampling systems
  - Optimized test kit management and workflow
  - Enhanced order visibility and tracking
  - Streamlined access to results
- Pacific Edge's operations benefit
  - Fewer errors, faster handling and results delivery
  - Reduced demand on the sales force and customer service

#### THE PACIFIC EDGE CUSTOMER PORTAL











## FOCUSED ON THE DNA ENHANCED PRODUCT LAUNCH AND THE IVD STRATEGY



### AN IVD PRODUCT MAY EXTEND THE MARKET OPPORTUNITY AND THE 'MOAT' AROUND CXBLADDER

#### READYING FOR THE LAUNCH OF TRIAGE PLUS AND MONITOR PLUS

- Ensure R&D, Digital and Lab Operations focus on the commercial scaling of Triage
   Plus and development of Monitor Plus
- Simplifying Cxbladder:
  - Aim to reduce technician time, lower cost of goods, lower turnaround time, increase throughput and increase automation of our lab testing services
  - Aim to automate lab operations from end-to-end lab for RNA and DNA workflows of our lab testing services
- Continued engagement with industry and academic research and development collaborations to address unmet clinical needs in bladder cancer diagnosis and management

#### ADVANCING OUR IN-VITRO STRATEGY FOR INTERNATIONAL MARKETS

- Accelerating the development of a kitted IVD (in vitro diagnostic) product from our existing lab service called Triage Plus IVD, for decentralized lab deployment and international market expansion
  - Establish IVD regulatory framework for our next generation tests that includes IVD-R (Europe), FDA (USA) and ISO-13485<sup>1</sup> (Rest of World)
  - Targeting prototypes by the end of CY 25; manufacture and commencement of clinical and analytical validation commencing in CY 26
- Achieving IVD-approved status may make it more difficult for competitors to develop parity with Cxbladder's level of evidence



Chief Scientific Officer Parry Guilford (center) and Chief Technology Officer Justin Harvey (right)





## **OUTLOOK**

#### RECENT CATALYSTS FOR STRONG GROWTH – VOLUME AND PRICING

- AUA microhematuria guideline enables sales, marketing and reimbursement activities. We are determined to maximize this milestone through existing and new initiatives
- Triage Plus draft pricing at US\$1,018 supports stronger unit economics, margins and sales force
  efficiency for a faster path to cash flow breakeven if successful in re-establishing Medicare
  coverage

#### **GROWTH STRATEGY - TO BE ACCELERATED WITH NEW CAPITAL**

- Entrench first-mover advantage and "moat" for Triage given AUA guideline inclusion
- Continue clinical evidence generation in an AV, CV and CU framework for coverage, guidelines and medical policy for Triage Plus and Monitor Plus
- Increase Triage throughput, throughput/sales headcount and throughput/clinician
- Seek reimbursement through the Medicare Appeals process, relying on the AUA guideline, ahead of the resolution of multiple reconsideration requests
- Increase the percentage of electronically ordered tests and patients with commercial insurance
- Emphasize the clinical and economic value of Cxbladder as a value-based care solution in our sales messaging for selling to institution, integrated hospital systems and payers
- "Client Billing" program to allow LUGPAs and hospitals to pay Pacific Edge for a test and bill commercial insurers themselves for reimbursement
- Invest in innovation and product development for IVD kits to support entry into international markets in a decentralized deployment model

#### **FURTHER CATALYSTS**

Cxbladder is under consideration by Te Whatu Ora for a National Pathway in New Zealand

# 2. CAPITAL RAISING OVERVIEW



## RAISING CAPITAL TO DRIVE GROWTH

Pacific Edge's strategy has not materially changed since the capital raising in 2021. However, the implementation of the strategy has not been as fast as intended given the focus on gaining reliable Medicare coverage

Pacific Edge's priority is to ensure it has the resources and capacity to capitalize on its recent clinical and commercial milestones, grow in non-Medicare channels and regain Medicare coverage

#### Funds raised will be used to:

- · Accelerate adoption of Triage in the US with AUA Guidelines as a tailwind for sales, marketing and reimbursement
- Continue clinical evidence generation in an AV, CV and CU framework for coverage, guidelines and medical policy for Triage Plus and Monitor Plus
- Invest in innovation and product development for IVD kits to support entry into international markets in a de-centralized deployment model
- Extend cash runway to support operations for over 12 months without Medicare coverage and reimbursement, or reductions in its
  cost base (assuming at least NZ\$20 million is raised in the capital raising to add to net cash of NZ\$22.6 million at 31 March 2025 and
  an average monthly cash burn of less than NZ\$2.6 million)



## **CAPITAL RAISING OVERVIEW**

Offer size and structure	<ul> <li>An equity raising, comprising:</li> <li>A NZ\$15 million Placement</li> <li>A NZ\$5 million Retail Offer</li> </ul>
Placement details	<ul> <li>The Placement Price will be NZ\$0.100 per share representing:         <ul> <li>22% premium to the last NZX closing price of NZ\$0.082 per share on 29 May 2025</li> <li>18% premium to the 20-day VWAP on NZX of NZ\$0.085 per share<sup>1</sup></li> </ul> </li> <li>Shareholder approval is required to complete the Placement given the Placement exceeds Pacific Edge's placement capacity (15% of Pacific Edge's current shares on issue) and due to the expected presence of Related Party participation. The Placement will also be conditional on all necessary regulatory approvals. In this regard, Pacific Edge intends to seek a waiver from NZX Listing Rule 4.19.1 to permit the allotment of shares under the Placement after shareholder approval is obtained</li> <li>The Placement offer will be made to selected investors under a trading halt</li> </ul>
Retail Offer details	<ul> <li>Pacific Edge reserves the right to vary the size of the placement based on the size and quality of investor demand</li> <li>Pacific Edge is offering up to NZ\$5 million of shares (with the ability to scale applications or accept oversubscriptions at the Board's discretion) to Pacific Edge's eligible existing shareholders resident in New Zealand (up to a maximum of NZ\$50,000 per shareholder) under a Retail Offer, structured as a share purchase plan<sup>2</sup></li> <li>The Retail Offer will be priced at the Placement Price of NZ\$0.100 per share</li> <li>Allotment of shares under the Retail Offer will be conditional on the Placement becoming unconditional</li> </ul>
Ranking	The new shares to be issued under both the Placement and Retail Offer will be fully paid ordinary shares which, on allotment, will rank equally in all respects with Pacific Edge's existing ordinary shares then on issue
Financial adviser	<ul> <li>Cameron Partners Limited is acting as financial adviser to Pacific Edge</li> <li>Neither the Placement nor the Retail Offer are underwritten</li> </ul>
	1 Volume weighted average price on N7X for the period 2 May 2025 to 29 May 2025

<sup>1.</sup> Volume weighted average price on NZX for the period 2 May 2025 to 29 May 2025

<sup>2.</sup> The Board reserves the right to extend the Retail Offer to Australian resident shareholders, subject to receiving any necessary Australian regulatory relief

## TIMETABLE<sup>1</sup>

Placement	
Placement conducted under trading halt	Friday, 30 May 2025
Announcement of the Placement results (subject to shareholder approval) and trading halt lifted on the NZX and ASX <sup>2</sup>	Tuesday, 3 June 2025
Shareholder approval for the Placement	By Early August 2025
Settlement, allotment and trading of Placement shares on NZX and ASX commence	By Mid August 2025
Retail Offer	
Record date	July/August 2025
Retail Offer opens and documentation sent to eligible shareholders	July/August 2025
Retail Offer closes	August 2025
Announcement of results of Retail Offer	August 2025
Settlement, allotment and trading of Retail Offer shares on NZX commence	August 2025

<sup>1.</sup> These dates are indicative and subject to change.

<sup>2.</sup> NZX closed on Monday, 2 June 2025 due to King's Birthday

# 3. KEY RISKS AND FOREIGN SELLING RESTRICTIONS



## **KEY RISKS**

#### **IMPORTANT:**

Like any investment, there are risks associated with an investment in Pacific Edge shares. Before investing in Pacific Edge, you should be aware than an investment in Pacific Edge has a number of risks, some of which are specific to Pacific Edge and some of which relate to listed securities generally, and many of which are beyond the control of Pacific Edge. Additionally, some risks may be unknown and other risks, currently believed to be immaterial, could turn out to be material. Whilst the section below aims to highlight some of the key risks, it is not exhaustive.

Before deciding whether to invest in Pacific Edge shares, you must make your own assessment of the risks associated with the investment and consider whether such an investment is suitable for you having regard to all other Pacific Edge continuous disclosure announcements and publicly available information and consult your financial adviser and other professional advisers.



# **KEY RISKS (CONT)**

	Medicare coverage uncertainty	Pacific Edge does not currently have Medicare coverage for its Cxbladder products. Medicare previously accounted for the majority of its US test volumes and, therefore, a significant percentage of Pacific Edge's revenue. Although Pacific Edge is confident that it will regain coverage for Triage as a result of recent AUA guideline inclusion and new clinical evidence, there are no guarantees as to the timing or outcome of the re-coverage process. Regaining Medicare coverage could be delayed or not achieved at all. If Medicare re-coverage was not achieved or was significantly delayed, it would have a material adverse impact on Pacific Edge's financial performance and growth and could result in the company using up all available cash before it is able to become profitable from its ongoing operations.  If the current reconsideration request is unsuccessful, Pacific Edge will likely need to complete further clinical studies to provide new published evidence when submitting
		another reconsideration request. That clinical study will take a number of years to undertake. Accordingly, if the current reconsideration request is unsuccessful, Pacific Edge will need to undertake a significant restructure of its business to substantially reduce costs and, potentially, seek to raise further capital.
	Ongoing Financial Viability	Pacific Edge is operating at a 'cash burn', which means that the company spends more cash that it generates. The capital raise outlined in this presentation is in part to provide sufficient cash to regain Medicare coverage. If the capital raise is undersubscribed, if Medicare coverage is not achieved or significantly delayed, or the business is impacted adversely by other events, there is a risk to the ongoing financial viability of Pacific Edge, which may result in investors losing some or all of their investment.
	Regulatory, industry body and guideline risks	Pacific Edge's Cxbladder products and laboratories are regulated and certified by various government and industry entities in territories and markets in which the tests are performed and/or sold. Reimbursement for these tests may be influenced by reimbursement rulings from private and/or government payers. Guidelines issued by various industry bodies also influence the treatment and management regimes for patients, with the potential to impact on the uptake and use of Cxbladder. If Pacific Edge is unable to retain or, in certain markets, gain inclusion in guidelines, or the current regulatory approvals and reimbursement obtained for existing products are removed or reduced, such matters could have an adverse impact on Pacific Edge's financial performance and its ability to achieve its business plans. If Pacific Edge's financial performance and its ability to achieve its business plans.
-	Competition	The global cancer diagnostics industry is highly competitive, with research undertaken by a large number of commercial and not for profit institutions globally on new diagnostic tools. There are also a large number of well capitalised diagnostics competitors operating in the industry. There is a risk that Pacific Edge's competitors may discover, develop or commercialise products more successfully than Pacific Edge, which could render Pacific Edge's products obsolete or otherwise uncompetitive, resulting in adverse effects on Pacific Edge's revenue, margins and profitability.
	Product and technology risk	Pacific Edge relies on the performance and reliability of its Cxbladder suite of products, laboratory operations and IT and technical systems. While the performance of Cxbladder has been demonstrated in various scientific journal publications, any change to the reliability, repeatability, reproducibility or accuracy of Cxbladder products and technology systems has the potential to impact Pacific Edge's business and reputation. Cyber attacks on Pacific Edge digital systems and platforms also have the potential to impact the delivery of test results. Financial, reputational and litigation consequences relating to underperformance and unreliability, or the inability to deliver, test results (including due to adverse cyber incidents) have the potential to be significant and could be materially adverse to the company's financial performance and position.
3	General economic conditions	Pacific Edge's operating and financial performance is influenced by a variety of general economic and business conditions in New Zealand, the United States, Southeast Asia and globally. A prolonged deterioration in general economic conditions, which may lead to a decrease or reprioritisation of healthcare spending, has the potential to have a material adverse effect on Pacific Edge's business or financial condition (or both).

adverse effect on Pacific Edge's business or financial condition (or both).

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# **KEY RISKS (CONT)**

Litigation	In the ordinary course of conducting its business, Pacific Edge is exposed to potential litigation and other proceedings, including through claims of intellectual property infringement or breach of agreements. If such proceedings are brought against Pacific Edge, Pacific Edge could incur considerable defence costs (even if successful), with the potential for damages and costs awards against Pacific Edge if it were unsuccessful, which could have a significant adverse financial impact on Pacific Edge.  Circumstances may also arise in which Pacific Edge considers that it is reasonable or necessary to initiate litigation or other proceedings, including for example to protect its intellectual property rights.		
Key Person Risk	The success of our business depends significantly on the continued contributions of our executive team, scientific leaders, and key technical staff. The unexpected departure of any of these individuals could disrupt operations, delay research and development efforts, and negatively impact strategic initiatives. Attracting and retaining top talent in a competitive biotech labor market remains a critical challenge.		
Market volatility of Pacific Edge's shares	Any investment in equity capital markets carries general risks. Pacific Edge's shares are currently listed on NZX and the ASX, and are subject to the usual market-related forces which impact on Pacific Edge's share price. There can be no assurance that trading in the shares following the offer will not result in the share price trading at levels below the price paid by investors in the offer. The equity markets can be subject to pronounced volatility. This volatility could have a materially adverse impact on the market price of Pacific Edge shares.  Factors such as the risk factors disclosed in this presentation as well as other factors could cause the market price of Pacific Edge's shares to decline or to materially fluctuate. It also is possible that new market risks may develop as a result of the New Zealand or Australian markets experiencing extreme stress, or due to existing risks manifesting themselves in ways that are not currently foreseeable.  A weakening in the New Zealand or Australian dollar as against other currencies will cause the value of the shares to decline in any portfolio which is denominated in a currency other than New Zealand dollars.		
New product development	Pacific Edge continues to leverage its suite of patents and intellectual property to explore new products and applications. There is a risk that those development efforts may not be successful or may take longer and be more expensive than anticipated, and as a result Pacific Edge's investment will be delayed or lost. This risk could arise due to a number of factors, including delays in commencement or completion of scientific studies. Any failure or significant delay in the development of one or more of Pacific Edge's new products and product extensions may have a material negative impact on Pacific Edge's financial performance and growth.		

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## **FOREIGN SELLING RESTRICTIONS**

#### **International Offer Restrictions**

This document does not constitute an offer of new ordinary shares (New Shares) of Pacific Edge in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares, may not be offered or sold in any country outside NZ except to the extent permitted below.

#### Australia

This document and the offer of New Shares are only made available in Australia to persons to whom an offer of securities can be made without disclosure in accordance with applicable exemptions in sections 708(8) (sophisticated investors), 708(11) (professional investors), 761G (wholesale clients) of the Australian Corporations Act 2001 (Cth) (the "Corporations Act"). This document is not a prospectus, product disclosure statement or any other formal "disclosure document" for the purposes of Australian law and is not required to, and does not, contain all the information which would be required in a "disclosure document" under Australian law. This document has not been and will not be lodged or registered with the Australian Securities & Investments Commission. Prospective investors should not construe anything in this document as legal, business or tax advice nor as financial product advice for the purposes of Chapter 7 of the Corporations Act and the information provided does not take into account the investment objectives, financial situation or particular needs (including financial and tax issues) of any prospective investor. Prospective investors should review the risks set out on slides 28 and 29 before making any investment decision

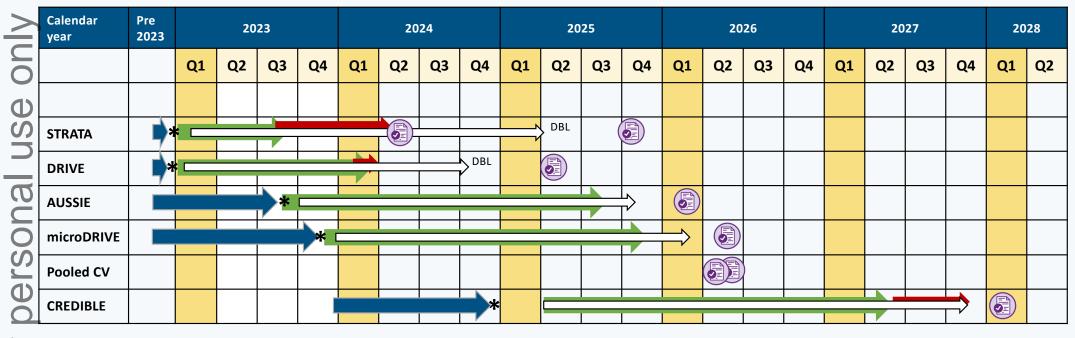
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This presentation is not for distribution or release in the United States. This presentation does not constitute an offer to sell, or the solicitation of an offer to buy, any securities in the United States. The New Shares have not been, and will not be, registered under the US Securities Act of 1933, as amended, or the securities laws of any state or other jurisdiction of the United States, and may not be offered or sold in the United States except in transactions exempt from, or not subject to, registration under the US Securities Act of 1933, as amended, and applicable US state securities laws.

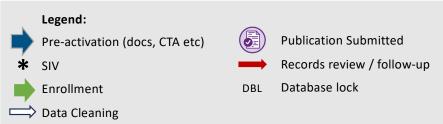




## **HEMATURIA EVALUATION FIVE YEAR CLINICAL STUDIES ROADMAP**







## **SURVEILLANCE FIVE YEAR CLINICAL STUDIES ROADMAP**

Calendar year	Pre 2023		20	23			20	24			20	25			20	26			20	27		20	28
		Q1	Q2	Q3	Q4	Q1	Q2																
"The 1800"																							
LOBSTER	*																						
OCTOPUS															ŕ								





## **SUMMARY OF CXBLADDER CLINICAL EVIDENCE**

		Publication or Study	Population	Sensitivity (Sn)	NPV	Specificity (Sp)	Comment
	AV	Harvey et al., submitted	Synthetic Analytes MH + GH	93.6%	99.4%	90.8%	Publication submitted; development dataset (n=987) including MH (38.7%) & GH (61.3%) producing defined Sn, NPV and Sp. TNR in development data set is 84.1%
		DRIVE (Savage et al., submitted)	MH + GH	94%	99.3%	77%	Publication submitted; TNR 71%.; PPV 26% at lower cut-point, 51% at higher cut-point with a Sp of 97%
CTriage Plus	cv	AUSSIE	MH + GH	TBC	TBC	TBC	Study in progress on MH and GH patients
$\circ$		microDRIVE	MH	TBC	TBC	TBC	Study in progress on MH patients
4	CU	CREDIBLE	MH	TBC	TBC	TBC	Study in progress on MH patients
Φ							
S	AV	Harvey et al., 2024	Synthetic Analytes	N/A	N/A	N/A	Multi-product analytical validation of Cxbladder Triage, Detect and Monitor
$\overline{}$		Kavalieris et al., 2015	MH + GH	95%	98.5%	45%	Sn, Sp, NPV values when TNR is 40%
	cv	Davidson et al., 2019	MH + GH	95.5%	98.6%	34.3%	GH only: Sn (95.1%), NPV (98%), Sp (32.8%); MH only: Sn (100%), NPV (100%), Sp (42.6%); Cxb Triage & imaging combined performance had a Sn of 97.7% & NPV of 99.8%
Triage		Lotan et al., 2023	MH + GH	89%	99%	63%	Pooled data from US and Singapore cohorts (n=804); TNR 59%; PPV 16%
Thage		DRIVE (Savage et al., submitted)	MH + GH	93%	98.5%	38%	Publication submitted and under peer review; TNR 35%; PPV 11%
O	CU	Davidson et al., 2020	MH + GH	89.4%	98.9%	59%	39% of patients testing negative for Cxb Triage & imaging did not get cystoscopy & were managed at primary care; Study wide CV: Cxb Triage & imaging combined performance: Sn 98.1%, NPV 99.9%, Sp 98.4%
rs L	CO	Lotan et al., 2024	MH + GH	90%	99%	56%	Clinicians using Triage used 59% fewer cystoscopies on low-risk patients presenting with MH; CV was provided study wide (UC, n=22): Sn 90%, Sp 56%, PPV 15%, NPV 99%
<u>(1)</u>							
	AV	Harvey et al., 2024	Synthetic Analytes	N/A	N/A	N/A	Multi-product analytical validation of all Cxbladder products
	cv	Kavalieris et al., 2017	NMIBC	93%	97%	N/A	Internally validated "bootstrap corrected estimates" from development dataset (n=1036), TNR 34%; Sn of CxbM was 97% (N = 70/72) for HG tumors and 85% (N = 66/78) for LG tumors.
$\overline{C}$		LOBSTER	NMIBC	TBC	TBC	TBC	Study in progress on NMIBC patients
Monitor		Koya et al., 2020	NMIBC	100	100	77.8	Integration of Cxb Monitor into the surveillance schedule reduced annual cystoscopies (39%)
щ.	CU	Li et al., 2023	NMIBC	100	100	72	Cxbladder Monitor safely postpones a patient's next scheduled cystoscopy, the current 'gold standard' for bladder cancer surveillance
		Guduguntla et al., 2025	NMIBC	N/A	N/A	N/A	Australian single-center study in NMIBC patients showed that alternating Cxbladder Monitor with cystoscopy safely reduced cystoscopy use without increasing recurrence risk

NOTE #1: Full references provided on following slide

NOTE #2: Development, feasibility and/or proof of concept studies are detailed within the references on the following slide
Abbreviations - MH: Microhematuria, GH: Gross Hematuria, Sn: Sensitivity, Sp: Specificity, NPV: Negative Predictive Value, PPV: Positive Predictive Value, TNR: Test Negative Rate

# **REFERENCES SUMMARY OF CLINICAL EVIDENCE**

	References	Comment			
	Holyoake et al., (2008). Development of a Multiplex RNA Urine Test for the Detection and Stratification of Transitional Cell Carcinoma of the Bladder. Clin Cancer Res 14(3): 742-749	Feasibility of urine-based assay including biomarker discovery for urothelial cancer detection initial algorithm development			
	O'Sullivan et al., (2012). A multigene urine test for the detection and stratification of bladder cancer in patients presenting with hematuria. The Journal of urology, 188(3), 741-747.	Development/feasibility of Cxbladder Detect assay and algorithm based on RNA expression biomarkers			
Proof of Concept	Unitary at al. (2023) Urinary Analysis of EGER3 and TERT Gang Mutations Enhances Partormance of Cyhladder Tests and Improves Patient Rick Stratitication. The	Pooled data from MH and GH cohorts (n=804) for 'multi-modal' (RNA+DNA) assay and algorithm development for next generation Cxbladder product including TERT and FGFR3 SNPs. Called Detect+ in publication.			
O	Tyson et al., (2024). Budgetary Impact of Including the Urinary Genomic Marker Cxbladder Detect in the Evaluation of Microhematuria Patients. Urol Prac 11(1):54-60	Budget impact model for hematuria pathway, incorporating Cxbladder Detect into patient management			
S					
		Analytical validation of Triage Plus			
Triage P	Savage et al., submitted. Diagnostic Performance of Cxbladder® Triage Plus for the Identification and Stratification of Patients at Risk for Urothelial Carcinoma: The Multicenter, Prospective, Observational DRIVE Study.	Clinical validation of Triage Plus (DRIVE Study)			
$\overline{\alpha}$					
	Kavalieris et al., (2015). A segregation index combining phenotypic (clinical characteristics) and genotypic (gene expression) biomarkers from a urine sample to triage outpatients presenting with hematuria who have a low probability of urothelial carcinoma. BMC urology, 15(1), 1-12.	Algorithm development and clinical validation of Cxbladder Triage			
0	Harvey et al., (2024). Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.	Analytical validation of all Cxbladder products Triage, Detect and Monitor			
S	Davidson et al., (2019). Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. NZ Med J, 132(1497), 55-64.	Clinical validation of Cxbladder Triage			
Triage	Davidson et al., (2020). Assessment of a clinical pathway for investigation of haematuria that reduces the need for cystoscopy. The New Zealand Medical Journal (Online), 133(1527), 71-82.	Clinical utility of Cxbladder Triage			
<u>o</u>	Lotan et al., (2023). Urinary Analysis of FGFR3 and TERT Gene Mutations Enhances Performance of Cxbladder Tests and Improves Patient Risk Stratification. The Journal of Urology, 10-1097.	Clinical validation of Cxbladder Triage from pooled data (USPrimary and Singapore pooled analysis; n=804)			
_	Lotan et al., (2024). A Multicenter Prospective Randomized Controlled Trial Comparing Cxbladder Triage to Cystoscopy in Patients With Microhematuria. The Safe Testing of Risk for Asymptomatic Microhematuria Trial. The Journal of Urology Vol 212 1-8 Jul 2024.	Clinical utility of Cxbladder Triage from STRATA study showing a 59% relative reduction in cystoscopy when comparing test and control arms			
LL.	Harvey et al., (2024). Analytical Validation of Cxbladder® Detect, Triage, and Monitor: Assays for Detection and Management of Urothelial Carcinoma. Diagnostics. 2024; 14(18):2061.	Analytical validation of all Cxbladder products Triage, Detect and Monitor			
	Kavalieris et al., (2017). Performance characteristics of a multigene urine biomarker test for monitoring for recurrent urothelial carcinoma in a multicenter study. The Journal of Urology, 197(6), 1419-1426.	Algorithm development and clinical validation of Cxbladder Monitor			
Monito	Koya et al., (2020). An evaluation of the real-world use and clinical utility of the Cxbladder Monitor assay in the follow-up of patients previously treated for bladder cancer. BMC urology, 20(1), 1-9.	Clinical utility of Cxbladder Monitor with low risk NMIBC patients			
	Li et al., (2023). Cxbladder Monitor testing to reduce cystoscopy frequency in patients with bladder cancer. Urologic Oncology: Seminars and Original Investigations, 41 (7), 326.e1 – 326.38.	Clinical utility of Cxbladder Monitor with NMIBC patients			
	Tyson et al., accepted. Economic Impact Model of Incorporating Cxbladder Monitor in the Surveillance of Non-Muscle Invasive Bladder Cancer. JU Open Plus, accepted	Budgetary impact model when Cxbladder Monitor was incorporated into patient management			

# **Glossary**

- Sensitivity (Sn) the frequency with which a test correctly identifies patients with a disease.
- Specificity (Sp) the frequency with which a test correctly identifies patients without a disease.
- Negative Predictive Value (NPV) the percentage of negative tests being true negatives (by standard of care).
- Positive Predictive Value (PPV) the percentage of positive tests being true positives (by standard of care).
- Rule-out Rate (ROR) the percentage of tests that return a negative result.
- Evidence definitions:
  - Analytical validity (AV) Evidence that a test is repeatable in the lab for a given indication and population.
  - Clinical validity (CV) Evidence a test works in the same way on an independent eligible population for a given indication.
  - Clinical utility (CU) Evidence that a test in the hands of a physician can usefully change patient management within the context of care for the defined population and indication.
- EMR Electronic Medical Record
- ASP Average Sales Price
- FTE Full Time Equivalent



# **SOURCES AND ASSUMPTIONS - TOTAL ADRESSABLE MARKET**

ı	REGION	STATISTIC		SOURCE					
		Population		https://www.census.gov/popclock/					
		Incidence of hematuria	7,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019					
		Referred for clinical workup		Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019					
		Receive a cystoscopy	>1,000,000	Kenigsberg, A, et al. The Economics of Cystoscopy: A Microcost Analysis, Urology 157: 29–34, 2021					
		Annual cases of bladder cancer	84,870	National Cancer Institute					
	US								
		Patients living with bladder cancer	744,044	National Cancer Institute					
		Test opportunities	4,616,066	Pacific Edge estimate					
		Price of Cxbladder (US\$)	US\$1,018 (Triage Plus), US\$760 (Monitor)						
		TAM (US\$b)	US\$4.4						
-		(0070)	·						
		Population	600,000,000	World-population - Europe; World-population - Russia					
		Incidence of hematuria	12,000,000	Science Direct					
		Referred for clinical workup	6,000,000	Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019					
		Receive a cystoscopy	4,000,000	Rindorf, D, et al. The extent of experiencing availability issues and deteriorating performance associated with reusable					
	Europe (excluding			cystoscopies, a multicentre study.					
	Russia)	Annual cases of bladder cancer	180,000	Uroweb					
		Patients living with bladder cancer		Pacific Edge estimate - 5 years of annual cases					
		Test opportunities		Pacific Edge estimate					
		Price of Cxbladder EURO		Pacific Edge estimate					
L		TAM (US\$b)	US\$2.0						
		Population		World population - Southeast Asia; Population Pyramid - Japan;					
		Incidence of hematuria		Science Direct					
٠ ا		Referred for clinical workup		Presentation from Dr Sia Daneshmand (Director of Urologic Oncology and Clinical Research, USC) July 2019					
	APAC (excluding India	Receive a cystoscopy	· · ·	Pacific Edge estimate					
	and China)	Annual cases of bladder cancer		WHO; Hong Kong Pacific Edge estimate - 5 years of annual cases					
		Patients living with bladder cancer Test opportunities		Pacific Edge estimate - 5 years or annual cases					
		Price of Cxbladder (US\$)		Pacific Edge estimate  Pacific Edge estimate					
		TAM (US\$b)	55U 11S\$2.1	<u> </u>					



## **KEY CLINICAL ADVISORS AND CONSULTANTS**



#### Professor Yair Lotan, MD

Institution: UT Southwestern Medical Center Relationship: Consultant, CAB member, IIT PI, CT PI

Brief Bio: Published >500 articles. Contributor to AUA/ASCO/ASTRO MIBC and hematuria guidelines. Chair of AUA Core Curriculum, BCAN

Adboard



#### Professor Sam Chang, MD, MBA

Institution: Vanderbilt Cancer Center Relationship: Consultant, CAB member

Brief Bio: Published >200 articles. Chair of AUA NMIBC Guidelines, SUO Executive Board, ABU/AUA Examination Committee, BCAN

Adboard, AUA representative to the AJCC



#### **Assistant Professor John Sfakianos**

Institution: Icahn School of Medicine at Mount Sinai

Relationship: Consultant, CAB member

Brief Bio: Published >20 articles. Reviewer for J Urol and Urologic

Oncology



#### Professor Dan Barocas, MD, MPH, FACS

Institution: Vanderbilt University Medical Center

Relationship: Consultant, CAB member

Brief Bio: Published >100 articles. AUA guidelines panel for microscopic hematuria. Reviewer for AUA educational materials



#### Associate Professor, Siamak Daneshmand, MD

Institution: Keck School of Medicine at USC Relationship: Consultant, CAB member, CT PI

Brief Bio: Published >200 articles. Editorial board of the J Urol, Bladder Cancer Journal, Current Opinions in Urology, BCAN Adboard,

AUA/SUO Guideline Committee on NMIBC



FACS: Fellow of the American College of Surgeons IIT PI: Investigator Initiated Trial Principal Investigator J Urol: Journal of Urology KOL: Key Opinion Leader MPH: Master of Public Health SUO: Society of Urologic Oncology



#### **Associate Professor Katie Murray, DOMS, FACS**

Institution: NYU Langone

Relationship: Consultant, CAB member,

Brief Bio: Published >80 articles. Deputy Editor for J Urol.

Leadership roles for SUO Young Urologic Oncology Clinical Trials



#### Professor Jonathan Wright, MD, MS, FACS

Institution: Fred Hutchinson Cancer Center at UW Relationship: Consultant, CAB member, CT PI

Brief Bio: Member of ACS, SUO, AUA



#### Professor Wade Sexton, MD

Institution: University of South Florida & Moffitt Cancer Center

Relationship: Consultant, CAB member

Brief Bio: Published >100 articles. NCCN Bladder Cancer

guidelines, AUA Annual Board Review Course



#### Professor Jay Raman, MD

Institution: Penn State and Hershey Medical Center

Relationship: Consultant, CAB member, CT PI

Brief Bio: Published >350 articles. Chair of AUA Office of Education and Past-President of the Mid-Atlantic AUA section. Urology

Advisory Council for ACS, hematuria guidelines member



#### Associate Professor Kristen Scarpato, MD, MPH, FACS

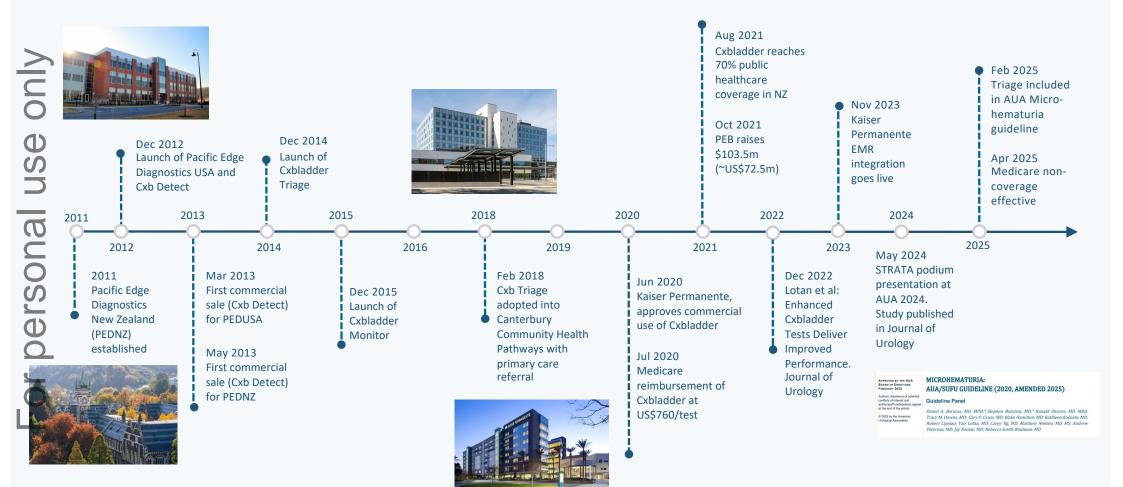
Institution: Vanderbilt University Medical Center Relationship: Consultant, CAB member, CT PI

Brief Bio: SUO Education Committee, AUA Core Curriculum.

**Urology Practice Editorial Committee** 



## PACIFIC EDGE – TAKING NEW ZEALAND INNOVATION GLOBAL



## PACIFIC EDGE BOARD AND MANAGEMENT



### **CHRIS GALLAHER** Chairman

Chris has held senior positions in both CEO and CFO roles with large international companies and was a partner in Arthur Young, Chartered Accountants. Prior to retiring from full time corporate life, he was CFO of Fulton Hogan, a large Australasian civil contractor



## **DR PETER MEINTJES Chief Executive Officer**

Peter is a molecular diagnostics and genomics leader focused on nascent market development of disruptive innovations to drive commercial success. Prior to joining Pacific Edge, he was based in Boston in a succession of diagnostic leadership roles. Most recently he was the Chief Commercial Officer at Eurofins Transplant Genomics and before that he was CEO at Omixon

#### INDEPENDENT DIRECTORS

SARAH PARK ANATOLE MASFEN **BRYAN WILLIAMS ANNA STOVE TONY BARCLAY** 

#### **SENIOR LEADERSHIP TEAM**

**GRANT GIBSON** 

Chief Financial Officer

**GLEN COSTIN** 

President Asia Pacific

**ZOE O'DONNELL** 

Global Head of People & Culture

#### **DAVID LEVISON**

President Pacific Edge Diagnostics USA

**DARELL MORGAN** 

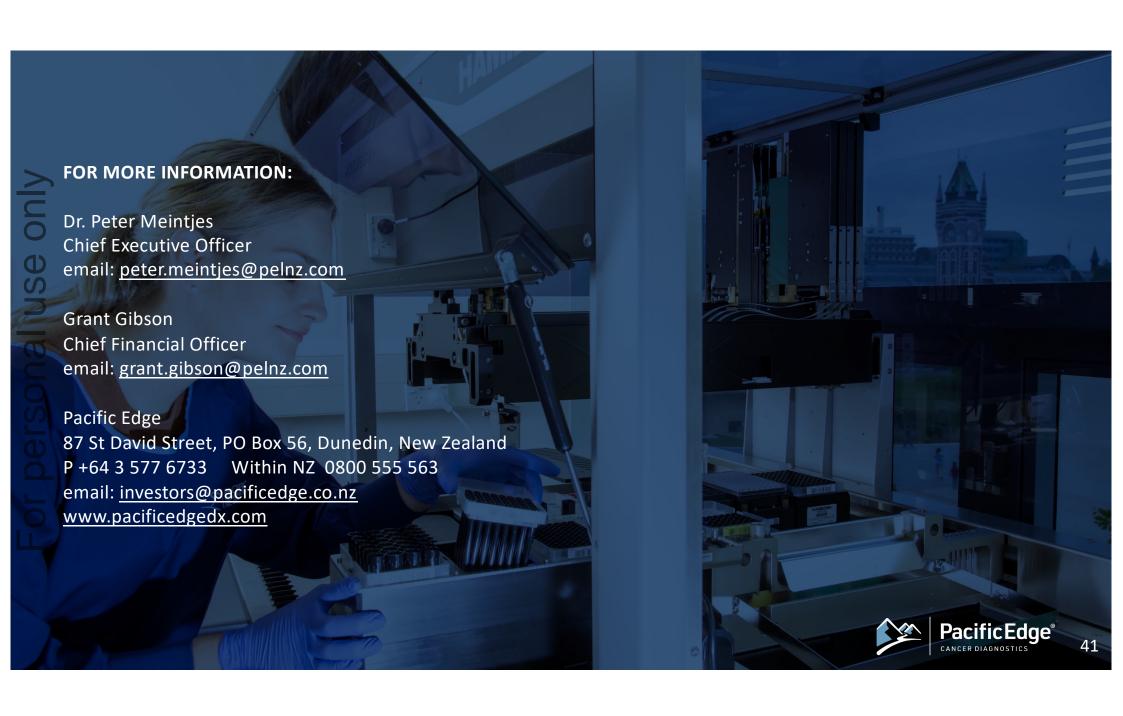
**Chief Operating Officer** 

PROFESSOR PARRY GUILFORD

Chief Scientific Officer

DR TAMER ABOUSHWAREB Chief Medical Officer **DR JUSTIN HARVEY Chief Technology Officer** 







29 May 2025

NZX Limited Level 1, NZX Centre 11 Cable Street Wellington 6011

ASX Limited 20 Bridge Street Sydney NSW 2000

# NOTICE PURSUANT TO CLAUSE 20(1)(A) OF SCHEDULE 8 TO THE FINANCIAL MARKETS CONDUCT REGULATIONS 2014 AND PARAGRAPH 708(12J) OF THE CORPORATIONS ACT 2001 (CTH) AS NOTIONALLY INSERTED BY ASIC INSTRUMENT 21-0811

- Pacific Edge Limited (NZX/ASX: PEB) ("PEB") has announced that it intends to undertake an offer of new fully paid ordinary shares in PEB of the same class as already quoted on the Main Board of NZX Limited and the Australian Securities Exchange operated by ASX Limited ("New Shares"), comprising:
  - (a) a non-underwritten placement of New Shares to selected investors to raise up to NZ\$15 million (with the ability for PEB to increase the size of the placement at its discretion) ("Placement"); and
  - (b) a non-underwritten share purchase plan to PEB's eligible existing shareholders with a registered address in New Zealand<sup>1</sup> to raise up to NZ\$5 million (subject to the ability for PEB to scale applications or accept oversubscriptions at its complete discretion) ("SPP"),

(together, the "Offer").

- 2. The Offer is being made to investors in New Zealand in reliance upon the exclusion in clause 19 of Schedule 1 to the Financial Markets Conduct Act 2013.
- 3. This notice is provided under subclause 20(1)(a) of Schedule 8 to the Financial Markets Conduct Regulations 2014 (the "Regulations") and under paragraph 708A(12J) of the Corporations Act 2001 (Cth) ("Corporations Act"), as notionally inserted by ASIC Instrument 21-0811.
- PEB will issue the relevant shares under the Offer without disclosure to investors under Part 6D.2 of the Corporations Act.
- 5. As at the date of this notice:
  - (a) PEB is in compliance with the continuous disclosure obligations that apply to it in relation to PEB's ordinary shares;
  - (b) PEB is in compliance with its financial reporting obligations (as defined in subclause 20(5) of Schedule 8 to the Regulations);
  - (c) there is no information that is "excluded information" (as defined in subclause 20(5) of Schedule 8 to the Regulations) in respect of PEB; and
  - (d) PEB has complied with its obligations under Rule 1.15.2 of the listing rules of ASX Limited.

PEB reserves the right to extend the SPP to PEB's eligible existing shareholders with a registered address in Australia, subject to PEB obtaining all necessary regulatory relief to permit it to do so.

6. The Offer is not expected to have any effect on the control of PEB within the meaning set out in clause 48 of Schedule 1 to the Financial Markets Conduct Act 2013.

#### **Ends**

This notice has been authorised for release to NZX and ASX by the PEB Board.

For further information please contact: Grant Gibson Chief Financial Officer +64 275 999 943



# **Corporate Action Notice**

(Other than for a Distribution)

Updated January 2024

Section 1: Issuer information (mandate	ory)						
Name of issuer	Pacific Edge Limited						
Class of Financial Product	Ordinary shares						
NZX ticker code	PEB	PEB					
ISIN (If unknown, check on NZX website)	NZPEBE0002S1						
Name of Registry	MUFG Pension & I	Market Se	ervices				
Type of corporate action (Please mark with an X in the relevant box/es)	Share Purchase Plan/retail offer	X	Renounceable Rights issue or Accelerated Offer				
	Capital reconstruction		Non- Renounceable Rights issue or Accelerated Offer				
	Call		Bonus issue				
	Placement	X					
Record Date	The Record Date for the share purchase plan is yet to be determined. It is currently anticipated that it will be in July/August. PEB will release a further Corporate Action Notice when this is determined.						
Ex Date (one business day before the Record Date)	The Ex Date for the share purchase plan is yet to be determined. It is currently anticipated that it will be in July/August. PEB will release a further Corporate Action Notice when this is determined.						
Currency	NZD						
External approvals required before offer can proceed on an unconditional basis?	Yes. The placement is conditional on PEB obtaining all necessary or desirable shareholder approvals, and all necessary regulatory approvals, to complete the placement. In addition, completion of the share purchase plan will be conditional on the placement becoming unconditional.						
Details of approvals required	PEB shareholder approval to the placement by ordinary resolution, under NZX Listing Rule 4.2.1 and, if applicable, NZX Listing Rule 5.2.1.						

	PEB will also seek a waiver from NZX Listing Rule 4.19.1 to permit allotment of shares under the placement after shareholder approval is obtained.
Section 6: Share Purchase Plans/retain	l offer
Number of Equity Securities to be issued OR Maximum dollar amount of Equity Securities to be issued	\$5 million of new fully paid ordinary shares (subject to the ability for PEB to scale applications or accept oversubscriptions at its complete discretion).
Minimum application amount (if any)	N/A
Maximum application amount per Equity Security holder	\$50,000
Subscription price per Equity Security	The placement price of \$0.100 per ordinary share
Scaling reference date	The Record Date.
Closing Date	The Closing Date for the share purchase plan is yet to be determined. It is currently anticipated that it will be in July/August. PEB will release a further Corporate Action Notice when this is determined.
Allotment Date	The Allotment Date for the share purchase plan is yet to be determined. It is currently anticipated that it will be in August. PEB will release a further Corporate Action Notice when this is determined.
Section 7: Placement	
Number of Equity Securities to be issued	150,000,000 new fully paid ordinary shares, based on a \$15 million placement (with the ability for PEB to increase the size of the placement and, therefore, the number of shares to be issued under the placement, at its complete discretion).
Issue price per Equity Security	\$0.100 per ordinary share.
AA	
Maximum dollar amount of Equity Securities to be issued	\$15 million (with the ability for PEB to increase the size of the placement, at its discretion).
Securities to be issued	size of the placement, at its discretion).  The issue date for the placement is yet to be determined, as the date for obtaining shareholder approval is currently unknown. It is currently anticipated that the issue date will be in August. PEB will release a further Corporate Action Notice when
Securities to be issued  Proposed issue date	size of the placement, at its discretion).  The issue date for the placement is yet to be determined, as the date for obtaining shareholder approval is currently unknown. It is currently anticipated that the issue date will be in August. PEB will release a further Corporate Action Notice when this is determined.

Purpose(s) for which the Issuer is issuing the Equity Securities	Raise capital to ensure the company has the resources and capacity to capitalise on its recent clinical and commercial milestones, grow into non-Medicare channels and regain Medicare coverage.					
Reason for placement rather than a pro-rata rights issue or an offer under a Share Purchase Plan in which the Issuer's existing Equity Security holders would have been eligible to participate	PEB considers a placement structure to be in the best interests of PEB and its existing shareholders, as the placement will allow PEB to access a broader pool of potential investors, provide greater certainty around the achievement of the targeted raising size and more favourable pricing for PEB. A Share Purchase Plan is intended to be offered in conjunction with the Placement.					
Equity Securities to be issued subject to voluntary escrow	No					
Number and class of Equity Securities to be issued that will be subject to voluntary escrow and the date from which they will cease to be escrowed	N/A					
Section 8: Lead Manager and Underwr	iter (mandatory)					
Lead Manager(s) appointed	No					
Name of Lead Manager(s)	N/A					
Fees, commission or other consideration payable to Lead Manager(s) for acting as lead manager(s)	N/A					
Underwritten	No					
Name of Underwriter(s)	N/A					
Extent of underwriting (i.e. amount or proportion of the offer that is underwritten)	N/A					
Fees, commission or other consideration payable to Underwriter(s) for acting as underwriter(s)	N/A					
Summary of significant events that could lead to the underwriting being terminated	N/A					
Section 9: Authority for this announcement (mandatory)						
Name of person authorised to make this announcement	Grant Gibson					
Contact person for this announcement	Grant Gibson					
Contact phone number	+64 275 999 943					
Contact email address	grant.gibson@pelnz.com					
Date of release through MAP	29 May 2025					