**ASX & Media Release**

# Quarterly Activities Report and 4C Quarterly Cash Flow Report

## Highlights:

- **Final investigation and audit of manufacturing process nearing completion—targeting new production run for Q1 FY2024 subject to availability of production slot**
- **Final reports on PAT-DX1 GLP toxicology studies expected this current quarter which will complete toxicology data package required to support first-in-human clinical trial**
- **Master Cell Bank established and integration run to enable GLP production of PAT-DX3 completed**
- **Cash and short-term investment balance of $2.6 million on 30 September 2023 with additional $2.7 million R&D Tax Incentive refund expected in the current quarter.**

---

**Melbourne, Australia; 20 October 2023:** Patrys Limited (ASX: PAB, "Patrys" or the "Company"), a therapeutic antibody development company, today released its Quarterly Activities Report and Appendix 4C Quarterly Cash Flow report for the quarter ended 30 September 2023.

**Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said:** "While the delay in the production of GLP PAT-DX1 drug material for the first-in-human clinical trial of PAT-DX1 has been challenging, the investigation and audit process are near completion. The investigation has confirmed the manufacturing process is robust and repeatable and we remain confident that we will be able to initiate a new production run in H1 CY2024, the timing of which is being finalised. We are also delighted to have established the reagents and processes that will enable PAT-DX3 to enter into a formal development process. Having these available will assist with advancing development and collaboration opportunities that are currently in progress, and will enable Patrys to initiate its own production run and development program when it has the available capital."

## Operations Update

During the previous quarter, Patrys' CDMO (Contract Development and Manufacturing Organisation) reported that a comprehensive internal investigation and audit had yet to identify any systemic issues that could have caused the issue that resulted in the termination of the previous production run of PAT-DX1. Accordingly, the reviews by both the CDMO and independent, external evaluator confirm that the manufacturing process is robust and repeatable and that the unexpected manufacturing issue was neither predictable or preventable. The investigation and final testing is on track to be completed

during the current quarter (ie. by the end of CY2023), and will lead to additional risk mitigation checks during manufacturing. When the investigation is completed, Patrys will be able to secure a slot for a new production run with its CDMO. Subject to availability with the CDMO, Patrys will be targeting the initiation of this new production for H1 CY2024.

In May 2024, Patrys announced it had received two draft report for completed Good Laboratory Practice (GLP) toxicology studies testing PAT-DX1 in rats and in a non-human primate species. The Company remains on track to have the final reports for all toxicology studies in hand during the current quarter. These reports will complete the toxicology data required to support an application to initiate the-in-human clinical trial of PAT-DX1.

In parallel to activities directed at supporting initiation of the Phase 1 clinical trial of PAT-DX1, Patrys is developing a production process for its full-sized IgG deoxymab, PAT-DX3, that will enable it to be used in a formal, clinical development program. The Master Cell Bank (MCB) for PAT-DX3 has been characterised and validated, and an integration run which combines the upstream fermentation with downstream purification processes has been successfully completed. This means the reagents and processes have been established to enable GLP manufacturing of PAT-DX3 that can produce drug material of a grade that can be used in preclinical toxicology studies and clinical trials. At this stage, Patrys is focusing its resources on activities directed towards initiating the first-in-human studies of PAT-DX1. However, the availability of a GLP manufacturing process for PAT-DX3 will facilitate the progress on ongoing development and collaboration programs for this deoxymab and the Company could initiate a production run of PAT-DX3 once it has additional capital available.

As part of Patrys' active business development program, in June Patrys' CEO Dr James Campbell attended the BIO International Convention in Boston. This meeting was attended by over 20,000 registrants from 73 countries. Following this meeting, the Company has engaged with several global pharmaceutical and biotechnology companies who are interested in Patrys' deoxymab technology for applications ranging from cancer therapies through to the cellular and nuclear delivery of therapeutic payloads. These discussion are ongoing.



## Corporate Update

In September, Patrys announced that Ms Suzy Jones had retired as a Director of Patrys. Ms Jones had been a Director of the Company since 2011 and has played a pivotal role in the Company's evolution during that time. Her 20 years of experience at Genentech and in business and drug development has been invaluable to both the Board and Management.

During the quarter ended 30 September 2023, Patrys had net cash outflows from operating activities of A$1.5 million, with A$1.0 million invested in R&D activities. The R&D expenditure for this quarter was driven one-off costs associated with the investigation and audit of the issues associated with the production run, and the purchase of materials to be used in a future production run. At 30 September 2023, Patrys held A$1.6 million in cash with an additional A$1.0 million in term deposits. Patrys is entitled to a refund of approximately $2.7 million under the Federal Government's R&D Tax Incentive

Scheme which it expects to receive during 1H FY2024. Payments to related parties and their associates during the quarter, which are outlined in Section 6 of the accompanying Appendix 4C to this quarterly activity report, were A$179,000. These payments include non-executive director fees and consulting services as well as salary (including superannuation) for the CEO and Managing Director.

**-Ends-**

This announcement is authorised for release by the Board of Directors of Patrys Limited.

**For further information, please contact:**


**General enquiries**
James Campbell
Chief Executive Officer
P: +61 3 96703273
info@patrys.com

**Media enquiries:**
Haley Chartres
H^CK
P: +61 423 139 163
haley@hck.digital

**Registered Office Address**
Level 4, 100 Albert Road
South Melbourne VIC 3205


**About Patrys Limited**

Based in Melbourne, Australia, Patrys (ASX:PAB) is focused on the development of its deoxymab platform of cell-penetrating antibodies as therapies for a range of different cancers. More information can be found at www.patrys.com.

**About Patrys' deoxymab 3E10 platform**

Patrys' deoxymab platform is based on the deoxymab 3E10 antibody that was first identified as an autoantibody in a mouse model of the human disease systemic lupus erythematosus (SLE). While most antibodies bind to cell surface markers, deoxymab 3E10 penetrates into the cell nuclei and binds directly to DNA where it inhibits DNA repair processes. Cancer cells often have high levels of mutations and underlying deficiencies in the DNA repair mechanisms. For these reasons, the additional inhibition of the DNA repair processes by deoxymab 3E10 can kill cancer cells, but appears to have little impact on normal cells. As a single agent, deoxymab 3E10 has been shown to significantly enhance the efficacy of both chemo- and radiotherapies. Further, deoxymab 3E10 can be conjugated to nanoparticles to target delivery of chemotherapeutics and imaging agents to tumours.

Patrys has developed two humanised forms of deoxymab 3E10, both which have improved activity over the original deoxymab 3E10 antibody. PAT-DX1 is a dimer (two joined subunits) of the short chain from the binding domain of deoxymab 3E10, while PAT-DX3 is a full-sized IgG antibody. In a range of pre-clinical studies, PAT-DX1 has shown significant ability to kill cancer cells in cell models, human tumour explants, xenograft and orthotopic models. PAT-DX1 has been shown to cross the blood brain barrier, reduce tumour size, and increase survival in multiple animal models of brain cancer, other

cancers, and cancer metastases. PAT-DX1 is tumour-agnostic, meaning that it can target many different tumour types in the body, regardless of specific tumour antigens. Patrys believes that PAT-DX1 may have application across a wide range of cancers including gliomas, melanomas, prostate, breast, pancreatic and ovarian cancers.

Deoxymabs, such as PAT-DX1 and PAT-DX3, can be used to target nanoparticles carrying a payload of anti-cancer drugs specifically to tumours. This allows specific delivery of cancer drugs to multiple types of cancer while having minimal impact on normal, healthy cells.

Patrys' rights to deoxymab 3E10 are part of a worldwide license to develop and commercialise a portfolio of novel anti-DNA antibodies and antibody fragments, variants and conjugates discovered at Yale University as anti-cancer and diagnostic agents. Six patents covering the unconjugated form of deoxymab 3E10 (and derivatives thereof) have already been granted (Europe, Japan, China, and 3 in the USA), and five patents covering nanoparticle conjugation have been granted (Australia, Canada, China, India and the USA).

# Appendix 4C

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

PATRYS LIMITED

| **ABN** | **Quarter ended ("current quarter")** |
|---|---|
| 97 123 055 363 | 30 September 2023 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (3 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | - | - |
| 1.2 | Payments for | | |
| | (a) research and development | (1,047) | (1,047) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | - | - |
| | (d) leased assets | - | - |
| | (e) staff costs* | (169) | (169) |
| | (f) administration and corporate costs | (208) | (208) |
| 1.3 | Dividends received | - | - |
| 1.4 | Interest received | 15 | 15 |
| 1.5 | Interest and other costs of finance paid | - | - |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | - | - |
| 1.8 | Others - IP expenditure | (50) | (50) |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,459)** | **(1,459)** |

**A portion of staff costs are reallocated into payments for research and development.*

| **2.** | **Cash flows from investing activities** | | |
|---|---|---|---|
| 2.1 | Payments to acquire or for: | | |
| | (g) entities | - | - |
| | (h) businesses | - | - |
| | (i) property, plant and equipment | - | - |
| | (j) investments in term deposits | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (3 months) $A'000 |
|---|---|---|---|
| | (k) intellectual property | - | - |
| | (l) other non-current assets | - | - |
| 2.2 | Proceeds from disposal of: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | - | - |
| | (d) investment in term deposits | 1,010 | 1,010 |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | - | - |
| 2.3 | Cash flows from loans to other entities | - | - |
| 2.4 | Dividends received (see note 3) | - | - |
| 2.5 | Other (provide details if material) | - | - |
| **2.6** | **Net cash from / (used in) investing activities** | **1,010** | **1,010** |

| **3.** | **Cash flows from financing activities** | | |
|---|---|---|---|
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | - |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of options | 5 | 5 |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | - | - |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | - | - |
| 3.7 | Transaction costs related to loans and borrowings | - | - |
| 3.8 | Dividends paid | - | - |
| 3.9 | Other (provide details if material) | - | - |
| **3.10** | **Net cash from / (used in) financing activities** | **5** | **5** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash and cash equivalents at beginning of period | 3,045 | 3,045 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,459) | (1,459) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (3 months) $A'000 |
|---|---|---|---|
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | 1,010 | 1,010 |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | 5 | 5 |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |
| **4.6** | **Cash and cash equivalents at end of period** | **2,601** | **2,601** |

| **5.** | **Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | Current quarter $A'000 | Previous quarter $A'000 |
|---|---|---|---|
| 5.1 | Bank balances | 1,591 | 3,045 |
| 5.2 | Call deposits | 1,010 | - |
| 5.3 | Bank overdrafts | - | - |
| 5.4 | Other (provide details) | - | - |
| **5.5** | **Cash and cash equivalents at end of quarter (should equal item 4.6 above)** | **2,601** | **3,045** |

| **6.** | **Payments to related parties of the entity and their associates** | Current quarter $A'000 |
|---|---|---|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 179 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | - |

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **Total facility amount at quarter end $A'000** | **Amount drawn at quarter end $A'000** |
|---|---|---|---|
| 7.1 | Loan facilities | - | - |
| 7.2 | Credit standby arrangements | - | - |
| 7.3 | Other (please specify) | - | - |
| 7.4 | **Total financing facilities** | - | - |
| | | | |
| 7.5 | **Unused financing facilities available at quarter end** | | - |
| 7.6 | Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well. | | |
| | N/A | | |

| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | (1,459) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 2,601 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3)* | 2,601 |
| | | |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 1.78 |
| | *Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.*<br><br>**In addition to the cash and cash equivalents balance noted above at 8.4, the Company expects to receive a R&D refund to its wholly-owned subsidiary Nucleus Therapeutics Pty Ltd of approximately $2.7 million for the FY23 financial year before the end of CY 2023. Adding this $2.7 million to the Cash and cash equivalents position of $2.6 million at September 30 gives a balance of $5.3 million, with a revised value for item 8.5 of 3.63 quarters.* | |
| 8.6 | If item 8.5 is less than 2 quarters, please provide answers to the following questions: | |
| | 8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not? | |
| | Answer: The 1 June through 30 September quarter included a range of one-off costs associated with preparations for future manufacturing and clinical trial of PAT-DX1, as well as pre-payments for R&D service providers. | |
| | 8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful? | |
| | Answer: The Company is anticipating a R&D refund to its wholly-owned subsidiary Nucleus Therapeutics Pty Ltd of approximately $2.7 million for the FY23 financial year, and expects to receive this refund before the end of CY 2023. In the absence of receipt of the R&D refund in a timely manner that Company has recourse to a range of service providers who can pre-pay R&D refunds. | |

| | |
|---|---|
| | 8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis? |
| | Answer: Yes. As noted, the Company expects a substantial R&D refund in the current calendar year. |
| | *Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.* |

## Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 20 October 2023

Authorised by: The Board.....
(Name of body or officer authorising release – see note 4)

**Notes**

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.