



ASX & Media Release

## Quarterly Activities Report and 4C Quarterly Cash Flow Report

### Highlights:

- Specification testing of drug product from GMP production run of PAT-DX1 completed;
- Based on results of specification testing, Patrys to focus internal development efforts on PAT-DX3 and seek partnering or licensing opportunities for PAT-DX1;
- Cash and short-term investment balance of \$1.3 million on 30 September 2024, with an R&D refund of \$1.3 million expected in the current quarter.

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**Melbourne, Australia; 30 October 2024:** 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 2024.

This commentary includes discussions of outcomes and decisions and a resulting announcement made immediately subsequent to the end of the quarter.

**Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said:** “Clearly, along with our shareholders, the Board and management are very disappointed that the material from the most recent GMP run of PAT-DX1 is not suitable for Patrys to initiate a Phase 1 clinical trial. However, the safety of patients is of paramount concern and the narrow margins that have been achieved for a number of parameters means it is not appropriate to proceed with planning a trial using this material. We remain confident that the unique properties of our deoxymab technology have the potential to unlock unique therapeutic approaches for treating a number of unmet medical needs. However, given our size and resources, we believe this will be best achieved by Patrys focussing on PAT-DX3, which has a traditional IgG antibody format and will, seek opportunities to co-develop or out-license PAT-DX1 with a partner with the resources and expertise to develop a more reliable and robust process for manufacturing this antibody fragment.”

### Operations Update

During the previous quarter, the large-scale fermentation for the production of PAT-DX1 was successfully completed, and the antibody product harvested and purified using a previously established and optimized purification process. Subsequent to manufacture, drug material needs to successfully complete specification testing which is effectively the final quality assessment of the drug material produced and establishes its purity, stability, and the presence of any breakdown products.



Meeting specification is essential for the material to be considered GMP grade and must be met for any material that is going to be given to human patients.

Due to some inconsistencies in the initial results from specification testing by the Company's Contract Development and Manufacturing Organisation (CDMO), there were a series of delays for the completion of this essential step. These delays were announced to the market as the Company became aware of them.

While the drug material from the GMP manufacturing run did meet the pre-determined specifications, for some attributes it only met those pre-determined thresholds by a narrow margin. Based on the Company's experience and the fact that PAT-DX1 is a small, antibody fragment rather than a full-sized antibody, it is at risk of degradation and other stability issues. As a consequence, there is a significant risk that it will not continue to meet specification for the time required to initiate and conduct a Phase-1 clinical trial. This poses a substantive risk that the Company may not be able to proceed with a trial due to the material being no longer being suitable to administer to patients either before the trial commences or while the trial is underway. In view of this, the Board of Patrys decided that is not appropriate to continue with plans to initiate a Phase 1 clinical trial of PAT-DX1 using this material. This was announced to the market on October 2, 2024 (subsequent to the completion of the quarter).

Given the challenges Patrys has experienced with manufacturing PAT-DX1 over several production runs, Patrys' Board made the strategic decision to prioritise its future investment development activities on progressing PAT-DX3, which is a full-sized IgG antibody structurally similar to the majority of therapeutic antibodies approved to date. It is our expectation that this means PAT-DX3 is less likely to experience the manufacturing challenges that have occurred over several manufacturing runs of PAT-DX1. The Company will aim to secure a co-development or licensing opportunity with a suitable partner to progress PAT-DX1. The GLP material from this recent run along with the extensive package of preclinical data that has been generated for this molecule will provide a substantive package for prospective partners.

For its internal programs, Patrys will focus its development efforts on PAT-DX3 which has shown very similar biological activity to PAT-DX1 including the ability to target tumour tissue throughout the body and to cross the blood-brain barrier. Furthermore, because PAT-DX3 is larger than PAT-DX1, it has been possible to use it as the basis for Antibody Drug Conjugates (ADC) where it can deliver multiple molecules of a therapeutic payload to target tissues. ADC constructs using PAT-DX3 have delivered cytotoxic drugs to tumour tissue in animal models of human cancer and significantly reduce their growth. Most recently, Patrys has shown that, by way of their DNA-binding properties, deoxymabs are able to inhibit a process call NETosis that is implicated in a number of autoimmune diseases including vasculitis.

While PAT-DX3 is not as advanced as PAT-DX1, the Company has made solid progress with its development and has already established a Master Cell Bank for the antibody. An integration run of PAT-DX3, which combines the upstream fermentation with the downstream purification process, has been successfully completed and has provided the Company with the reagents and processes required to undertake a GLP manufacturing run of PAT-DX3. This can provide drug material of a suitable grade



to conduct the preclinical toxicology studies required before initiating a clinical trial in human patients. Due to the greater familiarity with full-sized IgG antibodies, it is expected that the commercial scale GLP production of PAT-DX3 should be significantly more straightforward than that which has been experienced to date with PAT-DX1. In addition to focusing on PAT-DX3, Patrys is currently undertaking a strategic review of its options and actively evaluating other technologies and drug candidates for their potential to accelerate the maturation of the Company's product pipeline.

## Corporate Update

During the quarter ended 30 September 2024, Patrys had net cash outflows of A\$905,000. At 30 September 2024, Patrys held A\$1.3 million in cash and cash equivalents, and is expecting an R&D refund of \$1.3 million for the FY24 financial year before the end of CY 2024. During the quarter, Patrys invested A\$442,000 in R&D activities. 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\$151,000. 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:

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#### 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](http://www.patrys.com).

#### About Patrys' deoxymabs

Patrys has developed a new type of antibody - deoxymabs - which are attracted to cancer cells that do not have traditional cell surface markers of disease. Instead, they bind to fragments of DNA that are released from cells when they die - the rate of cell death is much higher in cancer cells than in healthy cells, meaning that deoxymabs can be used to target cancer cells regardless of their location or type.



In animal experiments, Patrys has successfully demonstrated that deoxymabs are able to seek out and kill cancer cells in a variety of tissues anywhere in the body and can cross the blood brain barrier. This suggests that deoxymabs have the potential to be a versatile treatment for cancers, including brain cancers.

Recent studies into the mechanism of action of deoxymabs have shown that they inhibit the formation of neutrophil extracellular traps (NETs), a process that underpins a range of inflammatory conditions. Patrys' collaborators have expanded these studies and shown that unlike other agents that reduce NETosis, deoxymabs do not reduce neutrophil function – a particular advantage in fighting inflammatory diseases. These discoveries in inflammatory diseases have the potential to complement our existing development programs and provide increased flexibility for deoxymabs' potential to address diseases with significant unmet medical needs.

Patrys' commitment to advancing these innovative antibody-based approaches brings hope for more effective and targeted therapies, potentially transforming the landscape of cancer treatment and NETosis-driven inflammatory diseases.

Patrys' rights to deoxymab 3E10 are part of a worldwide license to develop and commercialize a portfolio of novel anti-DNA antibodies and antibody fragments, variants and conjugates discovered at Yale University as anti-cancer 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**

97 123 055 363

**Quarter ended ("current quarter")**

30 September 2024

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1.</b>	<b>Cash flows from operating activities</b>		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(442)	(442)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(123)	(123)
	(f) administration and corporate costs	(244)	(244)
1.3	Dividends received	-	-
1.4	Interest received	10	10
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	(106)	(106)
<b>1.9</b>	<b>Net cash from / (used in) operating activities</b>	<b>(905)</b>	<b>(905)</b>
<i>*A portion of staff costs are reallocated into payments for research and development.</i>			

<b>2.</b>	<b>Cash flows from investing activities</b>		
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	-	-
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	-	-

<b>3.</b>	<b>Cash flows from financing activities</b>		
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	-	-
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	-	-

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	2,241	2,241
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(905)	(905)

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)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	<b>Cash and cash equivalents at end of period</b>	<b>1,336</b>	<b>1,336</b>

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	791	1,699
5.2	Call deposits	545	542
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>1,336</b>	<b>2,241</b>

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	151
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7.	<b>Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	<b>Total financing facilities</b>	-	-
7.5	<b>Unused financing facilities available at quarter end</b>		-
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.	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	(905)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,336
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,336
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	1.48
	<i>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..</i>	
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 refocus of the Company's activities away from clinical development of PAT-DX1 and towards the pre-clinical development of PAT-DX3 will reduce net operating cash flows in the near term.	
	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 \$1.285 million for the FY24 financial year, and expects to receive this refund before the end of CY 2024. 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. If the sum of cash and cash equivalents plus expected R&D refund is used as the basis of 8.5, the Company has 2.9 quarters of funding available.	



	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, and has significantly reduced its planned expenditure as it focussed on the pre-clinical development of PAT-DX3.
		<i>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.</i>

## 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: 30 October 2024

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.