



ASX & Media Release

Quarterly Activities Report and 4C Quarterly Cash Flow Report

Highlights:

- GMP manufacturing slot for PAT-DX1 secured for Q1 CY2024 to provide drug material for first-in-human clinical trial expected to commence in 2H CY2024
- GLP toxicology studies for PAT-DX1 have not identified any safety or tolerability issues that are likely to affect the proposed Phase 1 clinical trial of PAT-DX1
- A Master Cell Bank (MCB) for PAT-DX3 has been characterised and validated, and an integration manufacturing run has been successfully completed
- Cash and short-term investment balance of \$4.5 million on 31 December 2023.

Melbourne, Australia; 23 January 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 31 December 2023.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: “It is very exciting to be going into 2024 with a new manufacturing slot for PAT-DX1 secured which puts Patrys on a clear trajectory to initiate its first-in-human clinical trial in the second half of the year. Following the thorough investigation and audit that was conducted around the manufacturing process, Patrys is confident that the drug material from this manufacturing run will enable the Company to initiate this landmark trial. As the GLP toxicology studies that have been completed in rats and non-human primates have not identified any safety or tolerability issues associated with the administration of PAT-DX1, this is expected to be the final step before Patrys can commence engaging clinicians and trial sites in order to formally initiate the clinical trial process.”

Operations Update

Following the completion of a comprehensive internal investigation and audit of the manufacturing process by both its Contract Development and Manufacturing Organisation (CDMO) and independent, external consultants, Patrys has secured a manufacturing slot with its CDMO for Q1 CY2024. This GMP (Good Manufacturing Practice) production run is anticipated to complete by the end of Q1 CY2024 with final product characterisation and quality verification expected during Q2 CY2024. Once this has been achieved the Company will be able to initiate the clinical trial process including recruiting clinical



trial sites and securing clearance from the HRECs (Human Research Ethics Committees) at each trial site. On this timeline, Patrys expects to initiate its first-in-human clinical trial of PAT-DX1 in the second half of CY2024 as previously guided.

The GLP toxicology studies for PAT-DX1 conducted in both rats and non-human primates have been completed and the reports from these studies did not identify any safety or tolerability issues that are likely to affect the proposed Phase 1 clinical trial of PAT-DX1.

Patrys has established a Master Cell Bank (MCB) for PAT-DX3 which has been characterised and validated, and an integration run combining the upstream fermentation with the downstream purification processes has been successfully completed. This activity has established the reagents and processes necessary for GLP manufacturing of PAT-DX3 to produce drug material of a grade suitable for preclinical toxicology studies. The availability of a GLP manufacturing process for PAT-DX3 is expected to facilitate ongoing partnering discussions for this deoxymab and the Company intends to initiate its own production run of PAT-DX3 once it has access to additional capital.

As part of Patrys' ongoing business development activities Patrys' CEO Dr James Campbell attended the BIO-Europe partnering meeting in Munich in November where he updated a number of global pharmaceutical and biotechnology companies on the progress of Patrys' deoxymab program.

Corporate Update

During the quarter ended 31 December 2023, Patrys had net cash inflows of A\$1.9 million following the receipt of a A\$2.7 million refund under the Federal Government's R&D Tax Incentive Scheme in November 2023. At 31 December 2023, Patrys held A\$2.4 million in cash with an additional A\$2.0 million held in term deposits. During the quarter, Patrys invested A\$0.5 million 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.

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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.

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 has been granted (Australia, Canada, China, India and the USA).

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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")

31 December 2023

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(487)	(1,534)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(140)	(309)
	(f) administration and corporate costs	(226)	(434)
1.3	Dividends received	-	-
1.4	Interest received	30	45
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	2,732	2,732
1.8	Others - IP expenditure	(48)	(98)
1.9	Net cash from / (used in) operating activities	1,861	402

*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 (6 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
	(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

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
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

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,601	3,045
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,861	402

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	1,010
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	5
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	4,462	4,462

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	2,440	1,591
5.2	Call deposits	2,022	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)	4,462	2,601

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.	Financing facilities <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>	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)	1,861
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,462
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,462
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
	<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: N/A	
	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: N/A	
	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: N/A	
	<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: 23 January 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.