



ASX & Media Release

Quarterly Activities Report and 4C Quarterly Cash Flow Report

Highlights:

- Dosing for PAT-DX1 toxicology studies completed and on track for draft results in May
 - Master Cell Bank and integration run for PAT-DX3 completed
 - Preclinical study validates potential for PAT-DX3 in synthetic lethality strategies
 - US PTO grants two new patents for deoxymab technology providing coverage till 2039
 - Cash and short-term investment balance of \$6.68M on 31 March 2023.
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Melbourne, Australia; 24 April 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 31 March 2023.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: “While it was clearly disappointing to have to announce a delay to the initiation of our Phase 1 clinical trial of PAT-DX1, we are making good progress towards identifying and resolving the sporadic issue with the producer cell line. The other preparations for the clinical trial remain on track. In parallel, our second deoxymab asset, the full-sized IgG PAT-DX3, is progressing well with completion of the Master Cell Bank and an integration run that combines its production and purification. Furthermore, we were delighted to report positive preclinical data on the ability of PAT-DX3 to be used for synthetic lethality strategies which, along with its potential for the delivery of therapeutic payloads into the cell and cell nucleus, remains an area of high interest with potential partners.”

Operations Update

In March, Patrys advised that, based on recent updates from its Contract Development Manufacturing Organisation (CDMO) regarding the availability of clinical-grade PAT-DX1, it is now expecting to initiate the Phase 1 clinical trial of PAT-DX1 in calendar year 2024, rather than in H2 CY2023 as previously indicated. The reason for the delay is that despite prior successful manufacturing test runs, Patrys’ CDMO has reported a sporadic issue in the most recent production run of clinical grade PAT-DX1. While this issue is actively being investigated and resolved, it will result in a delay in the availability of investigational drug material required to initiate Patrys’ Phase 1 clinical trial of PAT-DX1.



Patrys has completed dosing of animals for the final, two non-clinical GLP toxicology studies of PAT-DX1. These studies have been conducted in two different species and will complete the preclinical data package required to support the initiation of the first-in-human clinical trial of PAT-DX1. The data from these studies is currently being analysed by Patrys' service provider and the Company expects to receive draft results in May 2023.

In March, Patrys announced results from a pre-clinical study that further supports the potential to use its full size IgG deoxymab, PAT-DX3, for synthetic lethality strategies to treat relevant cancers. This study was conducted by Patrys at the request of a potential partner and confirmed the ability to use deoxymabs as a single agent to treat cancers which have pre-existing mutations that compromise their DNA damage repair (DDR) systems including BRCA2-negative breast cancer and other cancers.

Patrys' development program for PAT-DX3 remains on track with two major milestones achieved during the March quarter. First, the Master Cell Bank (MCB) for the production of PAT-DX3 has been completed and is currently undergoing stability testing. Second, Patrys' CDMO successfully completed a small-scale integration run for the production of PAT-DX3. An integration run is a scaled-down version of an engineering run that combines the two major aspects of manufacturing; production (the growing of cells in culture to produce antibody material); and purification (isolation of the antibody from the production run).

Once the stability of the MCB is confirmed, Patrys will be able to initiate an engineering run of PAT-DX3 to produce larger amounts of antibody that can be used in the GLP toxicology studies to required support the initiation of possible clinical trials. Furthermore, having an established production and purification process for PAT-DX3 is expected to significantly enhance the attractiveness of PAT-DX3 for potential partnership opportunities.

In April, and subsequent to the end of the quarter, Patrys announced that the US Patent and Trademark Office (US PTO) had granted two patents which provide further intellectual property protection for Patrys' deoxymab antibody technology until 2039. The first patent provides robust intellectual property protection around the deoxymabs themselves, including variants thereof, as well as their use for therapeutic applications. The second patent covers the combination of deoxymabs with nanocarriers that simultaneously cause DNA damage or inhibit the repair of damaged DNA to potentially provide a powerful new approach for treating cancer. There are now five granted patents covering the use of conjugated deoxymabs that provide opportunities for both internal development programs and partnering opportunities for Patrys.

As part of Patrys' active business development program, in March Patrys' CEO Dr James Campbell attended the Bio-Europe Spring meeting that was held in Basel where he met with representatives from pharmaceutical and biotechnology companies to increase broad interest in Patrys' deoxymab technology for applications ranging from cancer therapies through to the cellular and nuclear delivery of therapeutic payloads.

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Corporate Update

During the quarter ended 31 March 2023, Patrys had net cash inflows of A\$869k, mainly as a result of the receipt of A\$3.35M from the R&D Tax Incentive Refund for eligible research activities conducted during 2021/2022 financial year. A\$2,097k was invested in R&D activities during the quarter. At 31 March 2023, Patrys held A\$4.68M in cash and A\$2M in term deposits. 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\$176k. 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.

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.

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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

97 123 055 363

Quarter ended ("current quarter")

31 March 2023

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(2,097)	(5,204)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(155)	(439)
	(f) administration and corporate costs	(233)	(692)
1.3	Dividends received	-	-
1.4	Interest received	37	46
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3,347	3,347
1.8	Others - IP expenditure	(30)	(175)
1.9	Net cash from / (used in) operating activities	869	(3,117)
*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	(26)	(26)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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)	-	-
2.6	Net cash from / (used in) investing activities	(26)	(26)

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	6	6
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	6	6

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,832*	7,818*
4.2	Net cash from / (used in) operating activities (item 1.9 above)	869	(3,117)

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

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(26)	(26)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6	6
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period*	4,681*	4,681*

*In addition to the cash and cash equivalents balance above as at 31 March 2023, the Company holds an additional \$2million in term deposits (31 December 2022 and 30 June 2022: \$2million), classified in the statement of financial position as short-term investments.

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	4,681	3,832
5.2	Call deposits	-	-
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)	4,681*	3,832*

*In addition to the cash and cash equivalents balance above as at 31 March 2023, the Company holds an additional \$2million in term deposits (31 December 2022 and 30 June 2022: \$2million), classified in the statement of financial position as short-term investments.

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	176
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>		

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

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)	869
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,681
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,681
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>	
	<i>*In addition to the cash and cash equivalents balance noted above at 8.4, the Company holds an additional \$2 million in term deposits, classified in the statement of financial position as short-term investments, due to the maturity date being greater than 3 months.</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>	

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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: 24 April 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.