



ASX & Media Release

28 April 2022

Quarterly Activities Report and 4C Quarterly Cash Flow Report

Highlights:

- Work on second engineering run of PAT-DX1 expected to complete in current quarter;
- Stable cell line for production of PAT-DX3 established;
- Receipt of \$1.2 million R&D Tax Incentive Refund;
- Balance sheet capacity with closing cash balance of \$10.16M at 31 Mar 2022, with an additional \$2M in short-term investments.

Melbourne, Australia; 28 April 2022: 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 2022.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: “The key focus for this quarter has been on the manufacture of our deoxymabs. While we were clearly disappointed that our first engineering run did not provide sufficient drug product for the final preclinical toxicology studies and to initiate our Phase-1 clinical trial as planned, we are very pleased that the effort put in by Patrys and our Contract Development Manufacturing Organisation (CDMO) has allowed us to commence work on a second engineering run so quickly. We expect this manufacturing run, which will include an improved, large-scale purification process, will complete during the current quarter. We were also pleased to report that we have now established a stable, cell line for the production of our full-sized deoxymab, PAT-DX3 ahead of schedule. With two assets in development we are now attracting global interest in our deoxymab platform and we look forward to updating our shareholders on these developments in coming months.

R&D Update

In January, Patrys advised the market that the first engineering run of PAT-DX1 did not provide the yield anticipated, based on previous, smaller-scale runs. The production yield from the fermentation process for PAT-DX1 was consistent with previous small scale production runs. However, the process for purifying PAT-DX1 from the cell harvest resulted in lower recoveries of drug product than expected. In view of this, the Company announced that an additional engineering run would be required to provide sufficient drug product to complete the final animal toxicology studies and to initiate the planned Phase-1 clinical trial of PAT-DX1. During the quarter, Patrys has worked closely with its CDMO



to develop an improved, large-scale purification process. On the back of this, Patrys' CDMO will undertake a second engineering run of PAT-DX1 which is expected to complete during the current quarter. As announced previously Patrys expects it will now submit a Human Research Ethics Application (HREA) for phase 1 clinical trial in mid 2023.

In February 2022, Patrys announced it has identified and selected an optimised stable cell line for production of its full-sized IgG deoxymab, PAT-DX3. This allows the Company to commence work on developing a commercial scale manufacturing process for GMP-grade (Good Manufacturing Practice) PAT-DX3 deoxymab that is required to commence its clinical development. This milestone was achieved ahead of schedule. Patrys has established that the selected cell line is both stable and able to deliver reproducible and consistent production of PAT-DX3 protein over time. This cell line will be stored as a Master Cell Bank (MCB) which will form the basis for all future production of PAT-DX3.

In March, Patrys was advised that a patent entitled "*Antibody-mediated autocatalytic, targeted delivery of nanocarriers to tumors*" has been granted by the Indian Patent Office. This new patent provides protection until August 2037. This patent will provide patent protection for the sale of therapeutic products in India as well as enable Patrys to use Indian manufacturers for the commercial-scale production of PAT-DX1.

Corporate Update

During the quarter ended 31 March 2022, Patrys had net cash outflows from operating activities of A\$575k, with A\$1,161k invested in R&D activities. In January, Patrys announced that its wholly-owned subsidiary Nucleus Therapeutics Pty. Ltd, had received a \$1.2 million R&D Tax Incentive Refund for eligible research activities conducted during the 2020/2021 financial year. At 31 March 2022, Patrys held A\$10.16M in cash and A\$2.0M in short-term investments. 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\$153k. 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 platform:

Patrys' deoxymab platform is based on the deoxymab 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 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 can kill cancer cells, but appears to have little impact on normal cells. As a single agent, deoxymab has been shown to significantly enhance the efficacy of both chemo- and radiotherapies. Further, deoxymabs can be conjugated to nanoparticles to target delivery of chemotherapeutics and imaging agents to tumours.

Patrys has developed two humanised forms of deoxymab, both which have improved activity over the original deoxymab antibody. PAT-DX1 is a dimer (two joined subunits) of the short chain from the binding domain of deoxymab, 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.

Patrys has completed proof of concept studies showing that it is possible to conjugate small molecule payloads to PAT-DX3, and is advancing antibody drug conjugate (ADC) efforts using deoxymabs. In addition, 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 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. Overall, eight patents in the portfolio have been granted with 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 two patents covering nanoparticle conjugation (Australia and India).

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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 March 2022

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	28	28
1.2	Payments for		
	(a) research and development	(1,161)	(5,968)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(122)	(469)
	(f) administration and corporate costs	(403)	(902)
1.3	Dividends received	-	-
1.4	Interest received	1	8
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,189	1,189
1.8	Other		
	- IP expenditure	(107)	(212)
	- Government Incentive	-	-
1.9	Net cash from / (used in) operating activities	(575)	(6,326)

*Some staff costs are reallocated into payments for research and development.

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-

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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
	(d) investments in term deposits	2	(2,000)
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investment in term deposits	-	4,000
	(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	2	2,000

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	7,833
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	66
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(345)
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)		
	- Share issue cost	-	-
3.10	Net cash from / (used in) financing activities	-	7,554

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	10,763*	6,917*
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(575)	(6,326)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	2	2,000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	7,554
4.5	Effect of movement in exchange rates on cash held	(32)	13
4.6	Cash and cash equivalents at end of period*	10,158*	10,158*

*In addition to the cash and cash equivalents balance above as at 31 March 2022, the Company holds an additional \$2million in term deposits (31 December 2021 :\$2million, 30 September 2021 and 30 June 2021: \$4million), 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	8,153	8,758
5.2	Call deposits	2,005*	2,005*
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)	10,158**	10,763**

*The Call deposits included in item 5.2 above, have a maturity of 3 months.

**In addition to the cash and cash equivalents balance above as at 31 March 2022, the Company holds an additional \$2million in term deposits (31 December 2021: \$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	153
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 <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)	(575)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,158
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,158
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	17.67*
	<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. As a result, the estimated quarters of funding available will be greater than the figure provided in 8.5 due to holding these additional short-term investments. On a pro-forma basis with the \$2million included, the Group would have estimated quarters of funding available amounting to 21.14. It is noted that the total operating expenditure noted above at 1.9 includes the receipt of approximately \$1.2 million relating to the FY21 R&D tax incentive refund received in January 2022. As such, the figure provided in 8.5 is not a true representation of the number of quarters of funding available, given that this receipt has the effect of reducing net cash used in operating activities.</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: 28 April 2022

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.