



ASX & Media Release

31 January 2022

Quarterly Activities Report and 4C Quarterly Cash Flow Report

Highlights from the quarter

- PAT-DX3 manufacturing development program significantly ahead of schedule;
- Non-clinical studies further define biological and pharmaceutical profile of PAT-DX3 deoxymab and potential use for expanded clinical applications;
- Business development focus;
- Rodent, non-GLP toxicology studies confirm an acceptable safety and tolerability profile for PAT-DX1; and,
- Balance sheet capacity with closing cash balance of \$10.76M at 31 Dec 2021, with an additional \$2M in short-term investments.

Melbourne, Australia; 31 January 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 December 2021.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: “During the quarter, we have progressed the development of both of our deoxymabs assets, PAT-DX1 and PAT-DX3. The non-clinical studies that we completed during this quarter have highlighted the opportunities of our expanded deoxymab platform, including their potential to be used as targeting agents for antibody drug conjugates (ADCs). Clearly, we are frustrated that the scale-up purification of PAT-DX1 in the engineering run has introduced a 6-month delay into our clinical program. Such technical issues, however, are not uncommon in the scale-up manufacture of biological drugs and we remain confident that we will be able to address them and are looking forward to significant progress with both assets in the coming months.”

R&D Update

In Q4 CY 2021, Patrys initiated a formal development program for the commercial-scale production of clinical-grade drug material of its full-sized IgG deoxymab antibody, PAT-DX3. Progress for this



program has exceeded expectations, with multiple cell lines already meeting the prespecified selection criteria required for commercial scale production. The Company intends to identify and select a cell line for commercial-scale production of clinical-grade PAT-DX3 antibody in coming months. The upstream and downstream development programs have also advanced faster than expected, these are critical steps in preparation for PAT-DX3 manufacturing.

During the quarter, Patrys also completed several studies which compared the biological activity and pharmaceutical profiles of PAT-DX1 and PAT-DX3. These studies have shown, that like PAT-DX1, PAT-DX3 is able to cross the blood brain barrier in animal models of brain cancer and penetrate cancer cells. PAT-DX3 appeared to have a higher affinity for DNA than PAT-DX1, suggesting that it may be more efficacious than PAT-DX1. Indeed, in an animal model of colon cancer, PAT-DX3 was more effective at reducing tumour growth and increasing survival than PAT-DX1. In addition, Patrys reported that PAT-DX3 was able to be used as a targeting agent to deliver an anticancer drug and inhibit tumour growth and increase survival in an animal model of human breast cancer. This data set confirmed that PAT-DX3 has therapeutic potential both as a single agent and as a targeting agent for antibody drug conjugates (ADCs), and the Company is accelerating non-clinical development of this asset through its global network of collaborators and suppliers.

During the December quarter, Patrys completed a non-GLP (Good Laboratory Practice) toxicology study in rodents for its lead asset PAT-DX1. This study found that PAT-DX1 was safe and well-tolerated at all doses tested with no mortalities or significant changes to body weight. A range of biochemical tests were conducted as part of this study which confirmed safety and tolerance. A similar set of non-GLP toxicology studies with PAT-DX1 in non-human primates will be initiated in coming months.

Corporate Update

The Company was actively involved in a range of global business development conferences during the quarter under review. These meetings have resulted in several ongoing discussions with a range of pharmaceutical and biotech companies who are attracted to both the anti-cancer activity of deoxymabs generally, and the specific potential of PAT-DX3 to be used in ADCs for targeted intracellular delivery of cancer drugs and a range of other payloads such as nucleic acids. ADCs continue to be one of the most commercial active areas in terms of deal making with substantial licensing deals being announced by Genmab, ADC Therapeutics, and Legochem in recent months.



In the 3 months ended 31 December 2021, Patrys successfully raised \$7.8M via a Placement and fully underwritten Rights Issue. Patrys is extremely grateful for the strong support provided by its shareholders during 2021, which has put the Company in a strong fiscal position with the financial capacity to advance both its assets, PAT-DX1 and PAT-DX3 towards the clinic.

In October 2021, Ms. Melanie Leydin stepped down as Company Secretary and was replaced by Mr. Stefan Ross. Mr. Ross has over 10 years of experience in accounting and secretarial services for ASX-listed companies, with extensive experience in ASX compliance, corporate governance control and implementation, statutory financial reporting and board and secretarial support.

During the quarter ended 31 December 2021, Patrys had net cash outflows of A\$4.58M, with A\$4.20M invested in R&D activities. At the conclusion of the quarter, Patrys held A\$10.76M in cash and A\$2.0M in short-term investments, a total of \$A12.76M, and remains in a strong financial position. Payments to related parties and their associates during the quarter as outlined in Section 6 of the accompanying Appendix 4C to this quarterly activities report were A\$145k. These payments are related to executive director salary, non-executive director fees and consulting services for the quarter.

Subsequent events

Subsequent to the end of the quarter, Patrys provided an update on the engineering run of PAT-DX1 that was being conducted to provide GLP-quality drug material for the remaining toxicology studies and the planned Phase-1 clinical trial. The product yield from the fermentation process was consistent with a previous small scale pilot production run. However, the scaled-up process for purifying PAT-DX1 from the harvested cells resulted in lower recoveries than had been experienced previously. As a result, the final yield of GLP-quality PAT-DX1 did not provide sufficient drug material to conduct the final GLP toxicology studies needed before the planned Phase-1 clinical trial of PAT-DX1. Patrys is working with its Contract Development Manufacturing Organisation (CDMO) to implement improvements to this scaled-up purification process. Based on work conducted by the CDMO to date, it is anticipated that an additional engineering run for PAT-DX1 using an improved large-scale purification process will commence in Q2 CY2022. While Patrys fully expects this technical issue will be resolved, the need to conduct an additional manufacturing run for PAT-DX1 means that the final



GLP toxicology studies, and consequently the Phase-1 clinical trial of PAT-DX1, will be delayed by approximately 6 months.

On 24 January 2022, Patrys announced it had received \$1.2M under the Australian Government's R&D Tax Incentive scheme for eligible research activities conducted during FY21 (ending 30 June 2021).

-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 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 payloads including small molecules, nanoparticles and imaging agents to target delivery to tumours.



Patrys has developed two humanised forms of deoxymab, 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, 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 and cancer metastases. PAT-DX1 has also been shown to reduce tumour size and increase survival in non-brain cancers such as triple negative breast cancer and pancreatic cancer. PAT-DX3 can cross the blood brain barrier to target cancers of the brain. Both PAT-DX1 and PAT-DX3 are tumour-agnostic, meaning that they can target many different tumour types in the body, regardless of specific tumour antigens. Patrys believes that PAT-DX1 and PAT-DX3 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. To date, seven patents have been granted across the deoxymab portfolio. Six patents protecting deoxymabs (and derivatives thereof) have already been granted (Europe, Japan, China, and 3 in the USA), and one patent covering nanoparticle conjugation to deoxymabs has been granted (Australia).

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 2021

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*	(4,202)	(4,807)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(125)	(347)
	(f) administration and corporate costs	(219)	(499)
1.3	Dividends received	-	-
1.4	Interest received	5	7
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other		
	- IP expenditure	(35)	(105)
	- Government Incentive	-	-
1.9	Net cash from / (used in) operating activities	(4,576)	(5,751)

* Payments for research and development include a payment amounting to \$2,626,000 to an overseas supplier, which was paid by the Company prior to 31 December 2021. This payment was received by the supplier and the liability was extinguished in January 2022.

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
	(c) property, plant and equipment	-	-
	(d) investments in term deposits	-	(2,002)
	(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	2,000	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	2,000	1,998

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,833	7,833
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1	66
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(345)	(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	7,489	7,554

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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	5,862*	6,917*
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,576)	(5,751)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	2,000	1,998
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,489	7,554
4.5	Effect of movement in exchange rates on cash held	(12)	45
4.6	Cash and cash equivalents at end of period*	10,763*	10,763*

*In addition to the cash and cash equivalents balance above as at 31 December 2021, the Company holds an additional \$2million in term deposits (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	8,758	5,862
5.2	Call deposits	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)	10,763**	5,862**

*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 December 2021, the Company holds an additional \$2million in term deposits (30 September 2021: \$4million), 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	145
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)	(4,576)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,763
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,763
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.35*
	<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 \$2 million included, the Group would have estimated quarters of funding available amounting to 2.79. It is noted that the R&D spend for the quarter of \$4.2M is not representative of the anticipated average spend for coming quarters as it includes manufacturing costs and costs for the purchase of media to be used in future manufacturing efforts. As such, the figure provided in 8.5 is not a true representation of the number of quarters of funding available.</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: 31 January 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.