ASX & Media Release

26 July 2023

Quarterly Activities Report and 4C Quarterly Cash Flow Report

Highlights:

- **Investigation and audit suggest production issue was a one-off event**
- **Patrys commencing preparations for a replacement production run of PAT-DX1**
- **No toxicology or safety issues identified in draft reports from GLP toxicology studies**
- **US PTO grants two new patents for deoxymab technology providing coverage till 2039**
- **Cash and short-term investment balance of $4.0 million on 30 June 2023, with expected R&D rebate of $2.7 million**

Melbourne, Australia; 26 July 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 30 June 2023.

Patrys Chief Executive Officer and Managing Director, Dr. James Campbell said: "We are delighted that the investigation and audit by both the CDMO and our independent investigator have not identified any issue so far that is likely to impact on our future ability to manufacture GMP-grade PAT-DX1 for clinical trials. Given the importance of this material and the time and cost associated with conducting a production run, it is essential that this rigorous investigation is allowed to complete. However, based on the results to date, we believe we should be able to initiate a new production run in the coming months and have already commenced preparations for this. We were also pleased to receive the initial draft reports from our GLP toxicology studies of PAT-DX1 that indicate that there are no safety or tolerability issues have been identified that would impact on our ability to initiate a human clinical trial of PAT-DX1. From my recent attendance at BIO in Boston, there is a lot of interest in our deoxymab technology, both for cancer applications and the unique properties they offer for the delivery of therapeutic payloads across the blood-brain barrier, into cells and into the cell nucleus."

Operations Update

In March 2023, Patrys announced that its Contract Development and Manufacturing Organisation (CDMO) had reported a sporadic issue in the production run of Good Manufacturing Practice (GMP) PAT-DX1. At that time, the nature and significance of this sporadic issue were unknown, and

accordingly the time and steps required to remedy the issue in order to enable the production of GMP-grade PAT-DX1 for the clinical trial could not be determined.

During the past quarter, Patrys' CDMO has completed a comprehensive internal investigation and audit which Patrys further verified by engaging an independent, external auditor. This process is nearly complete, and to date has not identified any systemic issues that could have caused the issue that resulted in the termination of the previous production run. Accordingly the findings of the reviews by both the CDMO and independent, external evaluator suggest that the unexpected manufacturing issue was most likely a one-off event.

Once this process is formally completed, which is expected in the coming months, Patrys and its CDMO intend to schedule a new production run to provide GMP-grade PAT-DX1 for the planned clinical trial. The final timing of this will be determined by the availability of a production slot with the CDMO. Patrys will inform shareholders of the timing for this run once the availability of a production slot has been confirmed by its CDMO.

In April, 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.

In the previous quarter, Patrys completed dosing of animals for the final, two non-clinical Good Laboratory Practice (GLP) toxicology studies of PAT-DX1. These studies have been conducted in rats and non-human primates, and will complete the toxicology data required to support the initiation of the first-in-human clinical trial of PAT-DX1.

In May, Patrys announced it had received draft reports for two of the completed GLP toxicology studies. No safety or tolerability issues associated with PAT-DX1 were observed in either species that are likely to impact on the ability to initiate human clinical studies with PAT-DX1. This is consistent with the favourable safety profile for PAT-DX1 seen in prior non-GLP toxicology studies. Two additional draft reports that will provide further toxicological characterization of the GLP PAT-DX1 antibody material are expected during the current quarter and Patrys expects to receive the final reports from these studies towards the end of the year.

As part of Patrys' active business development program, in May Patrys' CEO Dr James Campbell attended the BIO International Convention in Boston. This meeting was attended by over 20,000 registrants from 73 countries. Over the course of the convention, Dr Campbell met with representatives from numerous pharmaceutical and biotechnology companies that have an interest

in Patrys' deoxymab technology for applications ranging from cancer therapies through to the cellular and nuclear delivery of therapeutic payloads.

Corporate Update

During the quarter ended 30 June 2023, Patrys had net cash outflows from operating activities of A$2.662 million, with A$1.983 million invested in R&D activities. The R&D expenditure for this quarter was uncharacteristically high due to one-off costs associated with the recently completed toxicology studies, and the investigation and audit of the issues associated with the production run. At 30 June 2023, Patrys held A$3.045 million in cash with an additional A$1.0 million in term deposits, meaning a total of A$4.045 available. Patrys is entitled to a refund of approximately $2.7 million under the Federal Government's R&D Tax Incentive Scheme which it expects to receive during 1H FY2024. 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$270,000. These payments include non-executive director fees and consulting services as well as salary (including superannuation) and bonus payment 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:

General enquiries
James Campbell
Chief Executive Officer
P: +61 3 96703273
info@patrys.com

Media enquiries:
Haley Chartres
H^CK
P: +61 423 139 163
haley@hck.digital

Registered Office Address
Level 4, 100 Albert Road
South Melbourne VIC 3205

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.

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	**Quarter ended ("current quarter")**
97 123 055 363	30 June 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,983)	(7,187)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(251)	(690)
	(f) administration and corporate costs	(409)	(1,101)
1.3	Dividends received	-	-
1.4	Interest received	31	77
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	3,347
1.8	Others - IP expenditure	(50)	(225)
1.9	**Net cash from / (used in) operating activities**	**(2,662)**	**(5,779)**

**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 (12 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	1,026	1,000
	(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**	**1,026**	**1,000**

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
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**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,681*	7,818*
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,662)	(5,779)

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
4.3	Net cash from / (used in) investing activities (item 2.6 above)	1,026	1,000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	6
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period***	**3,045***	**3,045***

**In addition to the cash and cash equivalents balance above as at 30 June 2023, the Company holds an additional $1million in term deposits (31 March 2023 and 30 June 2022: $2million), classified in the statement of financial position as short-term investments. Adding this $1 million in term deposits to the cash position of $3.045 million at June 30 gives a total of $4.045 million.*

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	3,045	4,681
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)**	**3,045***	**4,681***

**In addition to the cash and cash equivalents balance above as at 30 June 2023, the Company holds an additional $1million in term deposits (31 March 2023 and 30 June 2022: $2million), classified in the statement of financial position as short-term investments. Adding this $1 million in term deposits to the cash position of $3.045 million at June 30 gives a total of $4.045 million.*

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	270
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** *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.*	**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)	(2,662)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,045
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,045
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.14
	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. **In addition to the cash and cash equivalents balance noted above at 8.4, the Company holds an additional $1 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. Adding this $1 million to the cash position of $3.045 million at June 30 gives a balance of $4.045 million, with a revised value for item 8.5 of 1.52.*	
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 1 April through 30 June quarter included a range of one-off cost, particularly the recently completed toxicology studies (approximately 25% of total expenditure) and the investigation into failed manufacturing run of PAT-DX1 in the prior quarter. The anticpated expenditure for the coming quarter is considerably less than $2.6 million.	

	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 $2.7 million for the FY23 financial year, and expects to receive this refund before the end of CY 2023. 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.
	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 spend for the prior quarter was not indicative of future expenses, and the Company expects a substantial R&D refund in the current calendar year.
	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.

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: 26 July 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.