

# Q1 2024 SHAREHOLDER UPDATE

- PYC develops precision medicines for patients with severe diseases and no treatment options available today
- The Company's focus is on its three most advanced drug candidates as they progress through human safety and efficacy read-outs over the coming 18 months
- These 3 drug candidates include potential treatments for:
  - a progressive and irreversible blinding eye disease of childhood (Retinitis Pigmentosa type 11) for which there are no treatment options available today;
  - a kidney disease affecting 1 in every 1,000 people<sup>1</sup> (Polycystic Kidney Disease) that causes the majority of patients to require an organ transplant due to the absence of effective treatments; and
  - a second blinding eye disease (Autosomal Dominant Optic Atrophy) also lacking any available treatment options for patients.

### PERTH, Australia and SAN FRANCISCO, California - 26 April 2024

PYC Therapeutics Limited (ASX:PYC) (**PYC** or the **Company**) updates shareholders on the progress made towards its objectives in Q1 2024. PYC remains on track for delivery of its near-term objective of advancing three drug candidates with best-in-class potential into human trials before the end of this year<sup>2</sup>.

### Q1 2024

Material progress was made in each of the Company's three most advanced programs.

• **Retinitis Pigmentosa type 11 (RP11)** – PYC completed dosing in the third cohort of patients enrolled in the ongoing Single Ascending Dose (SAD) study in Q1 2024. The objective of this study is to establish a safe and well-tolerated dose of the drug candidate to progress into a Multiple Ascending Dose (MAD) study.

<sup>&</sup>lt;sup>1</sup> Willey C, et al. Analysis of Nationwide Data to Determine the Incidence and Diagnosed Prevalence of Autosomal Dominant Polycystic Kidney Disease in the USA: 2013-2015. Kidney Dis (Basel). 2019;5(2):107-17

<sup>&</sup>lt;sup>2</sup> PYC anticipates submitting regulatory documents to enable the first in human study in autosomal dominant polycystic kidney disease to commence in Q4 2024 with the clinical trial to begin in early 2025 if PYC is successful in this regard

The MAD study is scheduled to commence in Q2 subject to a successful review of the safety and tolerability profile of PYC's drug candidate in this patient cohort 3. This review is scheduled to occur in April 2024. Successful completion of the SAD and MAD studies will enable PYC to progress its drug candidate for RP11 into a registrational trial directed towards a New Drug Application and successful launch of the first therapy available for patients with this blinding eye disease.

Polycystic Kidney Disease (PKD) – PYC conducted a safety and tolerability study
of its clinical drug candidate in Non-Human Primates (NHPs). This study will provide
important information on the path to human trials that are expected to commence
in early 2025<sup>3</sup>.

The results of these studies will be used to design both the Good Laboratory Practice (GLP) toxicology studies that will follow (through Q2/Q3 2024) and the subsequent First In Human (FIH) dosing protocol as the program moves into human trials expected to commence in early  $2025^4$ .

 Autosomal Dominant Optic Atrophy (ADOA) – PYC completed GLP toxicology studies in the ADOA program during the quarter. The Company is now preparing for progression to FIH studies with first patient dosing anticipated in Q3 2024<sup>5</sup>.

Successful execution of the implementation plan in PYC's ADOA program will see the Company deliver clinical proof of concept data (Phase 1/2 safety and efficacy data) in 2025<sup>6</sup>.

# **Funding and Cash Runway**

During the quarter the Company announced an entitlement issue of new shares to existing shareholders to raise a total of \$74.6m in additional funds. The issue closed in Q2 2024 with the full amount raised.

The successful re-financing leaves the Company with a cash runway expected to exceed \$100m<sup>7</sup>. These funds will enable PYC to deliver multiple human safety and efficacy readouts – the currency of the biotechnology industry - in 2024 and 2025.

As of 31 March 2024, the Company had \$49.7 million of cash on hand. Subsequent to the end of the quarter, an additional \$34.6 million (before costs) is expected to be received in relation to settlement of the Retail Entitlement Offer and Shortfall placement<sup>8</sup>. R&D payments during the quarter included payment of a \$6.5 million Google Cloud AI drug discovery project instalment<sup>9</sup>. The Company also received a \$4.5 million up front fee from this collaboration during the quarter.

#### **Related Party Payments**

Section 6 of the Appendix 4C released today discloses payments to related parties of \$175k, reflecting fees paid to executive and non-executive directors during the quarter.

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<sup>&</sup>lt;sup>3</sup> See footnote 2

<sup>&</sup>lt;sup>4</sup> See footnote 2

 $<sup>^{\</sup>rm 5}$  Subject to successful GLP toxicology study outcomes and successful regulatory engagement

<sup>&</sup>lt;sup>6</sup> Subject to successful execution of the GLP tox. studies, regulatory engagement and clinical trials

<sup>&</sup>lt;sup>7</sup> Consisting of a 31 March 2024 cash balance of \$49.7m, an additional \$34.6m anticipated from completion of the retail component of the rights issue and associated placement of the shortfall (before costs), and FY24 R&D rebates estimated to add a further \$16m

<sup>&</sup>lt;sup>8</sup> See ASX announcement of 10 April 2024.

<sup>&</sup>lt;sup>9</sup> See ASX announcement of 16 February 2024

This announcement was approved for release by the Board of PYC Therapeutics Limited.

# **About PYC Therapeutics**

PYC Therapeutics (ASX: PYC) is a clinical-stage biotechnology company creating a new generation of RNA therapies to change the lives of patients with genetic diseases. The Company utilises its proprietary drug delivery platform to enhance the potency of precision medicines within the rapidly growing and commercially proven RNA therapeutic class. PYC's drug development programs target monogenic diseases – **the indications with the highest likelihood of success in clinical development**<sup>10</sup>.

The Company was the first to progress a drug candidate for a blinding eye disease of childhood (Retinitis Pigmentosa type 11) into human trials. The Company is progressing a second drug program targeting a blinding eye disease (Autosomal Dominant Optic Atrophy) and a third program targeting Polycystic Kidney Disease which are anticipated to commence human trials in mid-2024 and early 2025 respectively.

For more information, visit pyctx.com, or follow us on LinkedIn and Twitter.

# Forward looking statements

Any forward-looking statements in this ASX announcement have been prepared on the basis of a number of assumptions which may prove incorrect and the current intentions, plans, expectations, and beliefs about future events are subject to risks, uncertainties and other factors, many of which are outside the Company's control. Important factors that could cause actual results to differ materially from assumptions or expectations expressed or implied in this ASX announcement include known and unknown risks. Because actual results could differ materially to assumptions made and the Company's current intentions, plans, expectations, and beliefs about the future, you are urged to view all forward-looking statements contained in this ASX announcement with caution. The Company undertakes no obligation to publicly update any forward-looking statement whether as a result of new information, future events or otherwise.

This ASX announcement should not be relied on as a recommendation or forecast by the Company. Nothing in this ASX announcement should be construed as either an offer to sell or a solicitation of an offer to buy or sell shares in any jurisdiction.

# **CONTACTS:**

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 $<sup>^{10}</sup>$  Advancing Human Genetics Research and Drug Discovery through Exome Sequencing of the UK Biobank https://doi.org/10.1101/2020.11.02.20222232

# **Appendix 4C**

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

# Name of entity

PVC THERAPELITICS LIMITED	
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ABN		Quarter ended ("current quarter")	
	48 098 391 961	31 March 2024	

Con	solidated 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	(19,120)	(40,916)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(7)	(44)
	(e) staff costs	(488)	(1,302)
	(f) administration and corporate costs	(312)	(1,211)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	34	249
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	16,492
1.8	Other - (Receipt of collaboration fee from Al drug discovery project)	4,590	4,590
1.9	Net cash from / (used in) operating activities	(15,303)	(22,142)

Note: R&D payments during the quarter included payment of a \$6.5 million Google Cloud AI drug discovery project instalment.

2.	Cash flows from investing activities		
2.1 Payments to acquire:			
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(28)	(307)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date 9 months) \$A'000
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(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	(28)	(307)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	40,000	57,400
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(268)	(268)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings (leases)	(79)	(214)
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	39,653	56,918

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	25,414	15,572
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(15,303)	(22,142)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(28)	(307)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	39,653	56,918
4.5	Effect of movement in exchange rates on cash held	(82)	(387)
4.6	Cash and cash equivalents at end of period	49,654	49,654

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	49,654	25,414
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)	49,654	25,414

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	(175)
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

During the quarter \$175k directors remuneration was paid, which was included in item 1.2.

	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 qu	arter end	-
7.6	Include in the box below a description of eac rate, maturity date and whether it is secured facilities have been entered into or are proposinclude a note providing details of those facilities	or unsecured. If any add sed to be entered into af	itional financing
N/A			
8.	Estimated cash available for future op	perating activities	\$A'000
8.1	Net cash from / (used in) operating activities	(Item 1.9)	(15,303)
8.2	Cash and cash equivalents at quarter end (It	em 4.6)	49,654
8.3	Unused finance facilities available at quarter	end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)		49,654
8.5	Estimated quarters of funding available (I Item 8.1)	tem 8.4 divided by	3.24
Note:	The Company expects to receive \$34.6m (be the Retail component of the rights issue.  If Item 8.5 is less than 2 quarters, please pro		
06			
8.6	Does the entity expect that it will con cash flows for the time being and, if it		level of net operating
0.0			level of net operating
0.0	cash flows for the time being and, if i	not, why not? nes it propose to take any	steps, to raise further
0.0	cash flows for the time being and, if the Answer: n/a  2. Has the entity taken any steps, or do cash to fund its operations and, if so	not, why not? nes it propose to take any	steps, to raise further
0.0	cash flows for the time being and, if the Answer: n/a  2. Has the entity taken any steps, or do cash to fund its operations and, if so believe that they will be successful?	not, why not? nes it propose to take any , what are those steps ar	steps, to raise further d how likely does it

# **Compliance statement**

- 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.

	26 April 2024
Date:	
	The Board of PYC Therapeutics Limited
Authorised by:	(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".
- 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.