

# **Q3 2024 SHAREHOLDER UPDATE**

- PYC is a clinical-stage biotechnology company developing a pipeline of first-in-class precision medicines for patients who have genetic diseases and no treatment options available today
- The Company has entered the critical window of generating clinical proof of concept data (Phase 1/2 safety and efficacy read-outs) with multiple assets set to realise this milestone over the coming 15 months<sup>1</sup>
- Specific progress through Q3 2024 included:
  - Lead drug program (Retinitis Pigmentosa type 11)
    - Demonstrated improvements in vision in multiple patients who received a single dose of PYC's investigational drug candidate<sup>2</sup>
    - Completion of repeat dosing in patient cohort 1 of the Multiple Ascending Dose study<sup>3</sup> - setting the foundation for establishing clinical proof of concept for this asset in the near future<sup>4</sup>
    - Subsequent to the end of the quarter, the RP11 drug candidate received Orphan Drug Designation from the US Food and Drug Administration (FDA)<sup>5</sup>
  - Second drug program (Autosomal Dominant Optic Atrophy)
    - Received approval to commence clinical trials for this investigational drug candidate<sup>6</sup>
    - Attracted Rare Pediatric Disease designation from the US Food and Drug Administration<sup>7</sup>
- In addition to the milestones listed above in its two clinical-stage programs, PYC continued to progress:

 $<sup>^{\</sup>rm 1}\,{\rm Subject}$  to the risks and uncertainties outlined in the Company's ASX filings of 14 March 2024

 $<sup>^{\</sup>rm 2}$  See ASX announcements of 5 and 12 August 2024

 $<sup>^{\</sup>rm 3}\,\text{See}$  ASX announcements of 10 and 17 July 2024

 $<sup>^{4}</sup>$  Subject to the risks and uncertainties outlined in the Company's ASX filings of 14 March 2024

<sup>&</sup>lt;sup>5</sup> See ASX announcement 21 October 2024

<sup>&</sup>lt;sup>6</sup> See ASX announcement of 15 August 2024

<sup>&</sup>lt;sup>7</sup> See ASX announcement of 30 August 2024

- Its third pipeline program in Polycystic Kidney Disease towards a regulatory submission (expected to occur in Q4 2024<sup>8</sup>) required to enable human trials to commence; and
- A fourth drug discovery program in Phelan-McDermid Syndrome towards nomination of a clinical candidate (also expected to occur in Q4 2024<sup>9</sup>)

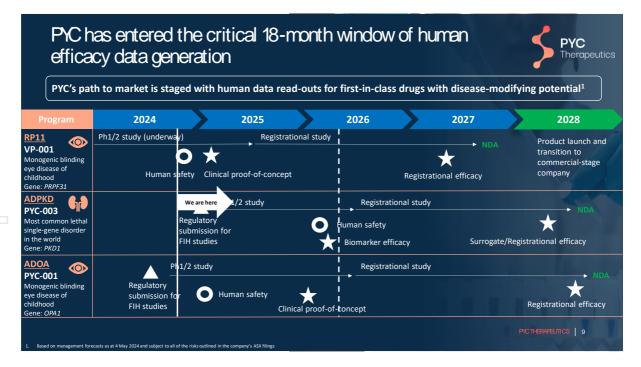
## PERTH, Australia and SAN FRANCISCO, California - 25 October 2024

PYC Therapeutics Limited (ASX:PYC) (**PYC** or the **Company**) today updates shareholders on progress made towards realisation of the Company's vision and objectives through the third quarter of 2024.

The Company continued to progress according to its published operational roadmap through the third quarter of the year (See Figure 1) with all programs remaining on track to realise their designated 2024 objective. During the quarter, PYC:

- 1) Demonstrated improvements in vision in multiple patients with RP11 following treatment with a single dose of PYC"s investigational drug candidate<sup>10</sup>; and
- 2) Progressed its second drug development program, a drug candidate with disease-modifying potential in patients with another blinding eye disease called Autosomal Dominant Optic Atrophy, into clinical trials<sup>11</sup>.

Figure 1. PYC operational roadmap



 $<sup>^{\</sup>rm 8}$  Subject to the risks and uncertainties outlined in the Company's ASX filings of 14 March 2024

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<sup>&</sup>lt;sup>9</sup> Subject to the risks and uncertainties outlined in the Company's ASX filings of 14 March 2024

<sup>&</sup>lt;sup>10</sup> See ASX announcements of 5 and 12 August 2024

<sup>&</sup>lt;sup>11</sup> See ASX announcement of 15 August 2024

The Company has reached a critical window and is set to deliver clinical proof of concept data across its three most advanced drug programs before the end of next year<sup>12</sup>. Collectively, these drug programs hold the potential to change the lives of tens of millions of patients globally living with one of the three targeted indications.

#### **Funding and Cash Runway**

As of 30 September 2024, the Company had \$45.5 million of cash on hand. Research and development payments during the quarter related to the continuation of clinical studies, studies to support clinical trial regulatory submissions and progression of discovery programs. The Company expects to receive an R&D tax rebate of approximately \$17 million in the December quarter.

#### **Related Party Payments**

Section 6 of the Appendix 4C released today discloses payments to related parties of \$148k, reflecting fees paid to executive and non-executive directors during the quarter.

#### **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>13</sup>.

#### PYC's drug development programs

#### **Retinitis Pigmentosa type 11**

- A blinding eye disease of childhood affecting 1 in every 100,000 people<sup>14</sup>
- Currently progressing through clinical trials with human safety and efficacy readouts anticipated in 2024<sup>15</sup>

#### **Autosomal Dominant Optic Atrophy**

- A blinding eye disease of childhood affecting 1 in every 35,000 people<sup>16</sup>
- Currently progressing through clinical trials with human safety and efficacy readouts anticipated in 2024 and 2025<sup>17</sup>

 $<sup>^{\</sup>rm 12}$  Subject to the risks set out in the Company's ASX disclosures of 14 March 2024

 $<sup>^{13}</sup>$  Advancing Human Genetics Research and Drug Discovery through Exome Sequencing of the UK Biobank https://doi.org/10.1101/2020.11.02.20222232

<sup>&</sup>lt;sup>14</sup> Sullivan L, et al. Genomic rearrangements of the PRPF31 gene account for 2.5% of autosomal dominant retinitis pigmentosa. Invest Ophthalmol Vis Sci. 2006;47(10):4579-88

 $<sup>^{\</sup>rm 15}$  Subject to the risks outlined in the Company's ASX announcement of 14 March 2024

<sup>&</sup>lt;sup>16</sup> Yu-Wai-Man, P. et al. The Prevalence and Natural History of Dominant Optic Atrophy Due to OPA1 Mutations Ophthalmology. 2010;117(8):1538-46 doi: 10.1016/j.ophtha.2009.12.038

<sup>&</sup>lt;sup>17</sup> Subject to the risks outlined in the Company's ASX announcement of 14 March 2024

#### **Autosomal Dominant Polycystic Kidney Disease**

- A chronic kidney disease affecting 1 in every 1,000 people<sup>18</sup> that leads to renal failure and the need for organ transplantation in the majority of patients
- Clinical trials are expected to commence in early 2025 with human safety and efficacy data anticipated in 2025 and 2026<sup>19</sup>

# **Phelan McDermid Syndrome**

- A severe neurodevelopmental disorder affecting 1 in every 10,000 people<sup>20</sup>
- PYC will initiate Investigational New Drug (IND)-enabling studies in 2025 to facilitate progression into human trials

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.

This ASX announcement was approved and authorised for release by the Board of PYC Therapeutics Limited

#### **CONTACTS:**

**INVESTORS and MEDIA** info@pyctx.com

<sup>&</sup>lt;sup>18</sup> Harris PC, Torres VE. Polycystic Kidney Disease, Autosomal Dominant. 2002 Jan 10 [Updated 2022 Sep 29]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews. Seattle (WA): University of Washington, Seattle; 1993-2023.

<sup>&</sup>lt;sup>19</sup> Subject to the risks outlined in the Company's ASX announcement of 14 March 2024

<sup>&</sup>lt;sup>20</sup> Phelan-McDermid Syndrome Foundation. https://pmsf.org/about-pms/

# **Appendix 4C**

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

# Name of entity

PYC THERAPEUTICS LIMITED

ABN Quarter ended ("current quarter")

48 098 391 961 30 Sep 2024

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date 3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(20,059)	(20,059)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(8)	(8)
	(e) staff costs	(399)	(399)
	(f) administration and corporate costs	(558)	(558)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	344	344
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other -	-	-
1.9	Net cash from / (used in) operating activities	(20,680)	(20,680)

2.	Cash flows from investing activities	
2.1	Payments to acquire:	
	(a) entities	-
	(b) businesses	-
	(c) property, plant and equipment	(567)
	(d) investments	-
	(e) intellectual property	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date 3 months) \$A'000
	(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	(567)	(567)

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	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings (leases)	(78)	(78)
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	(78)	(78)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	66,875	66,875
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(20,680)	(20,680)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date 3 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(567)	(567)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(78)	(78)
4.5	Effect of movement in exchange rates on cash held	(105)	(105)
4.6	Cash and cash equivalents at end of period	45,445	45,445

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	45,445	66,875
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)	45,445	66,875

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	(148)
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 \$148k directors remuneration was paid, which was included in item 1.2.

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7.	Note: th arrange Add not	te term "facilities" includes all forms of financing ments available to the entity. The sas necessary for an understanding of the standard of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000		
7.1	Loan f	acilities	-	-		
7.2	Credit	standby arrangements	-	-		
7.3	Other	(please specify)	-	-		
7.4	Total 1	financing facilities	-	-		
			<u> </u>	<u>i</u>		
7.5	Unuse	ed financing facilities available at qu	arter 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.	Estim	nated cash available for future op	erating activities	\$A'000		
8.1	Net ca	sh from / (used in) operating activities	(Item 1.9)	(20,680)		
8.2	Cash a	and cash equivalents at quarter end (It	45,445			
8.3	Unuse	ed finance facilities available at quarter	-			
8.4	Total available funding (Item 8.2 + Item 8.3)			45,445		
8.5	Estimate 18	ated quarters of funding available (I 3.1)	2.20			
	Note:	O of approximately				
8.6	If Item	8.5 is less than 2 quarters, please pro	vide answers to the follo	wing questions:		
	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?					
	Answe	er: 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?				
	Answer: n/a					
	3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?					
	Answe	er: n/a				

### **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.

	25 October 2024
Date:	
	The Board of PYC Therapeutics Limited
Authorised by:	(Name of body or officer authorising release – see note 4)

#### **Notes**

- 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.
- 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.
- 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.