



# REPORT FOR THE QUARTER ENDED 30 SEPTEMBER 2021 (Q3)

# COMPLETION OF NON-GLP TOLERABILITY AND SAFETY STUDIES HEADLINE Q3 2021 PROGRESS

PYC confirmed successful target engagement in the cell type of interest in rabbit eyes in its co-lead drug development program

PYC completed critical tolerability and safety studies in non-human primates – Results are expected in the near future once the histopathology analysis is complete

The Q3 milestones achieved further validate and de-risk PYC's drug delivery platform and deep ocular pipeline

The Company remains on course to transition to a clinical-stage genetic medicine company in 2022 with its highly scaleable underlying platform technology

**PERTH, Australia and SAN DIEGO, California – October 28, 2021** – PYC Therapeutics (ASX:PYC) is a biotechnology company which combines two complementary platform technologies:

- Proprietary drug delivery technology; and
- RNA drug design capabilities.

Together they are being developed to create a new generation of RNA therapeutics to change the lives of patients with inherited diseases. The Company's initial focus is on blinding diseases of the eye.

The Company's co-lead drug candidate is the first disease-modifying therapy for patients with a blinding eye disease called Retinitis Pigmentosa type 11 (RP11). The RP11 co-lead program is supported by a deep ocular pipeline which share both a common delivery technology and backbone chemistry with the RP11 drug candidate.

Critical pieces of PYC's non-clinical RP11 data pack were added in Q3. The new data demonstrates for the first time that PYC's proprietary RNA drug technology can effectively engage its molecular target in the deepest layer of cells within the retina in a large eye<sup>1</sup>. This data was obtained from *in vivo* studies that employ the same route of administration that is planned for the Company's upcoming first in human clinical trials.

PYC also completed the critical exploratory tolerability and safety assessment in nonhuman primates with the results of these studies anticipated to be available in the near future.

<sup>&</sup>lt;sup>1</sup> see ASX announcement of 28 September 2021

PYC's third quarter update highlights progress made in its transition to becoming a clinicalstage company. The anticipated timing for completion of this milestone is the second half of 2022.

These milestones achieved in Q3 are important for two reasons, they:

- i) support the build-up of information in the Company's plan to submit an Investigational New Drug (IND) application to the United States Food and Drug Administration in the RP11 program within the next 12 months; and
- ii) validate and de-risk PYC's platform and deep ocular pipeline due to the similarities between the drug candidate evaluated in these studies and the rest of PYC's pipeline for blinding eye diseases caused by different genetic mutations.

Successful safety and tolerability assessments in the RP11 program (the data to be released in the near future) will see PYC:

- Progress to within reach of a first in human study;
- With a validated and highly scalable platform technology that supports multiple drug programs;
- Where the cornerstone of PYC's pipeline (its first in class and best in class diseasemodifying therapies for monogenic diseases) have an extraordinarily high prospect of successful approval<sup>2</sup>.

In addition to the progress made in the co-lead program, the Company also announced additional appointments to its Clinical Advisory Board in the quarter. These prominent clinical researchers bring significant expertise in inherited retinal diseases. The Clinical Advisory Board will initially focus on PYC's co-lead drug candidate, VP-001 for the treatment of RP11.

PYC's Clinical Advisory Board members include:

- **David Birch PhD** Dr. Birch is the Scientific Director of the Retina Foundation of the Southwest, where he is also the Director of the Rose-Silverthorne Retinal Degenerations Laboratory.
- **Fred Chen MD**, **PhD** Dr. Chen is the head of the Ocular Tissue Engineering Laboratory at the Lions Eye Institute in Perth, Western Australia and is focused on the diagnosis and treatment of IRDs and macular degeneration.
- Jacque Duncan MD Dr. Duncan is an ophthalmologist who specializes in treating retinal degenerative diseases, such as retinitis pigmentosa and age-related macular degeneration, and a Professor at the University of California, San Francisco (UCSF), where she is Vice Chair for Clinical Trials and Academic Director of the Retina Service
- Mark Pennesi MD, PhD Dr. Pennesi is Professor of Ophthalmology at Oregon Health & Science University's (OHSU) School of Medicine. He also holds the Kenneth C. Swan Endowed Professorship and is the Chief of the Ophthalmic Genetics Division at the Casey Eye Institute at OHSU.

Payments in the September quarter to related parties of \$355,000 included in item 6 in the attached Appendix 4C comprised fees and remuneration paid to Directors.

<sup>&</sup>lt;sup>2</sup> Szustakowski, J.D., Balasubramanian, S., Kvikstad, E. et al. Advancing human genetics research and drug discovery through exome sequencing of the UK Biobank. Nat Genet 53, 942–948 (2021). https://doi.org/10.1038/s41588-021-00885-0

#### **About PYC Therapeutics**

PYC Therapeutics (ASX: PYC) is a pre-clinical stage biotechnology company pioneering a new generation of RNA therapeutics that utilize PYC's proprietary library of naturally derived cell penetrating peptides to overcome the major challenges of current genetic medicines. PYC believes its PPMO (Peptide conjugated Phosphorodiamidate Morpholino Oligomer) technology enables a safer and more effective RNA therapeutic to address the underlying drivers of a range of genetic diseases for which no treatment solutions exist today. The Company is leveraging its leading-edge science to develop a pipeline of novel therapies including three preclinical stage programs focused on inherited eye diseases and a preclinical discovery program focused on neurodegenerative diseases. PYC's discovery and laboratory operations are located in Australia, and its pre-clinical, clinical and regulatory operations are performed in the US. For more information, visit <u>pyctx.com</u>, or follow us on <u>LinkedIn</u> and <u>Twitter</u>.

#### 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 authorized for release by the Board of PYC Therapeutics Limited

## **CONTACTS:**

# INVESTORS Deborah Elson/Matthew DeYoung

Argot Partners <u>deborah@argotpartners.com</u> <u>matthew@argotpartners.com</u> MEDIA Leo Vartorella Argot Partners leo@argotpartners.com

# Appendix 4C

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

### Name of entity

PYC THERAPEUTICS LIMITED

#### ABN

48 098 391 961

Quarter ended ("current quarter")

30 September 2021

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	(4,448)	(4,448)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(58)	(58)
	(e) staff costs	(731)	(731)
	(f) administration and corporate costs	(608)	(608)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	2
1.5	Interest and other costs of finance paid	-	
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(5,843)	(5,843)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(35)	(35)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	(11)	(11)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date 3 months) \$A'000
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	(46)	(46)

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	-
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	-

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	51,502	51,502
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,843)	(5,843)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(46)	(46)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date 3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	5	5
4.6	Cash and cash equivalents at end of period	45,618	45,618

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	12,551	18,435
5.2	Call deposits	33,067	33,067
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)	45,618	51,502

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	(355)
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 \$418k directors remuneration was paid, which was included in item 1.2.

## 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.

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 Total financing facilities

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
-	-
-	-
-	-

### 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

Estimated cash available for future operating activities	\$A'000
Net cash from / (used in) operating activities (Item 1.9)	(5,843)
Cash and cash equivalents at quarter end (Item 4.6)	45,618
Unused finance facilities available at quarter end (Item 7.5)	-
Total available funding (Item 8.2 + Item 8.3)	45,618
Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	7.81
	Net cash from / (used in) operating activities (Item 1.9) Cash and cash equivalents at quarter end (Item 4.6) Unused finance facilities available at quarter end (Item 7.5) Total available funding (Item 8.2 + Item 8.3) Estimated quarters of funding available (Item 8.4 divided by

- 8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:
  - 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

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

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

### **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.

#### 28/10/2021

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.
- 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.