

#### 6 January 2020

# **Quarterly Shareholder Update**

#### Highlights

- Lead drug molecule finalised in Q4 2019
- Major milestones coming in Q1 2020 efficacy read-outs in human cells and 3D 'eyeball in a dish' imminent
- 'First In Human' studies to follow next year if successful making PYC a clinical stage platform company
- No known competitors in our multi-billion dollar target indication
- Ability to scale rapidly into new indications

PYC Therapeutics, (ASX: PYC) ('The Company' or 'PYC') has finalised its lead drug molecule (a treatment for a form of Retinitis Pigmentosa, the leading cause of childhood blindness) in the final quarter of 2019. The Company anticipates starting Investigational New Drug (IND)-enabling studies for this drug molecule in the first half of 2020. Upon successful completion of IND-enabling studies, the drug is expected to progress to clinical testing in humans next year.

PYC's lead drug is comprised of two primary elements joined together:

- i) A drug cargo an RNA therapeutic or a 'precision medicine' known as an Anti-Sense Oligonucleotide (ASO); and
- ii) A delivery vehicle: A Cell Penetrating Peptide (CPP) that delivers the drug cargo to the diseased cell and across the cell membrane to the target in the diseased cell's nucleus.

In order to arrive at the drug molecule with the highest chance of success in clinical development, more than 200 CPPs have been evaluated in animals and 74 ASOs tested in cells along with multiple linkers before the decision on the optimal combination was made. This extensive preclinical work-up leaves us with the strongest prospects of success in the transition to first in human studies and beyond.

### Upcoming milestones

Looking forward to what lies ahead, we have an exciting path both to and through the clinic. This journey will include:

- A final additional assessment of PYC's lead drug's ability to reverse a disease process in human cells that have the target disease (Retinitis Pigmentosa) – known as a 'phagocytosis assay', this provides an assessment of whether our drug can restore the diseased cells' ability to rid themselves of toxic build up (anticipated at the end of Q1 2020);
- ii) A 'clinical trial on a benchtop' with 'optic cups'/'retinal organoids' from patients likely to be enrolled in our phase 1 study (anticipated at the end of Q1 2020); and
- iii) Initiation of IND-enabling studies demonstrating the safety of the lead drug candidate in larger animal species (anticipated to begin in Q2 2020).

## Pipeline expansion

The pharmaceutical industry trend towards RNA therapeutics is very strong<sup>1</sup>. PYC is positioning itself to benefit from this trend through both:

- i) Expansion of our pipeline in inherited retinal diseases; and
- ii) Evaluation of additional target tissues and indications to pursue beyond the eye.

The Company has an opportunity to leverage the compressed timelines for the development of RNA therapeutics in the creation of shareholder value. These timelines can be drastically reduced for RNA therapeutics when compared to traditional timelines for drug development.

PYC has made a substantial investment in the optimisation of both our chemistry and delivery technologies and is now well positioned to translate this into rapid pipeline expansion in 2020. As recently observed in *Nature Medicine*, 'the timeline from target identification to preclinical proof of concept in animal models, to having a lead compound ready to be tested in clinical trials, can be as short as 6 months'<sup>2</sup> for this class of molecule.





<sup>&</sup>lt;sup>1</sup> See Nature Medicine Editorial, 'Delivering the promise of RNA therapeutics', Vol 25 September 2019 for an overview. Available at: https://doi.org/10.1038/s41591-019-0580-6

<sup>&</sup>lt;sup>2</sup> Nature Medicine Editorial, 'Delivering the promise of RNA therapeutics', Vol 25 September 2019

#### **About PYC Therapeutics**

PYC Therapeutics (ASX: PYC) is a drug development company solving a major challenge in the development of a revolutionary new class of drugs – delivering large drugs into cells. Cell Penetrating Peptides (CPPs) can overcome 'the delivery challenge' and provide access for a wide range of potent and precise drug 'cargoes' to the 'undruggable genome' – the highest value drug targets that exist inside cells. PYC Therapeutics is using its CPP platform to develop a pipeline of novel therapies with an initial focus on inherited retinal diseases.

#### 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.

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