

## PYC announces strategic partnership and lead program

### Background

PYC owns a drug delivery technology that addresses the major obstacle in the path of precision medicine. PYC's technology has the unique ability to deliver precise and potent drugs to the highest value targets on the inside of cells. This technology is being used to develop a powerful new class of treatments. The Company's immediate focus is on taking drugs for blinding eye diseases into clinical development.

### Headlines

**PYC achieves major milestones towards the commercialisation of its delivery technology by:**

- 1) **Entering a new strategic partnership with the Lions Eye Institute** – leading global experts in the development of drugs for eye diseases;
- 2) **Appointing Professor Sue Fletcher**, industry leading expert in the design and development of precision medicines, as our Chief of Research and Development on a part-time basis; and
- 3) **Selecting a lead drug candidate for immediate progression to clinical development** - a treatment for the leading cause of childhood blindness – a **\$1bn p.a. target market with no existing treatment options** – our lead drug candidate has already demonstrated preliminary evidence of the ability to **reverse this disease process in human cells** (see Figure 1 - below).

The combined impact of these developments means that:

- i) PYC now has the ability to **independently take drugs to market** through its commercial collaboration with the Lions Eye Institute and the appointment of Professor Fletcher;
- ii) PYC has advanced **from 'platform only' to 'platform and product'**. Previously PYC has been advancing its cell penetrating peptide technology as a platform to deliver drugs. Now it will be combining that technology with drugs to internally develop a new class of therapies to cure blinding diseases of the eye;
- iii) PYC will continue to commercialise its platform delivery technology either **by third party licensing arrangements or internally through additional drug development programs**.

In short, these developments make PYC a drug development company whilst still retaining its core drug delivery technology for simultaneous exploitation.

## Comments

- Commenting on the formation of the strategic partnership involving an investment in Vision Pharma Pty Ltd:
  - **Fred Chen, specialist ophthalmologist at the Lions Eye Institute:**

*'The formation of Vision Pharma in WA is a culmination of decades of research into splice therapy (Sue Fletcher) and cell penetrating peptides (PYC), the establishment of the Australian Inherited Retinal Diseases Registry since the 1980s, and the more recently developed local expertise in stem cell retinal disease modelling facility (Lions Eye Institute)';*
  - **Professor Sue Fletcher:**

*'We look forward to the clinical development of therapeutics for Retinitis Pigmentosa and other degenerative retinal diseases'; and*
  - **Alan Tribe, PYC Chairman:**

*'I am excited by the prospects for this new partnership. It brings together the PYC drug delivery system and an elegant drug to treat the leading cause of childhood blindness.*

*Importantly it also brings together world class expertise in drug design, delivery and development as well as the treatment of eye diseases. The team that has been created will be capable of achieving much'.*

## Supporting Highlights

### Strategic partnership and Executive appointment

- PYC established Vision Pharma Pty Ltd (**Vision**) as a commercial vehicle for the strategic partnership to advance its priority application of a new class of RNA therapies in blinding diseases of the eye
- PYC and Vision will add in-house drug development expertise with **Professor Sue Fletcher joining the Company as Chief of Research and Development** on a part-time appointment. Sue is the co-inventor of Eteplirsen, an FDA approved treatment for Duchenne Muscular Dystrophy (~\$500m in annual sales) and a global leader in the design and development of RNA therapeutics (the class of precise and potent drug cargoes prioritised by PYC and its new subsidiary)
- Vision has genuine **'bench to bedside' capability to take drugs to market** through a combination of world leading technology and expertise:
  - PYC – owners of an intracellular drug delivery platform capable of delivering RNA therapeutics to the highest value targets inside cells; and

- o the Ocular Tissue Engineering Laboratory at the Lions Eye Institute (LEI) - experts in inherited retinal diseases and sponsors of multiple clinical trials

### **Strategic partnership - Our Lead Program**

- Vision's lead program uses PYC's best-in-class delivery technology to create a competitively differentiated drug to **treat a form of the leading cause of childhood blindness – Retinitis Pigmentosa**
- This lead drug molecule has shown preliminary evidence of the **ability to reverse the features of our target disease in human cells** (see Figure 1 below)
- Our strategic partnership with Vision intends to **commence Investigational New Drug (IND)-enabling studies for this lead program in the first half of 2020** – Successful IND-enabling studies will culminate in approval for testing in humans
- The **target market for this drug is currently estimated to be US\$1bn per annum. No alternative treatment options exist**

**1 October 2019:** Phylogica Limited trading as PYC Therapeutics (ASX: PYC) 'The Company' or 'PYC' has entered into a new strategic partnership with the Lions Eye Institute (LEI) to develop a pipeline of treatments for blinding eye diseases ('Commercial Collaboration'). Vision Pharma Pty Ltd ('Vision'), our strategic partnership vehicle, combines PYC's delivery technology with global leading expertise in both:

- i) Anti-Sense Oligonucleotide (ASO) design and validation (Our drug cargo class of interest); and
- ii) the eye (Our initial target tissue of interest).

PYC has also formalised our relationship with Professor Sue Fletcher, a global leader in the design of ASOs for rare diseases. Prof. Fletcher will join PYC on a part-time basis as Chief of Research and Development to support both our Retinitis Pigmentosa program and build our pipeline of CPP-ASO drugs. Prof. Fletcher is the inventor of Eteplirsen, marketed as Exondys 51 by Sarepta Therapeutics, a world's first treatment for Duchenne Muscular Dystrophy generating ~\$500million AUD in sales over the last 12 months.

Professor Fletcher's appointment gives PYC and Vision the ability to create proprietary drug molecules to couple with our delivery platform. The product of this design and delivery capability is a pipeline of RNA therapeutics set to fulfil the promise of precision medicine. LEI's co-investment in Vision gives PYC the ability to take drug molecules through the entire development cycle or from 'bench to bedside'. The Ocular Tissue Engineering Laboratory at LEI has expertise spanning both pre-clinical and clinical drug development and evaluation.

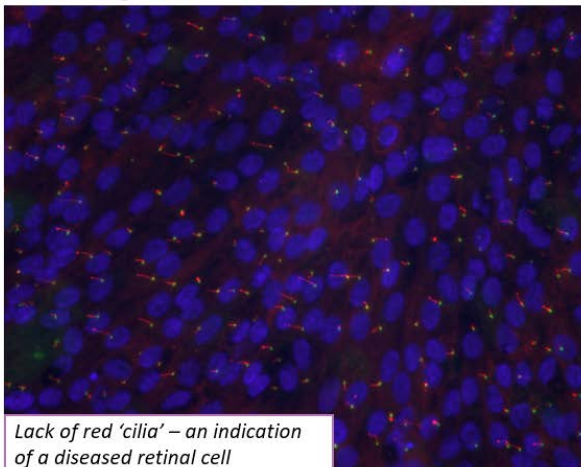
Vision's lead program combines PYC's Cell Penetrating Peptide (CPP) delivery technology with a proprietary drug cargo known as an AntiSense Oligonucleotide (ASO) for the treatment of a form of Retinitis Pigmentosa – the leading cause of childhood blindness. This drug molecule is in advanced pre-clinical development and is scheduled to enter Investigational New Drug (IND)-enabling studies in the first half of 2020. Successful completion of these studies will enable the drug to be used in humans.

Vision is developing a pipeline of other ASO candidates for the treatment of different forms of inherited retinal disease and expects to progress them into the clinic in a staged yet parallel format alongside the lead drug candidate. This pipeline will benefit from the rapid scalability of PYC's delivery technology in light of the extensive evaluation already performed in the development of Vision's lead drug program.

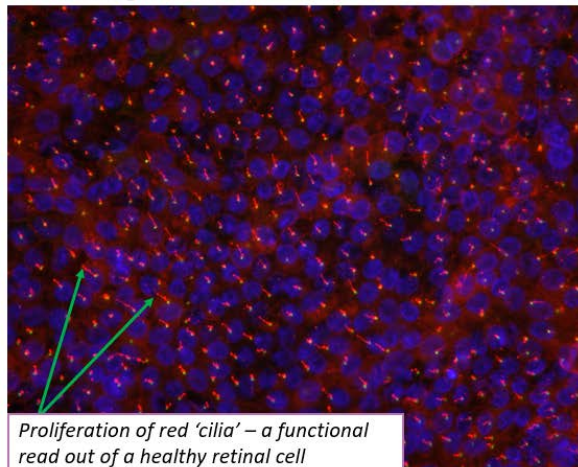
### Results to date are extremely promising

**Figure 1. Human RPE cells from patients with retinitis pigmentosa treated with 'naked' ASO (left) vs. PYC's CPP-ASO<sup>1</sup> (right)**

**A. ASO drug alone**



**B. ASO drug combined with PYC's CPP**



Note: this experiment has not been repeated and therefore should be interpreted with caution until a repeat is available

1. Human derived retinal pigment epithelium from a patient with a mutation in a gene causing Retinitis Pigmentosa treated with 5uM ASO alone or CPP-ASO for 48 hours

Through our Commercial Collaboration with the Lions Eye Institute, Vision's lead drug candidate has shown preliminary evidence that it can reverse the features of retinitis pigmentosa in human cells. Figure 1 (above) compares the effectiveness of Vision's CPP-ASO to a 'naked-ASO' drug. Healthy retinal cells express the red cilia, whilst diseased cells do not. The CPP-ASO treatment significantly increases the expression of these red cilia by the diseased patient cells, a key functional readout for drugs intending to rescue our target form of Retinitis Pigmentosa. The ASO joined to PYC's CPP increases both the amount of cells expressing cilia, and the length of these cilia above the naked ASO (as demonstrated in the photograph).

This data will be presented publicly for the first time at the Oligonucleotide Therapeutics Society meeting in Munich, Germany in October 2019.

### Commercial terms of the strategic partnership

PYC are the majority shareholder and commercialisation partner within Vision Pharma. In return for its shareholding, PYC have granted Vision a non-exclusive license for the use of our CPPs in specific indications in the eye that Vision Pharma wishes to progress into clinical development programs. PYC can increase its shareholding in Vision in return for providing funding for the progression of Vision Pharma's programs through IND-enabling and, subsequently, clinical studies.

HWL Ebsworth Lawyers advised the Company on its strategic partnership with LEI.

## ENDS

For further information, please contact:

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### About PYC Therapeutics

*Phylogica Limited trading as 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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