Phylogica Ltd

(PYC $0.032) Speculative Buy - Initiation of Coverage

Analyst	Date	Price Target
Ben Laird	**6th April 2017**	**$0.075/sh**

Always exciting science, now it's becoming commercially relevant.

Investment case

After a decade of development PYC are now close to entering preclinical trials for an in house oncology drug that aims to target and inhibit "Myc", a gene which when over active is seen as a "driver" of most human cancers. The prize should this program ultimately be successful is huge. We see the progression of PYC's Myc inhibition (iMyc) oncology program to the preclinical phase of development as a key inflection point for PYC. We believe that towards the back end of the preclinical period, if the in vivo efficacy and toxicology data is positive, it could be catalyst for a potential partnership deal with Pharma Co that could underpin multiples of the current share price.

We initiate coverage on PYC with a Spec BUY recommendation and a price target of $0.075/sh.

It has been a long slow road but we are coming to the pointy end

PYC has been a listed entity for more than 10 years and has from a science perspective made considerable advances in both identifying promising new drugs and improving drug delivery to the inside of a cell. Over the journey ~$100m has been sunk into PYC's platform and the company has formed partnerships with the likes of Roche, AstraZeneca, Pfizer and Johnson & Johnson. While the company has been able to achieve funding to pursue particular drug programs they have not been far enough down the development path to attract material Pharma Co dollars. Taking the iMyc program into and then through preclinical trials is a paradigm shift in our view.

The potential of PYC's in house oncology program is massive

If you are talking about potentially impacting 7 out of 10 human cancers the market for a successful drug is huge. Despite the inherent risks of bringing a new drug to market, due to the size of the prize we see PYC as being in a position to attract Pharma Co interest at multiples of PYC's current valuation well before commercialisation. Namely we see this being an option the company could explore after key hurdles are met during preclinical trial period (late CY'18). We see a partnership with Pharma Co for an upfront payment of US$50-150m plus back end payments of US$200-400m+ as being achievable upon success. PYC listed peers who have managed similar licensing deals at or during the preclinical phase trade at valuations of A$400m+ vs PYC's current A$64m market capitalisation. We think this is a good risk/reward proposition.

More than a one hit wonder

PYC's drug discovery platform could yield significant value beyond the iMyc program. PYC's core asset is their propriety ownership of a Phylomer® peptide library which comprises of billions of biologically active molecules. PYC have refined a technique to actively and efficiently screen this database for potential new drug targets and intracellular drug delivery candidates. PYC currently has programs in place targeting other cancer targets (aside from Myc), antibiotic resistant bacteria and genetic diseases with various Pharma Co and academic partners. These programs are early stage but demonstrate PYC's long term potential and underpin a baseline value proposition in our view.

Phylogica Ltd	Year Ended 30 June	
Share Price	**0.032**	**A$/sh**
Price Target	**0.075**	**A$/sh**
Valuation	0.075	A$/sh

Shares on issue	2004	m, undiluted
Options on issue	64	m
Market Capitalisation - undiluted	64	A$m
Enterprise Value	59	A$m
Debt	0	A$m
Cash	5.5	A$m
Turnover	1.6m	sh/day
12 Mth Hi-Lo	0.012-0.045	cps
Balance date		June 30th

Dirctors & Management

Ms Stephanie Unwin	Non-Exec Chair
Dr Paul Watt	NED
Mr Jeremy Curnock Cook	NED
Dr Bernard Hockings	NED
Dr Rohan Hockings	alt NED

Shareholders

Bernard Hockings	30.8%
David Sietsma	10.0%
Anthony Barton	5.0%

Company Details

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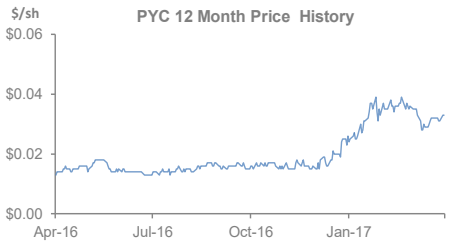
Subiaco, WA 6008
Telephone: +61 8 9489 7777
www.phylogica.com

Share Price Chart



Disclosure

This analyst declares that he has a beneficial interest in Phylogica Ltd.

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Introduction

PYC is a platform technology company whose core asset is a library made up of protein fragments (peptides) expressed from the genetic material (Phylomers) of micro-organisms such as bacteria and fungi. The idea behind using this as a source of drug candidates is that the sequences and structures found in nature are highly evolved and are therefore likely to be enriched for proteins that have the ability to interact with the human body in a manner that yields therapeutic benefit.

The company has spent the last decade developing screening technologies to select the few peptides from within the libraries that are able to:

i. cross the cell wall and gain access to the intracellular space (where there are many more targets for drugs than on the outside of cells); and

ii. interact with the high value targets that exist on the inside of cells.

The peptides that have the ability to cross the cell wall are known as Functional Penetrating Peptides (FPPs) and these FPPs are able to 'carry' a large molecule (such as an active intracellular drug cargo) into an environment to which it could not otherwise gain access because of its large size. The ability to provide access for large molecules to intracellular drug targets is a major step forward because of the greater sensitivity and specificity that interacting with these targets affords (resulting in better drugs with fewer side effects). To exploit this development, PYC have identified drug cargoes from within their libraries active against the high value intracellular target (Myc – discussed below) and are fusing these to an FPP to create a Myc inhibitor (iMyc) for the treatment of cancer.

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Valuation

We value PYC at $0.075/sh with a Spec BUY rating.

Due to the early stage nature of the iMyc program we choose to value PYC based on a risk weighted potential outcome of a license deal with Pharma Co post successful preclinical trials.

Table 1 below outlines the value and nature of several license deals completed in the Immuno-oncology (IO) field in 2016 at the preclinical phase of a drug's development. We see the IO field as a relevant comparison to PYC's iMyc program as IO is a relatively new pathway of cancer treatment that has attracted significant Pharma Co interest. PYC are planning to enter preclinical trials for their iMyc program by end CY'17 and complete the bulk of the technical data by 2H CY'18.

Company	PharamCo Partner	Trial Stage	Field	Drug	Notes	Upfront Terms	Ongoing Terms	Carry on Spend
Jounce Therapeutics	Celgene	Preclinical	Immuno-oncology	JTX-2011	Designed to treat solid tumors as a single agent or in combination	US$225 plus US$36m equity investment	Jounce retains 60% US profit share for JTX-2011	50% going forward
							Jounce keeps 25% US profit sharefor first additional program	
							Jounce keep 50% US profit sharefor next three additional programs	
Argenx	AbbVie	Preclinical	Immuno-oncology	ARGX-115	Due to it's mechansim of action it can treat a broad range of cancers and could be used with other meds	US$40m plus potential US$20m top up	Potential additional US$625m as various hurdles are met	
							Double digit royalties if drugs reaches sales	
Advaxis	Amgen	Preclinical	Immuno-oncology	ADXS-NEO	Highly targeted, patient specific treatment	US$40 plus US$25m equity investment	Potential additional US$475m as various hurdles are met	
							High single digit royalties if drugs reaches sales	
Flexus	Bristol-Myers Squibb	Preclinical	Immuno-oncology	FLX925	Potential ability for an acquirer to combine the drug with other drug assets.	US$800m	Potential additional US$450m as various hurdles are met	

Table 1. Source: Fierce Biotech

The reason for the disparity in up front terms between the Flexus/BMS deal and the rest is because FLX925 can potentially be combined with other drugs to produce compounding beneficial effects. The result being that an acquiring Pharma Co could potentially lift the commercial value of their broad portfolio of drugs as opposed to just a single silo.

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We see PYC's iMyc program of potentially being in this category. iMyc acts via a different but complimentary pathway to IO drugs. In laymen's terms IO drugs 'hit the brakes' on tumour progression while iMyc is akin to 'taking the foot off the accelerator'. These two distinct mechanisms of action could in theory be combined to produce improved therapeutic effects of existing drugs on the market.

Table 2 shows the market capitalisation (where applicable) for the same companies outlined above:

Company	Stock Ticker	Exchange	Market Capitalisation (A$m)	Notes
Jounce Therapeutics	JNCE	NASDAQ	998	
Argenx	ARGX	Euronext	469	
Advaxis	ADXS	NASDAQ	434	
Flexus	n/a	n/a	1067	IO program taken over, other assets spun out

Table 2. Source Bloomberg

Taking all of the above into account we believe PYC could potentially secure a licensing deal with Pharma Co for an upfront payment of US$50-150m with longer term milestone payments of US200-400m+ and a double digit royalty stream.

We also ascribe a nominal value of $50m for PYC's peptide platform and other drug candidates.

On the basis of the potential upside outlined above vs the risk of successfully completing preclinical trials we derive the following valuation for PYC:

PYC Valuation		
iMyc Program	A$m	100
Other Assets	A$m	50
Cash	A$m	5.5
Total	**A$m**	**155.5**
SOI (fully diluted)	m	2068
Valuation	**A$/sh**	**0.075**

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Share Price Catalysts

1. Entering preclinical trials: This is a key milestone for PYC and is expected to occur by late CY'17/early CY'18. We see this point as when many investors will "place their bets" for an outcome.
2. In vivo Efficacy & Toxicology results: Once preclinical trials have commenced the first key data point is the outcome of efficacy and toxicology trials in mice. These results are estimated to be available in Q1/Q2 CY'18. A positive result would significantly de-risk the iMyc platform. Importantly it would also demonstrate that the FPP portion of the conjugate is effective. This would have a multiplicative effect on the value of the broader PYC platform. While in all likelihood too early for a Pharma Co alliance deal this should lead to a rerating of PYC.
3. Non-GLP toxicology trials in primates: Once data from the efficacy and toxicology trials is analysed PYC's iMyc drug will be administered to Monkeys in a non-GLP (non-Good Laboratory Practice) trial. This is to test the toxicology of the drug in a metabolic system as close to human as possible. If this phase is a success the risk of failure to move to Phase 1 clinical trials is low. Once this phase is completed we see a high likelihood that Pharma Co would look to engage PYC in a meaningful way. We estimate this could occur in Q4 CY'18.
4. GLP toxicology trials in primates: Post the non-GLP trial a more formal Good Laboratory Practice (GLP) toxicology trial is conducted in Monkeys. This is the final major technical step required to complete the preclinical phase. This is expected to occur in late CY'18.
5. PYC is currently without a CEO: We would see any bolstering of management/board ranks with someone from industry background as a positive. PYC are currently screening candidates. Outside of an alliance deal we see the ability of PYC to attract key staff as important third party validation for the company.
6. Maturation of other early stage drug programs: PYC has a plethora of parallel drug programs with reputable partners. Should any of these programs mature or lead to more alliances with Pharma Co it would add to our positive stance.

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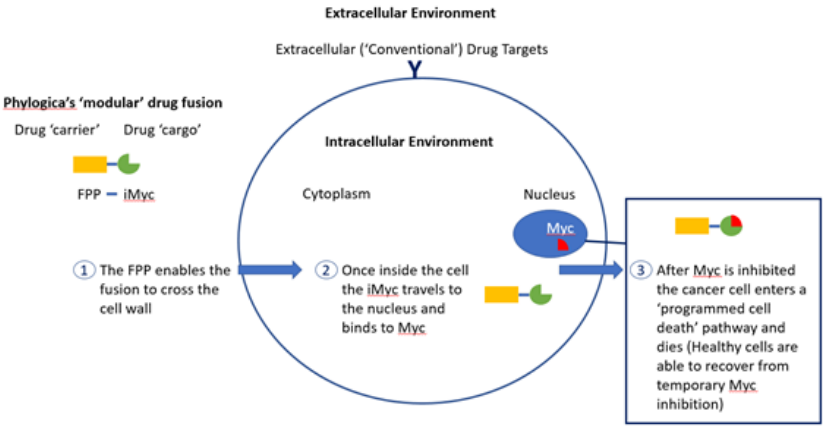
Phylogica's iMyc program overview

Below we outline the information required to understand the technical and commercial relevance of PYC's in house oncology program focused on the inhibition of Myc. We see this program as the largest value driver of PYC in the medium term.



Source: Phylogica Ltd

Figure 2. Above is a visual depiction of PYC's core areas of focus 1) Functional Penetrating Peptides (FPP's) and 2) in house drug cargos (iMyc) and how they interact with a target cell.

Nomenclature

FPP (Functional Penetrating Peptide) – a peptide with the ability to cross the cell wall and access the intracellular environment. These FPPs ideally have no pharmacological activity of their own once inside the cell but rather can 'carry' a drug cargo with this property into the cell with them.

Myc - the 'super-controller' found on the inside of cells responsible for 'driving' most human cancers.

iMyc (Myc inhibitor) – PYC's proprietary drug cargoes that directly inhibit Myc when carried inside cells by PYC's proprietary FPPs.

Why is Myc such an important and potentially high value drug target?

Cancer Research UK (CRUK) has identified the inhibition of Myc as one of its 'Grand Challenges' because of its promise as a breakthrough in cancer treatment. CRUK describe the challenge of Myc inhibition in the following terms:

'Researchers already know how to theoretically cure a significant proportion of all human cancers. The problem is actually doing it.

At the heart of this challenge lies a molecule called MYC. In the same way that a conductor directs all the various parts of an orchestra to work together in harmony, MYC co-ordinates the actions of many different genes inside cells to keep things running smoothly.'

Myc is a gene that is mutated or overactive in the majority of human cancers – it's a hallmark of the disease in nearly seven out of ten cases.

It is well understood that overactive Myc helps tumours grow and multiply by producing a protein that acts as a powerful 'super controller' at the centre of a vast communication network within cells. Conversely it has also been shown in

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animal models that inhibiting Myc can have a dramatic detrimental impact on certain types of cancer.

A summary of a 2015 animal study conducted at Cambridge University, UK that back this thesis is outlined below:

Genetically engineered mice whose MYC gene could be specifically switched off throughout their whole bodies were created. When these animals developed lung cancer, turning off MYC completely killed the cancer cells. Importantly, the treatment only caused mild, reversible side effects, suggesting the impact of temporarily blocking MYC in the rest of the body – which is what would happen with a drug – might not be as severe as was first thought.

These remarkable results re-ignited interest in targeting MYC as a potential cancer cure. But the system that Cambridge team used relies on complex genetic engineering – something that's not technically or ethically possible in humans.

Ref: Cancer Research, UK

A key hurdle that needs to be overcome to act on these encouraging findings is to find an efficient and safe means to drug Myc. Thus far this has proved very elusive due to the distinct physical properties of the Myc molecule. This is where PYC are hoping their FPP molecules can play a role.

What is required to successfully drug Myc?

There are two basic requirements for an effective direct inhibitor of Myc:

i. access to the environment where Myc is present (the nucleus of the cell); and
ii. the ability to bind to Myc in a manner that effectively limits its ability to function.

One major reason that Myc has previously been considered 'undruggable' is 'that the protein expressed by the Myc gene does not lend itself to conventional drug discovery approaches – it has no deep 'pockets' like many other cancer drug targets and carries out its role through fleeting interactions with other proteins'. Small molecules that have the ability to cross the cell membrane can't adequately bind to Myc and the large molecular weight biologic drugs that could bind to Myc don't have the ability to cross the cell membrane. PYC addresses these barriers in a 'modular' format by using its FPP to overcome the delivery problem and leaving the iMyc to bind to and inhibit Myc.

Phylogica's competitive position

PYC's current FPPs are approximately 50 times more potent than the previous gold standard in intracellular delivery (a molecule derived from HIV known as TAT). PYC's iMyc is equivalent to or better than the current gold standard Myc inhibitor known as OmoMyc and this is before they have been through the 'lead optimisation' process which aims to increase their potency.

If successful in its lead optimisation efforts (3Q CY'17) PYC will, therefore, have the world's most potent iMyc (that is several orders of magnitude more effective than the current gold standard). Encouragingly, PYC has already seen marked reductions in tumour volumes (~50%) in animal models of disease after treatment with a systemically delivered unoptimised drug conjugate.

Commercial relevance

After completing lead optimisation and a proof of concept (POC) data pack by end CY'17 we expect PYC to be in a position to commence preclinical trials. This process is expected to take until around Q3/Q4 CY'18 to complete. In our view, we see PYC as being in a position to crystallise material value via an alliance deal with Pharma Co at or around the positive outcome of non-GLP/GLP toxicology results in primates.

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Other applications of the Phylomer libraries

There are at least three further applications of the Phylomer library that have the potential to add substantial value beyond the iMyc program. Broadly, these include:

1. pursuit of other high value intracellular targets such as Stat5 and YB1 through internally controlled programs;
2. licensing of the delivery peptides (FPPs) to third parties for delivery of their own drug cargoes in non-competitive fields (e.g. Genetic diseases outside of oncology such as the collaboration with Murdoch University aimed at treating Duchenne's Muscular Dystrophy or oncology programs directed towards non-competitive intracellular targets); and
3. utilisation of the Phylomer libraries against non-human cell lines such as the company's existing collaboration with Genentech (Roche group) directed towards the treatment of drug-resistant micro-organisms.

These additional paths to a commercial outcome are less mature than the iMyc program. We ascribe a nominal value of A$50m to this entire portfolio, not onerous in our view.

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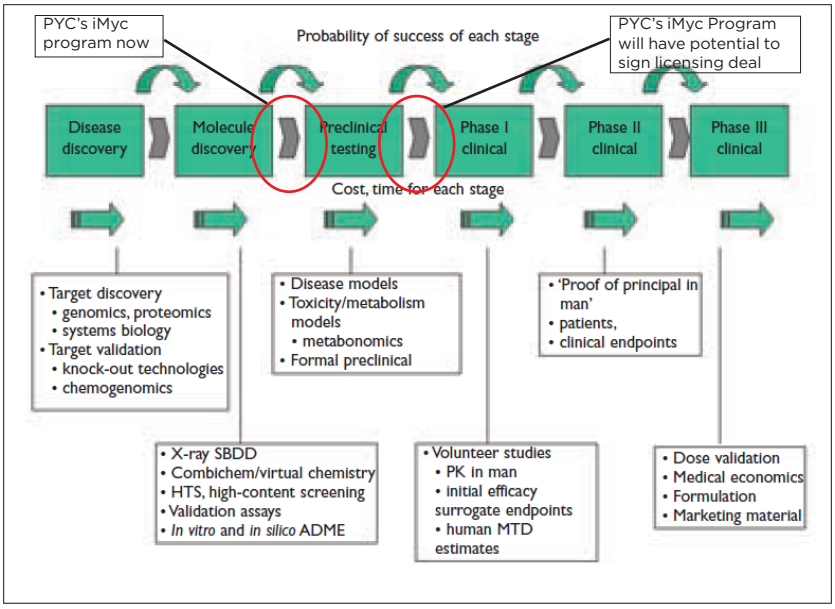
A brief summary of the Drug Approval Process

Drug discovery in junior companies is a high risk/high reward game.

We thought it would be useful to provide a broad outline of the drug approval process, where PYC's iMyc program currently sits and what the key catalysts are to generate Pharma Co interest.

Below is a depiction of the drug discovery process.



Source: Drug Discovery World

After 10 years and ~$100m sunk, PYC are now in a position to bring their iMyc cancer treatment program to preclinical trials. Getting to this stage represents a considerable de-risking of PYC in its own right. The key data point whereby we would expect a share price rerating is post the release of efficacy and toxicology data in Q1 CY'18. We would expect Pharma Co interest after the toxicology results in primates are known to be positive, expected Q2/Q3 CY'18.

In a broad study of the pharmaceutical industry it was estimated that once a company has reached the preclinical phase, the probability of failure is 34% (Ref 1). In other words, 2 out of 3 drugs will make it through to Phase 1 Clinical trials once they enter the preclinical phase.

We see PYC as being potentially lower risk of failure as peptide drugs (PYC's drug candidates) are known to be relatively safe and well tolerated by the human body (Ref 2). Perhaps the single biggest risk of failure it is in the Pharmacokinetic (PK) profile of the drug. This refers to how long the active ingredient in the drug stays in the target tissue. This is often an issue in peptide drugs (Ref 2). Encouragingly PYC have recently announced (4th April 2017) significant improvement in the PK profile of their iMyc drug candidates.

Ref 1 – Drug Discovery World, Failure Rates in drug discovery and development: Will we get any better? Fall 2004.

Ref 2 – Fosgerau and Hoffman, 2015. Drug Discovery today, peptide therapeutics – current status and future directions. Vol 20, No 1, Jan 2015.

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Financials

Cash/Cashflow

- We estimate PYC currently has ~ $5.5m in cash.
- We also expect PYC company to be granted an R&D rebate of $2.25m in the short term.
- In the next 12mths we expect cash burn to be $6-8m.
- PYC would also be due a further $2m in R&D grants in that time.

Issued capital

- Quoted Shares on Issue 2,004,138,734
- Unquoted Options (ex price $0.025, exp date 23rd Sept 2017) 33,593,750
- Unquoted Options (ex price Nil, exp date 30th Nov 2019) 10,000,000 issued to key personal
- Unquoted Options (ex price Nil, exp date 30th Jun 2018) 20,000,000 issued to key personal

Fully diluted issued capital = 2,067,732,484

Top Shareholders

	Shareholder	Shares (m)	%
1	Bernard Hockings	615.9	30.7
2	Sietsma Holdings	199.7	9.97
3	Anthony Barton	100.5	5.01

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Board and Management

Ms Stephanie Unwin, LLB, B Econ, GAICD
Non-Executive Chairman

Ms Stephanie Unwin's background is in corporate law and has previously worked with ASIC, Herbert Smith Freehills, Pullinger Readhead Stewart and Maxim Litigation Consultants before joining Verve Energy as its General Counsel and Company Secretary.

Ms Unwin is currently an Executive General Manager, Commercial at Synergy - a role she has held since March 2014. She has also held the role of General Manager Strategy and Business Development with Verve Energy prior to its merger with Synergy on 1 January 2014.

Previously Ms Unwin has been a non-executive director of Alcar Gold Corp and Integra Mining Limited and is currently the director of Vinalco Energy Pty Ltd, Greenough River Solar farm and Mumbida Wind Farm. She holds a Bachelor of Law and Economics Degree from Murdoch University.

Mr Jeremy Curnock Cook, MA
Non-Executive Director

Mr Jeremy Curnock Cook is an experienced entrepreneur, fund manager, executive and non-executive director in the life science sector. Mr Curnock Cook is currently Executive Chairman of International Bioscience Managers Limited. He was formerly the head of the life science private equity team at Rothschild Asset Management in the UK and an active investor in the Australian life science sector. At Rothschild, Mr Curnock Cook was responsible for the launch of the first dedicated biotechnology fund for the Australian market.

Over his 40-year career, Mr Curnock Cook has specialised in creating value in emerging biotech enterprises, through active participation with management. He has served on over 40 Boards in various roles, including Chairman, of private and public biotechnology companies listed on NASDAQ, LSE, TSX and ASX.

Mr Curnock Cook received his MA in Natural Sciences from Trinity College in Dublin, Ireland.

Dr Bernard Hockings, R.F.D., MD (WA), M.B.B.S (WA), F.R.A.C.P., F.C.S.A.N.Z
Non-Executive Director

Dr Hockings is an Interventional Cardiologist in Private Practice in Western Australia and is a Clinical Associate Professor in Medicine at the University of Western Australia. Previously he was Director of the Coronary Care Unit at Royal Perth Hospital, Chairman of the Medical Advisory Committee at the Mount Hospital and Director of Health Reserves (WA) for the Royal Australian Air Force.

Dr Hockings has a lifelong interest in medical research. His Doctoral Thesis involved Vasodilator Therapy in the treatment of Heart Failure. He has been closely involved with clinical teaching throughout his career. Dr Hocking is a major shareholder in Phylogica.

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CSO - Dr Paul Watt, BSc (Hons), DPhil

Paul is a founder and the CSO of Phylogica and is the principal inventor of Phylogica's drug discovery technologies. He has published more than 48 peer reviewed papers, and has filed more than 22 patent applications many of which are granted in the US and Europe. Specialising in drug discovery biotechnology and experimental genetics, he has attracted over A$5 million in research funding from Australia and the United States to develop the technology underpinning Phylogica.

Previously Paul founded InfaMed Ltd., now owned by Cambridge, UK-based Avita Medical Ltd. They are commercialising an FDA-approved / CE-marked paediatric drug delivery device that he invented, which is currently being marketed internationally. He was also an Honorary Research Fellow at the Telethon Institute for Child Health Research (now Telethon Kids Institute), Perth, Western Australia and was appointed Adjunct Professor at the School of Paediatrics and Child Health at the University of Western Australia.

Paul carried out postdoctoral research in yeast genetics at Harvard and Oxford Universities, where he discovered and characterised proteins involved in maintaining genome stability. He has a DPhil in Molecular Biology from Oxford University and BSc (Hons) from the University of Western Australia.

CFO - Mr Graeme Boden, BEc (Hons)

Graeme is an experienced business executive with more than 30 years in senior corporate or financial roles, particularly in the planning and evaluation function of the resources industry. And also in finance and administration function of a range of industries, including biotechnology, medical devices and pharmaceuticals. He has more than 26 years experience as a Director or Secretary of ASX listed companies.

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Risks

Timing Risk – In drug development clinical work often takes longer than initially anticipated. This is a risk in PYC's iMyc program.

Clinical Risk – There is risk that PYC's iMyc program will fail to meet the required efficacy and toxicology thresholds. This could lead to termination or delay of the planned preclinical program.

Commercial Risk – In drug development there is always a risk that new or more advanced therapies become available to treat underlying disease. PYC's iMyc program is exposed to this risk.

Regulatory Risk – Positive data in the preclinical trial phase still requires FDA approval to commence Phase 1 clinical trials. This regulatory approval is not a given.

Small Company/Biotech sector Risk – PYC is a junior biotechnology company trying to develop new drug candidates. The nature of this sector is that very few drug development companies reach a commercial outcome and news flow and share prices are often volatile.

Funding Risk – PYC is a small ASX listed company with no meaningful revenue stream. This implies that to continue normal operations the company requires either equity, alliance funding, government grants or debt. These sources of funds are sporadic and uncertain in terms of availability and cost.

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Peter Schwarzbach - Executive Director	+61 8 9488 1492
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