Pharmaxis

PXS.ASX

MST Access

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9 October 2023

Pharmaxis evolves into Syntara: sells mannitol unit; sharpening operational focus and cutting costs

NEED TO KNOW

- Mannitol respiratory business sale for royalty stream
- Formation of Syntara to accelerate clinical pipeline
- Restructure to reduces board size and lower costs

Mannitol business unit sale: Pharmaxis has announced the sale of its mannitol respiratory business unit (MBU) to Arna Pharma Pty Ltd (Arna Pharma), an Australian company with healthcare and pharmaceutical operations in Australia and major world markets. The MBU, now considered non-core, manufactures and supplies proprietary Bronchitol® and Aridol® to global markets. Under the terms of the sale agreement Pharmaxis will be reimbursed for the bulk of expenses incurred through to May 2024, and receive ongoing royalties for eight years based on an undisclosed percentage of the Arna Pharma's net operating profit. The Pharmaxis brand name will remain with the mannitol business unit.

Syntara to focus on blood related cancers: Following the sale, and subject to shareholder approval, Pharmaxis will be renamed Syntara to focus all resources and management time on advancing its portfolio of clinical assets based on proprietary amine oxidase inhibitors to target blood related cancers.

Impact on cash: The MBU sale should reduce annual core costs, excluding external research costs, by more than 60%, or by $14m (based on FY23 results) with more corporate and admin savings expected post separation.

Investment Thesis

A rare combination of skills and assets to facilitate bench-to-bedside research: PXS has brought a combination of assets and skills to its drug discovery platform. As a result, the company has a powerful capability to harness in-house scientific research to develop clinical trial programs and create novel treatments, a 'bench-to-bedside' process known as 'translational research'.

Amine oxidase platform generating multiple candidates, with many more possibilities: PXS's drug discovery platform focuses on amine oxidases, an important class of regulatory enzymes widespread in the body whose biological function depends on cofactors and location in human tissue and organs.

Deep clinical pipeline: The company's most advanced clinical asset, PXS-5505, targeting primary myelofibrosis (MF, a rare bone marrow cancer involving fibrosis), is currently in Phase 2 clinical trials. PXS-5505 is a novel small molecule and irreversible inhibitor to key enzymes involved in forming collagen, specifically the lysyl oxidase (LOX) family of proteins, whose overproduction is implicated in many conditions of chronic inflammation and pathological fibrosis.

Valuation

Our revised valuation for Pharmaxis stands at $251m or A$0.33/share fully diluted, using a risk adjusted NPV-based SOTP (sum-of-the-parts) approach. This comprises the three clinical programs (PXS-5505, PXS-6302, PXS-4728) and 8 year royalty stream from the divested mannitol respiratory business.

Risk

Our valuation is most sensitive to clinical and funding risk associated with the PXS-5505 and PXS-6302 programs at this point.

Equities Research Australia

Pharmaceuticals, Biotechnology and Life Sciences

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pharmaxis

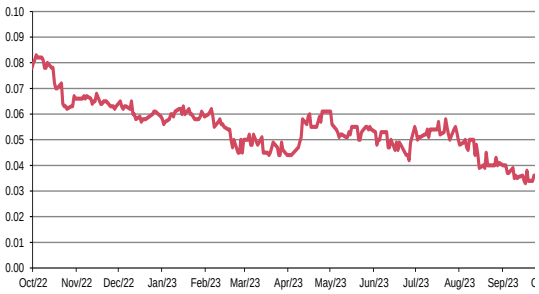
Pharmaxis is a clinical-stage drug discovery company developing novel small molecule drugs for inflammatory and fibrotic diseases with major unmet medical need. It is a leader in mechanism-based inhibitors of amine oxidases. It is targeting cancers (e.g., myelofibrosis, pancreatic and liver cancer), diseases of organs including the liver (NASH, liver fibrosis), lungs (pulmonary fibrosis) and kidneys (chronic kidney disease), and fibrotic scarring from burns and other trauma. Pharmaxis previously commercialised two respiratory products (Bronchitol®, Aridol®) now sold globally.

Valuation	**A$0.33** *(Prev $0.34)*
Current price	**A$0.04**
Market cap	**A$26m**
Cash on hand	**A$9.23m** *(30 June 2023)*

Upcoming Catalysts/Newsflow

Period	
2HCY23	PXS-5505: FDA guidance on additional arm of the MF study in combination with a JAK inhibitor protocol with first patient by 4Q CY23
2HCY23	PXS-4728: neurodegenerative disease Phase 2 trial to start recruiting patients in 3Q CY23
2HCY23	PXS-6302: scarring program to start recruitment by 4Q CY23
2HCY23	PXS-5505: final result of Phase 2 trial in MF as monotherapy with plans to present at ASH
2HCY24	PXS-5505: interim data from Phase 2 trial in MF (combination w/ standard of care)

Share Price (A$) scale on graph & font



Source: FactSet, MST Access.

Financial Summary

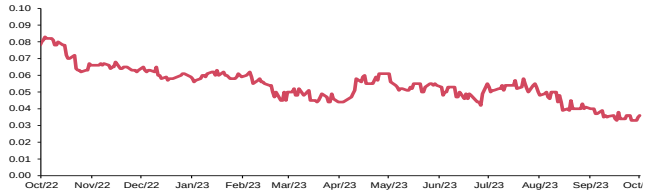
Pharmaxis — PXS-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.04**
52 week high / low	$	0.03-0.08
Valuation	**$**	**0.33**
Market capitalisation	$m	26.0
Shares on issue (basic)	**m**	722.1
Options / rights	m	38.2
Other equity	m	0.0
Shares on issue (diluted)	**m**	**760.3**

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY22A	FY23A	FY24E	FY25E	FY26E
Reported NPAT	$m	(1.9)	(11.4)	(17.1)	(11.0)	(11.0)
Underlying NPAT	**$m**	**(1.9)**	**(11.4)**	**(17.1)**	**(11.0)**	**(11.0)**
Reported EPS (diluted)	¢	(0.3)	(1.7)	(2.3)	(1.0)	(1.0)
Underlying EPS (diluted)	**¢**	**(0.3)**	**(1.7)**	**(2.3)**	**(1.0)**	**(1.0)**
Growth	%					
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**nm**
Operating cash flow per share	¢	(3.0)	(1.0)	(2.0)	(0.7)	(0.9)
Free cash flow per share	¢	(3.0)	(1.0)	(2.0)	(0.7)	(0.9)
Price to free cash flow per share	**x**	**nm**	**nm**	**nm**	**nm**	**nm**
FCF Yield	%	nm	nm	nm	nm	nm
Dividend	¢	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	**%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Franking	%	0.0%	100.0%	200.0%	300.0%	400.0%
Enterprise value	**$m**	**21.3**	**21.3**	**18.8**	**25.5**	**20.5**
EV/EBITDA	x	(1.7)	(2.3)	(2.5)	(2.4)	(1.9)
EV/EBIT	x	(1.4)	(1.9)	(2.3)	(2.3)	(1.9)
Price to book (NAV)	x	1.8	2.7	9.1	5.6	6.5
Price to NTA	x	2.0	2.9	10.7	6.0	7.0

KEY RATIOS		FY22A	FY23A	FY24E	FY25E	FY26E
EBITDA margin	%	nm	nm	nm	nm	nm
EBIT margin	%	nm	nm	nm	nm	nm
NPAT margin	%	nm	nm	nm	nm	nm
ROE	%	nm	nm	nm	nm	nm
ROA	%	nm	nm	nm	nm	nm
Net tangible assets per share	$	0.0	0.0	0.0	0.0	0.0
Book value per share	$	0.0	0.0	0.0	0.0	0.0
Net debt/(cash)	$m	(4.6)	(4.6)	(7.2)	(0.5)	(5.5)
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	nm	nm
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm

DUPONT ANALYSIS		FY22A	FY23A	FY24E	FY25E	FY26E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	0.3	0.2	0.4	0.0	0.0
Return on Assets	%	nm	nm	nm	nm	nm
Financial Leverage	x	397.1	448.8	530.2	261.5	301.3
Return on Equity	%	nm	nm	nm	nm	nm

KEY PERFORMANCE INDICATORS		FY22A	FY23A	FY24E	FY25E	FY26E
Bronchitol	$m	5.8	4.3	5.1	5.1	5.1
Aridol	$m	1.6	1.6	1.6	1.6	1.6

Clinical development pipeline	**Indication**	**Status**
PXS-5505	**Myelofibrosis**	**Phase 2a**
PXS-6302	**Anti-scarring**	**Phase 1c completed**
PXS-4728	**isolated REM Sleep Behaviour Disorder (iRBD)**	**Phase 2**

HALF YEARLY DATA		2H21	1H22	2H22	1H23	2H23
Total Revenue	$m	9.9	8.5	1.6	9.2	10.0
Operating expenses	$m	(11.3)	(15.6)	(12.5)	(12.6)	(16.0)
EBITDA	$m	(1.4)	(7.1)	(10.9)	(3.4)	(6.0)
EBIT	$m	(1.4)	(8.6)	(12.4)	(4.8)	(6.5)
PBT	$m	(3.0)	(8.8)	1.3	(4.9)	(6.6)
Reported NPAT	$m	(3.0)	(8.8)	1.3	(4.9)	(6.6)

PROFIT AND LOSS *		FY22A	FY23A	FY24E	FY25E	FY26E
Revenue	**$m**	**7.4**	**5.8**	**6.1**	**0.0**	**0.0**
Other income	$m	8.3	13.4	5.5	3.6	4.5
Total Revenue	**$m**	**15.8**	**19.2**	**11.6**	**3.6**	**4.5**
Operating expenses	$m	(28.1)	(28.6)	(19.3)	(16.4)	(8.5)
EBITDA	**$m**	**(12.3)**	**(9.4)**	**(7.7)**	**(12.8)**	**(4.0)**
Depreciation & Amortisation	$m	(3.2)	(1.8)	(0.5)	(0.4)	(0.4)
EBIT	**$m**	**(15.5)**	**(11.3)**	**(8.1)**	**(13.2)**	**(4.4)**
Net interest	$m	0.2	0.1	0.0	0.0	(0.0)
Pretax Profit	**$m**	**(1.9)**	**(11.4)**	**(17.1)**	**(11.0)**	**(11.0)**
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(1.9)**	**(11.4)**	**(17.1)**	**(11.0)**	**(11.0)**
Shares on issue	m	549.1	722.1	972.1	1,222.1	1,222.1

GROWTH PROFILE		FY22A	FY23A	FY24E	FY25E	FY26E
Revenue	%	(33.3)	21.8	(39.6)	(69.0)	24.2
EBITDA	%	(2,557.1)	(23.6)	(18.6)	67.0	(68.6)
EBIT	%	486.5	(27.6)	(27.9)	62.5	(66.9)
Reported NPAT	%	(34.8)	486.8	50.7	(35.5)	(0.1)
DPS	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY22A	FY23A	FY24E	FY25E	FY26E
Cash	$m	8.9	9.2	2.6	7.5	4.9
Receivables	$m	8.0	7.8	2.7	0.0	0.0
Other	$m	2.3	1.6	3.3	0.0	0.0
Current assets	**$m**	**19.2**	**18.7**	**8.6**	**7.5**	**4.9**
PPE	$m	3.2	1.8	1.6	1.4	1.3
Intangible assets	$m	1.0	0.7	0.6	0.5	0.5
Other	$m	1.7	2.8	2.8	2.8	2.8
Non current assets	**$m**	**6.0**	**5.3**	**5.0**	**4.8**	**4.6**
Total assets	**$m**	**25.2**	**24.0**	**13.6**	**12.3**	**9.5**
Trade and other payables	$m	2.7	4.7	3.4	0.0	0.0
Borrowing	$m	2.0	2.0	2.0	2.0	2.0
Other	$m	1.4	1.3	1.3	1.3	1.3
Current liabilities	**$m**	**6.1**	**8.0**	**6.7**	**3.3**	**3.3**
Borrowing and leases	$m	2.3	0.0	0.0	0.0	0.0
Other liability	$m	6.0	6.4	2.8	2.5	2.2
Non current liabilities	**$m**	**8.3**	**6.4**	**2.8**	**2.5**	**2.2**
Total liabilities	**$m**	**14.4**	**14.5**	**9.5**	**5.8**	**5.5**
Net assets	**$m**	**10.8**	**9.6**	**3.9**	**7.8**	**6.8**
Share capital	$m	380.4	389.7	401.1	416.1	426.1
Retained earnings	$m	(393.1)	(404.5)	(421.6)	(432.6)	(443.6)
Other	$m	23.5	24.3	24.3	24.3	24.3
Total equity	**$m**	**10.8**	**9.6**	**3.9**	**7.8**	**6.8**

CASH FLOW		FY22A	FY23A	FY24E	FY25E	FY26E
Net loss for period	**$m**	**(1.9)**	**(11.4)**	**(17.1)**	**(11.0)**	**(11.0)**
Depreciation & Amortisation	$m	3.2	1.8	0.5	0.4	0.4
Changes in working capital	$m	(5.9)	(0.1)	2.2	2.6	0.0
Other	$m	(11.7)	2.3	(0.0)	0.0	0.0
Operating cash flow	**$m**	**(16.3)**	**(7.3)**	**(14.5)**	**(8.1)**	**(10.7)**
Payments for PPE	$m	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Other	$m	(0.2)	0.0	0.0	0.0	0.0
Investing cash flow	**$m**	**(0.3)**	**(0.1)**	**(0.1)**	**(0.1)**	**(0.1)**
Equity	$m	9.1	9.3	10.0	15.0	10.0
Lease liability payments	$m	(2.4)	(2.2)	(2.2)	(0.3)	(0.3)
Other	$m	(0.1)	(0.0)	0.0	0.0	0.0
Financing cash flow	**$m**	**6.6**	**7.0**	**7.8**	**14.7**	**9.7**
Cash year end	**$m**	**8.9**	**9.2**	**2.6**	**7.5**	**4.9**
Free cash flow	**$m**	**(16.6)**	**(7.4)**	**(14.6)**	**(8.2)**	**(10.8)**

Source: Company reports, MST Access estimates

Sale of non-core mannitol respiratory business unit

Pharmaxis has announced the sale of its mannitol respiratory business unit (MBU) to Arna Pharma Pty Ltd (APL), an Australian company that is part of an alliance with healthcare and pharmaceutical operations in Australia and major world markets. The MBU contains two products developed by Pharmaxis using its proprietary spray drying technology from its Sydney facility - Bronchitol® and Aridol®.

Bronchitol® – cystic fibrosis treatment: Bronchitol® is a proprietary formulation of mannitol taken in a dry powder inhaler system. It was developed for the treatment of respiratory diseases – in particular, cystic fibrosis, bronchiectasis, and chronic bronchitis. Cystic fibrosis is a genetically inherited disease with an imbalance of fluid in airways causing dryness and infections to set in. Bronchitol® helps the lungs of people with cystic fibrosis clear mucus more effectively. This improves lung function, reduces the number of infectious episodes, and consequently reduces the need for patients to use antibiotics. Bronchitol® is approved and marketed in the United States, Europe, Russia, and Australia.

Aridol® – diagnostic test for asthma: Aridol® is also a proprietary formulation of mannitol, used in testing of lung function in people with diseases such as asthma. When inhaled by a patient with active airway inflammation, Aridol® decreases lung function, which facilitates clinical testing by respiratory scientists and physicians to inform treatment protocols for individual patients. Each Aridol® test kit contains dry powder mannitol capsules in graduated doses and a single patient use inhaler necessary to perform one bronchial challenge test. Aridol® is approved and marketed in the United States, Europe, Australia, and Asia.

Key terms of sale

- Under the terms of the agreement, the sale is scheduled to complete by the end of October 2023 when APL will take over day to day operations of MBU and commence an eight-month technology transfer period to its multi-product Sydney facility.
- During this transition period Pharmaxis will make employees and production facility available to support the manufacture of mannitol products under the direction of APL to supply market demand.
- Pharmaxis expects its residual net exit costs over the transition period to be less than $1m
- Post transition, APL will engage a contract manufacturer to product bulk mannitol poweder and capsules for subsequent packaging at its Sydney multi-product facility.
- After the transition period Pharmaxis will earn royalties on the net operating profits of APL products manufactured in its Sydney facility which will include Bronchitol® and Aridol®. We have assumed these are in the high single digits.

Impact on cashflow

The major impact of the transaction will be to lower core expenses by more than 60% (from $23m to $9m), given:

- Reduction in employee numbers from ~70 to ~25 in the new company (Syntara)
- Reduction in leasing costs given small footprint required for research labs and small corporate office
- Downsize of corporate and administration requirements
- Removal of all direct and indirect costs associated with the mannitol business

Syntara – Nimble and focused clinical stage drug development company

Following the sale, and subject to shareholder approval, Pharmaxis will be renamed Syntara to focus all resources, including its in-house drug discovery capability, and management time on advancing its existing portfolio of clinical assets. Management plans to have five clinical programs underway with readouts over the next two years (see figure 1).

Syntara's lead asset PXS 5505

Syntara's lead asset will be PXS-5505. PXS-5505 is being developed to treat myelofibrosis (MF), which affects 0.5–1.5 per 100,000 people worldwide. PXS-5505 has been awarded Orphan Drug Designation for this indication, with data to date suggesting it could modify the disease. Current drugs only address symptoms and yet generate over $1bn p.a. worldwide.

PXS-5505 has already reported positive Phase 2 data in MF patients with plans to present the final results of the monotherapy study at the American Society of Hematology (ASH) conference in December 2023. The next phase of clinical development for PXS-5505 will be the commencement of an additional arm of the MF study in combination with a JAK inhibitor which is the current standard of care.

Syntara will also investigate the use of PXS-5505 in myelodysplastic syndrome, another blood related malignancy following encouraging preclinical data rendered early in 2023.

Other clinical programs – PXS-6302 in scarring and PXS-4728 in neurodegenerative disease

Syntara will also continue development of its topical pan-LOX inhibitor, PXS-6302, in Phase 2 scar prevention and scare modification programs in conjunction with Professor Fiona Wood and the University of Western Australia.

Further, Syntara will continue development of PXS-4728, its novel anti-inflammatory drug candidate for the treatment of early-stage neurodegenerative diseases. In September 2022 the company secured £ 2.9m (Ã$5m) in funding from Parkinson's UK to conduct a phase 2 clinical trial of PXS-4728 in Parkinson's disease. The study is being carried out in collaboration with researchers at the Universities of Oxford and Sydney. The study will recruit patients with isolated Rapid Eye Movement Sleep Behaviour Disorder (iRBD),

a strong predictor of Parkinson's, to evaluate whether PXS-4728 can reduce neuroinflammation with results measured by nuclear imaging of the brain.

Figure 1: Clinical development pipeline

Drug Candidate	Indication	Phase	Trial design	Status	Upcoming Milestones	Addressable market (US$)
PXS-5505	Myelofibrosis (MF)	Phase 2	Open label 12 month study (n=15) MF patients receiving a stable dose of ruxolitinib (JAK inhibitor)	First patient 4Q CY23	2H CY24: Interim 6mth data	~$1b
PXS-5505	Myelodysplastic Syndrome (MDS)	Phase 1c/2	Protocol development underway	TBD	TBD	~$3b
PXS-6302	Scar prevention	Phase 1c	6 month placebo controlled trial Patients with scarring subsequent to burn injury (n=60)	First patient 4Q CY23	1H CY25	~$3.5b
PXS-6302	Modification of established scars	Preclinical	Plan to initiate Phase 1/2 trial Patients with keloid or hypertrophic scars Protocol under development	TBD	TBD	~$3.5b
PXS-4728	iRDB* and neuro inflammation	Phase 2	Double blind, placebo controlled Patients with Isolated REM sleep behaviours disorder iRBD (n=40)	First patient 4Q CY23	1H CY25	~$3.5b

*Source: Pharmaxis * isolated Rapid Eye Movement Sleep Behaviour Disorder*

Valuation

We have revised our valuation to reflect both the divestment of the mannitol business unit in lieu of a share of Arna Pharma's net profit, and the addition of the Phase 2 clinical trial of PXS-4728 to the active clinical development pipeline. As such, we value Pharmaxis at A$251m based on the sum-of-the-parts (SOTP). This uses a risk-adjusted net present value (rNPV) method to value the two lead clinical assets of PXS-5505 (in Myelofibrosis) and PXS-6302 (in keloid scarring) through to 2039, and now PXS-4728 (in Parkinson's disease) through to 2032, consistent with expiry of current patent families and each asset being out-licensed prior to phase 3 by a development partner who will carry the remaining costs of development through to commercialisation. Our out-licensing assumptions incorporate upfront payments of A$39m and royalty streams of 11% for each asset, based on the previous out-licencing of PXS-4728A. We use an NPV calculation, using a discount rate of 10% to value the share of Arna Pharma's net profit over the eight-year period ending in 2031. Our valuation incorporates current shares on issue of 722.1m, and 38m options outstanding exercisable at various prices. Our fair value of the shares on a fully diluted basis is A$0.33 per share.

Figure 2: Sum of the parts valuation

Product	Status	Indications	Dose (delivery)	Launch	Peak sales (US$m)	NPV (US$m)	Likelihood of approval	rNPV (A$m)
PXS-5505	Phase 2a	Myelofibrosis	Oral	**2026**	1,212	243	20%	114
PXS-5505	Preclinical	Other indications including some cancers	Oral	TBD				
PXS-6302	Phase 1c	Keloid scarring*	Topical	**2025**	620	191	15%	99
PXS-5382	Phase 2 ready	Chronic kidney disease	Oral	TBD				
PXS-5382	Phase 2 ready	Idiopathic pulmonary fibrosis	Oral	TBD				
PXS-5382	Phase 2 ready	Non-alcoholic steatohepatitis (NASH)	Oral	TBD				
PXS-4728	Phase 2	Neuro inflammatory/Neurodegenrative	Oral	**2026**	504	61	12%	25
PXS-5370	Phase 1 ready	Anti-inflammatory for multiple indications	Oral	TBD				
PXS-4699	Preclinical	Duchene Muscular Dystrophy	Oral	TBD				
Bronchitol® and Aridol®	Arna Pharma royalty stream	Cystic fibrosis/Asthma diagnostic	Insufflation	On market			100%	3
							Net cash (30 June 2023)	9
							Total	251
							Shares outstanding (m)	722
							Options	38
							rNPV/share (A$) *fully diluted*	0.33

* NB. Phase 1c trial will evaluate PXS-6302 as both a prophylactic and treatment in scarring, target indication assumed as treatment for keloid scarring

Source: MST Access

Board changes: Reducing board size in new Syntara

With the retirement of Malcom McComas (independent chairman) and Dr Neil Graham (non-executive director) the board will reduce in size to four members. We continue to regard the technical expertise, international pharmaceutical company experience and investment market expertise as highly relevant to advancing both the clinical pipeline and its commercialisation in the new Syntara entity. As such, the Syntara board will comprise the following personnel:

Kathleen M Metters – Independent Chairman: Dr Metters joined the Pharmaxis Board of Directors in 2017 bringing over 25 years of experience in the discovery and development of novel therapies. She was formerly the Senior Vice President and Head of Worldwide Basic Research for Merck & Co. with oversight of all the company's global research projects. In a subsequent role at Merck & Co., she led work on External Discovery and Preclinical Sciences. She is also an independent biopharma consultant and a senior advisor to New York–based Bridge Medicines. Between 1993 and 1997 she was Associate Professor of Epidemiology at John Hopkins University School of Hygiene and Public Health, focusing on HIV, tuberculosis, and hepatitis. Dr Metters is a member of the company's Scientific Advisory Board.

Gary J Philips – Chief Executive Officer: Mr Philips was appointed CEO in 2013, having previously been the Chief Operating Officer of Pharmaxis. He has more than 30 years of operational management experience in the pharmaceutical and healthcare industry. Prior to Pharmaxis, Mr Phillips was CEO at Ciba Geigy in Hungary (which merged to form Novartis in 1996) where he was successful in launching new products and respective portfolios.

Simon Green - – Non-Executive Director: Dr Green joined the Pharmaxis Board of Directors in December 2022 bringing 30 years of experience in the biotechnology industry. His roles include Senior Vice President, Global Plasma R&D and General Manager of CSL's manufacturing plants in Germany and Australia over a 17-year period abd during a period of global expansion of the company. Prior to joining CSL Dr Green was based in the USA where he worked with biotechnology companies Genentech Inc and Chiron Corporation.

Hashan De Silva, CFA – Non-Executive Director: Mr De Silva joined the Pharmaxis Board of Directors in January 2023 as a life science investment professional with extensive knowledge of the biotech, pharmaceutical and medical technology sectors. Life science investment roles include associate healthcare analyst at Macquarie Group and lead healthcare analyst at CLSA Australia before joining Karst Peak Capital in February 2021 as head of healthcare research. Prior to moving into life science investment Mr De Silva worked at Eli Lilly in various roles focused on the commercialisation of new and existing pharmaceuticals.

Sensitivities and Risks

Pharmaxis (Syntara) is subject to all the risks typically associated with drug development, including the possibility of unfavourable outcomes in clinical trials, regulatory decisions, success of competitors, financing, and commercial decisions by partners or potential partners. In addition, key stock-specific sensitivities include:

Clinical risk

The company's medicinal chemistry expertise and proprietary assays underpin substantial drug discovery capabilities and provide significant opportunities to design, test, and optimise potential drug candidates in preclinical settings. This has been demonstrated by the development of a broad portfolio of small molecule amine oxidase inhibitors over the last five years.

However, drug development carries a raft of associated clinical risks including clinical trial delays or failures which could have a significant impact on the progress of individual assets and related candidates in the pipeline. The most important near-term development sensitivity is related to PXS-5505, given its Orphan Drug Designation status, and to a lesser extent PXS-6302. Both assets are pan-LOX inhibitors and are entering Phase 2a and Phase 1c trials respectively designed to demonstrate efficacy in patients. Clinical asset specific clinical risk considerations also include:

- **Clinical target risk**: Although PXS-5505 was shown to be well tolerated at the highest dose given and has delivered complete inhibition of the target enzymes Phase 2a will answer the question of whether the disease modifying effect seen in animal models can be replicated in patients.

- **Clinical development path risk:** Targeting of keloid scarring using PXS-6302 could be face additional challenges from a clinical development perspective given the heterogeneity of these scars, variability in patient and skin types, and the less objective measures available to monitor progress.

As such, success at this stage will determine the next leg of development activities and have a major bearing on partnering and commercialisation prospects for both clinical assets.

Key person risk is also a consideration for the company, given its reliance on its drug discovery engine and the highly experienced team currently in place.

Regulatory risk

Market approval will depend on satisfying the requirements of multiple regulators. As in the case of Bronchitol®, this can result in additional data requirements and lead to time delays and increased funding needs. However, the company's experience in bringing Bronchitol® to market despite such delays bodes well for future submissions.

Commercialisation risk

The launch of Bronchitol® and Aridol® demonstrated the company's ability to develop a drug candidate through to commercialisation. Nonetheless, and notwithstanding competition, adoption of the company's amine oxidase inhibitors, if successful in reaching the

market, could be lower than expected. This could occur if clinical findings are not compelling compared to the standards of care or if the cost of using the drug if in combination outweighs the added clinical benefit. A related issue in commercialisation risk is the company's reliance on appropriate partners and/or government grants for ongoing development of its clinical assets.

Funding risk

Pharmaxis' currently solid cash position should be adequate to meet near-term goals given the prioritisation of clinical programs and strategic partnerships established to date. However, cost of trials and operational expenses may overrun estimates and require additional capital to be raised. This is offset to a degree by the reduction in operating costs associated with restructuring of the business following the sale of the mannitol business unit.

Methodology & Disclosures

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