



## MAJOR COMPANY RESTRUCTURE:

- Sale of mannitol business unit
- Creation of clinical development company SYNTARA
- Restructured Board and >60% core cost reductions saving more than \$14m per annum

# PHARMAXIS ANNOUNCES MAJOR COMPANY RESTRUCTURE



**Sale of mannitol respiratory business to Arna Pharma**

Residual net exit costs of less than A\$1m



**Pharmaxis to be renamed Syntara<sup>1</sup>**

Renewed focused on drug development primarily to treat cancer



**Board under new leadership**

Dr Kathleen Metters appointed Chair



**Phase 2 myelofibrosis clinical trial to commence in Q4 2023**

At least 3 key clinical readouts from MF and other trials by mid-2025



**Significant reduction in cost base:**

Core expenses to be reduced by over 60% saving the company over \$14m p.a.



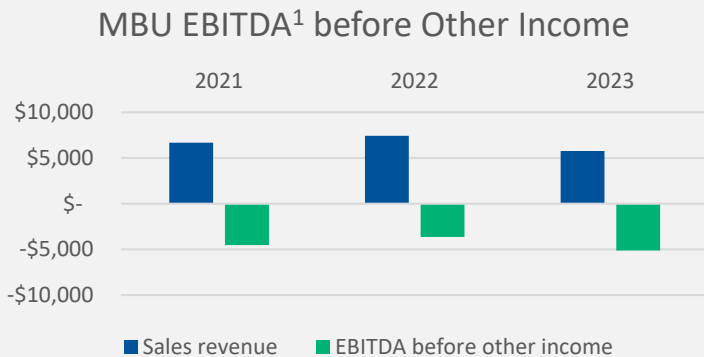
**Syntara to receive product royalties from Arna Pharma**

# Sale of Mannitol respiratory business unit (MBU) ; Bronchitol® and Aridol®

Sale of mannitol business unit positions it for long term profitability

## Pharmaxis ownership

- High fixed cost of MBU (~\$10m pa) plus rent of the manufacturing facility required a large sales base
- One-off initiatives over recent years (sale of Orbital device, distribution rights) provided opportunity for sales to grow – particularly Russia and US
- Russia is well positioned, but US sales have not eventuated at the expected or needed levels despite best efforts of US distributor



1. Before rent



## Arna Pharma (APL)

- APL will own and operate the MBU business from completion in October.
- APL will complete a technology transfer to new Sydney based facility and a contract manufacturer to maintain supplies after Pharmaxis facility is closed in May 2024.
- Resulting lower cost of goods supports long term profitability and maintains supplies for Pharmaxis distributors and patients world wide.
- Pharmaxis employees will support the tech transfer and have job opportunities at the APL Sydney facility.

# Mannitol Business Unit – key terms of sale

- **As from completion in October 2023 Pharmaxis is exiting the mannitol business**
  - APL will own and operate the MBU business.
  - The Pharmaxis brand name will continue to be associated with the mannitol business unit
- **During the Transition period up to the end of Pharmaxis facility lease in May 2024**
  - Pharmaxis will make PXS employees and its production facility available to support the manufacture mannitol products under the direction of APL.
  - APL will manufacture an inventory of product to supply the market while a technology transfer is completed.
  - APL will relocate any plant and equipment it wishes to utilise in its own facility.
- **In the post transition phase after May 2024 Pharmaxis distributors and patients will continue to be supplied with Bronchitol and Aridol**
  - APL will produce bulk mannitol powder and capsules at contract manufacturer and then package it in their Sydney multi product facility.
- **Deal financials; Pharmaxis incurs minimal net exit costs and will earn royalties on future sales**
  - Pharmaxis continues to be responsible until May 2024 for rent, employees, certain operational costs and closure of the Pharmaxis facility.
  - The sale agreement includes a number of payments from APL to Pharmaxis in relation to costs incurred over the transition period.
  - PXS expects its residual net exit costs over the transition period to be less than \$1m.
  - After the transition period Pharmaxis will earn royalties on the operating profits of mannitol products Aridol and Bronchitol and Arna Pharma products manufactured in APL's new Sydney facility for 8 years

# Mannitol Business Unit sale; Impact on cashflow

Sale of the mannitol business unit allows the new company to focus resources and management time on its clinical development pipeline and removes the need to support a non core business.

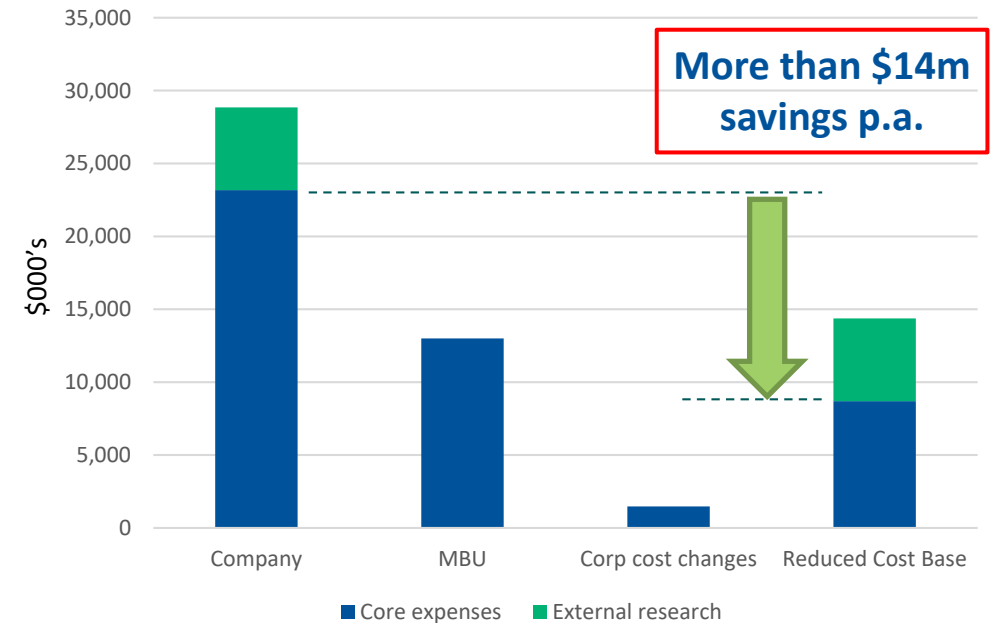
The main factors impacting cash from separation of the two businesses are:

- Employee numbers dropping from ~70 to ~25 in the new company with Arna Pharma creating job opportunities for MBU employees
- Move from being the lease holder on current 7,000 m<sup>2</sup> Frenchs Forest facility to a much reduced new lease for research labs and a small corporate office
- Downsized Corporate and Admin requirements
- Removal of all direct and indirect costs associated with the manufacture of the two pharmaceutical products and their regulatory and safety support in global markets

Core expenses (excluding external clinical trial and drug discovery costs) cut by more than 60%<sup>1</sup>

- Cash expenses excluding clinical trials drops from ~\$23m to \$9m
- More corporate & admin savings to be realized after the separation is complete

Proforma Cash Expenses 2023



Core expenses include employee costs, rent, utilities, manufacturing, regulatory and admin expenses

# Pharmaxis after the sale of the Mannitol Business Unit



- A clinical stage drug development company
- Focused on first and best in class disease modifying drugs to improve quality of life and extend life expectancy
- Prioritising haematological malignancies with high unmet need and market opportunities in excess of US\$1b per annum
- Retains an integrated drug discovery capability and pipeline of pre clinical and clinical stage assets in fibrosis and inflammation.

# Syntara Board under new leadership and downsized

Significant international pharmaceutical experience



## Dr Kathleen Metters – Chair

- Former 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
- Former CEO of biopharmaceutical company Lycera Corp



## Dr Simon Green – Non-Executive Director

- Experienced senior global pharma executive with 30 years' of experience in the biotechnology industry.
- Actively involved in CSL's global expansion over a 17-year period where he held roles as Senior Vice President, Global Plasma R&D and General Manager of CSL's manufacturing plants in Germany and Australia.
- Prior to joining CSL he worked in the USA at leading biotechnology companies Genentech Inc and Chiron Corporation.



## Gary Phillips – Chief Executive Officer

- 30+ years' of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia
- Joined Pharmaxis in 2003 and was appointed Chief Executive Officer in March 2013 at which time he was Chief Operating Officer
- Previously held country and regional management roles at Novartis – Hungary, Asia Pacific and Australia



## Hashan De Silva – Non-Executive Director

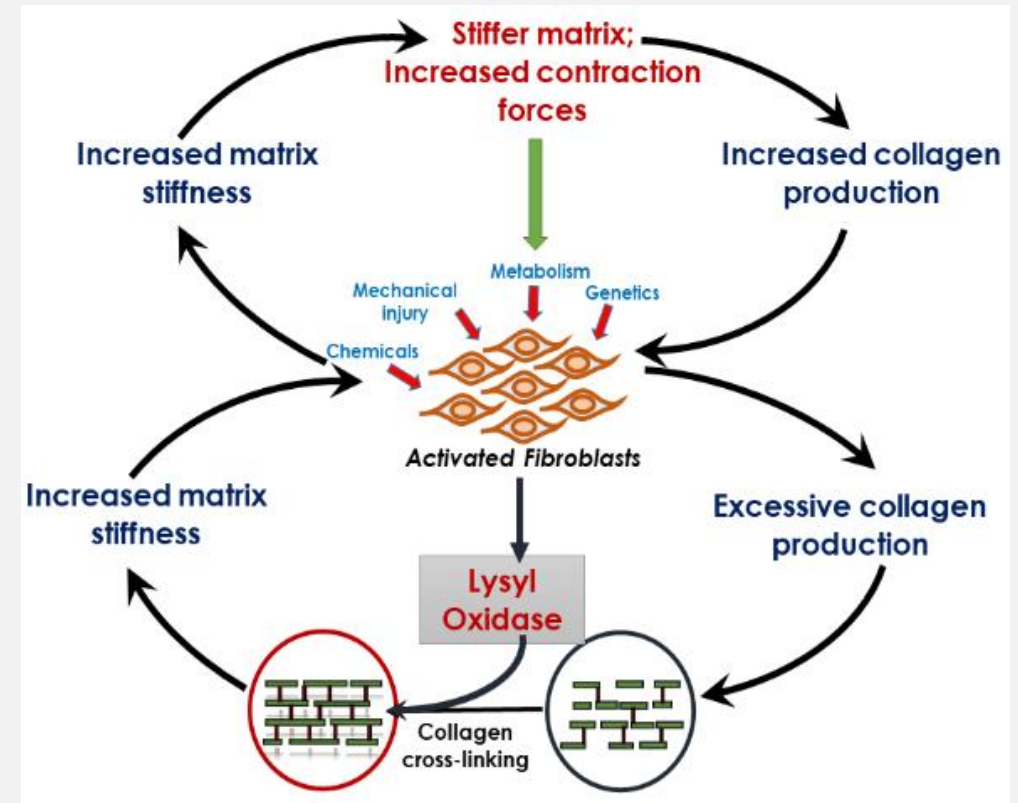
- Experienced life sciences investment professional with extensive knowledge of the biotech, pharmaceutical and medical technology sectors.
- Worked as associate healthcare analyst at Macquarie Group and lead healthcare analyst at CLSA Australia before joining Karst Peak Capital in February 2021 as head of healthcare research.
- Prior to moving into life science investment Hashan worked at Eli Lilly in various roles focused on the commercialisation of new and existing pharmaceuticals.

- Current Chair Malcolm McComas and non-executive director Neil Graham stepping down on announcement of this transaction.
- Anticipated staffing numbers of 20-25 FTE with no immediate changes to the existing management team.

# Scientific and clinical excellence – the foundations of Syntara

- Global leader in amine oxidase chemistry and biology; 3 Nature publications in 2022/23 on role of lysyl oxidases
- The anti-fibrotic effect of inhibiting lysyl oxidase (LOX) enzymes is proven in two phase 1c/2 studies reported in 2023:
  - Myelofibrosis: 5 out of 9 evaluable patients found to have an improvement in fibrosis grade of at least 1 after 6 months of treatment with PXS-5505
  - Established scars: patient scars found to have 30% reduction in collagen compared to placebo after 3 months treatment on PXS-6302
- FDA clear protocol for clinical trial studying PXS-5505 in combination with JAK inhibitor ruxolitinib for myelofibrosis patients.

## Lysyl oxidases are the final stage in fibrosis



Tissue stiffening due to increases in collagen and number of cross-links which is a hallmark of fibrosis, is preventable through lysyl oxidase inhibition; at the heart of a true anti-fibrotic therapy



# Five trials to deliver near term value

Pipeline creates multiple opportunities in high value markets

Drug Candidate	Indication	Phase	Trial design	Status	Upcoming Milestones	Addressable market (US\$)
PXS-5505	Myelofibrosis (MF)	Phase 2	<ul style="list-style-type: none"> <li>Open label 12 month study (n=15)</li> <li>MF patients receiving a stable dose of ruxolitinib (JAK inhibitor)</li> </ul>	First patient Q4 2023	2H 2024: Interim 6 month data	~\$1 billion
	Myelodysplastic Syndrome (MDS)	Phase 1c/2	<ul style="list-style-type: none"> <li>Protocol development underway</li> </ul>	TBD	TBD	~\$3 billion
Oral and Topical Pan-LOX inhibitors	Scar prevention	Phase 1c	<ul style="list-style-type: none"> <li>6 month placebo controlled trial</li> <li>Patients with scarring subsequent to burn injury (n=60)</li> </ul>	First patient Q4 2023	H1 2025	~\$3.5 billion
	Modification of established scars	Preclinical	<ul style="list-style-type: none"> <li>Plan to initiate Phase 1/2 trial</li> <li>Patients with keloid or hypertrophic scars</li> <li>Protocol under development</li> </ul>	TBD	TBD	~\$3.5 billion
PXS-4728	IRDB and neuro inflammation	Phase 2	<ul style="list-style-type: none"> <li>Double blind, placebo controlled</li> <li>Patients with Isolated REM sleep behaviours disorder IRBD (n=40)</li> </ul>	First patient Q3 2023	H1 2025	~\$3.5 billion

# News flow

Recent and anticipated news flow

***Strong and growing pipeline with advancement in studies expected to provide value inflection points***

## Q1-Q3 2023

- Pharmaxis strengthens Board with two new appointments
- PXS-5505 publication by KOL in hematological cancer myelodysplastic syndrome
- PXS-5505: Encouraging FDA feedback on plans to progress to JAK inhibitor combination study
- LOX topical drug PXS-6302 top line data from established scars study
- PXS-5505 myelofibrosis monotherapy study: significant data update

## Q4 2023

- Sale of Mannitol Business Unit with more than A\$14m of savings per year
- Creation of Syntara – clinical stage drug development company
- PXS-5505 phase 2a myelofibrosis combination study (add on to JAK inhibitor) commences recruitment
- Pan-LOX scar treatment and prevention - clinical development update and trial initiation
- PXS-4728 iRBD / neuro inflammation study commences recruitment
- PXS-5505 phase 2a myelofibrosis study (monotherapy) completed and reports safety and efficacy data at ASH

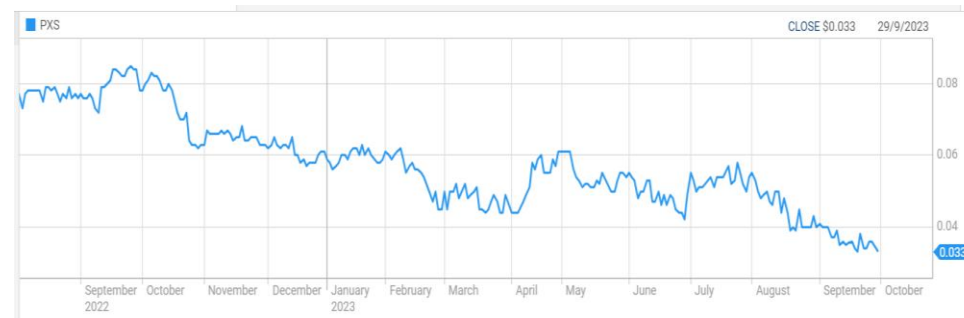
# Shareholders & cash



Financial Information	29 Sept 23
ASX Code	PXS
Share price	\$0.033
Liquidity (turnover last 12 months)	124m shares
Market Cap	A\$26m
Pro forma <sup>1</sup> Cash balance (30 June 2023)	A\$14m
Enterprise value	A\$12m
Clinical development program supported by:	
<ul style="list-style-type: none"> <li>• R&amp;D tax credits</li> <li>• Strategy of partnering deals with pipeline assets</li> </ul>	
1. Proforma cash includes cash of \$9.2m and 2023 R&D tax credit of \$5.2 million (expected receipt H2 CY23)	

Institutional Ownership	29 Sept 23
BVF Partners LP	14%
Karst Peak Capital Limited	12%
D&A Income Limited	11%
Platinum Investment Management Limited	8%
<b>Total Institutional Ownership</b>	<b>45%</b>

## Share Price





Pharmaxis Ltd ABN 75 082 811 630

[www.pharmaxis.com.au](http://www.pharmaxis.com.au)



### Contacts

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# Appendix

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# Experienced senior management team

Significant global experience in drug development, commercialisation and partnering



## Gary Phillips – CEO and Managing Director

- 30+ years' of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia
- joined Pharmaxis in 2003 and was appointed Chief Executive Officer in March 2013 at which time he was Chief Operating Officer
- Previously held country and regional management roles at Novartis – Hungary, Asia Pacific and Australia



## Jana Baskar – Chief Medical Officer

- 20+ years' experience both in clinical medicine and the biopharmaceutical industry
- Broad therapeutic knowledge and significant clinical research expertise having worked in several different specialties
- Former Medical Director at Novartis Oncology in Australia; former Medical Director for IQVIA in Australia and New Zealand



## Wolfgang Jarolimek – Drug Discovery

- 20+ years' experience in pharmaceutical drug discovery and published more than 30 peer reviewed articles
- Previously Director of Assay Development and Compound Profiling at the GlaxoSmithKline Centre of Excellence in Drug Discovery in Verona, Italy
- Spent 8 years as post-doc at the Max-Planck Institute in Munich, Germany; Baylor College of Medicine, Houston, Texas; Rammelkamp Centre, Cleveland Ohio; and University of Heidelberg, Germany



## David McGarvey – CFO

- more than 30 years' experience building Australian based companies from inception to globally successful enterprises
- joined Pharmaxis as Chief Financial Officer and Company Secretary in December 2002
- previously Chief Financial Officer of the Filtration and Separations Division of US Filter (1998-2002), and Memtec Limited (1985-1998)
- commenced career at PricewaterhouseCoopers



## Kristen Morgan – Alliance Management

- more than 20 years' experience in the pharmaceutical industry having previously held a senior role in medical affairs at Sanofi-Aventis, and a commercial sales role at GlaxoSmithKline
- responsibility for alliance management and medical and regulatory affairs



## Dieter Hamprecht – Head of Chemistry

- 20+ years' experience with small molecule and peptide drug discovery, contributed to greater than 10 drug candidates brought to development and co-inventor of 50 patent families, co-author of 30+ scientific publications
- Previously Managing Director – Boehringer Ingelheim's research group in Milan
- Senior medicinal chemistry positions at GSK

# Financials

## Income statement highlights

Periods ended (A\$'000)	Three months		Twelve months	
	Jun-23	Jun-22	Jun-23	Jun-22
<b>Segment Financials</b>				
<b>New drug development</b>				
Oral pan-LOX (external costs - MF & MDS)	(1,250)	(1,787)	(4,921)	(5,431)
Topical pan-LOX (external costs)	(985)	(280)	(1,852)	(993)
Other program external costs (net of grants)	(271)	(155)	(1,430)	(718)
Employee costs	(1,014)	(692)	(3,623)	(2,943)
Overhead	(131)	(86)	(501)	(374)
R&D tax credit and other income	5,214	4,900	5,268	5,600
EBITDA	1,563	1,900	(7,059)	(4,859)
<b>Mannitol respiratory business</b>				
Sales	1,069	630	5,765	7,427
Other revenue and income	-	(2)	7,192	2,342
	1,069	628	12,957	9,769
Expenses – employee costs	(1,347)	(1,224)	(4,855)	(4,760)
Expenses – manufacturing purchases	(794)	120	(2,706)	(2,729)
Expenses – other	(698)	(829)	(3,328)	(3,584)
EBITDA	(1,770)	(1,305)	2,068	(1,304)
<b>Corporate – EBITDA</b>	(1,064)	(194)	(1,993)	(4,080)
<b>Total Adjusted EBITDA</b>	(1,270)	401	(6,984)	(10,243)
<b>Net profit (loss)</b>	(1,334)	12,194	(11,270)	(1,934)

# Financials

## Cash

Periods ended (A\$'000)	Three months		Twelve months	
	Jun-23	Jun-22	Jun-23	Jun-22
<b>Cash</b>				
Cash at period end	9,230	8,937	9,230	8,937
<b>Cash Flow Statement Highlights</b>				
Operations				
Receipts from customers	1,437	2,801	3,919	9,006
R&D tax incentive	-	-	-	-
Grants received	-	64	1,448	316
Sale of Orbital/distribution rights	-	569	7,192	2,909
R&D tax credit (FY 2022)	4,953	-	4,953	-
Other	31	13	71	857
Payments to suppliers, employees etc (net)	(7,566)	(8,628)	(19,268)	(29,384)
Total operations	(1,145)	(5,181)	(1,685)	(16,296)
Investing (capex & patents)	(23)	(36)	(132)	(138)
Finance lease payments <sup>1</sup>	(563)	(635)	(1,662)	(2,379)
Financing agreement payments <sup>2</sup>	-	(21)	(8)	(33)
Share issue - net	-	-	9,261	9,071
Net increase (decrease) in cash	(1,731)	(5,873)	5,774	(9,775)

1. Lease over 20 Rodborough Rd (to May 2024) – total liability at 30 June 2023: \$2.0 million
2. Financing agreement – not repayable other than as % of US Bronchitol revenue through to March 2028





# pharmaxis

developing breakthrough treatments for fibrosis and inflammation

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