

phormoxis

Investor Presentation | February 2023

Gary Phillips CEO

developing breakthrough treatments for fibrosis and inflammation

## Forward looking statement

This document contains forward-looking statements, including statements concerning Pharmaxis' future financial position, plans, and the potential of its products and product candidates, which are based on information and assumptions available to Pharmaxis as of the date of this document. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these forward-looking statements. All statements, other than statements of historical facts, are forward-looking statements.

These forward-looking statements are not guarantees or predictions of future results, levels of performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this document. For example, despite our efforts there is no certainty that we will be successful in developing or partnering any of the products in our pipeline on commercially acceptable terms, in a timely fashion or at all. Except as required by law we undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise.

## Pharmaxis Overview



## **Executive Summary**

- Pharmaxis is a clinical stage drug development company targeting inflammation, fibrosis and selected cancer indications with first in class or best in class small molecule drugs in markets of high value
- Global leader in fibrosis driven by lysyl oxidase enzymes having invested in a multi year research program leveraged with extensive external scientific collaborations
- 5 studies currently recruited or recruiting in 2023 that will provide near term value opportunities
- Two studies that will deliver data on clinical proof of concept in 2023
- Pro forma cash position at 31 December 2022 of A\$21m<sup>1</sup>, funding the company's clinical programs into early 2024

### Pipeline creates multiple opportunities in high value markets

- 1. Lead asset PXS-5505 is in a multinational open label phase 2 trial a breakthrough clinical program with disease modifying potential in Myelofibrosis. Promising interim data; significant data update due mid 2023
- 2. US investigator led phase 1/2 trial in liver cancer with PXS-5505 as first line treatment added to existing chemotherapy opened to recruitment Q4 2022
- 3. Topical drug PXS-6302 trial in patients with potential to improve function and appearance of established scars. Promising interim data; topline results due Q2 2023.
- Additional PXS-6302 trial in scar prevention to commence recruitment in 1H 2023
- 5. Neuro inflammation drug PXS-4728 in phase 2 trial of patients with severe sleep disorder that can lead to neurodegenerative diseases e.g. Parkinson's to commence in 1H 2023



## Shareholders & cash



Financial Information	30 Jan 23
ASX Code	PXS
Share price	\$0.058
Liquidity (turnover last 12 months)	77m shares
Market Cap	A\$42m
Pro forma <sup>1</sup> cash balance (31 December 2022)	A\$21m
Enterprise value	A\$21m

Clinical development program supported by	t program supported by:	Clinical development
---	-------------------------	----------------------

- R&D tax credits
- Strategy of partnering deals with pipeline assets
- Proforma cash includes cash of \$16m and 2022 R&D tax credit of \$5m (received January 2023)

Institutional Ownership	31 Dec 22
BVF Partners LP	14%
Karst Peak Capital Limited	12%
D&A Income Limited	10%
Platinum Investment Management Limited	7%
Regal Funds Management Pty Ltd	7%
Total Institutional Ownership	51%



## Pharmaxis is the global leader in lysyl oxidase chemistry and biology

Multi year research program leveraged with extensive scientific collaborations worldwide has delivered 2 drugs in the clinic

### Lysyl oxidases are the final stage in fibrosis Stiffer matrix; Increased contraction forces Increased matrix Increased collagen stiffness production Activated Fibroblasts Increased matrix **Excessive** collagen stiffness production Lysyl Oxidase Collagen cross-linking

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

### PXS-5505

- Oral dosage form four capsules twice a day
- Patent filed priority date 2018
- Strong pre clinical evidence in models of fibrosis and cancer
- INDs approved for myelofibrosis and hepatocellular carcinoma
- Potential in multiple cancer indications
- Phase 1 data demonstrates a safe, well tolerated drug that gives >90% inhibition of LOX enzymes

### PXS-6302

- Topical dosage form
- Patent filed priority date 2019
- Strong pre clinical evidence in models of skin fibrosis and scarring
- Potential in prevention of scar formation and modification of existing scars
- Phase 1a (healthy volunteer) data demonstrates a safe, well tolerated drug that gives full inhibition of LOX enzymes in the skin with minimal systemic exposure



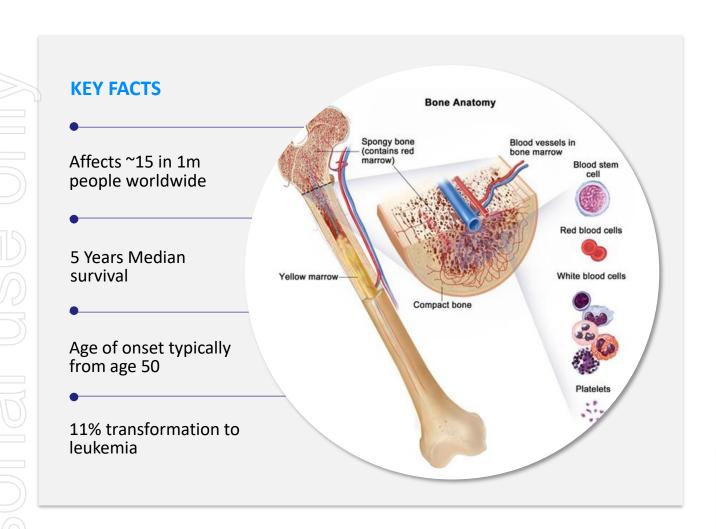
## Program Update





## Myelofibrosis

A rare type of bone marrow cancer that disrupts the body's normal production of blood cells



**Primary Myelofibrosis** is caused by a build up of scar tissue (fibrosis) in bone marrow reducing the production of blood cells:

- Reduced red blood cells can cause extreme tiredness (fatigue) or shortness of breath
- Reduced white blood cells can lead to an increased number of infections
- Reduced platelets can promote bleeding and/or bruising
- Spleen increases blood cell production and becomes enlarged
- Other common symptoms include fever, night sweats, and bone pain

#### **Current Standard of Care; JAK inhibition**

- Symptomatic relief plus some limited survival improvement. 75% discontinuation at 5 years
- Median overall survival is 14 16 months after discontinuation

### **Commercial Opportunity**

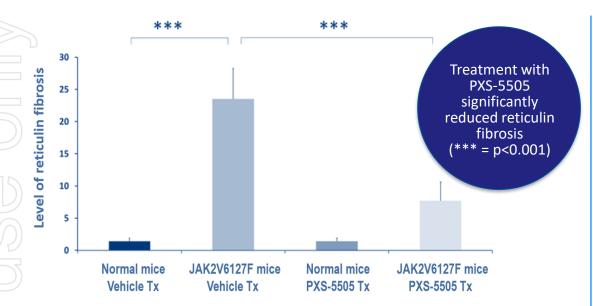
 Current standard of care; revenue ~US\$1b per annum

### **Program Update**

Myelofibrosis - PXS-5505; an effective and safe inhibitor of LOX in myelofibrosis patients

Pre clinical and clinical studies strongly support entry into long term phase 2 patient studies

#### PXS-5505 attenuates hallmarks of primary myelofibrosis in mice<sup>3</sup>

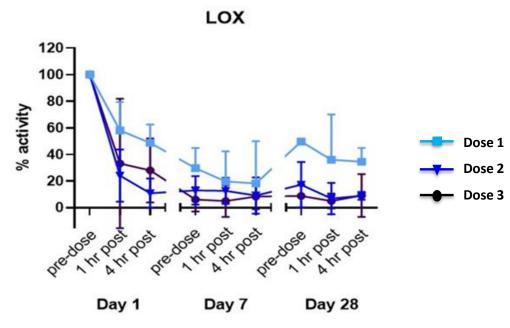


"None of the drugs approved to date consistently or meaningfully alter the fibrosis that defines this disease. PXS-5505 has a novel mechanism of action by fully inhibiting all LOX enzymes.

Preliminary data thus far, demonstrate that PXS-5505 leads to a dramatic, >90% inhibition of LOX and LOXL2 at one week and 28 days. This confirms what's been shown in healthy controls as well as mouse models, that this drug can inhibit the LOX enzymes in patients. Inhibiting these enzymes is a novel approach to the treatment of myelofibrosis by preventing the deposition of fibrosis and ultimately reversing the fibrosis that characterizes this disease"

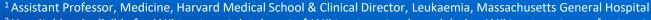
Dr Gabriela Hobbs<sup>1</sup>

#### PXS-5505 – Phase 1c dose escalation in MF patients

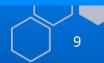


- Open label dose escalation in JAK-inhibitor unsuitable<sup>2</sup> primary MF or post-ET/PV MF patients
- Maximum of 3 patients on each dose for 28 days
- Good safety profile with no adverse events at highest dose
- >90% inhibition of LOX and LOXL2 at trough on highest dose at day 7 and 28





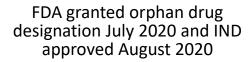
<sup>&</sup>lt;sup>2</sup> Unsuitable = ineligible for JAKi treatment, intolerant of JAKi treatment, relapsed during JAKi treatment, or refractory to JAKi treatment. JAKi – Janus Kinase inhibitor, MF myelofibrosis, ET Essential Thrombocythaemia, PV polycythaemia vera



## Myelofibrosis - PXS-5505 Phase 1/2a Trial

6 month monotherapy study with meaningful safety and efficacy endpoints

**DESIGN** TREATMENT COHORT **ENDPOINTS** Phase 2a open label **Cohort expansion: Primary:** Safety and tolerability study to evaluate safety, PXS-5505 PK/PD, and efficacy (n = 24 subjects) 26 weeks **Secondary:** PK/PD JAK-inhibitor unsuitable\* Bone Marrow Fibrosis Grade primary MF or post-ET/PV **IWG** Response MF patients with: Spleen Volume Response • INT-2 or High risk MF Haematology requiring therapy Symptom score Symptomatic • BMF Grade 2 or greater



20 sites across 4 countries (Australia, South Korea, Taiwan, USA)

Study budget to spend ~A\$3.7m

Study recruitment commenced Q4 2021, study targeted to report mid 2023



## Myelofibrosis - PXS-5505 Phase 2a Trial (INTERIM DATA)

Very well tolerated with encouraging signs of clinical efficacy in JAK inhibitor unsuitable patients

#### **DESIGN**

#### TREATMENT COHORT

#### **ENDPOINTS**

Phase 2a open label study to evaluate safety, PK/PD, and efficacy

JAK-inhibitor unsuitable\* primary MF or post-ET/PV MF patients with:

- INT-2 or High risk MF requiring therapy
- Symptomatic
- BMF Grade 2 or greater
- Median survival after JAKinhibitor discontinuation; approximately 1 year

Cohort expansion:
PXS-5505
(n = 24 subjects) 26 weeks

- A total of 18 patients have been enrolled
- 6 patients having completed 24 weeks of treatment.
- 6 patients have dropped out of the study due to due to a lack of clinical response.

#### **Primary:**

PXS5505 has been well tolerated with no serious treatment related adverse events reported.

#### **Secondary:**

- 2/6 patients show clinically important improvement in symptoms.
- 5/6 patients show either stable or improved bone marrow fibrosis scores of ≥1 grade.
- 5/6 have stable or improved platelet and/or haemoglobin scores
- No reductions were seen in spleen volume











(PXS-5505 continues to be very well tolerated in the clinic with no serious treatment related adverse events reported.

Though still early in the dose expansion phase of the study, PXS5505 appears to be stabilising and in some cases, improving the hemoglobin and platelet counts, which has also been associated with symptom improvements in those patients that were treated to 24 weeks.

This is encouraging given the poor prognosis seen after ruxolitinib discontinuation with a median overall survival of only 11-14 months typical of this study population. These results support further clinical investigation of PXS5505 in myelofibrosis."

Dr Gabriela Hobbs MD,

Assistant Professor, Medicine, Harvard Medical School & Clinical Director, Leukemia Service, Massachusetts General Hospital

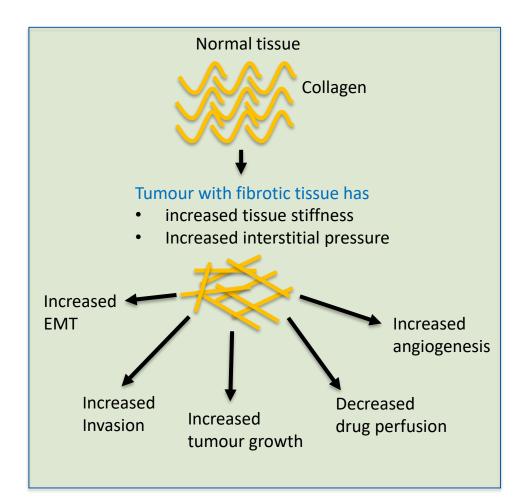


### **Program Update**

## Hepatocellular Carcinoma (HCC)

4th leading cause of cancer-related mortality worldwide with a 19.6% 5-year relative survival

- Primary liver malignancies have doubled in incidence over the last two decades.
- 4th leading cause of cancerrelated mortality worldwide with a 19.6% 5-year relative survival
- Accumulation of collagen cross-links increases stromal stiffening and interstitial fluid pressure reducing delivery of chemotherapy and immunotherapy
- Current standard of care
   20-30% are resectable at presentation with many patients relying on systemic therapy:
  - Tyrosine kinase inhibitors PD-L1 inhibitors + anti-VEGF



- Pre-clinical data (Rochester Uni; Aug 2021)
  - Tumour tissue specimens show LOX enzymes are significantly elevated in human liver cancer and correlate with poor prognosis.
  - PXS-5505 with or without chemotherapy treatment in a preclinical model significantly improves survival, delays tumour growth, and reduces intratumoral pressure.

### **Commercial Opportunity**

Drugs market currently worth ~US\$2bn with rising incidence forecasted to drive growth to ~US\$7bn by 2027

## Hepatocellular carcinoma - PXS-5505 Phase 1b/2a Trial

First line combination treatment with standard of care to assess safety and efficacy endpoints

#### **DESIGN** TREATMENT COHORT **ENDPOINTS** Open label phase 1b/2a of Phase 1b: **Primary:** PXS-5505 combined with Dose escalation design Maximum tolerated dose atezolizumab (PD-L1 3 dose levels antibody) and bevacizumab **Secondary:** n = 12-18 subjects (anti-VEGF antibody) 12 weeks Objective response rate (RECIST 1.1) in evaluable Newly diagnosed patients after completing at hepatocellular carcinoma least 4 cycles of treatment (3 months). Adult patients Phase 2a: Progression free survival Systemic therapy naïve Dose selected from phase 1b $n = ^40$ subjects Overall survival • Unresectable or metastatic ~26 weeks

IND (University of Rochester) reviewed by FDA November 2021

Phase 1b trial being conducted by Rochester Medical Centre, New York State, USA (Study sponsor).

Opened for enrollment 23 Sept

Phase 1b study budget to spend ~A\$1.1m

Study opened to recruitment in Q4 2022, study targeted to conclude H1 2024

https://clinicaltrials.gov/ct2/show/NCT05109052



## Hypertrophic and keloid scarring

Cutaneous scarring following skin trauma or a wound is a major cause of morbidity and disfigurement

#### **KEY FACTS**

100m patients develop scars in the developed world alone each year as a result of elective operations and operations after trauma

Hypertrophic scars and keloids are fibroproliferative disorders that may arise after any deep cutaneous injury caused by trauma, burns, surgery, etc.

Hypertrophic scars and keloids are cosmetically and functionally problematic significantly affecting patients' quality of life

"In (preclinical) models of scarring we found that topical application of PXS-6302 reduces collagen deposition and crosslinking and improves scar appearance without reducing tissue strength. This is a unique way of modulating a critical stage in scar formation and maintenance and holds out great promise for the treatment of scars."

- Dr Mark Fear, UWA

- Mechanisms underlying scar formation are not well established; prophylactic and treatment strategies remain unsatisfactory
- Current standard of care includes:
  - Corticosteroids
  - Surgical revision
  - Cryotherapy
  - Laser therapy
  - 5-fluorouracil



- Pre clinical evidence
  - Treatment with PXS-6302 monotherapy demonstrates cosmetic and functional improvements to scarring in pre clinical models<sup>1</sup>
- Clinical evidence
  - 1 month phase 1a in healthy volunteers demonstrates good tolerability and full inhibition of LOX in skin.
- Commercial Opportunity
  - Total scar treatment market in 2019 exceeded US\$19b. Keloid and hypertrophic scar segment ~US\$3.5b



## Established Hypertrophic Scarring - PXS-6302 Phase 1c Trial (Solaria 2)

3 month monotherapy study to assess dosage, tolerability and efficacy endpoints

#### **DESIGN** TREATMENT COHORT **ENDPOINTS** Phase 1c 3 month placebo Cohort 1: **Primary:** controlled study Safety and tolerability (n = 8 subjects) 12 weeks Objective: Confirm PK/PD of dose **Secondary:** selected in phase 1 Solaria 1 Characterize PK/PD Adult patients (18-60) with an <u>pa</u>rameters established hypertrophic scar: Physical and visual skin and • Scar 1-5 years of duration scar assessments (includes all surgery types). Cohort 2: • Scar $> 10 \text{cm}^2$ . (n = 42 subjects) 12 weeks Excludes patients with acute Objective: Confirm PK/PD, safety skin conditions or history of and efficacy of dose selected in keloids cohort 1

Investigator initiated study (sponsor UWA) - long term collaboration with UWA to research and develop PXS-6302 supported by Australian NHMRC grants

Single site study in Perth Australia

Study budget to spend; A\$0.2m Study completed recruitment Q4 2022, study targeted to report H1 2023





## Established Hypertrophic Scarring - PXS-6302 Phase 1c Trial (Solaria 2)

3 month monotherapy study to assess dosage, tolerability and efficacy endpoints

#### **DESIGN**

#### TREATMENT COHORT

#### **ENDPOINTS**

## Phase 1c 3-month placebo controlled study

Adult patients (18-60) with an established hypertrophic scar:

- Scar 1-5 years of duration (includes all surgery types).
- Scar  $> 10 \text{cm}^2$ .
- Excludes patients with acute skin conditions or history of keloids

#### Cohort 1:



#### Cohort 2:

- A total of 38 out of 42 patients have been enrolled
- Dosage regimen modified to reduce drug exposure but still maintain the overall high level of enzyme inhibition.

#### Cohort 1:

- Skin biopsies show skin penetration and high inhibition of LOX
- Reduction in biomarkers of the scarring process suggests a disease modifying effect.
- Clinician notes positive changes in appearance and pliability
- Four patients withdrew after experiencing redness & itchiness at the site of application that resolved on treatment cessation and informed the decision to reduce dosage frequency for Cohort 2







\_

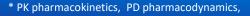
We have noted positive changes in appearance and pliability of scars in those patients on active drug that now need to be confirmed by the results from the placebo controlled phase of this trial later this year.

We are learning a lot as we move from the promising pre-clinical work done at UWA and into the clinic where we have many patients who are in great need of a treatment that can improve both the cosmetic appearance of their scars and improve the functionality of their scarred skin; factors that have a huge impact on patient's wellbeing."

#### **Professor Fiona Wood**

Burns Service of Western Australia Director of the Burn Injury Research Unit University of Western Australia

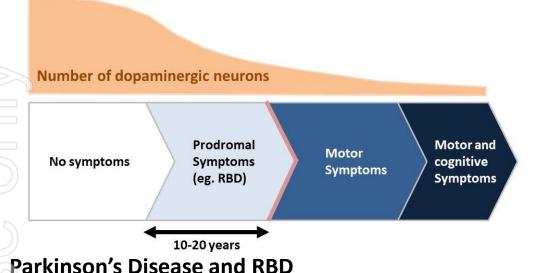




### **Program Update**

### iRBD & Neuro Inflammation - Using a sleep disorder to target Parkinson's Disease

SSAO inhibition proven effective mechanism against neuro inflammation and is neuro protective in pre clinical models



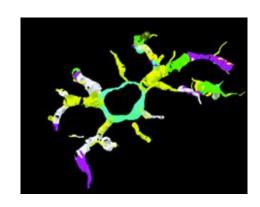
More than 50% of dopaminergic neurons in the substantia nigra are lost at the onset of motor symptoms in Parkinson's Disease.

Prodromal symptoms, such as isolating REM sleep behavior disorder (iRBD), proceed the onset of motor cognitive dysfunction by 10-20 years.

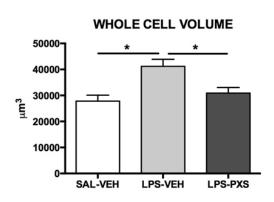
70% of iRBD patients transition to a neurodegenerative disease such as Parkinson's disease and Dementia with Lewy Bodies

#### PXS-4728 and neuro inflammation

- PXS-4728 has already undergone extensive development by Boehringer Ingelheim
- PXS-4728 inhibits SSAO and MAOB in the brain both of which play a role in neurodegenerative diseases such as Parkinson's.
- Dual SSAO & MAO-B inhibition protects against neuronal degradation in pre clinical models<sup>2</sup>
- MAO-B inhibition alone (selegiline) does not offer any protection in the same model<sup>2</sup>



Activated microglia - reconstruction



Change in Microglia whole cell volume in the Substantia Nigra (SN) after LPS<sup>1</sup>



<sup>1.</sup> Becchi et al. Semicarbazide Sensitive Amine Oxidase/Vascular Adhesion Protein-1 inhibition reduces lipopolysaccharide-induced neuroinflammation *Br. J. Pharmacol*; DOI:10.1111/bph.13832

### **Program Update**

## iRDB and Neuro Inflammation - Parkinson's UK Funding

PXS-4728 to proceed to phase 2 trial

### **Short and longer term commercial opportunities**

- Current standard of care for iRBD is melatonin. There remains a high unmet need.
- >8% of 70 89 year olds have iRBD
- >70 % of iRBD patients develop Parkinson's disease and the related  $\alpha$ -synuclein deposition disorders, dementia with Lewy bodies (DLB) and multiple system atrophy (MSA).
- Parkinson's market ~3.5bn in 2019

#### **Clinical Trial**

- 40 patients
- Randomised, double blind, placebo controlled clinical trial with iRBD
- 12 weeks of treatment with oral PXS-4728
- Two sites University of Sydney and the University of Oxford
- Expected to commence dosing in H1 2023
- Efficacy endpoints for iRBD and neuroinflammation

### **Parkinson's UK Funding Agreement**

### Clinical trial in precursor to Parkinson's Disease

- The funding agreement with Parkinson's UK entails up to £2.9m (~A\$4.9m) to be paid to Pharmaxis to run the phase 2 trial with advance payments received as the trial progresses.
- Pharmaxis is providing the study drug and the compound that will be used to measure inflammation in the brain scan of trial participants. The total is expected to cost approximately A\$5.5 million.
- Parkinson's UK will receive a return of up to 4 times their funding from royalties on future revenue Pharmaxis receives from commercialising PXS-4728 in neurological diseases and up to 2 times in other indications.

Parkinson's

Virtual Biotech



## Upcoming News Flow



### **Upcoming News Flow**

## Five trials to deliver near term value

Pipeline creates multiple opportunities in high value markets

	•	Indication	Addressable market (US\$)	Trial design	# patients	Status	Data
	PXS-5505	Myelofibrosis (MF)	\$1 billion	Phase 2 open label 6 month study in JAK intolerant / ineligible myelofibrosis patients	24	Recruiting	Interim data released Significant data update mid 2023
	PXS-	Hepatocellular Carcinoma (HCC)	\$7 billion	Phase 1c open label dose escalation study in newly diagnosed patients with unresectable HCC on top of standard of care (PD-L1 inhibitor + anti VEGF)	18	First Patient Q1 2023	2024
<b>3</b>	302	Modification of established scars	\$3.5 billion	Phase 1c 3 month placebo controlled study in patients with established scars (>1 year old)	50	Fully Recruited	H1 2023
	PXS-6302	Scar prevention post surgery	\$3.5 billion	Phase 1c 3 month placebo controlled study in patients with scarring subsequent to a burns injury	50	First patient 2023	2024
	PXS-4728	Isolated REM sleep behaviours disorder (iRDB) and neuro inflammation	\$3.5 billion	Phase 2 double blind, placebo controlled study in patients with iRBD	40	First patient H1 2023	H1 2025

### **Upcoming News Flow**

### News flow

Anticipated news flow

Strong and growing pipeline with advancement in studies expected to provide value inflection points in FY23

### Q1 2023

- PXS-5505 phase 1c liver cancer (HCC) study starts recruitment
- PXS-5505 phase 2a myelofibrosis study fully recruited

### Q2 2023

- PXS-5505: significant data update
- LOX topical drug PXS-6302 commences independent investigator patient studies – scar prevention
- LOX topical drug PXS-6302 top line data from established scars study
- PXS-5505 publications by KOL's in other cancers
- PXS-4728 iRBD / neuro inflammation study commences recruitment

#### H<sub>2</sub> 2023

 PXS-5505 phase 2a myelofibrosis study completed and reports safety and efficacy data





### Board

### Significant international pharmaceutical experience



#### Malcolm McComas - Chair

- Former investment banker and commercial lawyer
- Former MD Citi Group
- Has worked with many high growth companies across various industry sectors and has experience in equity and debt finance, acquisitions and divestments and privatisations
- Joined Pharmaxis Board in 2003
- Chair since 2012



#### **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



#### Dr Kathleen Metters – Non-Executive Director

- 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 Neil Graham - Non-Executive Director

- Former VP of immunology and inflammation responsible for strategic program direction overseeing pipeline development and clinical programs at Regeneron (REGN:US)
- Former SVP program and portfolio management at Vertex Pharmaceuticals
- Former Chief Medical Officer at Trimeris Inc and Tibotec Pharmaceuticals



#### 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.



#### 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.

## 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-Plank 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

## Mannitol respiratory business (Bronchitol® and Aridol®)

Sales growth expected from Bronchitol sales in US and Russia

#### **Sales**

- Bronchitol > 75% of sales
- Strong short term growth from Russia
- Sales growth expected in approved markets as patients access hospitals again post COVID-19 restrictions
- Strong longer term growth contribution expected from US

#### **Expenses**

Relatively fixed production cost base

### **Segment EBITDA**

- Negative EBITDA for FY 2022 \$1.3m
- Forecast positive EBITDA as CF clinics reopen post COVID
- US volumes contribute to mannitol segment generating profit



#### **Bronchitol in US**

 US CF market >65% of global market in value

US market doubles global cystic fibrosis patient opportunity with attractive pricing

- US sales commenced in Q1 CY 2021
   delay in patient initiation due to COVID
- High teens % of Chiesi sales + supply contract - ~20% of Chiesi US Bronchitol net sales flow directly to the Pharmaxis bottom line



## Financials

Income statement highlights

Pariods and ad (A\$'000)	Three n	Three months		Six months	
Periods ended (A\$'000)	Dec-22	Dec-21	Dec-22	Dec-21	
Segment Financials					
New drug development					
Oral pan-LOX (external costs - MF & MDS)	(871)	(1,102)	(1,880)	(2,569)	
Oral pan-LOX (external costs - liver cancer)	(321)	-	(321)	=	
Topical pan-LOX (external costs)	(206)	(378)	(276)	(459)	
Other program external costs (net of grants)	(349)	(84)	(579)	(306)	
Employee costs	(831)	(602)	(1,722)	(1,317)	
Overhead	(123)	(116)	(284)	(218)	
R&D tax credit and other income	53	-	53		
EBITDA	(2,648)	(2,282)	(5,009)	(4,869)	
Mannitol respiratory business					
Sales	521	2,524	1,281	5,796	
Other revenue and income	0	2	7,192	2,344	
	521	2,526	8,473	8,140	
Expenses – employee costs	(1,128)	(1,242)	(2,247)	(2,439)	
Expenses – manufacturing purchases	(334)	(1,038)	(982)	(2,243)	
Expenses – other	(1,030)	(933)	(1,836)	(2,075)	
EBITDA	(1,971)	(687)	3,408	1,383	
Corporate – EBITDA	530	(1,456)	197	(2,134)	
Total Adjusted EBITDA	(4,088)	(4,425)	(1,403)	(5,620)	
Net profit (loss)	(5,819)	(5,646)	(4,876)	(8,825)	

## Financials

### Cash

Pariods anded (A\$'000)	Three n	Three months		Six months	
Periods ended (A\$'000)	Dec-22	Dec-21	Dec-22	Dec-21	
Cash					
Cash at period end	16,450	20,866	16,450	20,866	
Cash received post period end					
2022 R&D tax credit - received 1/23	4,900				
Proforma cash at period end	21,350				
<b>Cash Flow Statement Highlights</b>					
Operations					
Receipts from customers	2,078	3,757	2,482	7,255	
R&D tax incentive	-	-	-	-	
Grants received	1,448	192	1,448	207	
Sale of Orbital/distribution rights	-	-	7,192	-	
Other	24	10	41	712	
Payments to suppliers, employees etc (net)	(7,649)	(7,669)	(12,604)	(13,829)	
Total operations	(4,099)	(3,710)	(1,441)	(5,655)	
Investing (capex & patents)	(65)	(30)	(91)	(70)	
Finance lease payments <sup>1</sup>	(554)	(591)	(1,099)	(1,184)	
Financing agreement payments <sup>2</sup>	(8)	(5)	(18)	(8)	
Share issue - net	9,261	9,071	9,261	9,071	
Net increase (decrease) in cash	4,535	4,735	6,612	2,154	

<sup>1.</sup> Lease over 20 Rodborough Rd (to May 2024) – total liability at 30 June 2022: \$4.4 million

<sup>2.</sup> Financing agreement – not repayable other than as % of US Bronchitol revenue through to March 2028



# phormoxis

developing breakthrough treatments for fibrosis and inflammation

Pharmaxis Ltd ABN 75 082 811 630 www.pharmaxis.com.au





### Contacts

Gary Phillips
Chief Executive Officer
gary.phillips@pharmaxis.com.au

David McGarvey
Chief Financial Officer
david.mcgarvey@pharmaxis.com.au