

phormoxis

Investor Presentation | 14 April 2021 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.

### Capital Raising Overview

Pharmaxis is raising ~A\$4.4m at A\$0.08 per share via a Private Placement

- Private Placement to institutional investors
  - A\$4.4m under existing placement capacity pursuant to ASX Listing Rule 7.1
  - A\$0.08 issue price represents a 1.3% premium to the last closing price of A\$0.079 on 12 April 2021
- Strong support from new and existing substantial shareholders
  - Karst Peak Capital Limited:
    - Asia/Australian healthcare investor with a contrarian, fundamental, long term oriented investment approach
    - committing A\$3.2m to take a 8.9% stake post capital raising
  - BVF Partners LP committing A\$0.8m to maintain their 19.5% shareholding of Company post capital raising

- Use of funds
  - Strengthen balance sheet. A\$20m pro-forma cash balance (31 March 2021 post raising)
  - Support the Company's clinical program for myelofibrosis (PXS-5505) and skin scarring (PXS-6302)
  - General working capital and capital raising costs
- Indicative timetable\*
  - Trading haltTuesday 13 April 2021
  - Placement announced and Company resumes trading
     Wednesday 14 April 2021
  - Settlement of issue of Placement Shares
     Tuesday, 20 April 2021
  - Allotment of issue of Placement Shares
     Wednesday, 21 April 2021



<sup>\*</sup>The timetable above is indicative only and may be varied subject to the ASX Listing Rules

## **Executive Summary**

- Pharmaxis is a clinical stage drug development company targeting fibrosis and cancer
- Lead asset PXS-5505 is in phase 1c /2a trial a breakthrough clinical program with disease modifying potential in Myelofibrosis
- PXS-5505 has further potential in oncology as an adjunct to standard of care
- Additional asset PXS-6302 is an anti-skin scarring drug in phase 1a/1c trial in 2021 – PXS-6302 to enter patient studies in commercially important dermatology indications with potential to improve function and appearance
  - Specific corporate strategy to deliver non-dilutive cash and cost savings from other parts of our business
  - Distribution license fees from currently un-partnered mannitol territories
  - Simplification and rationalisation across business
- Post capital raising Pharmaxis is in a strong position to fund its focused clinical program



## Cash and capital structure

#### Extended cash runway

Cash at March

#### Cash

	Casil at Marcil	ASTOIL
•	Proceeds of placement	A\$4m

Proforma cash balance as at March A\$20m

Mannitol business forecast to go from cash burn (FY 20: EBITDA (A\$4m)) to cash flow positive from FY 21 onwards (FY 26: EBITDA A\$10m+)

Sale of Russian Bronchitol distribution rights effective 1 May

- €1.25m (~A\$2m)\*\* 70% payable now, 30% in twelve months
- Cost reductions of ~A\$1m per annum

#### Further opportunities to extend cash runway

- Potential cost savings from rationalization across business
- Distribution license fees from currently un-partnered Aridol and Bronchitol territories
- Pipeline supported by grants and R&D tax credit (~A\$5m 2020)

\*Mannitol segment EBITDA only

Partnering deals with pipeline assets

#### **Share capital**

•	Current snares on issue	397.5m
•	Placement shares	54.6m
•	Shares on issue on completion of placement	452.1m

#### **Enterprise value**

	Market capitalisation at \$0.00 per share	\$30.ZIII
•	Less: proforma net cash	(\$20.0m)
•	Enterprise value	\$16.2m

Market capitalication at \$0.00 per chare

#### Lead institutional shareholders

**BVF Partners IP** 

	511 1 41 (11010 21	25.575
•	Karst Peak Canital Limited	8 9%



Δ\$16m

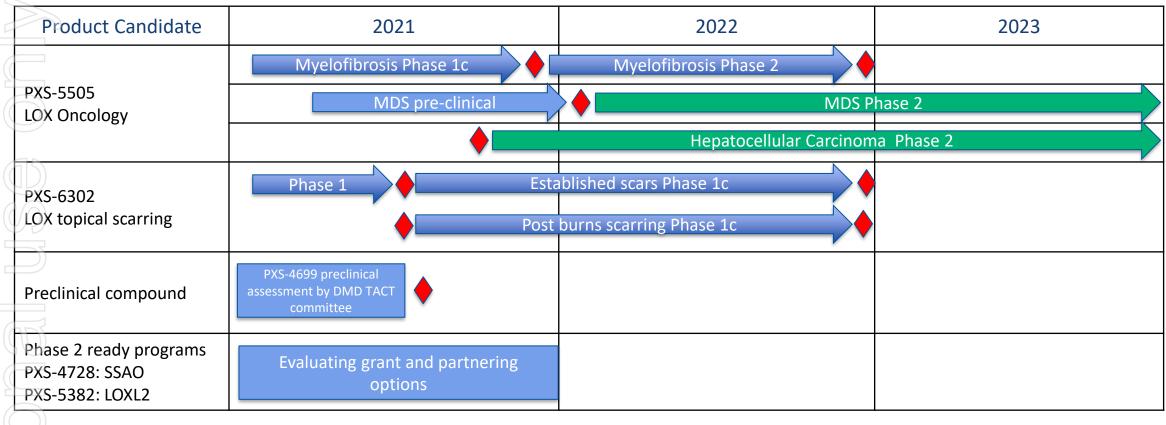
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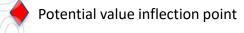
19.5%

## Multiple potential value inflection points over next two years

Pipeline creates multiple opportunities

Target timelines







Additional programs under evaluation



### Anticipated news flow: 2021 - 2022

Multiple anticipated value inflection points over next two years

#### H1 2021

- Feb 22: Breakthrough drug PXS-5505 phase 1c/2a myelofibrosis study commenced recruitment
- Mar 19: Chiesi pays US\$3m milestone on Pharmaxis shipment of US launch
- Mar 31: LOX topical drug PXS-6302 commenced independent investigator studies safety
  - April 14: Sale of Russian Bronchitol distribution rights
- Mannitol business simplification realising annual cost savings

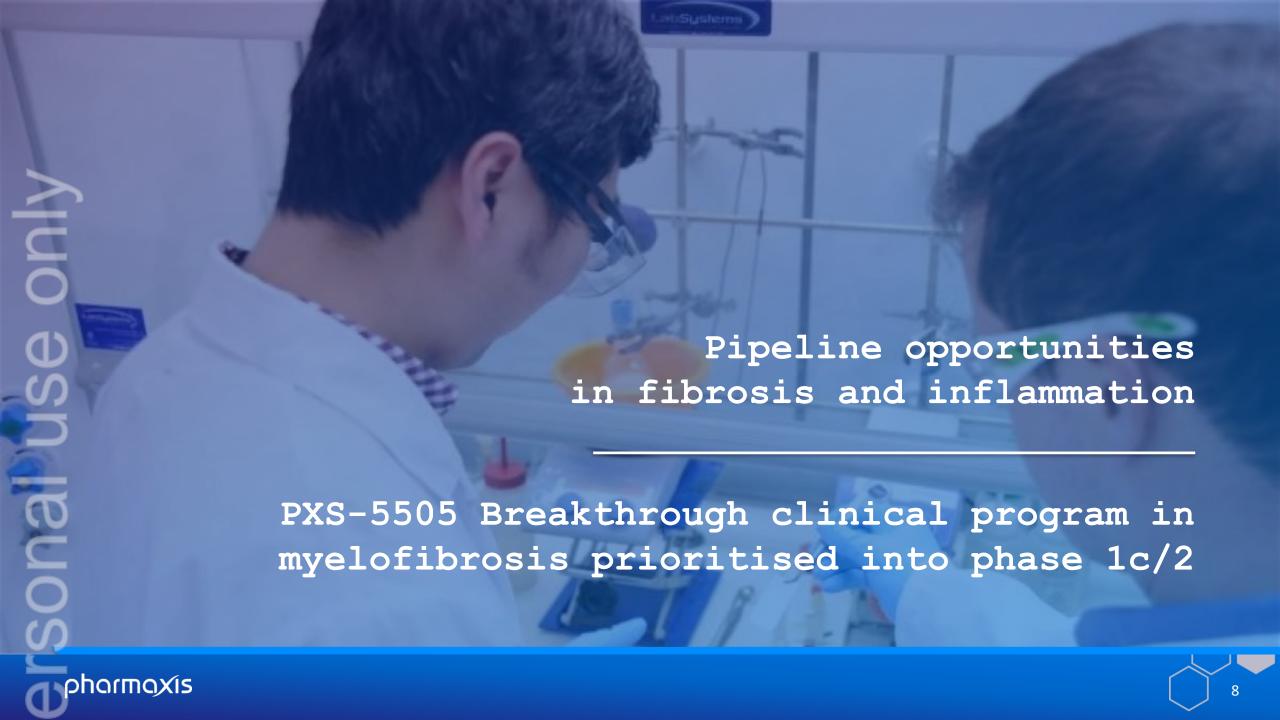
#### H<sub>2</sub> 2021

- PXS-5505 phase 2a myelofibrosis study dose expansion stage commence
- First collaborations to progress PXS-5505 into clinical trials in other cancer indications
- Ongoing cash receipts from supply of Bronchitol for US sales
- LOX topical drug PXS-6302 progresses into independent investigator patient studies - burns and established scars
- Feedback from global advisory committee (TACT) on development fast tracking for Duchenne muscular dystrophy clinical trials.

#### **CY 2022**

- PXS-5505 phase 2a myelofibrosis study safety and efficacy data
- LOX topical drug phase 1c studies burns and established scars safety and efficacy data





## First in class PXS-5505 IND approved and in the clinic

Novel anti fibrotic approach with broad applications in difficult to treat cancers



# Myelofibrosis: Orphan Disease with high unmet need forecast to exceed US\$1b

- Drug with disease modifying potential patent application filed 2018
- Six month tox and Phase 1 studies completed 1H 2020
- FDA orphan status granted July 2020
- IND approved August 2020
- Phase 1/2a proof of concept myelofibrosis study commenced recruitment O1 21



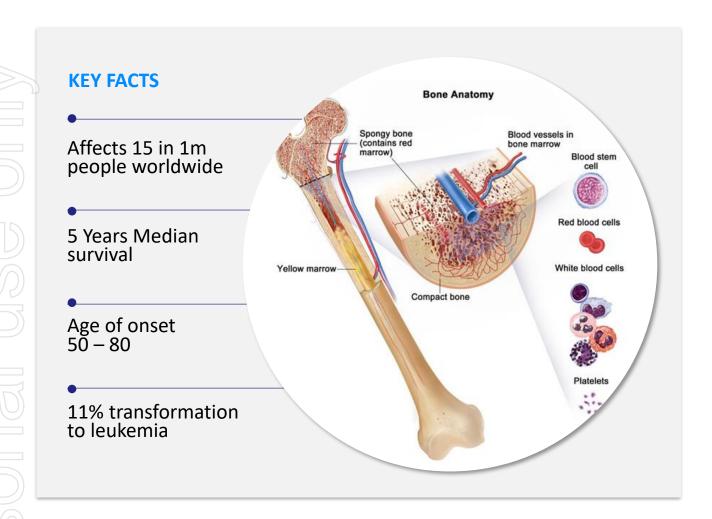
## Adjunct to best standard of care in multiple cancers

- LOX inhibition synergistic with current standard of care and potentially pharma development pipeline in many stromal cancers
- Academic and clinical interest in additional indications including;
  - Myelodysplastic syndrome ( MDS); liver carcinoma (Hepatocellular carcinoma); pancreatic cancer; glioblastoma
- International studies facilitated by IND approval and availability of drug product



### Myelofibrosis background

A rare type of bone marrow cancer that disrupts your 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:

- Driven by clonal mutations of a hematopoietic stem cell (JAK, MPL, CALR genes)
- 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

#### Standard of Care; JAK inhibition

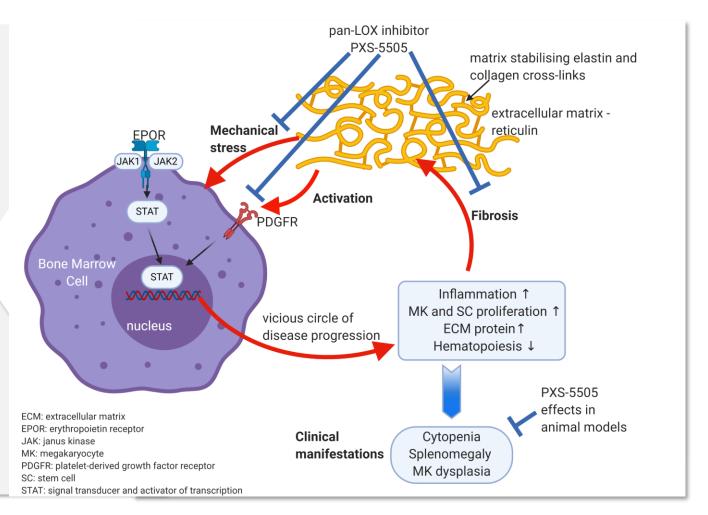
- Symptomatic relief plus some limited survival improvement. 75% discontinuation at 5 years
- Median overall survival is 14 16 months after discontinuation

## Mode of action in myelofibrosis

Disease modifying potential as monotherapy and on top of standard of care

Unique mechanism of action targeting the extracellular matrix Disease modifying potential Designed to provided efficacy on top of existing standard of care AND potentially pipeline drugs "Specific targeting of ECM dysregulation to prevent and diminish MF may prove the frontline of research and therapy development in PMF with the greatest promise of relieving symptoms and extending life expectancy of patients"

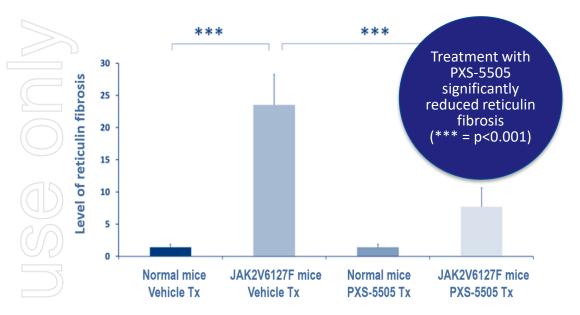
Blood Cancer Journal (2017) 7, e525; doi:10.1038/bcj.2017.6



## PXS-5505; LOX inhibitor with promising profile

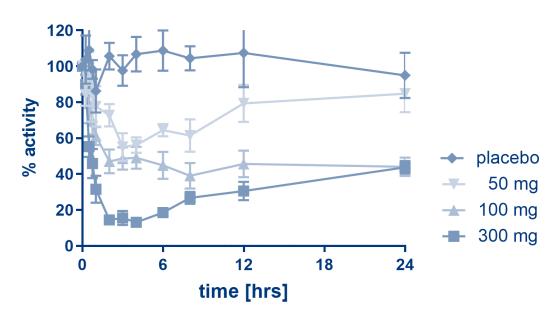
Pre clinical and clinical studies strongly support entry into patient studies

PXS-5505 attenuates hallmarks of primary myelofibrosis in mice.



"JAK inhibition alone is insufficient in the treatment of patients with myelofibrosis; it is not associated with changes in underlying disease biology and it can worsen blood counts, leading to high drug discontinuation rates over time. The trial utilizing PX-5505 is supported by a sound scientific rationale, based on pre-clinical work demonstrating the importance of lysyl oxidase in the development of myelofibrosis. PXS-5505 has a unique mechanism of action that has the potential for disease modification. I am looking forward to seeing the effect of this drug in clinical trials." 1

**PXS-5505 - Phase 1 SAD** 

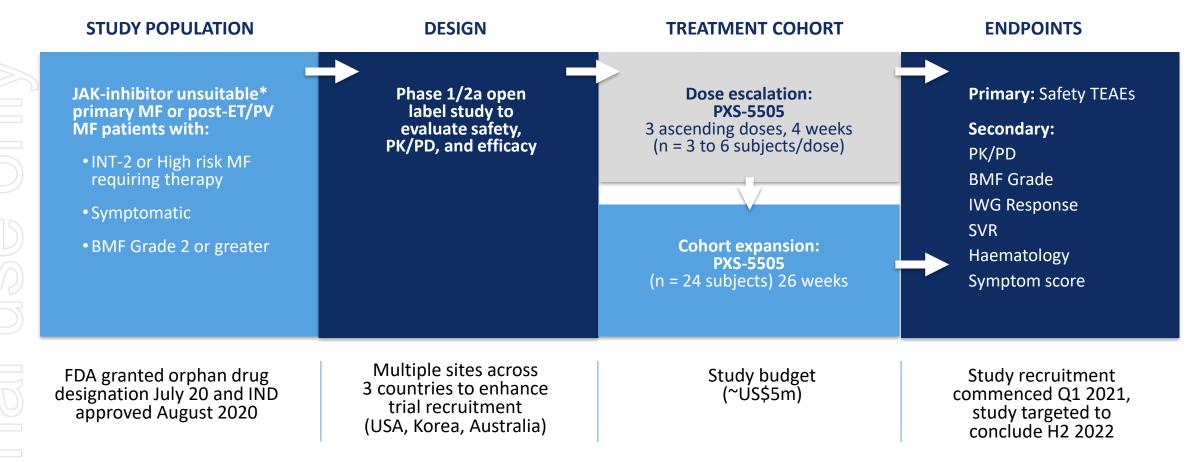


- Good safety profile with 6 month tox studies complete
- Dose dependant 24 hour inhibition of LOX enzymes from single once a day dose in humans
- No safety signal seen in phase 1 trials
- 2018 patent application filing date



## PXS-5505 Phase 1/2a Trial in myelofibrosis

6 month monotherapy study with meaningful safety and efficacy endpoints



\*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, INT intermediate,

BMF bone marrow fibrosis, RP2D recommended phase 2 dose, TEAE treatment emergent adverse event, PK pharmacokinetics, PD pharmacodynamics, SVR spleen volume response, IWG International Working Group Myeloproliferative Neoplasms

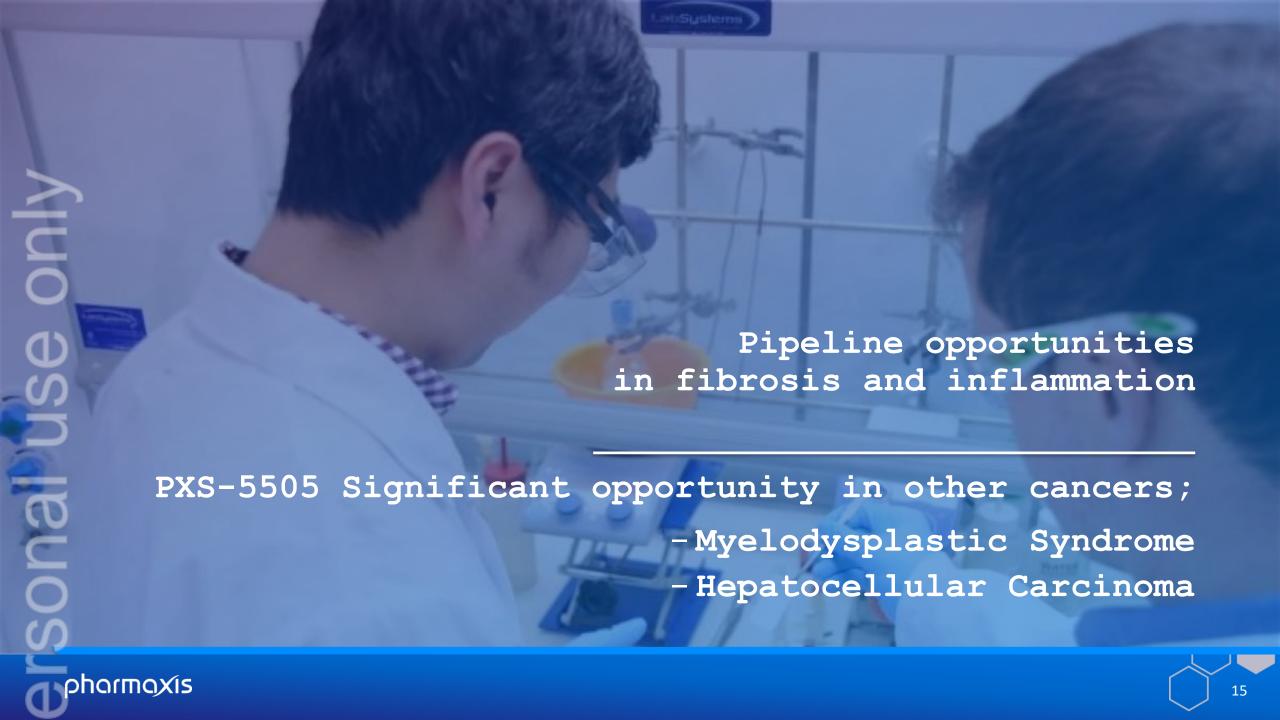
## Myelofibrosis - examples of other programs

PXS-5505 unique mechanism of action designed for disease modification and good tolerability

Company	Market cap <sup>(1)</sup>	Bourse	Asset	Description	Clinical phase
THERAPEUTICS	\$1.2bn	Nasdaq	KER-050	TGF-β ligand trap	Phase 2
Constellation PHARMACEUTICALS	\$1.1bn	Nasdaq	CPI-0610	BET inhibitor	Phase 3
KARTOS THERAPEUTICS	\$0.7bn <sup>(2)</sup>	n.a. – private	KRT-232	MDM2 antagonist	Phase 3
geron	\$0.5bn	Nasdaq	Imetelstat	Telomerase inhibitor	Phase 3
phormoxis	\$24m (A\$31m)	ASX	PXS-5505	LOX inhibitor	Phase 1c/2 commenced

PXS-5505 unique mechanism of action expected to deliver additional efficacy on top of existing standard of care and/or known pipeline drugs without adding to tolerability issues





## PXS-5505: Significant opportunity in other cancers

Global academic and clinical interest in LOX inhibition drives development plan

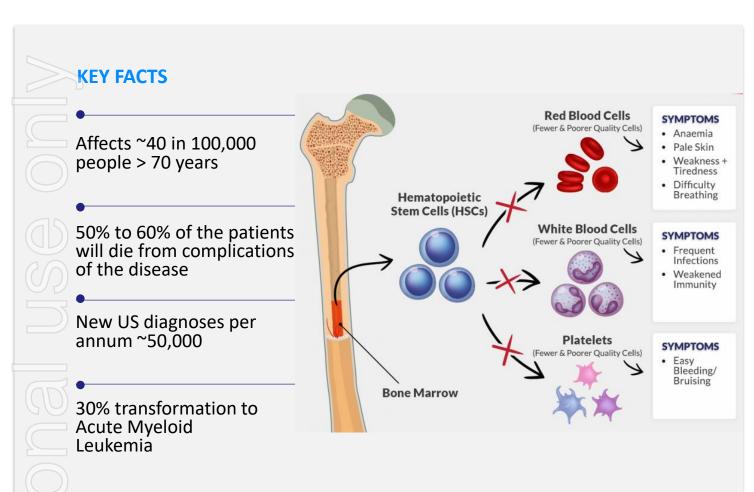
#### Normal tissue **Pharmaxis Research Collaborations** Myelodysplastic syndrome Collagen Germany **Liver Cancer** Rochester (NY) Tumour with fibrotic tissue has **Pancreatic Cancer** increased tissue stiffness Sydney, Rochester (NY) Increased interstitial pressure Melanoma and glioblastoma Houston Increased Increased **Head and Neck Cancer** angiogenesis **EMT** Boston, (MA) Increased Decreased Increased Invasion drug perfusion tumour growth

Multiple expected benefits from inhibition of LOX enzymes



## Myelodysplastic Syndrome (MDS)

A group of bone marrow cancers that disrupt normal production of blood cells

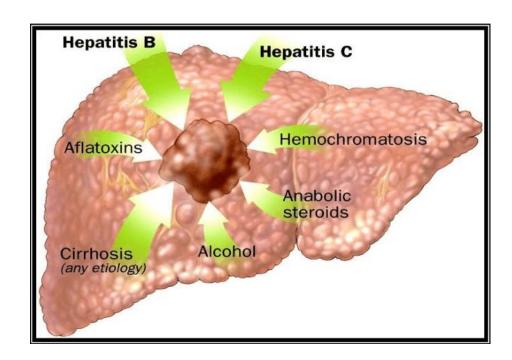


- A group of malignant hematopoietic neoplasms characterized by Bone marrow failure with resultant cytopenia and related complications
- Current standard of care
  - Allogeneic stem cell transplantation
  - Immunomodulatory drug lenalidomide,
  - Advanced disease: DNA hypomethylating agents (HMA), azacitidine (AZA), and decitabine
- Pre clinical evidence
  - Unpublished data from Pharmaxis scientific collaboration demonstrating strong proof of concept
- Proposed clinical strategy
  - Build on myelofibrosis strategy in hematological diseases
  - 6 month proof of concept study on top of standard of care

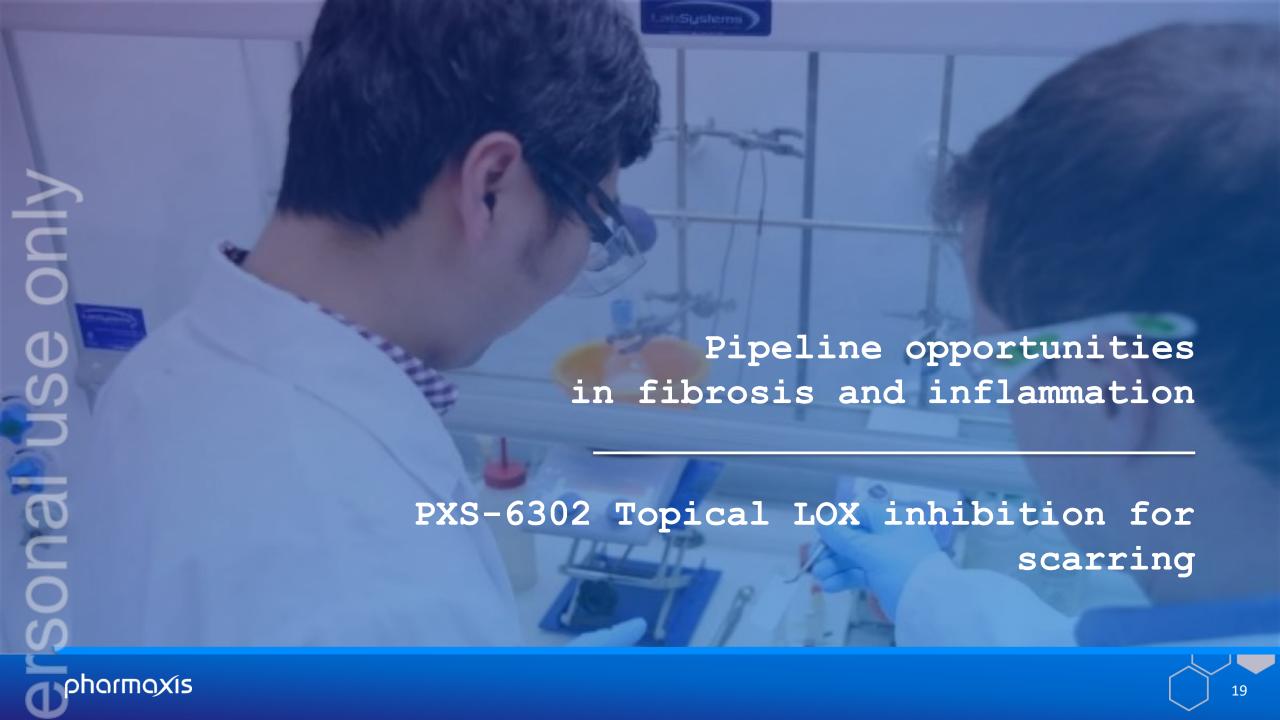
## Hepatocellular Carcinoma (HCC)

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.
- HCC is a stromal (fibrotic) tumour
  - Accumulation of collagen crosslinks increases stromal stiffening and interstitial fluid pressure (IFP) reducing delivery of chemotherapy and immunotherapy.
- Etiology
  - Extrinsic factors e.g. Virus infections
  - Intrinsic factors e.g. auto immune diseases, fatty infiltration, genetics
- Current standard of careTyrosine kinase inhibitorsPD-L1 inhibitors + anti-VEGF



- Pre-clinical data
  - High LOX expression associated with reduced survival
  - LOX is up-stream regulator of VEGF expression and inhibition of this enzyme could potentiate the intratumoral effects of anti-VEGF therapy
  - Combination anti-PD-1 therapy with LOX inhibition has demonstrated synergistic decrease in tumor growth
- Proposed clinical strategy
  - Enhance the intratumoral response to standard of care through the addition of LOX inhibition in human HCC
  - 6 month study combination PXS-5505 on top of standard of care in newly diagnosed unresectable or metastatic hepatocellular carcinoma



## Hypertrophic and keloid scarring

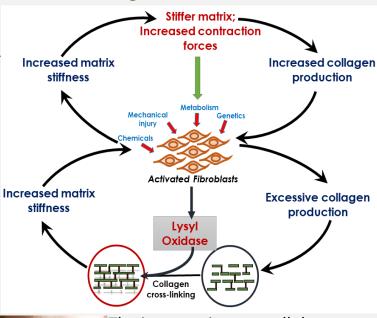
Cutaneous scarring following skin trauma or a wound is a major cause of morbidity and disfigurement

#### **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



Collagen turnover in keloid

The increase in extracellular matrix is a key factor and this depends on collagen and elastin cross-linking to make them less degradable.

- 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
  - Unpublished data from Pharmaxis scientific collaboration demonstrating strong proof of concept
  - Treatment with PXS-6302 monotherapy demonstrates cosmetic and functional improvements to the scar
- Clinical strategy
  - 3 month placebo controlled study in patients versus current standard of care
  - Initial patient groups will include those with established scars and those with scarring subsequent to burn injury

### Further non core pipeline opportunities in fibrosis and inflammation

Leveraging global leadership position in amine oxidase enzymes to deliver targeted drugs for fibrosis and inflammation

Product Candidate	Indications	Pre- clinical	Phase 1	Phase 2		Next Steps	
SSAO; PXS-4728	Repurposing for neuro inflammatory disease				•	Partnering discussions; phase 2 protocol and funding discussions with independent investigators	
LOXL2; PXS-5382	Chronic fibrotic disease e.g. chronic kidney disease, idiopathic pulmonary fibrosis				•	Partnering discussions; phase 2 protocol and funding discussions with independent investigators	
SSAO/MAOB; PXS-4699	Anti inflammatory Muscular Dystrophy					•	\$1m matched funding grant DMD TACT committee Q2 2021 Explore funding opportunities to advance to the clinic H1 2022
SSAO/MPO; PXS-5370	Anti inflammatory Multiple indications				•	Investigating funding opportunities including grants	



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

Transformational impact of FDA Bronchitol approval (Oct 2020) – business segment cash flow positive from FY 2021 onwards

#### **Sales**

- Mannitol respiratory sales forecast to double by FY 2022 with Bronchitol > 75% of sales
- Strong longer term growth contribution from US
- Growth in Ex-US markets including Russia

#### **Expenses**

- Relatively fixed production cost base
- Potential for simplified business model to reduce costs

#### **Segment EBITDA**

- Forecast positive EBITDA from FY 2021 onwards (before potential cost savings).
- 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

- Chiesi approval /launch milestone payments US\$10m received FY 2021
- US sales commenced in Q2 CY 2021
- High teens % of Chiesi sales + supply contract - ~20% of Chiesi US Bronchitol net sales flow directly to the Pharmaxis bottom line
- Three sales milestones totaling US\$15m payable on achieving annual sales thresholds



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Novel, small molecule medicines focused on inflammation, fibrotic diseases and cancer

## In house discovery and development capability

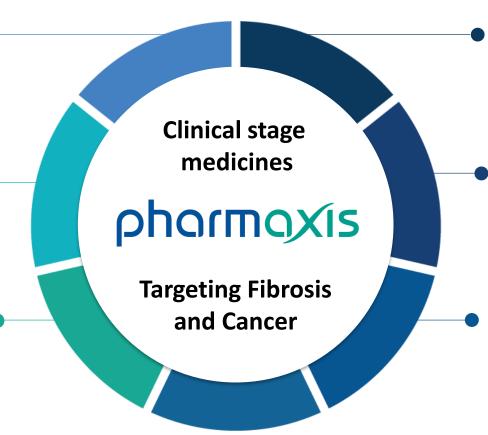
Experienced team delivering stream of novel drugs to the clinic

## Platform technology drives pipeline of clinical assets

Multiple opportunities from global leadership in amine oxidase enzymes

## Cash flow positive manufacturing business

FDA approval for Cystic Fibrosis drug transformative with Pharmaxis manufacturing business now cash flow positive



## Lead asset PXS-5505 in phase 1c/2a trial

Breakthrough clinical program with disease modifying potential in Myelofibrosis

## Broad potential for PXS-5505 in oncology

Global scientific and clinical collaborations to extend value of PXS-5505 in further oncology indications

## Anti skin scarring drug in phase 1a/1c trial in 2021

PXS-6302 to enter patient studies in commercially important dermatology indications

## Experienced Scientific Leadership Team

Significant global experience in drug development, commercialisation and partnering

#### In senior management



#### Wolfgang Jarolimek - Drug Discovery

- more than 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

#### On the board



#### **Gary Phillips – CEO and Managing Director**

- more than 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



#### **Dieter Hamprecht – Head of Chemistry**

- more than 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



#### 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



#### **Brett Charlton - Medical**

- more than 25 years experience in clinical trial design and management
- author of more than 80 scientific papers
- founding Medical Director of the National Health Sciences Centre
- previously held various positions with the Australian National University, Stanford University, the Baxter Centre for Medical Research, Royal Melbourne Hospital, and the Walter and Eliza Hall Institute



#### 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

#### 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



#### Will Delaat - Non-Executive Director

- more than 35 years' experience in the global pharmaceutical industry
- former CEO of Merck Australia
- former chair of Medicines Australia and Pharmaceuticals Industry Council
- joined Pharmaxis Board in 2008



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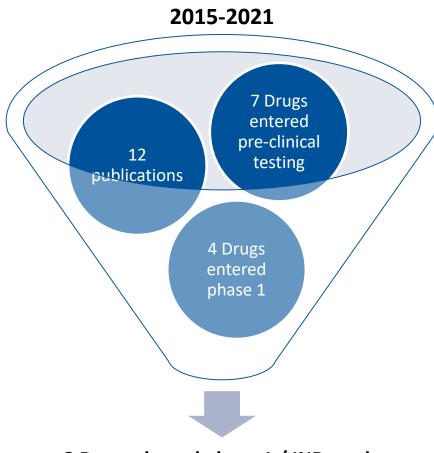
- former VP of immunology and inflammation responsible for strategic program direction overseeing pipeline development and clinical programs at Regeneron (REGN:US)
- former SVP program and portfolio management at Vertex Pharmaceuticals
- former Chief Medical Officer at Trimeris Inc and Tibotec Pharmaceuticals

### Drug development capability

Established team in Drug Discovery and Clinical Trials with broad experience across multiple regulatory agencies

### **Organisation**

- Leadership with extensive drug discovery/development experience from big pharma and biotech
- Extensive in house capabilities
- On site laboratories
- Leveraged with international network of external contract organisations
- Numerous collaborations with leading academic institutions in Australia and world-wide in pharmacology and medicinal chemistry
- High scientific reputation through peer-reviewed publications
- Direct management of regulatory interaction with FDA, EMA, etc.



3 Drugs cleared phase 1 / IND ready
2 Drugs in phase 2

### **Strategy**

- Focus on inflammation and fibrosis/cancer driven diseases with high unmet medical need
- Leverage global leading position in amine oxidase chemistry and biology
- Create first or best in class small molecule inhibitors with biomarker assays for early validation of clinical hypothesis in phase 1 trials
- Protect intellectual property by focused chemical matter, use and biomarker patents
- Capture advantages of Australian location:
  - Accelerated (and lower cost) Phase 1 entry
  - Australian Government R&D tax credit system



### Financials

Periods ended (AŚ'000)

#### Cash

relious elideu (A\$ 000)	HY	HY	FY	FY
Proforma cash				
Cash period end	18,249	25,864	14,764	31,124
R&D tax credit	-	-	5,048	6,221
Chiesi US FDA milestone payments	~4,0001	-	~14,000	-
	~\$22,249	\$25,864	~\$33,812	\$37,345
Cash Flow Statement Highlights				
Operations				
Receipts from customers	3,602	3,973	7,775	6,893
R&D tax incentive	5,099	6,221	6,271	-
Chiesi milestone	9,949	-	-	-
Payments to suppliers, employees etc	(13,602)	(13,886)	(27,330)	(26,691)
Total operations	5,048	(3,692)	(13,284)	(19,798)
Investing (capex)	(281)	(328)	(574)	(981)
Finance lease payments <sup>2</sup>	(1,147)	(1,111)	(2,232)	(1,593)
Financing agreement payments <sup>3</sup>	(135)	(129)	(270)	(254)
Share issue - net			-	22,677
Net increase (decrease) in cash	\$3,485	(\$5,260)	(\$16,360)	<b>\$51</b>

**Dec 2020** 

**Dec 2019** 

Jun 2020

Jun 2019

- 1. US\$3m milestone earned February 2021
- Lease over 20 Rodborough Rd (to 2024) total liability at 31 December 2020: \$7.1 million
- 3. NovaQuest financing not repayable other than as % of US & EU Bronchitol revenue up to 7 years

### Financials

Income statement highlights

Periods ended (A\$'000)	Dec 2020 HY	Dec 2019 HY	Jun 2020 FY	Jun 2019 FY
Segment Financials				
New drug development				
Oral LOX (external costs)	(1,323)	(1,400)	(3,124)	(3,833)
Other program external costs (net of grants)	(775)	(1,078)	(3,315)	(5,108)
Employee costs	(1,799)	(1,529)	(3,373)	(2,837)
Overhead	(238)	(281)	(460)	(606)
R&D tax credit	148	259	5,159	5,962
EBITDA	(3,987)	(4,029)	(5,113)	(6,764)
Mannitol respiratory business				
Sales	3,086	3,259	7,027	5,676
Other revenue and income	10,098	10	20	27
	13,184	3,269	7,047	5,703
Expenses – employee costs	(2,912)	(3,037)	(5,855)	(6,083)
Expenses – manufacturing purchases	(1,172)	(746)	(1,456)	(1,689)
Expenses – other	(2,376)	(1,755)	(3,713)	(2,944)
EBITDA	6,724	(2,269)	(3,977)	(5,013)
Corporate – EBITDA	(2,024)	(1,701)	(2,990)	(3,874)
Total Adjusted EBITDA	713	(7,999)	(12,080)	(15,651)
Net profit (loss)	\$46	(\$10,319)	(\$13,943)	(\$20,058)

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