

## Media Release

3 October 2023

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### **PHARMAXIS ANNOUNCES MAJOR COMPANY RESTRUCTURE – SALE OF MANNITOL BUSINESS AND CREATION OF SYNTARA; A CLINICAL-STAGE DRUG DEVELOPMENT COMPANY**

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#### **Key restructure features:**

- **Sale of mannitol respiratory business to pharmaceutical manufacturing specialist, Arna Pharma**
- **Pharmaxis to be renamed Syntara<sup>1</sup>**
- **Residual net exit costs of less than A\$1m with Syntara to receive product royalties from Arna Pharma**
- **Significant reduction in cost base: core expenses to be reduced by over 60% saving the company over A\$14m per year**
- **Syntara<sup>1</sup> to primarily focus on clinical development.**
- **Five planned clinical studies to deliver results in high unmet need diseases by mid-2025.**
- **Lead drug candidate PXS-5505 to commence FDA agreed phase 2 trial in myelofibrosis in current quarter, Q4 2023**

Pharmaxis Ltd (ASX: PXS) has announced details of the sale of the mannitol respiratory business which manufactures and supplies Aridol and Bronchitol to global markets and the formation of Syntara, a clinical stage drug development company primarily focusing on treatments for haematological malignancies (blood related cancers).

#### **Sale of mannitol business unit**

The mannitol respiratory business unit (MBU) is being sold to Arna Pharma Pty Ltd, (Arna Pharma) an Australian company that is part of an alliance of companies with healthcare and pharmaceutical operations in Australia and major world markets.

Definitive contract documentation for the MBU sale was signed yesterday (2 October 2023) and the sale is scheduled to complete before the end of October 2023 when Arna Pharma will take over the day to day operations of the MBU. It will immediately commence an eight month process of transferring production of Aridol and Bronchitol and creating job opportunities for Pharmaxis MBU employees at its multi-product Sydney facility with some elements of manufacturing being undertaken by specialist contract manufacturers.

#### **Financial considerations**

Under the terms of the sale agreement Pharmaxis will be reimbursed by Arna Pharma for the majority of the expenses Pharmaxis will incur through to May 2024. Pharmaxis will receive ongoing royalties for eight years from Arna Pharma's Sydney based business including Bronchitol and Aridol. The MBU sale and associated Pharmaxis restructure will result in a reduction of annual core costs, excluding external research costs, of more than 60% saving the company over \$14m per year. This

will be due in large part to the elimination of costs attached to operating a global pharmaceutical manufacturing and distribution business and a headcount that drops from approximately 70 to 25.

### Syntara's lead drug PXS 5505

Syntara will be a clinical-stage drug development company primarily focused on blood related cancers. The company's lead drug candidate, PXS-5505, is a best-in-class inhibitor of lysyl oxidase (LOX) that has already reported positive Phase 2 data in myelofibrosis patients. This program is expected to issue a further update at the American Society of Hematology conference in December 2023.

The next phase of clinical development for PXS-5505 will be the commencement of an FDA agreed study design in which PXS-5505 will be used in combination with a JAK inhibitor which is the standard of care. This program is expected to recruit its first patient in Q4 2023 and is expected to report interim data by the end of 2024. Syntara will also explore the use of PXS-5505 in another haematological malignancy, myelodysplastic syndrome, following breakthrough preclinical data published in Nature Communications earlier this year.

### Other Syntara programs

While the majority of resources will be focused on PXS-5505, Syntara will also be advancing both oral and topical pan-LOX inhibitors in Phase 2 scar prevention and scar modification programs as part of an ongoing collaboration with Professor Fiona Wood and the University of Western Australia which has already reported positive results in May 2023. In addition, Syntara will also be continuing a trial with PXS-4728, a novel anti-inflammatory drug candidate for the treatment of early stage neurodegenerative diseases which is being substantially funded by Parkinson's UK.

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

### Board changes

As part of the restructuring, the Pharmaxis Board will be reduced in size. Current Chair Malcolm McComas retires effective today after serving for 11 years as Chair. During that period, Pharmaxis partnered various assets with Boehringer, received global marketing approval for Bronchitol and Aridol and created a global partnership with Chiesi. Dr Neil Graham also retires today after 3 years of service as a non-executive director during which time Pharmaxis has advanced both of its pan-LOX inhibitor programs and its neuroinflammation drug into phase 2 clinical trials.

Current Pharmaxis director Dr Kathleen Metters has been appointed by the Board as Chair, effective today. Current non-executive directors, Dr Simon Green and Hashan De Silva will continue together with chief executive officer and managing director Gary Phillips.

## Comments from Gary Phillips, CEO and Dr Kathleen Metters, Chair

Pharmaxis CEO Gary Phillips said, “Over the last few years Pharmaxis has built a commanding position in lysyl oxidase biology and chemistry research. We have collaborated with leading clinicians and scientists worldwide and forged through the early stage studies that have given us a clinical pipeline with great potential and resulted in multiple Nature publications<sup>2</sup>. Building on this heritage and the proven capability of our discovery and development teams, the restructure announced today and the creation of Syntara enables us to focus and accelerate our clinical development programs. In PXS-5505 we have a best-in-class drug with an excellent safety profile that has the potential to offer disease modifying effect to patients with haematological malignancies. Syntara and its shareholders are in the unique position of having five planned clinical programs that can deliver company transforming results within a two year period and I am very excited to start on this new journey”.

Gary Phillips continued, “Pharmaxis has a proud legacy that has been achieved with the support of our shareholders, Board and employees and I thank them most sincerely and look forward to the next chapter in our drug development evolution. Arna Pharma is ideally placed to continue on the ground-breaking work Pharmaxis has done in getting two drugs through global regulatory approvals and marketed to patients worldwide, including adults and children living with cystic fibrosis. I am delighted that Bronchitol and Aridol will continue to be supplied without interruption.”

Incoming Chair, Dr Kathleen Metters, said, “Today, I particularly thank our retiring directors who played an important part in the formulation of the strategy that has led to today’s announcement. Malcolm McComas, who has been Pharmaxis Chair for 11 years, has guided the company through major milestones, and Dr Neil Graham who joined the Board more recently and has contributed greatly to the development of the clinical programs that are the foundations of Syntara. I am honoured to be appointed Chair of Syntara and look forward to working with this exceptional team to advance our pipeline, creating value for the company and its shareholders and benefit for patients.”

Syntara will hold further investor events later this year on its clinical pipeline and future plans.

### Investor briefing today

Pharmaxis will host an investor briefing at 10.30am today, 3 October 2023, to discuss this announcement. Join the briefing at [https://zoom.us/webinar/register/WN\\_3-xnkys5R1OzEap61vN4Pw#/registration](https://zoom.us/webinar/register/WN_3-xnkys5R1OzEap61vN4Pw#/registration)

A recording will be uploaded to the Pharmaxis Investor Centre after the call at <https://www.pharmaxis.com.au/investor-centre/investor-briefing/>.

### Notes:

1. Change of name from Pharmaxis Ltd to Syntara Limited subject to shareholder approval at the Pharmaxis annual general meeting to be held in Sydney on Tuesday 28 November 2023.
2. Nature publications from Pharmaxis collaborations with external researchers.
  - a. Inhibition of lysyl oxidases synergizes with 5-azacytidine to restore erythropoiesis in myelodysplastic and myeloid malignancies; *Nature Communications* 2023  
<https://doi.org/10.1038/s41467-023-37175-8>
  - b. Topical application of an irreversible small molecule inhibitor of lysyl oxidases ameliorates skin scarring and fibrosis, *Nature Communications* 2022  
<https://doi.org/10.1038/s41467-022-33148-5>

- c. A first-in-class pan-lysyl oxidase inhibitor impairs stromal remodeling and enhances gemcitabine response and survival in pancreatic cancer; *Nature Cancer 2023*  
<https://www.nature.com/articles/s43018-023-00614-y>

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**SOURCE:** Pharmaxis Ltd, Sydney, Australia

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**About Pharmaxis**

Pharmaxis Ltd is an Australian clinical stage drug development company developing drugs for inflammatory and fibrotic diseases, with a focus on myelofibrosis. The company has a highly productive drug discovery engine built on its expertise in the chemistry of amine oxidase inhibitors, with drug candidates in clinical trials. Pharmaxis has also developed two respiratory products which are approved and supplied in global markets, generating ongoing revenue.

Pharmaxis is developing its drug PXS-5505 for the bone marrow cancer myelofibrosis which causes a build up of scar tissue that leads to loss of production of red and white blood cells and platelets. The US Food and Drug Administration has granted Orphan Drug Designation to PXS-5055 for the treatment of myelofibrosis and permission under an Investigational Drug Application (IND) to progress a phase 1c/2 clinical trial that began recruitment in Q1 2021.

Other drug candidates being developed from Pharmaxis' amine oxidase chemistry platform are targeting fibrotic diseases such as kidney fibrosis, NASH, pulmonary fibrosis and cardiac fibrosis; fibrotic scarring from burns and other trauma; and other inflammatory diseases. PXS-4728 is being studied in collaboration with Parkinson's UK as a best in class SSAO/MAOB inhibitor to treat sleep disorders and slow progression of neurodegenerative diseases like Parkinson's by reducing neuroinflammation.

Pharmaxis has developed two products from its proprietary spray drying technology that are manufactured and exported from its Sydney facility; Bronchitol® for cystic fibrosis, which is approved and marketed in the United States, Europe, Russia and Australia; and Aridol® for the assessment of asthma, which is approved and marketed in the United States, Europe, Australia and Asia.

Pharmaxis is listed on the Australian Securities Exchange (PXS). Its head office, manufacturing and research facilities are in Sydney, Australia. [www.pharmaxis.com.au](http://www.pharmaxis.com.au)

**About Arna Pharma**

Arna Pharma is part of an alliance of pharmaceutical companies with a presence across more than 20 countries, including Australia and New Zealand. The Arna Pharma alliance develops, manufactures and markets its own, as well as 3rd party pharmaceutical and nutraceutical products. With a strong commitment to patient well-being and scientific excellence, Arna Pharma strives to make a positive impact on the lives of people worldwide.

Arna Pharma has its affiliated state-of-the-art facilities approved to manufacture various medicine formulations including Oral Solids (Tablets, Capsules, Oral Dispersible Films (ODF), Oral Liquids (Suspensions, Powder for Suspensions), Injectables,

Ophthalmic and Semi-Solid Dosage forms (Creams, Ointments). Arna Pharma Allaince's principal product development facilities is in Hyderabad, India with manufacturing, post-production packaging, labelling and other operations being developed in Sydney, NSW, Australia. Arna Pharma has future expansion plan to set up state-of-art facility in Fiji focusing Oral Liquids. Team Arna Pharma is excited to extend its capability by acquiring mannitol respiratory manufacturing unit and distribute its respiratory products globally. [www.arnapharma.com](http://www.arnapharma.com)

### **About Dr Kathleen Metters**

*Kathleen M. Metters PhD* was appointed to the Pharmaxis board of directors in June 2017. Dr Metters has over 25 years of experience in the discovery and development of novel therapies for treatment of serious diseases.

From 2011-2014 Dr Metters was President and Chief Executive officer for Lycera Corp., a biopharmaceutical company pioneering innovative approaches to novel oral medicines for treatment of autoimmune diseases and cancer.

From 1988 to 2011 Dr Metters was employed by Merck & Co. Her various roles at Merck & Co include head of External Discovery and Preclinical Sciences (created to expand Merck's scientific network to the greater research community in academia, biotechnology, and government, building partnerships in life sciences, medicine, engineering, and information technology); head of Worldwide Basic Research (with oversight of research activities at major sites around the globe, across all therapeutic modalities and therapeutic areas; and head of research at Merck Frosst, Canada.

Dr Metters graduated with a B.S. in biochemistry from the University of Manchester Institute for Science and Technology, and a Ph.D. from Imperial College of Science and Technology in London. She completed post-doctoral training at the Centre National de la Recherche Scientifique in France and at the Clinical Research Institute of Montréal.

### **Forward-looking statements**

Forward-looking statements in this media release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential of products and drug candidates. All forward-looking statements included in this media release are based upon information available to us as of the date hereof. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these 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.