

## Quarterly Shareholder Update – September 2022



Dear Shareholder,

In last quarter's report I expressed the opinion that Pharmaxis is fortunate to have a pipeline that is well advanced into the clinic and that we would have much to report on before the end of 2022. Those following the company will have seen us deliver on that promise this quarter with a stream of news flow across the business.

- **Positive interim data from PXS-5505 myelofibrosis trial**

Our lead asset delivered data from the first six completed patients which captured the attention of myelofibrosis experts. The improvement in fibrosis, blood counts and symptom scores combined with a very good tolerability profile suggests that we have a drug which could bring real benefit to patients over and above current standard of care and many of the other drugs under development. We have 15 patients recruited and look forward to completing this study mid-2023.

- **Promising interim data from PXS-6302 – trial in established scars**

This study being run in Perth under the guidance of Professor Fiona Wood AM is now over 80% recruited and the data from the first 8 patients who were on active treatment showed promise. Confirmation of enzyme inhibition and a marked change in biomarker levels suggests we have a scar modifying treatment. We did see some tolerability issues with reddening at the treatment site that has been addressed by reducing the dose frequency in the double blind phase of the study. This 3-month study should report in Q1 2023 and based on Professor Wood's positive assessment of progress to date we are already looking at the protocol for a follow up study looking at scar prevention.

- **Repurposing PXS-4728**

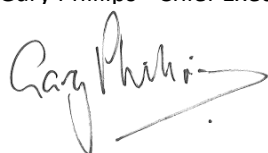
PXS-4728 had already delivered \$83m to Pharmaxis through the partnering with Boehringer Ingelheim for development in NASH before they returned it in 2020. Attracting \$5.2m from Parkinson's UK to fund a study in neuroinflammation for the same drug is a huge achievement that highlights the entrepreneurial, scientific, clinical and commercial skills of the Pharmaxis leadership team. I recommend you read the full story contained in this newsletter and hope you follow the development like I will with great anticipation.

- **Strengthened cash position**

I noted in the June quarter shareholder update that the financial markets were facing a difficult period with access to capital being especially difficult for Biotech companies across the world. It's therefore pleasing to record that Pharmaxis ended the quarter with a proforma cash balance of \$21m after closing a global license deal with Aptar for the Orbital technology in August that netted \$7m and a placement earlier this month that added a further \$5m with two new specialist healthcare funds joining our register. Subject to shareholder approval of the second tranche of the placement, proforma cash increases to \$26m.

I hope you find this report informative. Pharmaxis is a rarity amongst ASX Biotech companies with a pipeline of clinical phase assets and the cash to deliver value defining results in the next 12 months. I look forward to communicating further substantial progress in the upcoming quarter.

Gary Phillips - Chief Executive Officer



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## Products and Pipeline at a glance

Disease/target	Drug	Status
Cystic fibrosis	Bronchitol	Approved
Asthma	Aridol	Approved
Neuro inflammation (SSAO/MAOB inhibitor)	PXS-4728	Phase 2
Myelofibrosis (oral pan-LOX inhibitor)	PXS-5505	Phase 2a ongoing
Liver cancer (oral pan-LOX inhibitor)	PXS-5505	Phase 1c/2a
Scarring (Topical pan-LOX inhibitor)	PXS-6302	Phase 1c ongoing
Chronic fibrotic diseases (LOXL2 inhibitor)	PXS-5382	Phase 1 completed

## Impact of COVID-19

Pharmaxis has continued to effectively manage the challenges of the COVID-19 global pandemic, implementing a range of measures to protect employees and continue the manufacture and supply of its approved respiratory products.

The Company has continued an uninterrupted supply to local and global customers.

The effect on sales is discussed below. Overall, there are large variances in the impact of COVID between markets/countries. While we are seeing a recovery of Aridol and Bronchitol sales in some countries, Bronchitol in particular continues to lag pre-COVID-19 sales levels and the US launch by our partner Chiesi has been significantly disrupted.

The impact of COVID-19 on our clinical studies has been varied from both a regional and time perspective. In particular US centers in our myelofibrosis study have taken much longer than planned to open due to staff shortages and a backlog of earlier trials.

## Drug discovery

### Oral pan-LOX inhibitor program (PXS-5505) in myelofibrosis

Pharmaxis' primary drug development initiative is its pan-Lysyl Oxidase (pan-LOX) inhibitor program focussed on the rare blood cancer, myelofibrosis. PXS-5505 is an orally taken drug that inhibits the lysyl oxidase family of enzymes and was developed from the Company's amine oxidase chemistry platform. In pre-clinical models of myelofibrosis, PXS-5505 reversed the bone marrow fibrosis that drives morbidity and mortality in myelofibrosis and reduced many of the abnormalities associated with this disease.

A phase 1c/2a clinical trial (named MF-101; ClinicalTrials.gov Identifier: NCT04676529), cleared by the FDA under the Investigational New Drug scheme, commenced dosing in the March quarter of 2021. The study aims to demonstrate that PXS-5505 is safe and well tolerated as a monotherapy in myelofibrosis patients who are intolerant, unresponsive or ineligible for treatment with approved JAK inhibitor drugs. The trial has additional secondary endpoints to explore the impact of inhibiting lysyl oxidase enzymes on a number of important disease parameters such as bone marrow fibrosis, cytopenia and spleen volume.

Assessment of the highest dose in the phase 1c study showed inhibition of the target enzymes, LOX and LOXL2, at greater than 90% over a 24-hour period at day 7 and day 28. These levels of LOX and LOXL2 inhibition achieved in myelofibrosis patients exceeds the levels seen in preclinical models of myelofibrosis where PXS-5505 caused disease modifying effects with improvements in blood cell count, diminished spleen size and reduced bone marrow fibrosis. Read the announcement [here](#).

The trial progressed to the phase 2a dose expansion phase at the beginning of the fourth quarter of 2021. In this stage, 24 patients will be treated twice a day for 6 months. The trial has to date recruited 15 patients. Four patients dropped out of the study due to due to a lack of clinical response.

A total of 18 trial sites in Australia, South Korea, Taiwan and the United States are actively recruiting with an additional 2 sites expected to

shortly join the study. The trial aims to complete recruitment by late 2022.

On 19 October the Company released interim data on the first 6 patients to have completed the full 24 weeks of treatment:

- Primary endpoints:
  - PXS5505 has been well tolerated with no serious treatment related adverse events reported.
- Secondary endpoints:
  - 2 out of 6 patients show clinically important improvement in symptoms.
  - 5 out of 6 patients show either stable or improved bone marrow fibrosis scores of  $\geq 1$  grade.
  - 5 out of 6 have stable or improved platelet and/or haemoglobin scores
  - No reductions were seen in spleen volume

Dr Gabriela Hobbs MD, Assistant Professor, Medicine, Harvard Medical School & Clinical Director, Leukemia Service, Massachusetts General Hospital said, “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<sup>1</sup>, typical of this study population. These results support further clinical investigation of PXS5505 in myelofibrosis.”

Read more [here](#).

Watch an interview with CEO Gary Phillips outlining the study data [here](#).

Watch the online investor briefing on 19 October 2022 [here](#).

Myelofibrosis is a cancer with a poor prognosis and limited therapeutic options. Pharmaxis believes that the current treatments can be augmented by use of a pan-LOX inhibitor and the combination should be disease modifying in a market that is conservatively worth US\$1 billion per annum.

PXS-5505 was granted Orphan Drug Designation by the US Food and Drug Administration (FDA) in July 2020.

A presentation at our R&D Showcase Webinar in March by Dr Gabriela Hobbs (Massachusetts General Hospital) on the myelofibrosis landscape and MF-101 can be seen [here](#).

1.Vachhani P, Verstovsek, S Bose P et al: Disease Modification in Myelofibrosis: An Elusive Goal. J Clin Oncol 40:1147-1154, 2022

### Oral pan-LOX inhibitor program (PXS-5505) in liver cancer

Pharmaxis and Wilmot Cancer Institute, University of Rochester Medical Center are scheduled to shortly commence a phase 1c investigator initiated clinical trial of PXS-5505 in hepatocellular carcinoma (HCC) patients. The trial was opened for enrolment on 23 September 2022.

In quarter 4 of 2021 the United States FDA cleared an Investigational New Drug application (IND) submitted by the University of Rochester Medical Center for a phase 1c/2a clinical trial of PXS-5505 in HCC. The IND was submitted following positive preclinical results reported in August 2021. Read the announcement [here](#). The trial design approved by the FDA calls for PXS-5505 to be added to current standard of care; combination of two antibodies against PD-L1 and VEGF) as first line therapy in newly diagnosed patients with unresectable HCC.

Primary liver malignancies have doubled in incidence over the last two decades. These malignancies are now the 4th leading cause of cancer-related mortality worldwide with a 19.6% 5-year relative survival rate. Currently, just 20%-30% HCC are resectable at presentation with many patients relying on chemotherapy. A prominent feature of HCC is the presence of highly fibrotic tissue that increases tumour stiffness, and decreases access of drugs into the tumour.

The approved trial design envisages a phase 1c dose escalation stage where the safety of PXS-5505 in combination with anti- PD-L1 and anti-VEGF antibodies will be assessed at several different doses as well as measures designed to explore the impact of PXS-5505 on fibrosis and drug perfusion. This will be followed by a 6-month phase 2a trial of the selected dose with both

safety and efficacy endpoints. Read the announcement [here](#).

Watch a presentation by Dr Paul Burchard (Rochester NY) at our R&D Showcase Webinar in March on Hepatocellular cancer and details of this Rochester University investigator led study [here](#).

Pharmaxis and Wilmot Cancer Institute, University of Rochester Medical Center have an agreement for the initial phase 1c with a budgeted cost of approximately US\$1.2 million.

### Oral pan-LOX inhibitor program (PXS-5505) in other cancers

Pharmaxis' drug also has potential in several other cancers including myelodysplastic syndrome, pancreatic cancer, and melanoma, where it aims to breakdown the fibrotic tissue in the tumour and enhance the effect of existing chemo and immunotherapies. Pharmaxis has a number of scientific collaborations with centres of excellence across the world who have shown interest in PXS-5505. The Company aims to support these and encourage the use of PXS-5505 in independent investigator initiated clinical studies wherever possible.

Watch a presentation by Dr Tom Cox (Garvan Sydney) at our R&D Showcase Webinar in March on pancreatic cancer and his preclinical work on PXS-5505 [here](#).

### Topical pan-LOX inhibitor program (PXS-6302)

Pharmaxis has a second pan-LOX program that has developed a drug for topical application with the potential for use in scar revision, keloid scarring and scar prevention post surgery.

The Pharmaxis discovery, PXS-6302, has shown promising pre-clinical results in inhibiting the enzymes that play a critical role in the development of scar tissue and has successfully completed phase 1a/b clinical trials.

Pharmaxis is working with the University of Western Australia (UWA) and the Fiona Stanley Hospital to progress the program into two patient trials – a trial in established scars and a trial in scar prevention post surgery.

An initial eight patients with established scars have completed a more detailed safety monitoring and review over three months of treatment with drug.

On 26 September the Company released preliminary results from the first eight patients to complete treatment:

- Skin punch biopsies taken 24 hours after application at the end of the treatment period, show skin penetration and high inhibition of the lysyl oxidase enzymes that, based on pre-clinical models, are fundamental to the scarring process.
- Reduction in the scarring biomarkers hydroxyproline and LOX was observed in the biopsies and based on preclinical models of the scarring process, suggests a normalisation of physiological processes and a disease modifying effect.
- Four patients withdrew from the study after experiencing redness and itching at the site of application that resolved on treatment cessation.

Lead investigator, Professor Fiona Wood AM, Director of the Western Australia Burns Service said, "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."

In the second, placebo controlled phase of the study, 31 out of the planned 42 patients have been recruited. In response to the adverse skin reaction seen with some patients in the unblinded active phase, the treatment regimen has been reduced from once daily to three times a week application to reduce drug exposure whilst maintaining a high level of enzyme inhibition.

Final results are expected in the first half of 2023 when Pharmaxis hopes to confirm an acceptable safety profile, improvements in scar appearance and function for patients on active drug relative to those treated with placebo, and evidence that LOX inhibition is modifying scar tissue at a structural and biochemical level.

Read more [here](#).

Watch an interview with CEO Gary Phillips outlining the study data [here](#).



Watch the Channel Nine News story [here](#).

Watch the online investor briefing by chief executive officer Mr Gary Phillips on 26 September 2022 [here](#).

Pharmaxis is working with the UWA to design a follow up scar prevention study that will address the need for objective endpoints to meet anticipated regulatory hurdles and explore further indications that suit the profile of PXS-6302. It is expected to commence recruitment in the first quarter of 2023.

Also during the quarter, UWA researchers published the pre-clinical studies performed in collaboration with Pharmaxis on topical treatment of skin scars with a pan LOX inhibitor that underpinned the clinical trial. The pre-clinical studies, published in Nature Communications<sup>1</sup>, clearly demonstrated that lysyl oxidase enzymes play a critical role in scar formation and maintenance by stabilising collagen, and driving scar stiffness and appearance. The inhibition of these enzymes by Pharmaxis' topically applied drug was shown to normalise collagen assembly and reduce fibrosis in different skin scar models (scleroderma, burn and hypertrophic scars).

Dr Mark Fear, Senior Research Fellow at the Stan Perron Centre for Excellence in Childhood Burns said, "In these scar models we found that topical application of PXS-6302 reduces collagen deposition and cross-linking 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."

Watch a presentation by Professor Fiona Wood (UWA) and Dr Mark Fear (UWA) at our R&D Showcase Webinar in March on these clinical programs and the science behind them [here](#).

1: Chaudhari et al, 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>

### **SSAO inhibitor program (PXS-4728)**

On 1 September Pharmaxis announced that leading charity, Parkinson's UK, will provide £2.9m (~A\$5m) to fund a Phase 2 study of the Pharmaxis

drug discovery PXS-4728, with the aim of tackling Parkinson's disease at the earliest possible time.

Previous research has identified that the development of isolated Rapid Eye Movement Sleep Behaviour Disorder (iRBD), where otherwise healthy people start acting out their dreams, is the strongest predictor for the development of Parkinson's disease and dementia with Lewy Bodies. A recent multicentre study found that over 70% of iRBD patients transitioned to a neurodegenerative disease.

The study will examine whether targeting inflammation in the brain of people with iRBD might provide a viable neuroprotective strategy to prevent the disease. Working in collaboration, experts from the University of Sydney and the University of Oxford will recruit 40 patients with iRBD to participate in a placebo-controlled Phase 2 trial to evaluate whether PXS-4728 can reduce neuroinflammation as measured by state of the art nuclear scanning techniques.

Principal investigator, Professor Simon Lewis, Director of the Parkinson's Disease Research Clinic at the Brain & Mind Centre, University of Sydney said, "Currently, we have no disease modifying treatments for Parkinson's disease and by the time patients are diagnosed they have already lost a significant number of brain cells. Therefore, targeting patients with iRBD offers us our best strategy for slowing cell death when it could be most impactful. This trial provides an unprecedented opportunity to study the effect of PXS-4728 and its potential role to act as a neuroprotective agent by reducing neuroinflammation in regions of the brain associated with progression to disease."

PXS-4728 is a potent inhibitor of the inflammatory enzyme SSAO (semicarbazide-sensitive amine oxidase) that was discovered by the Pharmaxis research team at the company's Frenchs Forest laboratories in Sydney, Australia. The drug was licenced in 2015 by Boehringer Ingelheim and extensively studied in 11 clinical trials including the inflammatory diseases of NASH and diabetic retinopathy. Despite promising results, Boehringer returned the drug to Pharmaxis due to an off target effect on an additional inflammatory enzyme in the brain, MAO-B (monoamine oxidase B). The study in iRBD is seeking to reduce inflammation by inhibiting both SSAO and MAO-B, a concept supported by preclinical models in neuroinflammation and published literature in

Parkinson's disease. PXS-4728 has passed all long term toxicity studies and has been well tolerated in all clinical studies including two Phase 2 studies. It is therefore an ideal candidate for long term studies in neurodegenerative diseases like Parkinson's, Alzheimer's and Huntington's Disease where neuroinflammation plays a significant role in disease progression.

The funding agreement with Parkinson's UK entails up to £2.9m (~A\$5m) 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 scans of trial participants. The total is expected to cost approximately A\$5.8 million. The Parkinson's Virtual Biotech will receive a return of up to four times its funding from royalties on future revenue Pharmaxis receives from commercialising PXS-4728.

Read more [here](#).

### LOXL2 inhibitor program (PXS-5382)

The Lysyl Oxidase Like 2 (LOXL2) enzyme is fundamental to the fibrotic cascade that follows chronic inflammation in kidney fibrosis, the liver disease NASH, cardiac fibrosis and idiopathic pulmonary fibrosis (IPF) and it also plays a role in some cancers.

The Pharmaxis drug discovery group developed a small molecule inhibitor to the LOXL2 enzyme (PXS-5382) that has completed phase 1 clinical trials and 3-month toxicology studies.

Pharmaxis is currently pursuing a number of different options to enable PXS-5382 to enter the clinic in phase 2 trials in chronic kidney or lung disease and continues discussions with independent investigators in relation to study protocol design and funding options including grants.

## Mannitol respiratory business

### Bronchitol and Aridol

Bronchitol® (mannitol) is an inhaled dry powder for the treatment of cystic fibrosis (CF). The product is approved and marketed in the United States, Australia, Europe, Russia and several other countries.

Aridol® is an innovative lung function test designed to help doctors diagnose and manage asthma. Aridol is approved for sale in Australia, major European countries, the United States, Canada and South Korea.

Both Bronchitol and Aridol are manufactured at the Pharmaxis manufacturing facility in Sydney and sold in Australia and internationally by exclusive distributors and wholesalers.

The largest markets for Bronchitol are currently the United States, Russia and Australia. Chiesi is the Company's distributor in the United States as well as Western Europe; GEN Ilac is the distributor for Russia as well as Turkey, and BTC health is the distributor for both Bronchitol and Aridol in Australia.

### Aptar Pharma Pays Pharmaxis US\$5m to Acquire Orbital Technology

In August 2022 Aptar Pharma, after twelve months of technical and commercial evaluation, exercised its option to acquire the worldwide rights to Pharmaxis' proprietary inhaler Orbital, a unique device designed to deliver high payload dry powder to the lungs. This unique platform was originally developed as a life cycle extending product for Bronchitol® (mannitol). However, it also meets an increasing global need to deliver high doses of other drugs, such as antibiotics, to the lungs.



Aptar Pharma paid Pharmaxis US\$2.5m to exercise the option to the Orbital technology and

immediately exercised its subsequent right to outright acquire the technology by payment of a further US\$2.5m. Pharmaxis retains the rights to devices containing Orbital intellectual property used to deliver inhaled mannitol.

The acquisition by Aptar provided A\$ 7 million in total to Pharmaxis and is a further example of Pharmaxis strategy to generate non-dilutive cash from the mannitol respiratory business.

Read more [here](#).

## Bronchitol

### Impact of COVID

Before prescribing Bronchitol patients are required to have a respiratory test which must be administered in a hospital or clinic. Most respiratory tests were suspended as a result of COVID-19, in part because the resources are required to treat the pandemic and also because of health risks arising from patients exhaling multiple times with force as part of the test.

Furthermore, cystic fibrosis patients have not been visiting hospitals or clinics due the more serious consequences of COVID-19 for people with already compromised lungs.

All markets have been impacted by COVID, but particularly the US where the launch has been significantly constrained. While the outlook in 2022 remains uncertain, Chiesi is committed to the launch and report improving access to hospitals and clinics.

### Bronchitol sales

Pharmaxis supplies Bronchitol to its distributors only several time a year with the quantity and timing of orders based on in-market sales and distributor inventory levels. Quarter by quarter comparison of sales is therefore not indicative of underlying market trends.

While there were no sales to the larger US and Russian markets in the quarter, Pharmaxis has received large orders from its distributors in both territories for delivery later in the year.

Bronchitol sales for the three months ended 30 September 2022 and 30 September 2021 are as follows:

\$'000	Three months	
	2022	2021
<b>Australia</b>	137	185
<b>Western Europe</b>	204	425
<b>Russia</b>	-	2,251
<b>Eastern Europe</b>	253	89
<b>United States</b>	-	-
<b>Total</b>	<b>594</b>	<b>2,950</b>

In the US in-market sales by Chiesi are still small in number but the increase seen in the June quarter was maintained in the September quarter.

In Western Europe in-market sales by Chiesi continue at levels experienced in the 2022 financial year. Sales for the last four quarters are approximately 45% lower than pre-COVID-19 levels (2019 calendar year).

In Australia, in-market unit sales are running slightly below pre-COVID-19 levels (2019 calendar year).

### Aridol sales

As a result of the COVID-19 pandemic lung function testing continues to be limited to more severe cases due to increased risk of airborne infection from patients exhaling multiple times with force as part of the test. In market sales have reduced on country basis consistent with the impact of the pandemic and this impact continues, particularly in the United States.

Sales to Korea were disrupted due to a change in distributor completed in October and orders to supply the Korean market are now being manufactured.

Aridol sales for the three months ended 30 September 2022 and 30 September 2021 are as follows:

\$'000	Three months	
	2022	2021
Australia	107	81
Europe	59	154
USA & Canada	-	-
South Korea	-	87
Rest of world	-	-
<b>Total</b>	<b>166</b>	<b>322</b>

## Corporate

### Retirement of Pharmaxis Medical Director



On 1 July Pharmaxis founding scientist and Medical Director, Dr Brett Charlton, retired after more than 20 years' service with the company. Over this time Dr Charlton oversaw development programs that lead to two products achieving global regulatory approval and the transition of several pipeline products into clinical development including Pharmaxis' current two lead assets in myelofibrosis (PXS-5505) and scarring (PXS-6302).

In announcing the retirement Gary Phillips said, "I'd like to recognise and sincerely thank Dr Charlton for his extensive contribution to the Pharmaxis business and to advances in patient care. His experience and knowledge of transitioning drugs into early phase development has been extremely valuable and we will continue to seek his advice in a part time consultancy capacity until the end of 2022."

### Appointment of Chief Medical Officer



On 1 July the company announced the appointment of Dr Jana Baskar to the role of Chief Medical Officer.

Dr Baskar is a highly experienced executive who has worked in both pharmaceutical and contract research companies and brings significant oversight, clinical development and strategic expertise.

Dr Jana Baskar has over two decades of experience including overseeing more than 70 phase I-III trials of oncology treatments in his 6 years as Medical Director at Novartis Oncology in Australia. In his most recent role, he served as Medical Director for IQVIA in Australia and New Zealand where he also co-chaired the IQVIA ANZ Oncology Advisory Board providing strategic advice to Biopharma companies. Dr Baskar received his Bachelor of Medicine degree (MBBS) from the University of Western Australia. He holds a Master of Medical Science in Drug Development from the University of New South Wales, Sydney (MMedSc) and a Masters of Business Administration (MBA) from the Australian Graduate School of Management. Dr Baskar's extensive background and experience will be particularly valuable as the Company progresses its lead asset, PXS-5505, towards clinical proof of concept in myelofibrosis and other oncology indications.



## Vale: Mr Will Delaat



The directors and staff of Pharmaxis extend their deepest sympathies to the family of Pharmaxis' recently retired Director Mr Will Delaat AM, who recently passed away in Sydney.

Will made a highly significant contribution to the medicines and biopharma sectors over his long and distinguished 40-year career. His deep knowledge and thoughtful leadership encouraged innovation and medicine access and his work has undoubtedly contributed to the better health of countless patients both here and overseas.

Pharmaxis was fortunate to benefit from Will's experience as a global pharmaceutical industry executive. He served for 14 years on the Pharmaxis Board, fulfilling a key role in the Company's evolution including assisting with the international approval and marketing of two innovative respiratory products discovered in Australia, and helping to steer the company's drug discovery and clinical work in fibrosis and inflammation.

Will was a fine example of an executive who treated others with respect. In turn he was held in high regard and affection. He will have a lasting legacy and will be sadly missed.

## Pharmaxis Announces Two-Tranche Placement to Raise A\$10 Million

On 19 October Pharmaxis announced a two tranche placement to institutional investors to raise \$10 million at A\$0.06 per share. The first tranche of approximately \$4.9 million would be raised within the Company's 15% placement capacity while the second tranche of approximately \$5.1 million is subject to shareholder approval at the Company's Annual General Meeting on 29 November 2022.

The funds raised from the placement will be to advance the current clinical study in myelofibrosis as well as other clinical studies that are open or due to commence shortly in scarring, liver cancer and Parkinson's disease, as well as general working capital purposes and capital raising costs.

The placement received strong support from a small group of leading international and domestic institutional investors, including both existing substantial shareholders and new investors.

Read more [here](#).

## 2022 Annual General Meeting

The 2022 Annual General Meeting of Pharmaxis Ltd will be a virtual meeting, and is to be conducted online at 10.00am on 29 November 2022.

If you choose to participate online on the day of the meeting you will be able to view a live webcast of the meeting, ask the Directors questions and submit your votes in real time.

The notice of meeting, proxy form and information on how to participate in the virtual meeting were sent to shareholders on 29 October 2022.

Non-personalised information can be found on the Pharmaxis [website](#).

The Pharmaxis 2022 Statutory Annual Report is available [here](#).

## Recent broker research

MST Access, Morgans and Taylor Collison each updated their research during the quarter. Copies of analyst reports are available on the Pharmaxis [website](#).

## Pharmaxis investor presentation

Pharmaxis' most recent published investor presentation is available on the Company [website](#).

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# Financials

## Key financial metrics

	A\$'000 Three months ended	
	(unaudited) 30-Sep-22	30-Sep-21
<b>Segment results – adjusted EBITDA</b>		
<b>New drug development</b>		
Oral pan-LOX (external costs)	(1,009)	(1,467)
Topical pan-LOX (external costs)	(70)	(81)
Other program external costs (net of grants)	(230)	(222)
Employee costs	(891)	(715)
Overhead	(161)	(102)
R&D tax credit & other income	-	-
<b>EBITDA</b>	<b>(2,361)</b>	<b>(2,587)</b>
<b>Mannitol respiratory business</b>		
Sales	760	3,272
Other income	7,192	2,342
	7,952	5,614
Expenses – employee costs	(1,119)	(1,197)
Expenses – manufacturing purchases	(648)	(1,205)
Expenses – other	(806)	(1,142)
<b>EBITDA</b>	<b>5,379</b>	<b>2,070</b>
<b>Corporate – EBITDA</b>	<b>(333)</b>	<b>(678)</b>
<b>Total Adjusted EBITDA</b>	<b>2,685</b>	<b>(1,195)</b>
<b>Net profit(loss)</b>	<b>943</b>	<b>(3,029)</b>
<b>Statement of cash flows</b>		
Cash inflow/ (outflow) from:		
Operations	3,231	(1,945)
Investing activities	(26)	(40)
Financing activities	(545)	(596)
<b>Total cash generated/(used)</b>	<b>2,660</b>	<b>(2,581)</b>
<b>Cash at bank</b>	<b>11,597</b>	<b>16,131</b>

## Financial highlights

### New drug development

- Oral pan-LOX expenditure in the three months relates to the phase 1c/2a clinical trial in myelofibrosis that commenced patient dosing during the first quarter of 2021, and a small amount in support of pre-clinical work by a European university in relation to the effectiveness of PXS-5505 in models of myelodysplastic syndrome. Prior period expenditures also includes the phase 1c/2a trial.
- Topical pan-LOX expenditure in the three months relates to the phase 1c clinical trial in patients with existing scars that commence dosing in January 2022. Prior period expenditure includes the phase 1a/b clinical trial that reported in August 2021.

**Mannitol respiratory business**

- See above for detail and commentary in relation to Bronchitol and Aridol sales for the quarter.
- Other income includes the \$7.2 million received from Aptar for its purchase of the Orbital inhalation technology. The prior period includes a \$2 million distributor appointment fee received on sale of Australasian Bronchitol and Aridol distribution rights and the fee received for granting of the option over the Orbital technology (\$340,000).
- Manufacturing purchases vary with the level of sales and manufacturing activity.
- Other expenses have reduced by \$0.3m in the quarter compared to the prior period, the result of cost reductions in European distribution/logistics.

**Corporate**

- Excluding foreign exchange gains and losses Corporate EBITDA is typically between \$0.8 million and negative \$1.2 million per quarter. In the current quarter Corporate EBITDA excluding foreign exchange was negative \$1.0 million.

**Net profit (loss)**

- The difference between total adjusted EBITDA and net profit(loss) primarily relates to non-cash items (depreciation, amortization, share based payment expense) and foreign exchange rate gains and losses related to the financing agreement.

**Cash**

- The Company finished the quarter and half with \$11.6 million in cash, including the receipt of \$7 million from Aptar for its purchase of the Orbital inhalation technology.
- The Company expects to receive its 2022 R&D tax credit of \$4.9 million in the December quarter after completion and filing of its 2022 income tax return.
- On 19 October the Company announced a two-tranche placement to raise \$10 million. The first tranche of \$4.9 million settled on 25 October 2022 under the Company's 15% placement capacity. The second tranche of \$5.1 million will settle early December, subject to receiving shareholder approval at the 2022 annual general meeting to be held on 29 November 2022.
- Proforma cash at 30 September is therefore \$21.0 million, increasing to \$25.7 million when the second tranche of the placement is received in December, subject to shareholder approval.

**Other ASX Listing Rule required disclosures:**

Detail in relation to aggregate amount of payments during the quarter to related parties and their associates disclosed in section 6.1 of the Appendix 4C Quarterly Cash Flow Report:

	A\$'000
Non-executive directors' fees	69
Executive director remuneration	164
Total	233

## Additional financial information

Income statements and summary balance sheets are provided below.

### Income statements

	A\$'000 Three months ended	
	(unaudited) 30-Sep-22	30-Sep-21
<b>Revenue</b>		
Revenue from sale of goods	760	3,272
Sale of Orbital technology; distribution rights	7,192	2,340
Interest	17	2
R&D tax incentive	-	-
Other government grants	-	77
Other	113	202
<b>Total revenue</b>	<b>8,082</b>	<b>5,893</b>
<b>Expenses</b>		
Employee costs	(2,807)	(2,665)
Administration & corporate	(798)	(677)
Occupancy & utilities	(323)	(277)
Clinical trials	(1,114)	(1,316)
Drug development	(195)	(531)
Sales, marketing & distribution	(34)	(285)
Safety, medical and regulatory affairs	(305)	(449)
Manufacturing purchases and changes in inventory	(649)	(1,205)
Other	(52)	(75)
Depreciation & amortisation	(560)	(774)
Foreign currency exchange gains & losses	(30)	(536)
Finance costs	(272)	(132)
<b>Total expenses</b>	<b>(7,139)</b>	<b>(8,922)</b>
<b>Net profit (loss) before tax</b>	<b>943</b>	<b>(3,029)</b>
Income tax credit/(expense)	-	-
<b>Net profit (loss) after tax</b>	<b>943</b>	<b>(3,029)</b>

## Summary balance sheets

A\$'000 (unaudited)	30-Sep-22	30-Jun-22
<b>Assets</b>		
Cash	11,597	8,937
R&D tax incentive	4,900	4,900
Accounts receivable	3,687	3,238
Inventory	2,016	2,337
PP&E	2,702	3,212
Other	2,357	2,563
	<b>27,259</b>	<b>25,186</b>
<b>Liabilities</b>		
Accounts payable and accrued expenses	1,370	1,461
Lease liability (Frenchs Forest facility)	3,745	4,290
Financing agreement (not repayable other than as a % of US Bronchitol revenue)	6,830	6,196
Other liabilities	3,309	2,435
	15,254	14,382
<b>Net Assets</b>	<b>12,005</b>	<b>10,804</b>

Authorised for release to the ASX by Pharmaxis Ltd Disclosure Committee.

Contact: David McGarvey, Chief Financial Officer and Company Secretary: T +61 2 9454 7203, E david.mcgarvey@pharmaxis.com.au