

## Quarterly Shareholder Update – December 2022



Dear Shareholder,

Welcome to our first update for 2023 in which I am pleased to report on the solid progress across the Pharmaxis pipeline in the last quarter and the impressive new additions to our Board which will ensure the company is well equipped for what promises to be a busy year ahead. I have summarised some of the key points below but encourage you to read on to get a full understanding of our business as we approach critical milestones that have significant potential to positively impact valuation.

- **PXS-5505 featured in two poster presentations at American Society of Haematology conference**

The data from the first six completed patients of our myelofibrosis phase 2 trial were featured in one poster while another presented the first public disclosure of pre-clinical data from a collaboration we have with the University of Heidelberg in other forms of blood cancers. It was very pleasing to have these posters accepted at the premiere conference for haematologists. They not only garnered a lot of attention but also promoted positive discussion on the role of LOX enzymes in these diseases. The improvement in fibrosis, blood counts and symptom scores, combined with a very good tolerability profile in the myelofibrosis trial, is an attractive profile for physicians treating this disease. As of today we have 18 patients recruited and look forward to completing this study mid-2023. The emerging data will be closely watched by physicians and also by pharmaceutical companies who are active in the myelofibrosis treatment market.

- **PXS-6302 trial in established scars reaches full recruitment**

After a tremendous effort from Professor Fiona Wood AM and her team in Perth the last of the targeted 50 patients in this study were recruited in December. Given the promising data from the first 8 patients who were on active treatment we look forward to seeing the topline results from the remaining 42 patients in the placebo controlled phase of the study early in Q2 2023.

- **Pharmaxis Board strengthened**

With the untimely passing of Will Delaat last year and the fast development of a number of our pipeline assets the Pharmaxis Board moved decisively to strengthen its ranks and, after a comprehensive search process secured two new non-executive directors with impeccable qualifications. Dr. Simon Green and Mr. Hashan De Silva have been appointed to the Board bringing considerable experience and skills which will be highly relevant to the business and important as we navigate the year ahead. You can find summaries of their experience and track record later in this update.

- **The year ahead**

Any year in which a biotech company has not one but two trials reporting safety and efficacy data for the first time in two different diseases promises to be both exciting and significant for shareholders. I am very aware of the scrutiny our data will attract and the need to explain both its clinical and commercial consequences in a clear and timely fashion. Q2 in particular stands out as we schedule not only an update on data from the open label myelofibrosis study but also the topline results from a completed study in patients with established scars.

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 - iRDB (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 IIS recruiting
Scarring (Topical pan-LOX inhibitor)	PXS-6302	Phase 1c IIS fully recruited
Chronic fibrotic diseases (LOXL2 inhibitor)	PXS-5382	Phase 1 completed

## 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 focused 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.

The trial progressed to the phase 2a dose expansion phase at the beginning of the fourth quarter of 2021. In this stage, 24 patients are being treated twice a day for 6 months. The trial has to date recruited 18 patients. Six patients dropped out of the study due to a lack of clinical response.

A total of 19 trial sites in Australia, South Korea, Taiwan and the United States are actively recruiting.

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 exceed 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. PXS-5505 achieves the highest inhibition of lysyl oxidases in this drug class. Read the announcement [here](#).

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

- Primary endpoints:
  - PXS-5505 has been well tolerated with no serious treatment related adverse events reported.
- Secondary endpoints:
  - Excellent pharmacokinetic profile measured in healthy volunteers also present in patients.
  - 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, PXS-5505 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 PXS-5505 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](#).

The interim data was the subject of a poster presentation by Pharmaxis at the 2022 American Society of Hematology conference (ASH) in New Orleans in early December. The presentation reinforced the conclusion that PXS-5505 continues to exhibit an excellent safety profile with encouraging signs of clinical activity in patients ineligible for a JAK inhibitor.

Based on the increasing data that PXS-5505 is a safe and well tolerated drug achieving high target engagement with the potential to make a real difference to patients, the Company will schedule discussions with the FDA in Q2 2023 to discuss the next steps of clinical development for PXS-5505 in myelofibrosis. Read more [here](#).

Myelofibrosis is a cancer with a poor prognosis and limited therapeutic options. Pharmaxis believes that the current treatments can be augmented by the concurrent use of a pan-LOX inhibitor. The combination with standard of care 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 conducting 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 and is currently recruiting.

In 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 inhibits 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 along with 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](#).

The initial phase 1c has a budgeted cost of approximately US\$1.2 million to be funded by Pharmaxis.

## 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](#).

The potential use of PXS-5505 in myelodysplastic syndrome was also the subject of a poster presentation at the 2022 American Society of Hematology conference (ASH) in early December. The poster reported on ground breaking work done in collaboration with Professor Wolf-Karsten Hofmann and Professor Daniel Nowak at Heidelberg University, Germany. The full results will be the subject of a future publication.

## 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 which have been recently published in Nature Communications (<https://doi.org/10.1038/s41467-022-33148-5>). PXS-6302 inhibits the enzymes that play a critical role in the development of scar tissue and has successfully completed phase 1a/b clinical trials.

Pharmaxis, with the University of Western Australia (UWA) and the Fiona Stanley Hospital, has progressed the program into a trial in established scars and is planning further trials.

A phase 1c trial, known as SOLARIA2, is in 50 adult patients treated for scars of more than one year in age and greater than 10 square centimeters in size for a period of 3 months. The first 8 patients

treated were on active drug with the following cohort of 42 which completed recruitment in December randomised 1:1 to active or placebo.

Preliminary results, released in September from the open label phase with 8 patients treated for up to 3 months on active drug, showed a high level of inhibition of enzymes and changes in biomarkers that are implicated in scarring with Professor Fiona Wood commenting, "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." Read more [here](#).

Final results are scheduled for Q2 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.

The Company is working with Professor Wood and her team to design a follow up study that will address the need for objective endpoints to meet anticipated regulatory hurdles in indications that suit the profile of PXS-6302. It is expected to commence recruitment in 2023. 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 Gary Phillips on 26 September 2022 [here](#).

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](#).

## SSAO inhibitor program (PXS-4728)

In September 2022 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

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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 and oxidative stress in the brain of people with iRBD might provide a viable neuroprotective strategy to prevent the disease. This work is based on a long-standing collaboration with Prof Balleine, UNSW (<https://jneuroinflammation.biomedcentral.com/articles/10.1186/s12974-021-02288-8>). 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 study in iRBD is seeking to reduce inflammation and oxidative stress 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 in other indications. 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 and cardiac fibrosis and idiopathic pulmonary fibrosis (IPF). 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,

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major European countries, the United States, Canada and South Korea.

Both Bronchitol and Aridol are manufactured at the Pharmaxis 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.

## Bronchitol

### Impact of COVID

As discussed in prior updates, all markets have been impacted by COVID, but particularly the US where the launch has been significantly constrained. While the outlook in 2023 remains uncertain, Chiesi continues its commitment to the launch and report improving access to hospitals and clinics. The annual North American Cystic Fibrosis Foundation Conference was held in October 2022 - the first time since COVID, allowing a proper launch of Bronchitol to the US cystic fibrosis community.

### 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 shipped a large order to the US early in January and is due to ship a large order to Russia later in the quarter.

Bronchitol sales for the three and six months ended 31 December 2022 and 31 December 2021 are as follows:

\$'000	Three months		Six months	
	2022	2021	2022	2021
<b>Australia</b>	30	217	167	402
<b>Western Europe</b>	104	116	308	541
<b>Russia</b>	-	-	-	2,251
<b>Eastern Europe</b>	0	47	253	136
<b>United States</b>	-	1,616	-	1,616
<b>Total</b>	<b>134</b>	<b>1,995</b>	<b>728</b>	<b>4,945</b>

In the US in-market sales by Chiesi are still small in number but continue to increase.

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 50% lower than pre-COVID-19 levels (2019 calendar year).

In Russia in-market sales for the last four quarters have increased more than 200% since 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 by country basis consistent with the impact of the pandemic and this impact continues, particularly in the United States.

Sales to Korea had been disrupted due to a change in distributor completed in October. Supply to the Korean market has now recommenced.

Aridol sales for the three and six months ended 31 December 2022 and 31 December 2021 are as follows:

\$'000	Three months		Six months	
	2022	2021	2022	2021
<b>Australia</b>	77	92	184	173
<b>Europe</b>	130	349	189	503
<b>USA &amp; Canada</b>	-	-	-	-
<b>South Korea</b>	180	88	180	175
<b>Rest of world</b>	-	-	-	-
<b>Total</b>	<b>387</b>	<b>529</b>	<b>553</b>	<b>851</b>

## Corporate

### Quarterly investor calls

On 31 January Pharmaxis will host a quarterly investor briefing. Register for the briefing or listen to a recording of it [here](#).

### Appointment of Dr Simon Green to Pharmaxis Board



On 14 December Pharmaxis announced the appointment of experienced senior global pharma executive Dr Simon Green to the Board as an independent non-executive director.

Dr Green was actively involved in CSL's global expansion over a 17-year period and 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 Dr Green worked in the USA at leading biotechnology companies Genentech Inc and Chiron Corporation.

Dr Green's skills cover R&D drug development, corporate due diligence, mergers and acquisitions, strategic planning, portfolio management, financial management, intellectual property management, business development, contract management and organisational design.

Dr Green was educated at Monash University (Bachelor's Degree in Science with Honours) and the University of Melbourne (Doctor of

Philosophy, Biochemistry and Immunology). He is also a graduate member of the Australian Institute of Company Directors.

Dr Green is a non-executive director of Clover Corporation Limited and is the founder and CEO of Immunosis Pty Ltd, a start-up diagnostics company.

Announcing the appointment Pharmaxis Chair Malcolm McComas said, "We are delighted to welcome Simon to the Pharmaxis Board. He is an innovator with a strong drive to improve the lives of patients and his deep experience in product development at CSL is very relevant to our near term plans for the commercialisation of our drug candidates for myelofibrosis and other fibrotic diseases."

Read more [here](#).

### Appointment of Mr Hashan De Silva to Pharmaxis Board



On 16 January Pharmaxis announced the appointment of healthcare investment professional Hashan De Silva to the Board as a non-executive director.

Mr De Silva is an experienced life sciences investment specialist. He 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 Mr De Silva worked at Eli Lilly in various roles focused on the commercialisation of new and existing pharmaceuticals.

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Mr De Silva was educated at the University of New South Wales (Bachelor's Degree in Medicine and Master's Degree in Finance) and is a Chartered Financial Analyst.

Until December 2022 Mr De Silva was Head of Healthcare Research at Karst Peak Capital Limited, a Hong Kong and Australian based specialist healthcare fund. He is a non-executive director of Melbourne and Philadelphia based CurveBeam AI.

Announcing the appointment Pharmaxis Chair Malcolm McComas said, "We welcome Hashan to the Pharmaxis Board. He has been an enthusiastic supporter of the Company throughout his healthcare banking career including more recently as head of healthcare research at Karst Peak Capital where he conducted extensive diligence on our science which underpinned three separate investments in Pharmaxis. Hashan's knowledge of the Australian and international healthcare capital markets brings relevant insight and experience to the Pharmaxis board."

Read more [here](#).

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

On 29 November the Pharmaxis 2022 annual general meeting approved the second tranche (\$5.1 million) of a \$10 million placement at A\$0.06 per share. The first tranche (\$4.9 million) was raised within the Company's 15% placement capacity.

The funds raised from the placement will be used to advance the current clinical study in myelofibrosis and other clinical studies that are open or due to commence shortly in scarring, liver

cancer and Parkinson's disease, as well as for general working capital purposes and capital raising costs.

The placement received strong support from a small group of leading international and domestic institutional investors. Platinum Investment Management Regal Funds Management Pty Ltd both entered the share register (8% each) joining existing substantial shareholders BVF Partners LP (15%), Karst Peak Capital Limited (12%) and D&A Income Limited (10%). Read more [here](#).

### **2022 Annual General Meeting**

The 2022 Annual General Meeting of Pharmaxis Ltd was held on 29 November 2022. All resolutions were passed on a poll and received 96% support or greater.

### **Recent broker research**

MST Access and Taylor Collison each updated their research during the quarter, and Bioshares published two articles. 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		Six months ended	
	(unaudited)	31-Dec-22	31-Dec-21	31-Dec-21
<b>Segment results – adjusted EBITDA</b>				
<b>New drug development</b>				
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 & other income	53	-	53	-
<b>EBITDA</b>	<b>(2,648)</b>	<b>(2,282)</b>	<b>(5,009)</b>	<b>(4,869)</b>
<b>Mannitol respiratory business</b>				
Sales	521	2,524	1,281	5,796
Other 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)
<b>EBITDA</b>	<b>(1,971)</b>	<b>(687)</b>	<b>3,408</b>	<b>1,383</b>
<b>Corporate – EBITDA</b>	<b>528</b>	<b>(1,456)</b>	<b>196</b>	<b>(2,134)</b>
<b>Total Adjusted EBITDA</b>	<b>(4,090)</b>	<b>(4,425)</b>	<b>(1,404)</b>	<b>(5,620)</b>
<b>Net profit(loss)</b>	<b>(5,819)</b>	<b>(5,646)</b>	<b>(4,876)</b>	<b>(8,825)</b>
<b>Statement of cash flows</b>				
Cash inflow/ (outflow) from:				
Operations	(3,781)	(3,710)	(540)	(5,655)
Investing activities	(65)	(30)	(91)	(70)
Financing activities	8,699	8,475	8,144	7,879
<b>Total cash generated/(used)</b>	<b>4,853</b>	<b>4,735</b>	<b>7,513</b>	<b>2,154</b>
<b>Cash at bank</b>	<b>16,450</b>	<b>20,866</b>	<b>16,450</b>	<b>20,866</b>

## Financial highlights

### New drug development

- Oral pan-LOX (MF & MDS) expenditure in the three and six 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 include the phase 1c/2a trial.

- Oral pan-LOX (Liver cancer) expenditure relates to the clinical trial being run by the University of Rochester Medical Center which opened to recruitment in the December quarter.
- Topical pan-LOX expenditure in the three and 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. The current period expenditure also includes expenditure to advance additional topical candidates.

#### **Mannitol respiratory business**

- See above for detail and commentary in relation to Bronchitol and Aridol sales for the quarter.
- Other income for the six months includes the \$7.2 million received from Aptar for its purchase of the Orbital inhalation technology. The prior period six month 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 were reduced in the quarter and six months compared to the prior period as a result of cost reductions in European distribution/logistics, increasing in the current quarter due to payment of an annual product registration fee.

#### **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 \$1.1 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 \$16.45 million in cash.
- The Company received its 2022 R&D tax credit of \$4.95 million in January 2023.
- Proforma cash at 31 December is therefore \$21.4 million.
- Receipts for the quarter included the first milestone (A\$1.45m) received from Parkinson's UK in relation to its grant to the Company for a phase 2a study in iRDB. The grant is recorded as income only as the expenditure to which it relates is incurred.

#### **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	Three months ended 31 December 2022	Six months ended 31 December 2022
Non-executive directors' fees	60	129
Executive director remuneration	126	290
Total	186	419

## Additional financial information

Income statements and summary balance sheets are provided below.

### Income statements

	A\$'000 Three months ended		Six months ended	
	(unaudited) 31-Dec-22	31-Dec-21	31-Dec-22	31-Dec-21
<b>Revenue</b>				
Revenue from sale of goods	521	2,524	1,281	5,796
Sale of Orbital technology; distribution rights	-	-	7,192	2,340
Interest	24	10	41	12
R&D tax incentive	53	-	53	-
Grants	359	93	359	170
Other	115	148	228	200
<b>Total revenue</b>	<b>1,071</b>	<b>2,775</b>	<b>9,153</b>	<b>8,518</b>
<b>Expenses</b>				
Employee costs	(2,716)	(2,460)	(5,523)	(5,125)
Administration & corporate	(592)	(656)	(1,390)	(1,333)
Occupancy & utilities	(326)	(203)	(649)	(480)
Clinical trials	(1,412)	(921)	(2,526)	(2,237)
Drug development	(693)	(737)	(888)	(1,268)
Sales, marketing & distribution	(106)	(125)	(140)	(410)
Safety, medical and regulatory affairs	(535)	(514)	(840)	(963)
Manufacturing purchases and changes in inventory	(333)	(1,038)	(982)	(2,243)
Other	(200)	(187)	(252)	(262)
Depreciation & amortisation	(751)	(777)	(1,311)	(1,551)
Foreign currency exchange gains & losses	625	(741)	595	(1,277)
Finance costs	148	(62)	(124)	(194)
<b>Total expenses</b>	<b>(6,890)</b>	<b>(8,421)</b>	<b>(14,029)</b>	<b>(17,343)</b>
<b>Net profit (loss) before tax</b>	<b>(5,819)</b>	<b>(5,646)</b>	<b>(4,876)</b>	<b>(8,825)</b>
Income tax credit/(expense)	-	-	-	-
<b>Net profit (loss) after tax</b>	<b>(5,819)</b>	<b>(5,646)</b>	<b>(4,876)</b>	<b>(8,825)</b>

## Summary balance sheets

A\$'000 (unaudited)	31-Dec-22	30-Jun-22
<b>Assets</b>		
Cash	16,450	8,937
R&D tax incentive	4,953	4,900
Accounts receivable	1,622	3,238
Inventory	2,186	2,337
PP&E	2,042	3,212
Other	3,472	2,563
	<b>30,725</b>	<b>25,186</b>
<b>Liabilities</b>		
Accounts payable and accrued expenses	2,262	1,461
Lease liability (Frenchs Forest facility)	3,192	4,290
Financing agreement (not repayable other than as a % of US Bronchitol revenue)	6,459	6,196
Deferred grant revenue	1,096	-
Other liabilities	2,077	2,435
	<b>15,086</b>	<b>14,382</b>
<b>Net Assets</b>	<b>15,639</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