

Quarterly Shareholder Update – December 2021



Dear Shareholder,

I'll start by wishing you all a Happy New Year. For many 2021 was a year to forget after the disruptions forced upon us by the COVID-19 pandemic and the ongoing challenges of the Omicron variant. Despite that, I find myself in an optimistic frame of mind. We've seen ongoing progress in the Pharmaxis clinical program and the capital raise that shareholders overwhelmingly supported in November significantly strengthens our cash position as we look to deliver results from transformational trials of our drugs by the end of this year.

- **Cancer drug PXS-5505 myelofibrosis trial recruitment on track**

Myelofibrosis is an orphan disease and in our planning we are very mindful of the difficulty of initiating trials for orphan disease drugs in hospitals that are struggling to cope with Covid-19 patients and therefore find it hard to prioritise the required resources for any study that may only recruit one or two patients for their site. After reporting positive data from the dose escalation study last quarter we have therefore moved quickly to not only start recruitment in Australian and South Korean centres, but also add new sites in Taiwan and the USA which should come on stream later this quarter. Our target is to complete recruitment by mid-year so that the last patient to start on drug will complete the 6-month drug treatment before the end of the year and generate the safety and efficacy data we need to prove that PXS-5505 is capable of rewriting the standard of care in myelofibrosis.

- **Study in hepatocellular cancer planned start in 1H 2022**

Our recent capital raise followed swiftly on the heels of the announcement that one of our collaborators, The University of Rochester (NY), had secured an IND approval to study PXS-5505 on top of existing chemotherapy in patients newly diagnosed with hepatocellular carcinoma (liver cancer). The potential of exploring PXS-5505 as a first line treatment in a cancer with the fourth highest mortality rate is exciting. We have been in frequent discussion with our collaborators and the funds from our capital raise have allowed us to negotiate an agreement to provide both drug and funding that will enable the study to start in a matter of months.

- **Anti scarring drug PXS-6302 commences patient recruitment**

It was a busy few months for the Pharmaxis team as we finalised agreements with the University of Western Australia to provide study drug and funding for the trial of our topical anti scarring drug, PXS-6302, in patients with established scars. Today we separately announced dosing of the first patients and results are due later this year. This study is the first of two. Both of them are placebo controlled, three month studies that will each recruit 50 patients. The second study due to start later this year will focus on patients with burn injuries and assess the effectiveness of PXS-6302 in preventing the emergence of problematic scars after the initial surgery and healing process has been completed.

Our focus as a company is now to execute the trial recruitment strategies developed last year and to support our scientific and clinical collaborators to progress our joint projects. I look forward to reporting on the progress from these projects in the months ahead.

Sincerely,



Gary Phillips - Chief Executive Officer

Products and Pipeline at a glance

Disease/target	Drug	Status
Cystic fibrosis	Bronchitol	Approved
Asthma	Aridol	Approved
Neuro inflammation (SSAO inhibitor)	PXS-4728	Phase 2
Myelofibrosis (oral pan-LOX inhibitor)	PXS-5505	Phase 2a commenced
Liver cancer (oral pan-LOX inhibitor)	PXS-5505	Phase 1c/2a
Scarring (Topical pan-LOX inhibitor)	PXS-6302	Phase 1c
Chronic fibrotic diseases (LOXL2 inhibitor)	PXS-5382	Phase 1 completed
Duchenne Muscular Dystrophy (dual SSAO/MAOB inhibitor)	PXS-4699	Pre-clinical

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, and while we are seeing a recovery of Aridol sales in some countries, Bronchitol continues to lag pre-COVID-19 sales levels and the US launch by our partner Chiesi has been significantly disrupted. We are working with our commercial partners to respond on a country by country basis.

Importantly, there has not been to date any significant impact of COVID-19 on our clinical 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 bone 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 (IND) scheme, commenced dosing in the March quarter of 2021 at sites in Australia and South Korea. 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.

At the beginning of the quarter, based on the initial dose escalation phase 1c study, the trial safety committee cleared the trial to progress to the phase 2a dose expansion phase where 24 patients will be treated at the highest dose twice a day for 6 months. 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. Read the announcement [here](#).

All trial sites in Australia and Korea are actively recruiting with additional sites in Taiwan and the United States scheduled to be activated in the current quarter. The trial recruitment is on track to complete by mid 2022.

The levels of LOX and LOXL2 inhibition achieved in myelofibrosis patients in the phase 1c stage 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](#).

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.

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

In early November Pharmaxis announced that an Investigational New Drug application (IND) for a trial of PXS-5505 in hepatocellular carcinoma (HCC) patients had been cleared by the United States FDA. The IND was submitted by the University of Rochester Medical Center, New York State, following the 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 chemotherapy standard of care; combination of a PD-L1 inhibitor and an anti-VEGF drug as first line therapy in newly diagnosed patients with unresectable HCC carcinoma.

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. Under the guidance of Dr. Roberto Hernandez-Alejandro, MD (Chief Division of Transplantation / Hepatobiliary Surgery), the research team at the University of Rochester Medical Center, New York State, have been investigating the role of lysyl oxidase enzymes in liver cancer and whether Pharmaxis' cancer drug PXS-5505 can improve the efficacy of current chemotherapy drugs by inhibiting these enzymes.

Dr. Roberto Hernandez-Alejandro said, "At the University of Rochester Wilmot Cancer Center, we are excited about the prospect of combining PXS-

5505 with standard first line therapy for our unresectable hepatocellular carcinoma patients. The incidence of hepatocellular carcinoma is rising in part due to increasing incidence of cirrhosis and non-alcoholic steatohepatitis. Beyond resection, effective systemic therapies for this disease are lacking, thus new treatment regimens are of significant clinical need."

Dr. Nabeel Badri, (Wilmot Cancer Institute, University of Rochester) added, "PXS-5505 is a potent inhibitor of lysyl oxidase, a key enzyme in collagen crosslinking. By inhibiting the formation of fibrotic tissue in the tumor we hope to improve delivery and effectiveness of immunotherapy drugs which have so far had a limited impact on the survival of our patients. Through preclinical testing and translational research, we have developed a promising clinical trial design that has the potential to benefit these patients and improve our understanding of hepatocellular carcinoma."

The IND submitted by Rochester referenced the previous successful IND lodged by Pharmaxis for the ongoing phase 2 trial of PXS-5505 in myelofibrosis. The approved trial design envisages a dose escalation stage where the safety of PXS-5505 in combination with a PD-L1 inhibitor and an anti-VEGF drug 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 trial of the selected dose with both safety and efficacy endpoints. (read the announcement [here](#))

Subsequent to the end of the quarter Pharmaxis and Wilmot Cancer Institute, University of Rochester Medical Center have been negotiating an agreement under which the phase 1c/2a investigator initiated clinical trial is scheduled to commence in the first half of 2022. The trial is budgeted to cost approximately US\$2.5 million in total, with the initial phase 1c stage, the subject of the current agreement, budgeted to cost approximately US\$1 million. Further details concerning the trial will be released when the trial commences dosing.

Funding of the trial was secured by the recent placement and share purchase.

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

Pharmaxis' drug also has potential in several other cancers including myelodysplastic syndrome, pancreatic cancer, melanoma and glioblastoma, 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.

On 6 January 2022 Pharmaxis announced that Associate Professor Thomas Cox from the Garvan Institute of Medical Research has been awarded an \$827,500 NHMRC Development Grant to lead a multidisciplinary team investigating PXS-5505 as a promising new treatment approach for pancreatic cancer.

Associate Professor Cox said, "Treatment resistance in pancreatic cancer is partially driven by fibrosis – a process by which scar tissue builds up throughout and around the tumour tissue. This scar tissue can prevent treatments from reaching their tumour target and also stimulate cancer growth and spread. Tumours need specific enzymes called lysyl oxidases to build the main constituent of this damaging scar tissue. Our preclinical studies in experimental models have revealed that targeting lysyl oxidases can reduce fibrosis and improve the efficiency of chemotherapy. Further, they have pointed us to an experimental therapy that we will now help progress to clinical trials."

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 scarring from burn wounds.

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.

Subsequent to successful phase 1a/b clinical trial results announced in August (Read the media release [here](#)), the Company has worked with the

University of Western Australia and the Fiona Stanley Hospital to progress the program into two patient trials – a trial in established scars and a trial in burn scars. Ethics approval for the established scar trial was received during the quarter, the necessary agreements were finalised and patient screening for entry into the trial commenced in mid-January and on 31 January we announced dosing of the first patient.

SSAO inhibitor program (previously partnered with Boehringer Ingelheim) (PXS-4728)

The PXS-4728 development program undertaken by Boehringer Ingelheim (BI) from 2015 to 2020 was returned to Pharmaxis during the March quarter of 2021, including the extensive preclinical, clinical, safety and regulatory work carried out by BI. Further analysis of the data package by Pharmaxis scientists has uncovered potential in neuro inflammatory diseases where the clinical benefits would not be impacted by the findings that caused BI to discontinue development. Pharmaxis continues to progress discussions with independent investigators and patient organisations in relation to neuro inflammatory indications, study protocol design and funding options including grants.

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.

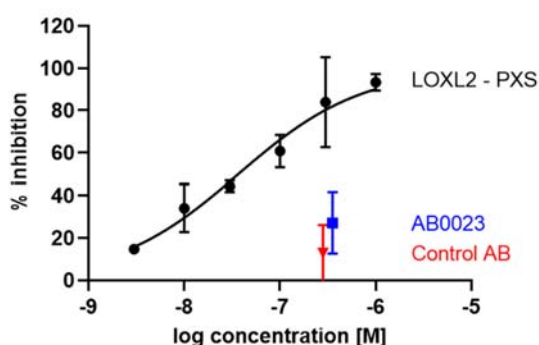
The Pharmaxis drug discovery group developed a small molecule inhibitor to the LOXL2 enzyme (PXS-5382) that has completed phase 1 clinical trials and 3-month toxicology studies.

During the quarter an article was published in Clinical Translational Medicine¹ concerning the Company's investigation of a lysyl oxidase-like 2 (LOXL2) antibody, provided under a material transfer agreement from Gilead. A humanised version of the antibody, simtuzumab, had previously failed to show any significant clinical benefit in five phase 2 clinical trials for a number of diseases, including idiopathic pulmonary

fibrosis (IPF) and NASH, casting doubt over the clinical relevance of LOXL2 as a therapeutic target.

The peer reviewed publication includes results from a number of investigations carried out by Pharmaxis scientists comparing the Gilead antibody AB0023 to one of the Company's small molecule inhibitors. Pharmaxis confirmed the published pharmacological profile of AB0023 in standard assays where it reaches a peak inhibition of LOXL2 of approximately 50%. However, in a Pharmaxis proprietary target engagement assay, AB0023 was found not to specifically inhibit LOXL2 in human plasma. This contrasts with the complete inhibition of LOXL2 enzymatic activity in vitro, in vivo and in a phase 1 study in healthy volunteers that has already been demonstrated by Pharmaxis inhibitors.

LOXL2 enzyme inhibition in human plasma vs drug concentration.



Progress of Pharmaxis effective LOXL2 inhibitors into clinical trials of chronic fibrotic conditions such as IPF, chronic kidney disease and NASH has been challenging given the widely publicised failures of Gilead's LOXL2 antibody, simtuzumab. The results provide a plausible explanation for the failure of simtuzumab in the clinic and clears the way for further development of LOXL2 inhibitors, including Pharmaxis' own PXS-5382.

PXS-5338 (assessed in the published study) and the more potent PXS-5382, are orally taken inhibitors of the enzymes LOXL2 and LOXL3 that are strongly upregulated in a number of chronic fibrotic conditions. Pharmaxis' lead candidate, PXS-5382, has shown strong anti-fibrotic activity in pre-clinical models of IPF, NASH, kidney and cardiac fibrosis, cleared 3 month GLP toxicity studies and completed two phase 1 healthy volunteer studies.

1. Reference: <https://doi.org/10.1002/ctm2.572>

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

Preclinical compound PXS-4699 targeting Duchenne Muscular Dystrophy

In September 2020 Pharmaxis was awarded \$1 million funding from the Biomedical Translation Bridge (BTB) program to significantly advance work on the Company's drug discovery for the treatment of the devastating genetic disorder Duchenne Muscular Dystrophy (DMD), which affects thousands of Australians. The BTB program is administered by MTPConnect.

The Company spent \$108,000 on the program in the quarter (year to date: \$297,000), of which approximately half is to be reimbursed by the BTB. The Company is currently conducting a small preclinical model in response to feedback from review of the program by a disease focused group of leading global DMD clinicians.

Other drug discovery news

New treatments for tissue repair and inflammatory skin disease

Professor Fiona Wood and Associate Professor Mark Fear, from UWA's Burn Injury Research Unit, together with Dr Mehra Haghi, University of Technology Sydney, and two Pharmaxis research staff have been awarded \$590,264 to examine a Pharmaxis' serine protease inhibitor as a potential new treatment for tissue repair and inflammatory skin disease.

Slow tissue repair, excessive scarring and many skin diseases are driven by the body's inappropriate or excessive immune response to an injury or environmental trigger. A key enzyme class that cause this excessive response are serine proteases which will be targeted in the research work.

Associate Professor Fear said, "It is great to be working with Pharmaxis on a new compound and drug target to modify tissue repair and inflammatory skin disease. As our previous collaboration with the anti-fibrotic drug PXS-6302

now moves into clinical trials, this new grant gives us an opportunity to target a new pathway with the potential to improve the healing trajectory for patients, reducing time in hospital and improving their outcomes.”

REDI Fellowship to test and optimise kidney-specific activity of Pharmaxis drug candidates

Continuing the long-standing and successful collaboration with Prof Carol Pollock’s Renal Research Group at the Kolling Institute of the University of Sydney, researcher Dr Long Nguyen has been awarded a REDI Fellowship. In his preclinical research he will investigate the role of Pharmaxis clinical candidate PXS-5370 in preventing the progression of acute kidney injury to chronic kidney disease. The REDI Fellowship is supported by MTPConnect’s Researcher Exchange and Development within Industry (REDI) initiative funded by the Medical Research Future Fund (MRFF). More information is available [here](#).

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.

Business streamlining and outlook

Subsequent to the FDA approval of Bronchitol in late 2020 Pharmaxis pursued a number of initiatives to generate additional non-dilutive cash and take cost out of the mannitol business. In the June quarter of 2021 the Company announced the sale of distribution rights to Bronchitol in Russia and both Bronchitol and Aridol in Australia, generating \$4 million in distributor appointment fees as well as approximately \$1 million per annum in expense savings. In the September quarter the Company announced it had licensed

drug delivery solutions provider Aptar Pharma an option to acquire the worldwide rights to Pharmaxis’ proprietary inhaler Orbital, a unique device designed to deliver high payload dry powder to the lungs. As part of the agreement, Aptar Pharma will evaluate the commercial applications for the Orbital device and further develop the prototype device for unmet market needs. Aptar paid Pharmaxis US\$250k for the 12-month option and will pay a further US\$2.5m on exercise of the option. If exercised, Aptar will pay Pharmaxis industry standard royalties on income received for Orbital. Pharmaxis retains the rights to devices containing Orbital intellectual property used to deliver inhaled mannitol. The Company continues to assist Aptar in its evaluation of the Orbital device.

During the current quarter the Company substantially completed a restructure of its European logistics. Chapper Healthcare was pointed as the distributor for Aridol in the UK and Ireland as well as the point of EU import for both Bronchitol and Aridol when the contract with the current importer expires early in the second quarter of 2022. The changes simplify the Pharmaxis EU quality and logistics operations and move from a fixed cost infrastructure to a volume related variable cost structure realizing savings of approximately \$400,000 per annum starting the June quarter of 2022.

Bronchitol

United States

Chiesi is responsible for the commercialisation of Bronchitol in the United States. Subsequent to the approval of Bronchitol in October 2020 by the US Food and Drug Administration (FDA), Chiesi announced the commercial launch of Bronchitol in the March quarter of 2021.

US launch – 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 have been 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 are not visiting hospitals or clinics due the more serious

consequences of COVID-19 for people with already compromised lungs.

Consequently, the US launch has been significantly impacted in 2021 and the outlook in 2022 remains uncertain with the onset of the Omicron variant.

Western Europe

In the EU, Chiesi is the Pharmaxis exclusive Bronchitol distributor for the markets of the UK, Ireland, Germany, Italy, Norway, Sweden, Finland, Denmark, Cyprus, Spain and Greece.

Pharmaxis also markets Bronchitol in Austria via its German based logistics provider and plans to market in Switzerland via an exclusive distributor once pricing reimbursement is received - expected in the first half of 2022.

Russia

Russia is a valuable, fast-growing Bronchitol market for Pharmaxis as it brings an additional drug to Russian cystic fibrosis patients. Pharmaxis distributor GEN İlaç ve Sağlık Ürünleri San. ve Tic. A.Ş. (GEN) has full responsibility for Bronchitol in Russia.

Australia

Effective 1 July 2021 the distribution rights for Bronchitol and Aridol in Australia (and New Zealand and several Asian territories) were sold to BTC health Ltd. Pharmaxis continues to manufacture and supply Aridol and Bronchitol to BTC Health from its factory in Sydney.

Other territories

Bronchitol is also sold in Turkey, the Czech Republic and Hungary by specialist distributors.

Bronchitol sales

Bronchitol sales for the three and six months ended 31 December 2021 and 31 December 2020 are as follows:

\$'000	Three months		Six months	
	2021	2020	2021	2020
Australia	217	298	402	544
Western Europe	116	103	541	120
Russia	-	1,365	2,251	1,365
Eastern Europe	47	136	136	167
United States	1,616	-	1,616	-
Total	1,995	1,902	4,945	2,196

The COVID-19 pandemic continues to impact the sale of Bronchitol in all markets. Refer to the commentary above in relation to the US launch for additional background. Furthermore, feedback from our commercial partners suggests that patient compliance with medication protocols has reduced as result of the suspension of regular visits to the clinics.

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.

Pharmaxis made a second shipment of Bronchitol to Chiesi for the US in the December quarter.

Pharmaxis supplied two large orders to GEN for Russia in the September quarter with the next order expected later in the calendar year.

In Western Europe in-market sales by Chiesi are approximately 40% lower than pre-COVID-19 levels (2019 calendar year).

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

The Company continues to monitor the situation whilst working with our commercial partners to better understand and respond on a country by country basis.

Aridol sales

As a result of the COVID-19 pandemic lung function testing continues to be limited to more severe cases due to health risks arising 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.

In Europe and Australia, while sales are recovering they are not as yet at pre COVID-19 levels.

The Company continues to monitor the situation.

Aridol sales for the three and six months ended 31 December 2021 and 31 December 2020 are as follows:

\$'000	Three months		Six months	
	2021	2020	2021	2020
Australia	92	116	173	201
Europe	349	139	503	241
USA & Canada	-	98	-	98
South Korea	90	170	177	350
Total	531	523	853	890

Corporate

Placement and Share Purchase Plan

During the quarter the Company raised a total of \$9.8 from a placement and share purchase plan (SPP).

The oversubscribed placement of \$7.2 million made within the Company's 15% placement capacity under ASX Listing Rule 7.1 was priced at \$0.105 per share and received strong support from existing substantial shareholders BVF Partners LP, Karst Peak Capital Limited and D&A Income Ltd, together with a number of new institutional and sophisticated investors. The issue price of A\$0.105 represented a 12.0% discount to the 5-day VWAP. Morgans Corporate Limited acted as the sole lead manager and bookrunner to the placement.

The SPP initially targeted \$2.0 million but the Company elected to accept all eligible applications which totaled \$2.6 million.

The SPP was priced at \$0.105 per share, being the same price that was paid by sophisticated and institutional investors under the placement.

The funds raised will be used to strengthen the Pharmaxis balance sheet as the Company conducts two clinical studies of its lead drug PXS-5505 in cancer - the phase 2a study in myelofibrosis and the phase 1c/2a investigator led study in liver cancer (Hepatocellular Carcinoma or HCC) to be conducted with the University of Rochester.

Initiation of research

During the quarter two firms initiated research coverage on Pharmaxis:



MST Access released an Initiation of Coverage Report on 1 November followed by two updates. The reports are prepared by Senior Life Science Analyst Chris Kallos.



Taylor Collison released an initiation report on 30 November. The report was prepared by Dr Dennis Hulme.

Copies of analyst reports are available on the Pharmaxis website at:

<https://www.pharmaxis.com.au/investor-centre/analyst-coverage/>

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](#).

Recent interviews and articles

- Proactive Investors: “Gary Phillips speaks to Proactive following the news an Investigational New Drug application for a trial of PXS-5505 in hepatocellular carcinoma (HCC) patients has been cleared by the FDA.” (9 November 2021). Watch the interview [here](#).

Pharmaxis investment summary

Pharmaxis most recent investment summary is available on the Company [website](#).

Pharmaxis investor presentation

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

Subscribe to our emails or follow us

If you would like to be advised directly by email each time Pharmaxis issues a media release please [subscribe](#) via our website. You can also follow us on [LinkedIn](#) and [Twitter](#).

Financials

Key financial metrics

	A\$'000	Three months		Six months ended	
	(unaudited)	31-Dec-21	31-Dec-20	31-Dec-21	31-Dec-20
Segment results – adjusted EBITDA					
New drug development					
Oral pan-LOX (external costs)		(1,102)	(546)	(2,569)	(1,323)
Topical pan-LOX (external costs)		(378)	(38)	(459)	(45)
Other program external costs (net of grants)		(84)	(440)	(306)	(730)
Employee costs		(602)	(875)	(1,317)	(1,799)
Overhead		(77)	(145)	(179)	(238)
R&D tax credit		-	-	-	148
EBITDA		(2,243)	(2,044)	(4,830)	(3,987)
Mannitol respiratory business					
Sales		2,526	2,425	5,798	3,086
Other income		-	9,956	2,342	10,098
		2,526	12,381	8,140	13,184
Expenses – employee costs		(1,243)	(1,529)	(2,440)	(2,914)
Expenses – manufacturing purchases		(1,038)	(1,101)	(2,243)	(1,172)
Expenses – other		(762)	(1,162)	(1,904)	(2,374)
EBITDA		(517)	8,589	1,553	6,724
Corporate – EBITDA		(1,895)	(1,164)	(2,573)	(2,024)
Total Adjusted EBITDA		(4,655)	5,381	(5,850)	713
Net profit(loss)		(5,677)	5,027	(8,856)	46
Statement of cash flows					
Cash inflow/ (outflow) from:					
Operations		(3,737)	9,414	(5,682)	5,048
Investing activities		(31)	(181)	(71)	(281)
Financing activities		8,503	(640)	7,907	(1,282)
Total cash generated/(used)		4,735	8,593	2,154	3,485
Cash at bank		20,866	18,249	20,866	18,249

Financial highlights

New drug development

- Oral pan-LOX 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 relate to the initial set up phase of the phase 1c/2a trial.

- Topical pan-LOX expenditure in the three and six months relates to the phase 1a/b clinical trial in scarring that reported in August 2021 and preparation for the phase 1c clinical trial in patients with existing scars due to shortly commence dosing.
- The Company expects to be eligible for a R&D tax credit of 43.5% for the 2022 financial year in respect of all of the Topical pan-LOX program, approximately 15% of the oral pan-LOX program as well as substantially all new drug development employee costs.

Mannitol respiratory business

- See above for detail and commentary in relation to Bronchitol and Aridol sales for the quarter and year.
- Other income includes the \$2 million distributor appointment fee received on sale of Australian and Aridol distribution rights and the fee received in relation granting of an option over the Orbital device (\$340,000).

Corporate

- The quarterly changes in Corporate EBITDA is predominantly due to foreign exchange gains and losses. When these are excluded, Corporate EBITDA is between \$0.9 million and \$1.1m per quarter for the first two quarters of both the 2021 and 2022 financial years.

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.

Cash

- The Company finished the quarter and half with \$20.1 million in cash, strengthened by a placement and share purchase plan that raised a total of \$9.6 million during the quarter.
- Other asset includes \$586,000 receivable in the June quarter of 2022 in relation to the sale of Russian distribution rights.

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-21	31-Dec-20	31-Dec-21	31-Dec-20
Revenue					
Revenue from sale of goods		2,526	2,425	5,798	3,086
Approval milestones		-	9,949	-	10,086
Sale of distribution rights & Orbital option fee		-	-	2,340	-
Interest		10	15	12	36
R&D tax incentive		-	-	-	148
Other government grants		93	97	170	97
Other		147	149	199	234
Total revenue		\$2,776	\$12,635	\$8,519	\$13,687
Expenses					
Employee costs		(2,460)	(3,166)	(5,125)	(6,200)
Administration & corporate		(656)	(691)	(1,333)	(1,220)
Rent, occupancy & utilities		(203)	(280)	(480)	(524)
Clinical trials		(921)	(620)	(2,237)	(1,279)
Drug development		(737)	(502)	(1,268)	(917)
Sales, marketing & distribution		(125)	(392)	(410)	(747)
Safety, medical and regulatory affairs		(514)	(420)	(963)	(977)
Manufacturing purchases and changes in inventory		(1,038)	(1,101)	(2,243)	(1,172)
Other		(221)	(79)	(296)	(126)
Depreciation & amortisation		(777)	(785)	(1,551)	(1,589)
Foreign currency exchange gains & losses		(741)	550	(1,277)	1,362
Finance costs		(60)	(122)	(192)	(252)
Total expenses		(8,453)	(7,608)	(17,375)	(13,641)
Net profit (loss) before tax		(5,677)	5,027	(8,856)	46
Income tax credit/(expense)		-	-	-	-
Net profit (loss) after tax		(5,677)	5,027	(8,856)	46

Summary balance sheets

A\$'000 (unaudited)	31-Dec-21	30-Jun-21
Assets		
Cash	20,866	18,712
Accounts receivable	2,671	1,823
Inventory	1,997	3,638
PP&E	4,794	6,226
Other	3,773	3,191
	\$34,101	\$33,590
Liabilities		
Accounts payable and accrued expenses	3,665	3,199
Lease liability (Frenchs Forest facility)	5,330	6,322
Financing agreement (not repayable other than as a % of US Bronchitol revenue)	19,805	19,080
Other liabilities	1,760	2,144
	\$30,560	\$30,745
Net Assets	\$3,541	\$2,845

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