Pharmaxis Ltd

ABN 75 082 811 630

ASX Half year report – 31 December 2022

Lodged with the ASX under Listing Rule 4.2A

This report is to be read in conjunction with the financial statements for the year ended 30 June 2022 and any public announcements made by Pharmaxis Ltd during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001.

Contents

Pharmaxis Ltd

ABN 75 082 811 630

Reporting period: Half year ended 31 December 2022

(Previous corresponding period: Half year ended 31 December 2021)

Results for announcement to the market

		A$'000		A$'000
Revenue from sale of goods	**Down**	**4,515**	to	**1,281**
Other revenue from ordinary activities	**Up**	**5,150**	to	**7,872**
Total revenue from ordinary activities	**Up**	**635**	to	**9,153**
Loss from ordinary activities after tax	**Down**	**3,949**	to	**4,876**
Loss for the year attributable to members	**Down**	**3,949**	to	**4,876**

Dividends

It is not proposed to pay a dividend.

Other Appendix 4D information

	31 December 2022	31 December 2021
Net tangible assets per ordinary share	**$ 0.020**	$ 0.005

Pharmaxis Ltd
Half-Year Report - 31 December 2022

Contents

This half-year report covers the consolidated entity consisting of Pharmaxis Ltd and its subsidiaries. The financial statements are presented in the Australian currency.

Pharmaxis Ltd is a company limited by shares, incorporated and domiciled in Australia. Its registered office and principal place of business is:

Pharmaxis Ltd
ABN: 75 082 811 630
20 Rodborough Road
Frenchs Forest, NSW 2086
Australia

This interim financial report does not include all the notes of the type normally included in the annual financial statements. Accordingly, this report is to be read in conjunction with the financial statements for the year ended 30 June 2022 and any public announcements made by Pharmaxis Ltd during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act 2001*.

A description of the nature of the consolidated entity's operations and its principal activities is included in the review of operations and activities in the directors' report which is not part of these financial statements.

The half-year report was authorised for issue by the directors on 10 February 2023. The Company has the power to amend and reissue the financial statements.

Through the use of the internet, we have ensured that our corporate reporting is timely, complete, and available globally at minimum cost to the group. Press releases, financial statements and other information are available on our website: www.pharmaxis.com.au.

Your directors present their report on the consolidated entity consisting of Pharmaxis Ltd and the entities it controlled at the end of, or during, the half-year ended 31 December 2022.

Directors

The following persons were directors of the Company during the half-year and up to the date of this report:

Malcolm McComas (Chair)
Gary Phillips (Chief Executive Officer)
Neil Graham
Kathleen Metters
Simon Green (appointed 16 December 2022)
Hashan De Silva (appointed 16 January 2023)
William Delaat (retired 5 August 2022)

Principal activities, review of operations and significant changes in the state of affairs

Overview

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

Established in 1998 and listed on the Australian Securities Exchange in 2003 the Company's head office, manufacturing and research facilities are located in Sydney, Australia.

The Company's product pipeline is founded on its expertise in the chemistry of amine oxidase inhibitors and includes the Company's primary program of oral pan-Lysyl Oxidase Inhibitors (LOX) targeting myelofibrosis and other cancers; topical pan-LOX inhibitors targeting skin scarring after events such as accidents, surgery or burns; selective Lysyl Oxidase Like Inhibitors (LOXL2) targeting chronic fibrotic diseases including kidney fibrosis, pulmonary fibrosis, liver fibrosis (NASH) and cardiac fibrosis; and Semicarbazide-Sensitive Amine Oxidase (SSAO) for neuro inflammatory diseases.

Pharmaxis manufactures and exports its approved products from a purpose built manufacturing facility in Sydney.

- Bronchitol®, an inhaled dry powder for the treatment of cystic fibrosis, has been the subject of three large scale global clinical trials conducted by Pharmaxis. The product is marketed in Europe, Russia, Australia and the United States.
- Aridol®, a lung function test for asthma, was also the subject of a clinical trial program run by Pharmaxis and is approved and sold in the United States, Europe, Australia, Canada and Asia.

The management and Board of Directors have significant relevant experience in drug discovery and pharmaceutical marketing.

Impact of COVID-19

Pharmaxis' response to the COVID-19 global pandemic has been outlined in its recent annual reports and in quarterly shareholder updates. 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 there is recovery of Aridol sales in some countries, Bronchitol continues to lag pre-COVID-19 sales levels and the US launch by the Company's partner Chiesi has been significantly disrupted. Pharmaxis is working with its commercial partners to respond on a country by country basis.

Other than the Company's clinical trial in myelofibrosis where US trial sites have been slower to engage as a result of COVID-19, there has not been to date any significant impact of COVID-19 on clinical trials.

The Company continues to monitor the situation.

Conflict in Ukraine/Russia

Pharmaxis supplies Bronchitol to cystic fibrosis patients in Russia by way of an exclusive distributor, GEN İlaç ve Sağlık Ürünleri San. ve Tic. A.Ş. (GEN) based in Turkey. Bronchitol is on the Russian "Essential Drugs List" and is one of few therapeutic products available for cystic fibrosis patients in Russia. The drug is shipped to Turkey after which

GEN attends to additional packaging requirements for distribution in Russia. GEN is responsible for transport into Russia.

New drug development

During the current half-year the Company made progress in its drug development pipeline as follows:

Oral pan-LOX inhibitor program (PXS-5505)

Pharmaxis is progressing two pan-lysyl oxidase (LOX) programs from its amine oxidase chemistry platform, both of which have now entered clinical trials in patients.

The most advanced pan-LOX program has developed an oral once-a-day drug (PXS-5505) that inhibits all lysyl oxidase family members (LOX, LOXL1, 2, 3 & 4). The compound has shown significant reductions in fibrosis in in-vivo models of myelofibrosis, kidney, liver and lung fibrosis, as well as pancreatic and liver cancer. It is suited to the treatment of severe fibrosis as well as cancer with prominent stroma (connective tissue) or fibrotic metastatic niches.

During the half year:

- The phase 2a stage of a clinical trial in myelofibrosis (MF-101) continued to recruit reaching 18 of the 24 targeted patients. In October the Company released interim data on the first six patients to have completed the full 24 weeks of treatment. In relation to the primary end point PXS-5505 was well tolerated with no serious treatment related adverse events reported. In relation to the secondary endpoints two out of six patients show clinically important improvement in symptoms; five out of six patients showed either stable or improved bone marrow fibrosis scores of greater than one grade; five out of six patients had stable or improved platelet and/or haemoglobin scores; and no reductions were seen in spleen volume. On reviewing the data 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, typical of this study population. These results support further clinical investigation of PXS-5505 in myelofibrosis."
- 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 US Food and Drug Administration in the first half of calendar 2023 to discuss the next steps of clinical development for PXS-5505 in myelofibrosis.
- 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 – a form of liver cancer. The trial was opened for enrolment on September 2022 and is currently recruiting.

While Pharmaxis' primary focus is the development of PXS-5505 for myelofibrosis, with the Company also supporting work by the University of Rochester in liver cancer, the drug has potential in several other cancers including myelodysplastic syndrome and pancreatic cancer. Pharmaxis has a number of scientific collaborations with centres of excellence across the world who have shown interest in PXS-5505. The potential use of PXS-5505 in myelodysplastic syndrome was the subject of a poster presentation at the 2022 American Society of Hematology conference in December 2022. 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)

The Company 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.

A phase 1c trial, known as SOLARIA2, is in 50 adult patients treated for scars of greater than one year in age and over ten 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 eight patients treated for up to three 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."

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.

SSAO inhibitor program (PXS-4828)

In September the Company 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 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 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.

Anti-fibrotic program targeting the LOXL2 enzyme

The Pharmaxis drug discovery group has developed a small number of selective inhibitors to the lysyl oxidase type 2 enzyme (LOXL2). LOXL2 is important in kidney fibrosis, NASH, and the fatal lung disease idiopathic pulmonary fibrosis (IPF). The program 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 a chronic fibrotic disease. The Company continues to have discussions with independent investigators in relation to study protocol design and funding options including grants.

Mannitol business

Approved products - Bronchitol for cystic fibrosis

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.

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.

Approved products – Aridol for asthma diagnosis

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.

Financial Highlights

Revenue from sale of goods

Sales for the half year ended 31 December 2022 were $1.2 million, a decrease of $4.6 million on 31 December 2021 half year sales of $5.8 million.

Sales of Bronchitol for the half year ended 31 December 2022 were $0.7 million, compared to $4.9 million in 2021.

Sales of Aridol in the half-year ended 31 December 2022 were $0.5 million, compared to $0.9 million in 2021.

Bronchitol sales by region are as follows:	**2022 $'000**	**2021 $'000**
Australia	167	402
Western Europe	308	541
Eastern Europe	253	136
Russia	-	2,251
United States	-	1,616
	728	**4,945**

Aridol sales by region are as follows:	**2022 $'000**	**2021 $'000**
Australia	184	173
Europe	189	503
USA & Canada	-	-
South Korea	180	175
	553	**851**

The COVID-19 pandemic continues to impact the sale of Bronchitol in all markets, especially the launch in the US. Before prescribing Bronchitol patients are required to have a respiratory test which must be administered in a hospital or clinic. There are health risks arising from patients exhaling multiple times with force as part of the test. In addition, cystic fibrosis patients are not visiting hospitals or clinics due to the more serious consequences of COVID-19 for people with already compromised lungs.

Pharmaxis supplies Bronchitol to its overseas distributors only several times a year with the quantity and timing of orders based on in-market sales and distributor inventory levels. Half year comparisons of sales are therefore not necessarily indicative of underlying market trends.

While there were no sales to the larger US or Russian markets in the half year, Pharmaxis shipped a large order to the US early in January 2023 and is due to ship a large order to Russia later in the same quarter where strong sales by the Company's distributor continue. In Russia, the in-market sales for the last four quarters have increased more than 200% since pre-COVID-19 levels (2019 calendar year).

In Western Europe the in-market Bronchitol sales by Chiesi are approximately 50% lower than pre-COVID-19 levels (2019 calendar year).

In Australia, the Company's distributor is achieving growth in Aridol sales while sales of Bronchitol have been disrupted by recent reimbursement approval for a new therapy.

Sale of Aridol to one of the Company's European distributors was delayed by packaging supply constraints which have now been resolved with product shipped in February 2023. Sales to South Korea had been disrupted due to a change in distributor completed in October. Supply to the Korean market has now recommenced.

Other revenue

The Company received other revenue of $7.2 million for the half year ended 31 December 2022 compared to $2.4 million for the half year ended 31 December 2021.

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$7.2 million in total to Pharmaxis.

The comparative half year included a distributor appointment fee of A$2 million in relation to the Australian distribution rights sold to BTC health Limited and a $340,000 option fee received from Aptar in relation to the Orbital device.

Other income

The Company received other income of $0.6 million for the half year ended 31 December 2022, compared to $0.4 million for the half year ended 31 December 2021. Other income includes the sub-leasing of parts of the Company's Frenchs Forest premises and grant income. The current half year includes the recognition of $0.3m of the first grant received from Parkinson's UK.

Employee costs

Employee related expenses were $5.5 million in the half-year ended 31 December 2022, a decrease of $0.4 million on the half-year ended 31 December 2021. Employee costs include share based payments (non-cash) totalling $0.4 million in the 2022 half year period, compared to $0.4 million in the corresponding 2021 half year period. At 31 December 2022 the Company employed 69 full time equivalents (31 December 2021: 66) of whom 60 percent were in the Bronchitol and Aridol business, 30 percent in drug development, and 8 percent in corporate.

Administration & corporate

Administration and corporate expenses include accounting & IT, legal & compliance, public company costs, patent portfolio and insurance costs. Administration expenses were $1.4 million in the 2022 half-year period similar to 2021.

Clinical trials

Clinical trials expenses were $2.5 million in the half-year ended 31 December 2022 compared to $2.2 million in the half-year ended 31 December 2021. Clinical trial expenses relate to external costs incurred and are predominately driven by fees paid to the clinical research organisations contracted to manage the clinical trials. In both the 2022 and 2021 half years clinical trial expenses predominantly related to the oral pan-LOX inhibitor program as well as smaller amounts in relation to the clinical trial programs associated with the topical pan-LOX inhibitor program for scarring and the SSAO inhibitor trial in iRDB.

Drug development

Drug development expenses were $0.9 million for the half-year ended 31 December 2022 compared to $1.3 million in the half-year ended 31 December 2021. The drug development expenses predominantly consist of external costs paid to contract research organisations to support the development and selection of new drug candidates that are then progressed through the pre-clinical development path. Drug development expenses also include the costs incurred in running the Company's research laboratory (excluding any allocation of utilities). Drug development expenditure in the 2022 and 2021 half years included the oral and topical pan-LOX inhibitor programs.

Sales, marketing & distribution

Sales & marketing expenses were $0.1 million in the half-year ended 31 December 2022 compared to $0.4 million in the half-year ended 31 December 2021 and represent external costs incurred in selling Bronchitol globally, primarily through distributors. The reduction in expenditure in the current half year is a result of cost reductions in European distribution/logistics effected in the June 2022 half year.

Safety, medical and regulatory affairs expenses

Safety, medical and regulatory affairs expenses relate to external costs directed at monitoring and reporting product safety to regulatory agencies, reviewing material provided to clinicians and patients by the Company and obtaining and maintaining product approvals. Expenses for the current half-year were $0.8 million compared to $1.0 million in the half-year ended 31 December 2021.

Manufacturing purchases and movements in inventory

Manufacturing purchases were $1.0 million in the half-year ended 31 December 2022 compared to $2.2 million in the half-year ended 31 December 2021. This group of costs includes raw material and consumable purchases, external costs associated with running the production and quality control processes and repair & maintenance costs associated with manufacturing equipment and our manufacturing facility as well as the net transfer of manufacturing labour and overhead to and/or from inventory and inventory adjustments. These costs vary with production volumes.

Foreign exchange gains & losses

Foreign exchange gains were $0.6 million in the half-year ended 31 December 2022 compared to losses of $1.3 million in the half-year ended 31 December 2021. The foreign exchange movements include unrealised gains and losses that relate to the movement on the USD denominated financing agreement, being a loss of $1.6 million in the 2022 half year and a loss of $1.0 million in the 2021 half year. The Company holds cash deposits in US dollars and Euros to be utilised for future contractual obligations in those currencies and therefore records foreign exchange gains and losses on those deposits at each period end.

Depreciation & amortisation

Depreciation and amortisation expense was $1.3 million in the half-year ended 31 December 2022, compared to $1.6 million in the year ended 31 December 2021. The decrease reflects certain assets being fully depreciated.

Finance expenses

Finance expenses were $0.1 million in the half-year ended 31 December 2022, similar to the half year ended 31 December 2021. The finance expense relates to the lease liability of our corporate manufacturing facility in Frenchs Forest, Sydney.

Income tax expense

The Company did not earn any taxable income.

Balance Sheet

The group ended the half-year with $16.4 million in cash and cash deposits. In January 2023 the Company received its R&D tax incentive in relation to the 2022 financial year of $4.95 million.

During the half year the Company raised a total of $9.3 million from a two tranche placement approved by shareholders on 29 November 2022.

During the half the Company also received its first payment (A$1.4 million) from the Parkinson's UK grant to fund the clinical trial in iRDB.

Events occurring after the end of the reporting period

On 9 January 2023 the Company received its R&D tax incentive in relation to the 2022 financial year of $4.95 million.

Except for the above, no matters or circumstances have arisen since 31 December 2022 that have significantly affected, or may significantly affect:

(a) the group's operations in future financial years, or

(b) the results of those operations in future financial years, or

(c) the group's state of affairs in future financial years.

Going concern

During the period, the Group generated an operating loss of $4.8 million (FY2022: $1.9 million operating loss and HY2022: $8.8 million operating loss) and net operating cash outflows of $1.0 million (FY2022: net operating cash outflows of $16.1 million and HY2022: $5.9 million net operating cash outflows). As at 31 December 2022, the Group has cash and cash equivalents of $16.4 million (FY2022: $8.9 million and HY2022: $20.8 million).

The Group's ability to continue as a going concern, to recover the carrying value of its assets and meet its commitments as and when they fall due is dependent on the ability of the Group to achieve it sales targets for approved products and manage its cost base, particularly its investment in its drug development pipeline, with its cash currently available, realisation of its other current assets and with additional funding potentially available from:

- additional sales revenue subsequent to the launch of Bronchitol in the US and continued growth of Bronchitol sales in Russia;
- securing new partnering arrangements for programs currently in its drug development pipeline;
- R&D tax incentive income; and/or
- access to additional sources of equity share capital.

The Board and management, having assessed the best available information at this time, believe that the Group will be successful in managing within currently available funds and/or realising additional funds as outlined above and, accordingly, have prepared the financial statements on a going concern basis. Refer to Note 1 of the consolidated financial statements (page 15)

Auditor's independence declaration

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on page 9.

Rounding of amounts

The Company is of a kind referred to in ASIC Corporations (Rounding in the Financial/Directors' Report) Instrument 2016/191, issued by the Australian Securities and Investments Commission, relating to the "rounding off" of amounts in the financial report. Amounts in the directors' report and financial statements have been rounded off to the nearest thousand dollars in accordance with that Instrument.

This report is made in accordance with a resolution of the directors.

Gary J Phillips
Director
10 February 2023

Auditor's Independence Declaration

As lead auditor for the review of Pharmaxis Ltd for the year ended 31 December 2022, I declare that to the best of my knowledge and belief, there have been:

(a) no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and

(b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Pharmaxis Ltd and the entities it controlled during the period.

David Ronald
Partner
PricewaterhouseCoopers

Sydney
10 February 2023

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Pharmaxis Ltd

Consolidated income statement

For the half-year ended 31 December 2022

	31-Dec 2022 $'000	31-Dec 2021 $'000
Revenue from continuing operations		
Revenue from sale of goods	1,281	5,796
Other revenue	7,233	2,352
Other income	639	370
	9,153	**8,518**
Expenses from ordinary activities		
Employee costs	(5,523)	(5,125)
Administration & corporate	(1,390)	(1,333)
Rent, occupancy & utilities	(649)	(480)
Clinical trials	(2,526)	(2,237)
Drug development	(888)	(1,268)
Sales, marketing & distribution	(140)	(410)
Safety, medical and regulatory affairs	(840)	(963)
Manufacturing purchases	(982)	(2,243)
Other	(252)	(262)
Depreciation & amortisation	(1,311)	(1,551)
Foreign exchange gains & losses	595	(1,277)
Finance costs	(123)	(194)
	(14,029)	**(17,343)**
Net profit / (loss) before income tax	**(4,876)**	**(8,825)**
Income tax	-	-
Net profit / (loss) for the period	**(4,876)**	**(8,825)**
Earnings per share:	**Cents**	**Cents**
Basic earnings / (loss) per share	(0.01)	(0.02)
Diluted earnings / (loss) per share	(0.01)	(0.02)

The above consolidated income statement should be read in conjunction with the accompanying notes.

Pharmaxis Ltd

Consolidated statement of comprehensive income

For the half-year ended 31 December 2022

	31-Dec 2022 $'000	31-Dec 2021 $'000
Net profit / (loss) for the period	**(4,876)**	**(8,825)**
Other comprehensive income		
Items that may be reclassified subsequently to profit or loss	-	-
Exchange differences on translation of foreign operations	-	-
Other comprehensive income / (loss) for the period, net of tax	-	-
Total comprehensive income / (loss) for the period	**(4,876)**	**(8,825)**
Total comprehensive income / (loss) for the period is attributable to:		
Owners of Pharmaxis Ltd	**(4,876)**	**(8,825)**

The above consolidated statement of comprehensive income should be read in conjunction with the accompanying notes.

Pharmaxis Ltd

Consolidated balance sheet

As at 31 December 2022

	Notes	31-Dec 2022 $'000	30-Jun 2022 $'000
ASSETS			
Current assets			
Cash and cash equivalents		16,450	8,937
Trade and other receivables		7,478	7,958
Inventories		2,186	2,337
Total current assets		**26,114**	**19,232**
Non-current assets			
Receivables		1,594	1,718
Property, plant and equipment		2,042	3,212
Intangible assets		975	1,024
Total non-current assets		**4,611**	**5,954**
Total assets		**30,725**	**25,186**
LIABILITIES			
Current liabilities			
Trade and other payables		3,152	2,702
Borrowings		2,361	2,031
Other liabilities		235	259
Provisions		2,148	1,107
Total current liabilities		**7,896**	**6,099**
Non-current liabilities			
Borrowings		831	2,259
Other liabilities		6,280	5,938
Provisions		80	86
Total non-current liabilities		**7,191**	**8,283**
Total liabilities		**15,087**	**14,382**
Net assets		**15,638**	**10,804**
EQUITY			
Contributed equity	5 (a)	389,701	380,440
Reserves		23,906	23,457
Accumulated losses		(397,969)	(393,093)
Total equity		**15,638**	**10,804**

The above consolidated balance sheet should be read in conjunction with the accompanying notes

Pharmaxis Ltd

Consolidated statement of changes in equity

For the half-year ended 31 December 2022

	Contributed equity	Reserves	Accumulated losses	Total
	$'000	**$'000**	**$'000**	**$'000**
Balance at 30 June 2021	**371,366**	**22,636**	**(391,157)**	**2,845**
Loss for the period	**-**	**-**	(8,825)	(8,825)
Other comprehensive income	**-**	**-**	**-**	**-**
Total comprehensive loss for the half year	**-**	**-**	**(8,825)**	**(8,825)**
Transactions with owners in their capacity as owners				
Contributions of equity, net of transaction costs	9,074	-	-	9,074
Employee share options	-	454	-	454
	9,071	**454**	**-**	**9,528**
Balance at 31 December 2021	**380,440**	**23,090**	**(399,982)**	**3,548**
Balance at 30 June 2022	**380,440**	**23,457**	**(393,093)**	**10,804**
Loss for the period	**-**	**-**	(4,876)	(4,876)
Other comprehensive income	**-**	**-**	**-**	**-**
Total comprehensive income for the half year	**-**	**-**	**(4,876)**	**(4,876)**
Transactions with owners in their capacity as owners				
Contributions of equity, net of transaction costs	9,261	-	-	9,261
Employee share options	-	449	-	449
	9,261	**449**	**-**	**9,710**
Balance at 31 December 2022	**389,701**	**23,906**	**(397,969)**	**15,638**

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

Pharmaxis Ltd

Consolidated statement of cash flows

For the half-year ended 31 December 2022

	31-Dec 2022 $'000	31-Dec 2021 $'000
Cash flows from operating activities		
Receipts from customers (inclusive of goods and services tax)	2,482	7,255
Payments to suppliers and employees (inclusive of goods and services tax)	(12,188)	(13,823)
	(9,706)	**(6,568)**
Grant receipts from government	-	207
Insurance proceeds	-	700
Sale of Orbital technology to Aptar	7,192	-
Grant received for clinical trial of PXS-4728	1,448	-
Interest received	41	12
Income taxes refunded	-	-
Net cash inflow / (outflow) from operating activities	**(1,025)**	**(5,649)**
Cash flows from investing activities		
Payments for plant and equipment	(93)	(47)
Payments for intangible assets	2	(23)
Net cash outflow from investing activities	**(91)**	**(70)**
Cash flows from financing activities		
Issuance of shares	9,261	9,071
Lease liability payments	(1,099)	(1,184)
Payments to Novaquest	(18)	(14)
Net cash inflow / (outflow) from financing activities	**8,144**	**7,873**
Net increase / (decrease) in cash and cash equivalents	**7,028**	**2,154**
Cash and cash equivalents at the beginning of the financial period	8,937	18,712
Effect of movement in exchange rates on cash held	485	-
Cash and cash equivalents at the end of the financial period	**16,450**	**20,866**

This above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

1. Basis of preparation of half-year report

This condensed consolidated interim financial report for the interim half-year reporting period ended 31 December 2022 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

This condensed consolidated interim financial statement does not include all the notes of the type normally included in annual financial statements. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2022 and any public announcements made by Pharmaxis Ltd during the interim reporting period in accordance with the continuous disclosure requirements of the *Corporations Act* 2001.

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

Going concern

During the period, the Group generated an operating loss of $4.8 million (FY2022: $1.9 million operating loss and HY2022: $8.8 million operating loss) and net operating cash outflows of $1.0 million (FY2022: net operating cash outflows of $16.1 million and HY2022: $5.9 million net operating cash outflows). As at 31 December 2022, the Group has cash and cash equivalents of $16.4 million (FY2022: $8.9 million and HY2022: $20.8 million).

The Group's ability to continue as a going concern, to recover the carrying value of its assets and meet its commitments as and when they fall due is dependent on the ability of the Group to achieve it sales targets for approved products and manage its cost base, particularly its investment in its drug development pipeline, with its cash currently available, realisation of its other current assets and with additional funding potentially available from:

- additional sales revenue subsequent to the recent launch of Bronchitol in the US and continued growth of Bronchitol sales in Russia;
- securing new partnering arrangements for programs currently in its drug development pipeline;
- R&D tax incentive income; and/or
- access to additional sources of equity share capital.

The Board and management, having assessed the best available information at this time, believe that the Group will be successful in managing within currently available funds and/or realising additional funds as outlined above and, accordingly, have prepared the financial statements on a going concern basis.

As a result of these matters, there is a material uncertainty that may cast significant doubt on the Group's ability to continue as a going concern and, therefore the Group may be unable to realise its assets and discharge its liabilities in the normal course of business. However, the Board and management, having assessed the best available information at this time including detailed cash flow forecasting and initiatives currently being pursued, believe that:

- the Group will be successful in managing within currently available funds and/or realising additional funds as outlined above and, accordingly, have prepared the financial statements on a going concern basis, and
- no asset is likely to be realised for an amount less than the amount at which it is recorded in the financial report at 31 December 2022. Accordingly, no adjustments have been made to the financial report relating to the recoverability and classification of the asset carrying amounts or the amounts and classification of liabilities that might be necessary should the Group not continue as a going concern.

New accounting standards and interpretations

There are no mandatory accounting standards and interpretations for the group to consider during the reporting period to 31 December 2022.

2. Segment information

(a) Description of segments

The group's senior management committee, consisting of the chief executive officer, chief financial officer, medical director, head of drug development and head of alliance management, considers the business from a product family group perspective and has identified two reportable segments:

1. Mannitol business – covering the clinical development, manufacture and sale of Bronchitol and Aridol globally. The committee monitors the performance of these two products collectively.
2. New Drug Development – this segment encompasses the drug discovery and early stage clinical development of the group's inflammatory and respiratory drug candidates.

The corporate head office related costs of the group's business are not regarded as a segment but are disclosed below.

(b) Segment information provided to the senior management committee

The segment information provided to the senior management committee for the reportable segments for the half-year ended 31 December 2022 is as follows:

	Mannitol	New Drug Development	Corporate	Total
Half-year 2022	**$'000**	**$'000**	**$'000**	**$'000**
Segment revenue				
Sales revenue	1,281	-	-	1,281
Other revenue and income	7,192	412	228	7,832
	8,473	412	228	9,113
Expenses from ordinary activities				
Employee costs	(2,247)	(1,722)	(1,107)	(5,076)
Administration & corporate	(331)	(96)	(962)	(1,389)
Occupancy & utilities	(435)	(68)	(146)	(649)
Clinical trials	-	(2,526)	-	(2,526)
Drug development	-	(888)	-	(888)
Sales, marketing & distribution	(140)	-	-	(140)
Safety, medical and regulatory affairs	(833)	(7)	-	(840)
Manufacturing purchases	(982)	-	-	(982)
Other (including foreign currency movements)	(97)	(113)	2,185	1,975
	(5,065)	(5,420)	(30)	(10,515)
Adjusted EBITDA	**3,408**	**(5,008)**	**198**	**(1,402)**
Half-year 2021				
Segment revenue				
Sales revenue	5,796	-	-	5,796
Other revenue and income	2,344	170	196	2,710
	8,140	170	196	8,506
Expenses from ordinary activities				
Employee costs	(2,439)	(1,317)	(915)	(4,671)
Administration & corporate	(277)	(118)	(938)	(1,333)
Occupancy & utilities	(380)	(45)	(55)	(480)
Clinical trials	-	(2,237)	-	(2,237)
Drug development	-	(1,268)	-	(1,268)
Sales, marketing & distribution	(410)	-	-	(410)
Safety, medical and regulatory affairs	(940)	(23)	-	(963)
Manufacturing purchases	(2,243)	-	-	(2,243)
Other (including foreign currency movements)	(68)	(31)	(422)	(521)
	(6,757)	(5,039)	(2,330)	(14,126)
Adjusted EBITDA	**1,383**	**(4,869)**	**(2,134)**	**(5,620)**

2. Segment information (continued)

A reconciliation of adjusted EBITDA to operating profit / (loss) before income tax is provided as follows:

	31-Dec 2022 $'000	31-Dec 2021 $'000
Adjusted EBITDA	(1,402)	(5,620)
Interest revenue	41	12
Finance costs - lease liability charges	(124)	(194)
Unrealised/realised net foreign exchange gains/(losses) on financing agreement	(1,631)	(1,018)
Depreciation and amortisation expense	(1,311)	(1,551)
Share-based payment expenses	(449)	(454)
Profit/ (loss) before income tax	**(4,876)**	**(8,825)**

3. Revenue

	31-Dec 2022 $'000	31-Dec 2021 $'000
Sales revenue		
Sale of goods	1,281	5,796
Other revenue		
Proceeds from sale of Australian distribution rights to BTC health Limited	-	2,000
Proceeds from grant of Orbital technology option granted to Aptar Pharma	-	340
Proceeds from sale of Orbital technology to Aptar	7,192	-
Interest	41	12
Other	-	-
	8,514	**2,352**

4. Other income

	31-Dec 2022 $'000	31-Dec 2021 $'000
Export Markets Developments Grant (EMDG) scheme	-	100
R&D tax incentive income	53	-
Biomedical Translation Bridge (BTB) grant	-	159
Other income	586	111
	639	**370**

5. Contributed equity

	Parent entity		Parent entity	
	31-Dec 2022 Shares	30-Jun 2022 Shares	31-Dec 2022 $'000	30-Jun 2022 $'000
(a) Share capital				
Ordinary shares				
Fully paid	718,994,705	549,078,163	389,699	380,440

Movements in ordinary share capital:

Details	Number of shares	Issue price	$'000
Opening balance as at 1 July 2022	549,078,163		380,440
Exercise of employee options	2,349,875	$ - (1)	-
Employee share plan	900,000	$ - (2)	-
Issuance of shares	166,666,667	$0.06	10,000
Transaction costs arising on share issue	-		(741)
Closing Balance at 31 December 2022	**718,994,705**		**389,699**

(1) These related to options issued under the Performance Rights Plan, which are issued with a zero grant price and zero exercise price.

(2) These shares are issued to eligible employees of the Group for a zero issue price.

(b) Ordinary shares

Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the Company in proportion to the number of and amounts paid on the shares held.

On a show of hands, every holder of ordinary shares present at a meeting in person or by proxy is entitled to one vote, and upon a poll each share is entitled to one vote.

6. Contingent liabilities

The group had contingent liabilities at 31 December 2022 in respect of:

Guarantees

The Group's bankers have issued bank guarantees secured by deposits at the bank for which no provision has been made in the accounts. The Group at 31 December 2022 had total deposits of $0.9 million (2020: $0.9 million) covering a rental bond and corporate credit card facility.

7. Events occurring after the end of the reporting period

On 9 January 2023 the Company received its R&D tax incentive in relation to the 2022 financial year of $4.95 million.

Except for the above there have been no circumstances that have arisen since 31 December 2022 that has significantly affected, or may significantly affect:

(a) The group's operations in the future financial years, or

(b) The results of those operations in future financial years; or

(c) The group's state of affairs in future financial years.

8. Earnings per share

	31-Dec 2022 Cents	31-Dec 2021 Cents
(a) Basic earnings per share		
Profit / (loss) attributable to the ordinary owners of the Company	(0.01)	(0.02)
(b) Diluted earnings per share		
Profit / (loss) attributable to the ordinary owners of the company	(0.01)	(0.02)
(c) Weighted average number of shares used as the denominator		
Weighted average number of ordinary shares used as the denominator in calculating basic earnings / (loss) per share	592,942,346	423,382,939
Weighted average number of ordinary shares used as the denominator in calculating diluted earnings / (loss) per share	606,263,888	428,389,094

(d) Information concerning the classification of securities

Options

Options granted to employees under the Pharmaxis Ltd Employee Option Plan are considered to be potential ordinary shares and have been included in the determination of diluted earnings per share to the extent to which they are dilutive.

Pharmaxis Ltd
Directors' declaration
31 December 2022

In the directors' opinion:

(a) the financial statements and notes set out on pages 10 to 19 are in accordance with the *Corporations Act 2001,* including:

  (i) complying with Accounting Standard AASB 134 "Interim Financial Reporting", the *Corporations Regulations 2001* and other mandatory professional reporting requirements; and

  (ii) giving a true and fair view of the consolidated entity's financial position as at 31 December 2022 and of its performance for the half-year ended on that date; and

(b) there are reasonable grounds to believe that Pharmaxis Ltd will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the directors.

Gary J Phillips
Director
Sydney
10 February 2023

Independent auditor's review report to the members of Pharmaxis Ltd

Report on the half-year financial report

Conclusion

We have reviewed the half-year financial report of Pharmaxis Ltd (the Company) and the entities it controlled during the half-year (together the Group), which comprises the consolidated balance sheet as at 31 December 2022, the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, significant accounting policies and explanatory notes and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Pharmaxis Ltd does not comply with the *Corporations Act 2001* including:

1. giving a true and fair view of the Group's financial position as at 31 December 2022 and of its performance for the half-year ended on that date

2. complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity* (ASRE 2410). Our responsibilities are further described in the *Auditor's responsibilities for the review of the half-year financial report* section of our report.

We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional & Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to the audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Material uncertainty relating to going concern

We draw attention to Note 1 in the half-year financial report, which indicates that the Group generated an operating loss of $4.8 million and net operating cash flow outflows of $1.0 million during the half-year ended 31 December 2022. The Group's ability to continue as going concern, to recover the carrying value of its assets and meet its commitments as and when they fall due is dependent on the ability of the Group to achieve its sales targets for approved products and manage its cost base particularly its investment in its drug development pipeline, with its cash currently available, realisation of its other current assets and/or secure additional sources of funding. These conditions, along with other matters set forth in Note 1, indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

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Responsibilities of the directors for the half-year financial report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement whether due to fraud or error.

Auditor's responsibilities for the review of the half-year financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2022 and of its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

PricewaterhouseCoopers

PricewaterhouseCoopers

David Ronald

David Ronald
Partner

Sydney
10 February 2023