Pharmaxis Ltd

ABN 75 082 811 630

ASX Half year report – 31 December 2021

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 2021 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 2021

(Previous corresponding period: Half year ended 31 December 2020)

Results for announcement to the market

		A$'000		A$'000
Revenue from sale of goods	**Up**	**2,710**	to	**5,796**
Other revenue from ordinary activities	**Down**	**7,879**	to	**2,722**
Total revenue from ordinary activities	**Down**	**5,169**	to	**8,518**
Loss from ordinary activities after tax	**Down**	**8,871**	to	**8,825**
Loss for the year attributable to members	**Down**	**8,871**	to	**8,825**

Dividends

It is not proposed to pay a dividend.

Other Appendix 4D information

	31 December 2021	31 December 2020
Net tangible assets per ordinary share	**$ 0.005**	$ 0.002

Pharmaxis Ltd
Half-Year Report - 31 December 2021

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 2021 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 11 February 2022. 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 2021.

Directors

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

Malcolm McComas (Chairman)
Gary Phillips (Chief Executive Officer)
William Delaat
Neil Graham
Kathleen Metters

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

Overview

Pharmaxis is an Australian clinical stage drug development company focused on inflammation and fibrosis (including some cancers) with a portfolio of products at various stages of development and approval.

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.

Importantly, there has not been to date any significant impact of COVID-19 on clinical trials.

The Company continues to monitor the situation.

New drug development

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

<u>Oral pan-LOX inhibitor program</u>

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 1c stage of a clinical trial in myelofibrosis (MF-101) successfully completed each of the three 28 day cohorts at increasing dose levels for each cohort. Assessment with Pharmaxis' proprietary assays of the highest dose showed inhibition of the target enzymes, LOX and LOXL2, at greater than 90% over a 24-hour period at day 7 and day 28. The trial safety committee reviewed the results, identified no safety signals and cleared the study to progress to the phase 2a dose expansion phase.
- the phase 2a dose expansion stage of MF-101 commenced dosing. A total of 24 patients will be treated twice a day for 6 months. The trial is scheduled to report at the end of CY 2022.
- a research team at the University of Rochester Medical Center, New York State, which had been investigating the role of lysyl oxidase enzymes in liver cancer, announced the first public presentation of data from a preclinical study of PXS-5505 in liver cancer. The preclinical study of PXS-5505 firstly examined tumour tissue specimens collected from patients at their institution over a 10-year period and found that LOX enzymes are significantly elevated in human liver cancer and correlate with poor prognosis. Secondly, the research team examined the effect of PXS-5505 with or without chemotherapy treatment in a pre-clinical model of liver cancer and found that the combination of PXS-5505 and chemotherapy significantly improves survival, delays tumor growth, and reduces intratumoral pressure. Finally, the research team proposed that PXS-5505 in combination with standard chemotherapy represents an innovative therapeutic strategy with potential for clinical translation in primary liver malignancy.
- an Investigational New Drug application (IND) for a trial of PXS-5505 in hepatocellular carcinoma (HCC) patients was cleared by the United States Food and Drug Administration (FDA). The IND was submitted by the University of Rochester Medical Center, New York State, following the positive preclinical results noted above. The trial design approved by the FDA calls for PXS-5505 to be added to current chemotherapy standard of care as first line therapy in newly diagnosed patients with unresectable HCC carcinoma (liver cancer).

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, pancreatic cancer, melanoma and glioblastoma. 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.

Topical pan-LOX inhibitor program

The Company's other pan-LOX program has developed a drug for topical application with the potential for use in scar revision, keloid scarring and scarring from burn wounds.

During the half year a phase 1a clinical trial was successfully completed and the Company has since 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 half year, the necessary agreements were finalised and on 31 January 2022 the Company announced dosing of the first patients.

Anti-inflammatory SSAO inhibitor PXS-4828 (formerly partnered with Boehringer Ingelheim).

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 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.

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 kidney disease. The Company continues to have discussions with independent investigators in relation to study protocol design and funding options including grants.

Anti-inflammatory dual SSAO/MAOB inhibitor (PXS-4699)

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 $297,000 in the half year 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.

Mannitol business

Approved products - Bronchitol for cystic fibrosis

Bronchitol is an inhaled dry powder for the treatment of cystic fibrosis. The product is approved and marketed in the United States, Europe, Russia and Australia.

- Pharmaxis has partnered its work on Bronchitol for the United States with Chiesi Group (Chiesi), a global pharmaceutical company headquartered in Parma, Italy. On 30 October 2020 the US FDA approved Bronchitol as an add-on maintenance therapy to improve pulmonary function in cystic fibrosis patients 18 years of age and older. Pharmaxis earns mid to high teen percentage of Chiesi net US sales and is the exclusive supplier of Bronchitol for the US market on a long term cost-plus basis. Three sales milestones totalling US$15.0 million are also payable on achieving annual sales thresholds. The additional volume of Bronchitol that Pharmaxis will produce to supply the US, on top of Russia, Australia and 17 other international markets, will greatly increase capacity utilisation and substantially improve the unit cost of goods. Pharmaxis expects Bronchitol sales in the US market to contribute strongly to the product's global sales growth and profit from its launch making the Pharmaxis mannitol business cash flow positive. Chiesi launched Bronchitol in the first half of 2021. However, the US launch has been significantly impacted by COVID-19 and the outlook remains uncertain with the onset of the Omicron variant.
- In the EU, Pharmaxis has appointed Chiesi as its exclusive distributor for Western Europe (the UK, Ireland, Italy, Germany, Norway, Sweden, Finland, Denmark, Cyprus and Greece).
- In Russia and Turkey Pharmaxis has appointed GEN İlaç ve Sağlık Ürünleri San. ve Tic. A.Ş. (GEN) as its exclusive distributor. While GEN has been a trusted Pharmaxis business partner in Turkey for many years, it only acquired the Russian rights in the first half of 2021 where it now has full responsibility for Bronchitol within Russia.
- Effective 1 July 2021 the Company sold the Australian distribution rights for Bronchitol (and Aridol) in Australia (and New Zealand and several Asian territories) to Bioimpact Pty Ltd, a wholly owned subsidiary of BTC health Limited. Pharmaxis received a distributor appointment fee of A$2 million in July 2021. Pharmaxis will manufacture and supply Aridol and Bronchitol to BTC health from its factory in Sydney.

Approved products – Aridol for asthma diagnosis

Aridol is designed to identify twitchy or hyper-responsive airways and to assist in diagnosing and managing asthma. It is a simple-to-use airways inflammation test administered as a dry powder in a hand-held inhaler.

Aridol is approved and sold in the United States, Canada, Australia, South Korea and a number of European countries.

Other

During the half year the Company licensed drug delivery solutions provider Aptar Pharma, purchased 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 half year the Company substantially completed a restructure of its European logistics and quality support. Chapper Healthcare was appointed and will be 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 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.

Financial Highlights

Revenue from sale of goods

Sales for the half year ended 31 December 2021 were $5.8 million, an increase of $2.7 million on 31 December 2020 half year sales of $3.1 million.

Sales of Bronchitol for the half year ended 31 December 2021 were $4.9 million, compared to $2.2 million in 2020.

Sales of Aridol in the half-year ended 31 December 2021 were $0.9 million, similar to 2020.

Bronchitol sales by region are as follows:	**2021 $'000**	**2020 $'000**
Australia	402	544
Western Europe	541	120
Eastern Europe	136	167
Russia	2,251	1,365
United States	1,616	-
	4,945	**2,196**

Aridol sales by region are as follows:	**2021 $'000**	**2020 $'000**
Australia	173	201
Europe	503	241
USA & Canada	-	98
South Korea	175	350
	851	**890**

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. 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 to the more serious consequences of COVID-19 for people with already compromised lungs. Feedback from our commercial partners suggests that patient compliance with medication protocols has also reduced as result of the suspension of regular visits to the clinics.

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 is therefore not necessarily 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 2022 calendar year.

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

In Australia, the current year sales of both Bronchitol and Aridol are at distributor pricing. In-market unit sales are now running above pre-COVID-19 levels (2019 calendar year).

As a result of the COVID-19 pandemic lung function testing such as Aridol 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 at an individual 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 whilst working with our commercial partners to better understand and respond on a country by country basis.

Other revenue

The Company received other revenue of $2.4 million for the half year ended 31 December 2021 compared to $10.1 million for the half year ended 31 December 2020. The current half year includes 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 Oribital device. The comparative half year included $9.9 million in milestones received for the approval of Bronchitol in the US.

Other income

The Company received other income of $0.4 million for the half year ended 31 December 2020, similar to the half year ended 31 December 2019. Other income represents the sub-leasing of parts of the Company's Frenchs Forest premises, an additional R&D tax credit claim from the prior financial years, and government and industry body grants.

Employee costs

Employee related expenses were $5.1 million in the half-year ended 31 December 2021, a decrease of $1.1 million on the half-year ended 31 December 2020. Employee expenses decreased in all segments of the business reflecting elimination of certain higher salaried positions and the 2020 half year including ex-gratia bonuses related to US Bronchitol approval. Employee costs include share based payments (non-cash) totalling $0.5 million in the 2021 half year period, compared to $0.4 million in the corresponding 2020 half year period. At 31 December 2021 the Company employed 66 full time equivalents (31 December 2020: 64) of whom 72 percent were in the Bronchitol and Aridol business, 20 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 $1.3 million in the 2021 half-year period similar to 2020.

Clinical trials

Clinical trials expenses were $2.2 million in the half-year ended 31 December 2021 compared to $1.3 million in the half-year ended 31 December 2020. 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 2021 and 2020 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.

Drug development

Drug development expenses were $1.3 million for the half-year ended 31 December 2021 compared to $0.9 million in the half-year ended 31 December 2020. 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 lease and utilities). Drug development expenditure in the 2021 half year included the oral pan-LOX inhibitor program, the topical pan-LOX inhibitor program and the SSAO/MAOB program, the latter being fifty percent grant funded by the Australian government BTB program, administered by MTPConnect. Drug development expenditure in the 2020 half year also included the SSAO/MPO program.

Sales, marketing & distribution

Sales & marketing expenses were $0.4 million in the half-year ended 31 December 2021 compared to $0.7 million in the half-year ended 31 December 2020 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 the sale of Russian Bronchitol distribution rights earlier in the year with the new distributor taking on selling activities previously the responsibility of Pharmaxis.

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 $1.0 million compared to $1.0 million in the half-year ended 31 December 2020.

Manufacturing purchases and movements in inventory

Manufacturing purchases were $2.2 million in the half-year ended 31 December 2021 compared to $1.2 million in the half-year ended 31 December 2020. 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 losses were $1.3 million in the half-year ended 31 December 2021 compared to gains of $1.4 million in the half-year ended 31 December 2020. The foreign exchange movements include unrealised gains and losses that relate to the movement on the USD denominated NovaQuest finance agreement, being a loss of $1.0 million in the 2021 half year and a gain of $2.3 million in relation to the 2020 half year. In the half year ended 31 December 2020, a loss of $0.7 million was realised on the receipt of the Chiesi FDA approval milestone.

Depreciation & amortisation

Depreciation and amortisation expense was $1.6 million in the half-year ended 31 December 2021, similar to the half-year ended 31 December 2020.

Finance expenses

Finance expenses were $0.2 million in the half-year ended 31 December 2021 compared to $0.3 million in the half year ended 31 December 2020. 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 $20.9 million in cash and cash deposits. During the half year the Company raised a total of $9.8 million 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 $0.105 represented a 12.0% discount to the 5-day VWAP. Morgans Corporate Limited acted as the sole lead manager and book runner to the placement.

The SPP initially targeted $2.0 million but the Company elected to accept all eligible applications, which totalled $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.

Events occurring after the end of the reporting period

No matters or circumstances have arisen since 31 December 2021 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 $8.8 million (FY2021: $3.0 million operating loss and HY2021: $0.05 million operating profit) and net operating cash outflows of $5.9 million (FY2021: net operating cash inflows of $3.1 million net operating cash inflows and HY2020: $5.0 million net operating cash inflows). As at 31 December 2021, the Group has cash and cash equivalents of $20.9 million (FY2021: $18.7 million and HY2021: $18.2 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.

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
11 February 2022

Auditor's Independence Declaration

As lead auditor for the review of Pharmaxis Ltd for the half-year ended 31 December 2021, I declare that to the best of my knowledge and belief, there have been:

1. no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
2. 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
11 February 2022

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Pharmaxis Ltd

Consolidated income statement

For the half-year ended 31 December 2021

	31-Dec 2021 $'000	31-Dec 2020 $'000
Revenue from continuing operations		
Revenue from sale of goods	5,796	3,086
Other revenue	2,352	10,122
Other income	370	479
	8,518	**13,687**
Expenses from ordinary activities		
Employee costs	(5,125)	(6,200)
Administration & corporate	(1,333)	(1,220)
Rent, occupancy & utilities	(480)	(524)
Clinical trials	(2,237)	(1,279)
Drug development	(1,268)	(917)
Sales, marketing & distribution	(410)	(747)
Safety, medical and regulatory affairs	(963)	(977)
Manufacturing purchases	(2,243)	(1,172)
Other	(262)	(126)
Depreciation & amortisation	(1,551)	(1,589)
Foreign exchange gains & losses	(1,277)	1,362
Finance costs	(194)	(252)
	(17,343)	**(13,641)**
Net profit / (loss) before income tax	**(8,825)**	**46**
Income tax	-	-
Net profit / (loss) for the period	**(8,825)**	**46**
Earnings per share:	**Cents**	**Cents**
Basic earnings / (loss) per share	(0.02)	(0.00)
Diluted earnings / (loss) per share	(0.02)	(0.00)

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 2021

	31-Dec 2021 $'000	31-Dec 2020 $'000
Net profit / (loss) for the period	**(8,825)**	**46**
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	**(8,825)**	**46**
Total comprehensive income / (loss) for the period is attributable to:		
Owners of Pharmaxis Ltd	**(8,825)**	**46**

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 2021

	Notes	31-Dec 2021 $'000	30-Jun 2021 $'000
ASSETS			
Current assets			
Cash and cash equivalents		20,866	18,712
Trade and other receivables		4,437	2,959
Inventories		1,997	3,638
Total current assets		**27,300**	**25,309**
Non-current assets			
Receivables		944	942
Property, plant and equipment		5,345	6,226
Intangible assets		1,062	1,113
Total non-current assets		**7,351**	**8,281**
Total assets		**34,651**	**33,590**
LIABILITIES			
Current liabilities			
Trade and other payables		4,294	3,765
Borrowings		2,267	2,032
Other liabilities		1,020	1,018
Provisions		1,075	1,072
Total current liabilities		**8,656**	**7,887**
Non-current liabilities			
Borrowings		3,614	4,290
Other liabilities		18,765	18,515
Provisions		68	53
Total non-current liabilities		**22,447**	**22,858**
Total liabilities		**31,103**	**30,745**
Net assets		**3,548**	**2,845**
EQUITY			
Contributed equity	5 (a)	380,439	371,366
Reserves		23,090	22,636
Accumulated losses		(399,981)	(391,157)
Total equity		**3,548**	**2,845**

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 2021

	Contributed equity	Reserves	Accumulated losses	Total
	$'000	**$'000**	**$'000**	**$'000**
Balance at 30 June 2020	**367,301**	**22,317**	**(388,187)**	**1,431**
Profit for the period	-	-	46	**46**
Other comprehensive income	-	-	-	**-**
Total comprehensive loss for the half year	**-**	**-**	**46**	**46**
Transactions with owners in their capacity as owners				
Contributions of equity, net of transaction costs	-	-	-	**-**
Employee share options	-	411	-	**411**
	-	411	-	**411**
Balance at 31 December 2020	**367,301**	**22,728**	**(388,141)**	**1,888**
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 income 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**

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 2021

	31-Dec 2021 $'000	31-Dec 2020 $'000
Cash flows from operating activities		
Receipts from customers (inclusive of goods and services tax)	7,255	3,602
Payments to suppliers and employees (inclusive of goods and services tax)	(14,115)	(13,638)
	(6,860)	**(10,036)**
Grant receipts from government	207	5,099
Insurance proceeds	700	-
Receipt of the Chiesi US FDA milestone	-	9,949
Interest received	12	36
Income taxes refunded	-	-
Net cash inflow / (outflow) from operating activities	**(5,941)**	**5,048**
Cash flows from investing activities		
Payments for plant and equipment	(47)	(126)
Payments for intangible assets	(23)	(155)
Net cash outflow from investing activities	**(70)**	**(281)**
Cash flows from financing activities		
Issuance of shares	9,071	-
Lease liability payments	(1,184)	(1,147)
Financing agreement payments	278	(135)
Net cash inflow / (outflow) from financing activities	**8,165**	**(1,282)**
Net increase / (decrease) in cash and cash equivalents	**2,154**	**3,485**
Cash and cash equivalents at the beginning of the financial period	18,712	14,764
Cash and cash equivalents at the end of the financial period	**20,866**	**18,249**

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 2021 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 2021 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 $8.8 million (FY2021: $3.0 million operating loss and HY2021: $0.05 million operating profit) and net operating cash outflows of $5.9 million (FY2021: net operating cash inflows of $3.1 million net operating cash inflows and HY2020: $5.0 million net operating cash inflows). As at 31 December 2021, the Group has cash and cash equivalents of $20.9 million (FY2021: $18.7 million and HY2021: $18.2 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.

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 2021.

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.

2. Segment information (continued)

(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 2021 is as follows:

	Mannitol	New Drug Development	Corporate	Total
Half-year 2021	**$'000**	**$'000**	**$'000**	**$'000**
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)
Rent, 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	(68)	(31)	(422)	(521)
	(6,757)	(5,039)	(2,330)	(14,126)
Adjusted EBITDA	**1,383**	**(4,869)**	**(2,134)**	**(5,620)**
Half-year 2020				
Total segment revenue				
Sales revenue	3,086	-	-	3,086
R&D tax credit	-	148	-	148
Other revenue and income	10,098	98	221	10,417
	13,184	246	221	13,651
Expenses from ordinary activities				
Employee costs	(2,912)	(1,799)	(1,078)	(5,789)
Administration & corporate	(192)	(99)	(929)	(1,220)
Rent, occupancy & utilities	(450)	(43)	(31)	(524)
Clinical trials	-	(1,279)	-	(1,279)
Drug development	-	(917)	-	(917)
Sales, marketing & distribution	(747)	-	-	(747)
Safety, medical and regulatory affairs	(915)	(62)	-	(977)
Manufacturing purchases	(1,172)	-	-	(1,172)
Other	(72)	(34)	(207)	(313)
	(6,460)	(4,233)	(2,245)	(12,938)
Adjusted EBITDA	**6,724**	**(3,987)**	**(2,024)**	**713**

2. Segment information (continued)

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

	31-Dec 2021 $'000	31-Dec 2020 $'000
Adjusted EBITDA	(5,620)	713
Interest revenue	12	36
Finance costs - lease liability charges	(194)	(252)
Unrealised/realised net foreign exchange gains/(losses)	(1,018)	1,549
Depreciation and amortisation expense	(1,551)	(1,589)
Share-based payment expenses	(454)	(411)
Profit/ (loss) before income tax	**(8,825)**	**46**

3. Revenue

	31-Dec 2021 $'000	31-Dec 2020 $'000
Sales revenue		
Sale of goods	5,796	3,086
Other revenue		
Chiesi US FDA approval milestone	-	9,949
Proceeds from sale of Australian distribution rights to BTC health Limited	2,000	-
Proceeds from milestone arrangement with Aptar Pharma	340	-
Interest	12	36
Other	-	137
	2,352	**10,122**

4. Other income

	31-Dec 2021 $'000	31-Dec 2020 $'000
Export Markets Developments Grant (EMDG) scheme	100	-
R&D tax incentive income	-	148
Government COVID-19 cash flow boost	-	50
Biomedical Translation Bridge (BTB) grant	159	98
Other income	111	183
	370	**479**

5. Contributed equity

	Parent entity		Parent entity	
	31-Dec 2021 Shares	30-Jun 2020 Shares	31-Dec 2021 $'000	30-Jun 2021 $'000
(a) Share capital				
Ordinary shares				
Fully paid	548,923,163	452,824,164	380,439	371,366

Movements in ordinary share capital:

Details	Number of shares	Issue price	$'000
Opening balance as at 1 July 2021	452,824,164		371,366
Exercise of employee options	2,792,450	$ - (1)	-
Employee Share Plan	522,000	$ - (2)	-
Issuance of shares	92,784,549	$0.1050	9,742
Transaction costs arising on share issue			(669)
Closing Balance at 31 December 2021	**548,923,163**		**380,439**

(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 2021 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 2021 had a 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

There have been no circumstances that have arisen since 31 December 2021 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 2021 Cents	31-Dec 2020 Cents
(a) Basic earnings per share		
Profit / (loss) attributable to the ordinary owners of the Company	(0.02)	0.00
(b) Diluted earnings per share		
Profit / (loss) attributable to the ordinary owners of the company	(0.02)	0.00
(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	423,382,939	396,233,387
Weighted average number of ordinary shares used as the denominator in calculating diluted earnings / (loss) per share	428,389,094	407,481,112

(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 2021

In the directors' opinion:

(a) the financial statements and notes set out on pages 9 to 18 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 2021 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
11 February 2022

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 2021, the consolidated statement of comprehensive income, consolidated statement of changes in equity, consolidated statement of cash flows and consolidated income statement 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 2021 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.

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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 2021 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

David Ronald
Partner

Sydney
11 February 2022