Pharmaxis Ltd

ABN 75 082 811 630

ASX Half year report – 31 December 2020

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 2020 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 2020

(Previous corresponding period: Half year ended 31 December 2019)

Results for announcement to the market

		A$'000		A$'000
Revenue from sale of goods	**Down**	**173**	to	**3,086**
Other revenue from ordinary activities	**Up**	**9,839**	to	**10,601**
Total revenue from ordinary activities	**Up**	**9,666**	to	**13,687**
Profit from ordinary activities after tax	**Up**	**10,365**	to	**46**
Net profit for the year attributable to members	**Up**	**10,365**	to	**46**

Dividends

It is not proposed to pay a dividend.

Other Appendix 4D information

	31 December 2020	31 December 2019
Net tangible assets per ordinary share	**$ 0.002**	$ 0.011

Pharmaxis Ltd
Half-Year Report - 31 December 2020

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
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 2020 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 2021. 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.

Pharmaxis Ltd

Directors' Report

For the half-year ended 31 December 2020

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 2020.

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
Kathleen Metters
Edward Rayner (retired 14th August 2020)
Neil Graham

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

Overview

Pharmaxis is an Australian pharmaceutical research company focused on inflammation and fibrosis 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 development pipeline is centred on its expertise in amine oxidase chemistry. The Company is currently focussed on development of its oral pan-Lysyl Oxidase (LOX) inhibitor that is in development for the rare bone cancer myelofibrosis, and is due to commence phase 1a/2c clinical trials in the first quarter of CY 2021. The inhibitor also has potential utility in other cancers with prominent connective tissue or fibrotic metastatic niches, such as pancreatic cancer.

Other development pipeline assets include:

- a topical pan-Lysyl Oxidase (LOX) inhibitor in development for scar revision, keloid scarring and scarring from burn wounds;
- a series of Lysyl Oxidase Like 2 (LOXL2) inhibitors targeting fibrotic diseases of the kidney, lung, liver and heart;
- an oral inhibitor of Semicarbazide-Sensitive Amine Oxidase (SSAO) previously partnered by Boehringer Ingelheim and;
- an anti- inflammatory dual SSAO/MAOB inhibitor targeting Duchenne Muscular Dystrophy.

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 the Europe, Russia and Australia and in October 2020 the US Food and Drug Administration (FDA) approved Bronchitol® as add-on maintenance therapy to improve pulmonary function in cystic fibrosis (CF) patients 18 years of age and older.
- 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 the 2020 Annual Report and in quarterly shareholder updates, where we have described the precautions the Company is taking to protect employees and to continue manufacturing and supply of its approved respiratory products.

The Company has continued an uninterrupted supply to local and global customers, despite a significant reduction in international freight routes.

The effect on sales is discussed below. Overall we are seeing an increase in sales compared to earlier in the year, with large variances between markets/countries.

Importantly, there has not been to date any impact of COVID-19 on the various clinical trials in which the Company has been involved, and the upcoming phase 1c/2a trial in myelofibrosis is proceeding for the dosing of its first patient in the first quarter of 2021.

We flex the ability for employees to spend more or less days in the office and labs depending on government advice. The current default is for employees to work from home where possible.

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:

Pan-LOX inhibitor program

Pharmaxis is progressing two pan-lysyl oxidase (LOX) programs from its amine oxidase chemistry platform, both of which are planned to partner after phase 2 clinical trials.

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 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 US Food and Drug Administration (FDA) granted Pharmaxis orphan-drug designation for PXS-5505 for the treatment of myelofibrosis.
- the FDA advised it had completed a safety review of the Company's Investigational New Drug (IND) application for PXS-5505 and gave Pharmaxis permission to proceed with a phase 1c/2 clinical trial for the treatment of myelofibrosis in adults. The IND application was a significant body of work containing over 20,000 pages of reports on the phase 1 studies in healthy volunteers, numerous individual pre-clinical studies and details of the manufacture of the drug substance and drug product to be used in human clinical trials.
- Pharmaxis appointed international clinical research organisation Parexel International (IRL) Limited to manage the phase 1c/2 clinical trial.

The phase 1c/2a clinical trial is scheduled to commence recruitment in the first quarter of CY 2021.

While Pharmaxis' primary focus is the development of PXS-5505 for myelofibrosis, the drug also has potential in several other cancers including liver and pancreatic cancers where it aims to breakdown the fibrotic tissue in the tumour and enhance the effect of existing chemotherapy. 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.

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. A lead candidate has been selected (PXS-6302) and completed pre-clinical development including initial stability studies of the topical formulation.

The Company has ongoing discussions with an Australian based hospital burns unit that is interested in commencing a series of investigator initiated clinical studies to assess the safety and initial efficacy of this drug in burns related scars and pre-existing scars.

The phase 1 study is scheduled to commence in the first half of the 2021 calendar year.

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 this drug to enter the clinic in phase 2 trials and will provide more information when the process concludes.

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

PXS-4728 was acquired by Boehringer Ingelheim in 2015 with an upfront payment to Pharmaxis of $41 million. Subsequent payments on the commencement of two clinical trials by Boehringer in two indications brought the total receipts by Pharmaxis to $83 million.

During the half year, Boehringer advised the discontinuation of the development of its PXS-4728 program for the treatment of patients with moderate-severe non-proliferative diabetic retinopathy (NPDR) after receiving results from a phase 2a clinical trial in patients with moderate-severe NPDR. PXS 4728 met its primary endpoint in ocular safety with the treatment being well tolerated. Boehringer decided not to further develop PXS 4728 in this indication based on the lack of a clear efficacy signal and risk of dose dependent drug interactions of the compound in NPDR patients identified in another Phase 1 study. Consequently, Boehringer advised that it would terminate the agreement with Pharmaxis.

Based on recent publications, SSAO remains an important clinical target. Pharmaxis has commenced a review of the extensive data generated by Boehringer over its five year development program to evaluate potential opportunities in other indications that already have supportive pre-clinical data and where the risk of drug interactions are of less concern.

Pharmaxis expects to have completed its review, including discussions with key opinion leaders and relevant pharma companies in the first half of 2021.

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

During the half year, Pharmaxis was awarded $1.0 million of 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). The Australian government matched funding will allow the company to take its amine oxidase inhibitors PXS-4699 through to the commencement of human clinical trials. A planned comprehensive program of pre-clinical studies will build on the pioneering work already conducted on Pharmaxis compounds by independent international researchers focused on Duchenne Muscular Dystrophy. PXS-4699 is a dual amine oxidase inhibitor which is expected to protect muscle and reduce inflammation as well as organ fibrosis in DMD. It is hoped this could result in better daily functioning for patients, improved quality of life and longer life expectancy.

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 Food and Drug Administration approved Bronchitol as add-on maintenance therapy to improve pulmonary function in cystic fibrosis patients 18 years of age and older. Chiesi plans to launch Bronchitol in the first half of 2021. Consequently, a US$7.0 million (A$10.0 million) milestone was paid by Chiesi to Pharmaxis during the quarter with a further US$3.0 million (~A$4.0 million) payable on shipment by Pharmaxis of commercial launch stock scheduled for the first quarter of 2021. 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 from FY 2021. Pharmaxis will earn mid to high teen percentage of Chiesi net sales and will be 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 Australia and 17 other international markets, will greatly increase capacity utilisation and substantially improve the unit cost of goods.
- In the EU, Pharmaxis has appointed Chiesi as its exclusive distributor for the markets of the UK, Ireland, Italy, Germany, Norway, Sweden, Finland, Denmark, Cyprus and Greece. Unit sales of Bronchitol by Chiesi in the UK, Germany and Italy for the half year decreased 1% below the December 2019 half year.

Approved products – Aridol

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 U.S.A., Canada, Australia, South Korea and a number of European countries.

Financial Highlights

Revenue from sale of goods

Sales for the half year ended 31 December 2020 were $3.1 million, a decrease of $0.2 million on 31 December 2019 half year.

Sales of Bronchitol for the half year ended 31 December 2020 were $2.2 million, similar to 2019.

The group sold Aridol to customers in North America, Europe, Australia and Asia during the period. Sales of Aridol in the half-year ended 31 December 2020 were $0.9 million, a decrease of $0.2 million on the half year ended 31 December 2019. The decrease was due to the impacts of Covid-19 and the limitations of lung function testing.

Bronchitol sales by region are as follows:	**2020**	2019
	$'000	$'000
Australia	**544**	571
Western Europe	**120**	862
Eastern Europe	**167**	147
Russia	**1,365**	588
	2,196	2,168

Aridol sales by region are as follows:	**2020**	2019
	$'000	$'000
Australia	**201**	260
Europe	**241**	502
USA & Canada	**98**	72
South Korea	**350**	257
	890	1,091

The COVID-19 global pandemic has not to date impacted purchasing of Bronchitol by our international distributors. In Western Europe, despite disruptions caused by the COVID-19 pandemic, in-market unit sales of Bronchitol by Chiesi in the UK, Germany, Italy and the Nordics for the six months ended 31 December 2020 were only 1% less than 2019 while sales for the 12 months ended 31 December 2020 increased 2.5% over 2019. In Australia where Pharmaxis sells directly to clinics, in-market unit sales of Bronchitol for the half year ended 31 December 2020 were only 1% less than the 2019 half year while sales for the 12 months ended 31 December 2020 increased 12% over 2019.

At the beginning of the COVID-19 pandemic a number of countries, including those where Aridol is sold, respiratory specialists were advised to limit all lung function testing to more severe cases due to health risks arising from patients exhaling multiple times with force as part of the test. In the markets where Pharmaxis sells Aridol directly to lung function testing laboratories (Australia and Europe) sales have reduced on a state and country basis consistent with the impact of the pandemic. In Australia unit sales decreased 24% for six months ended 31 December 2020 compared to 2019 and 25% for the 2020 calendar year compared to 2019. In Europe, unit sales decreased 51% for the six months ended 31 December 2020 December compared to 2019 and 44% for the 2020 calendar year compared to 2019. Unit sales for the December 2020 quarter were 22% above the September 2020 quarter.

The Company continues to monitor the situation.

Other revenue

The Company received other revenue of $10.1 million for the half year ended 31 December 2020 an increase of $9.9 million on the half year ended 31st December 2019. The increase represents the milestones received for the approval of Bronchitol in the US $10.0 million, and in Brazil $0.1 million. Interest income decreased by $0.2 million as a result of lower cash and cash equivalent balances and lower market interest rates available.

Other income

The Company received other income of $0.5 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 $6.2 million in the half-year ended 31 December 2020, an increase of $0.2 million on the half-year ended 31 December 2019. Employee costs include share based payments (non-cash) totalling $0.4 million in the 2020 half year period, compared to $0.5 million in the corresponding 2019 half year period. At 31 December 2020 the Company employed 64 full time equivalents (31 December 2019: 70) of whom 68 percent were in the Bronchitol and Aridol business, 23 percent in drug development, and 9 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 $1.2 million in the 2020 half-year period similar to 2019.

Clinical trials

Clinical trials expenses were $1.3 million in the half-year ended 31 December 2020 compared to $1.1 million in the half-year ended 31 December 2019, an increase of $0.2 million. 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. Clinical trials related to New Drug Development were $1.3 million in the December 2020 half year compared to $1.2 million in the December 2019 half year. There were no clinical trial costs in relation to the Mannitol Business in the December 2020 half year compared to a credit of $0.1 million in the December 2019 half year. The credit received was from the contract research organisation that managed the clinical trial CF303.

Drug development

Drug development expenses were $0.9 million for the half-year ended 31 December 2020 compared to $1.3 million in the half-year ended 31 December 2019. The decrease in the drug development expenditure is due to the LOX Systemic and LOX Topical programs advancing to clinical trials. 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).

Sales, marketing & distribution

Sales & marketing expenses are external costs incurred in selling Bronchitol globally, primarily through distributors. Limited resources are directed at the sale of Aridol. Sales & marketing expenses for the current half-year were $0.7 million similar to the half-year ended 31 December 2019.

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 an increase of $0.5 million on the half year ended 31 December 2019. The increase is a result of externalising the management of the pharmacovigilance function and additional resourcing required during a routine audit of our European pharmacovigilance during the 2020 half year.

Manufacturing purchases and movements in inventory

Manufacturing purchases were $1.2 million in the half-year ended 31 December 2020 compared to $0.7 million in the half-year ended 31 December 2019. 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.

Other

Other expenses were $0.1 million in the half-year ended 31 December 2020 a decrease of $0.2 million on the half-year ended 31 December 2019. These expenses include corporate travel related costs, shared office administration costs, and other costs including royalty costs payable to the Sydney Local Health District, based on gross profit on product sales of Aridol and Bronchitol.

Foreign exchange gains & losses

Foreign exchange gains were $1.4 million in the half-year ended 31 December 2020 compared to losses of $0.1 million in the half-year ended 31 December 2020. The foreign exchange gains are typically unrealised and relate to the movement on the USD denominated NovaQuest finance agreement. 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 2020, similar to the half-year ended 31 December 2019.

Finance expenses

Finance expenses were $0.3 million in the half-year ended 31 December 2020 similar to the half year ended 31 December 2019. The finance expense relates to the lease liability of 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 $18 million in cash and cash deposits. A US$3.0 million (~A$4.0 million) milestone is payable to the Company by Chiesi on shipment of US Bronchitol launch stock scheduled for the first quarter of 2021.

Events occurring after the end of the reporting period

On 8 February 2021 the Company shipped commercial launch stock of Bronchitol to its US partner Chiesi thereby earning a US$3 million milestone.

Except for the above no other matters or circumstances have arisen since 31 December 2020 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 profit of $0.05 million (FY2020: $13.9 million operating loss and HY2020: $10.3 million operating loss) and net operating cash inflows of $5.0 million (FY2020: $13.2 million net operating cash outflows and HY2020: $3.7 million net operating cash outflows). As at 31 December 2020, the Group has cash and cash equivalents of $18.2 million (FY2020: $14.7 million and HY2020: $25.8 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:

• milestone receivable by Pharmaxis upon shipment of Bronchitol for the approved US launch;

• additional sales revenue subsequent to the launch of Bronchitol in the US;

• securing new partnering arrangements for programs currently in its drug development pipeline;

• amending existing commercial relationships to realise cost savings and bring forward the value of future sales; and/or

• access additional sources of equity share capital.

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 2020. 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.

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 8.

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 2021

Auditor's Independence Declaration

As lead auditor for the review of Pharmaxis Ltd for the half-year ended 31 December 2020, 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.

Mark Dow
Partner
PricewaterhouseCoopers

Sydney
10 February 2021

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Pharmaxis Ltd

Consolidated income statement

For the half-year ended 31 December 2020

	Notes	**31 December 2020 $'000**	31 December 2019 $'000
Revenue from continuing operations			
Revenue from sale of goods	3	**3,086**	3,259
Other revenue	3	**10,122**	230
Other income	4	**479**	532
		13,687	4,021
Expenses from ordinary activities			
Employee costs		(6,200)	(6,005)
Administration & corporate		(1,220)	(1,153)
Rent, occupancy & utilities		(524)	(483)
Clinical trials		(1,279)	(1,069)
Drug development		(917)	(1,311)
Sales, marketing & distribution		(747)	(668)
Safety, medical and regulatory affairs		(977)	(487)
Manufacturing purchases and changes in inventory		(1,172)	(746)
Other		(126)	(374)
Depreciation & amortisation		(1,589)	(1,616)
Foreign exchange gains & losses		1,362	(121)
Finance costs		(252)	(307)
		(13,641)	(14,340)
Net profit / (loss) before income tax		**46**	(10,319)
Income tax		**-**	-
Net profit / (loss) for the period		**46**	(10,319)
Earnings per share:		**Cents**	Cents
Basic earnings / (loss) per share	8	**0.00**	(0.03)
Diluted earnings / (loss) per share	8	**0.00**	(0.03)

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 2020

	31 December 2020	31 December 2019
	$'000	$'000
Net profit / (loss) for the period	**46**	(10,319)
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	**46**	(10,319)
Total comprehensive income / (loss) for the period is attributable to:		
Owners of Pharmaxis Ltd	**46**	(10,319)

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 2020

	Notes	31 December 2020 $'000	30 June 2020 $'000
ASSETS			
Current assets			
Cash and cash equivalents		**18,249**	14,764
Trade and other receivables		**2,235**	7,098
Inventories		**2,690**	2,630
Total current assets		**23,174**	24,492
Non-current assets			
Receivables		**1,081**	1,077
Property, plant and equipment		**7,512**	8,906
Intangible assets		**1,027**	941
Total non-current assets		**9,620**	10,924
Total assets		**32,794**	35,416
LIABILITIES			
Current liabilities			
Trade and other payables		**3,783**	3,475
Borrowings		**1,930**	1,832
Other liabilities		**295**	478
Provisions		**998**	1,040
Total current liabilities		**7,006**	6,825
Non-current liabilities			
Borrowings		**5,329**	6,322
Other liabilities		**18,492**	20,722
Provisions		**79**	116
Total non-current liabilities		**23,900**	27,160
Total liabilities		**30,906**	33,985
Net assets		**1,888**	1,431
EQUITY			
Contributed equity	5 (a)	**367,301**	367,301
Reserves		**22,728**	22,317
Accumulated losses		**(388,141)**	(388,187)
Total equity		**1,888**	1,431

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 2020

	Notes	Contributed equity	Reserves	Accumulated losses	Total
		$'000	$'000	$'000	$'000
Balance at 30 June 2019		367,301	21,757	(374,244)	14,814
Loss for the period		-	-	(10,319)	(10,319)
Other comprehensive income		-	-	-	-
Total comprehensive loss for the half year		-	-	(10,319)	(10,319)
Transactions with owners in their capacity as owners					
Contributions of equity, net of transaction costs		-	-	-	-
Employee share options		-	538	-	538
		-	538	-	538
Balance at 31 December 2019		367,301	22,295	(384,563)	5,033
Balance at 30 June 2020		**367,301**	**22,317**	**(388,187)**	**1,431**
Profit for the period		**-**	**-**	**46**	**46**
Other comprehensive income		**-**	**-**	**-**	**-**
Total comprehensive income 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**

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 2020

	31 December 2020 $'000	31 December 2019 $'000
Cash flows from operating activities		
Receipts from customers (inclusive of goods and services tax)	**3,602**	3,973
Payments to suppliers and employees (inclusive of goods and services tax)	**(13,638)**	(14,116)
	(10,036)	(10,143)
Grant receipts from government	**5,099**	6,221
Receipt of the Chiesi US FDA milestone	**9,949**	-
Interest received	**36**	230
Income taxes refunded	**-**	-
Net cash inflow / (outflow) from operating activities	**5,048**	(3,692)
Cash flows from investing activities		
Payments for plant and equipment	**(126)**	(117)
Proceeds from disposal of plant & equipment	**-**	-
Payments for intangible assets	**(155)**	(211)
Net cash outflow from investing activities	**(281)**	(328)
Cash flows from financing activities		
Lease liability payments	**(1,147)**	(1,111)
Financing agreement payments	**(135)**	(129)
Net cash inflow / (outflow) from financing activities	**(1,282)**	(1,240)
Net increase / (decrease) in cash and cash equivalents	**3,485**	(5,260)
Cash and cash equivalents at the beginning of the financial period	**14,764**	31,124
Cash and cash equivalents at the end of the financial period	**18,249**	25,864

The 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 2020 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 2020 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 profit of $0.05 million (FY2020: $13.9 million operating loss and HY2020: $10.3 million operating loss) and net operating cash inflows of $5.0 million (FY2020: $13.2 million net operating cash outflows and HY2020: $3.7 million net operating cash outflows). As at 31 December 2020, the Group has cash and cash equivalents of $18.2 million (FY2020: $14.7 million and HY2020: $25.8 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:

• milestone receivable by Pharmaxis upon shipment of Bronchitol for the approved US launch;

• additional sales revenue subsequent to the launch of Bronchitol in the US;

• securing new partnering arrangements for programs currently in its drug development pipeline;

• amending existing commercial relationships to realise cost savings and bring forward the value of future sales; and/or

• access additional sources of equity share capital.

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 2020. 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 interpreations for the group to consider during the reporting period to 31 December 2020.

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 2020 is as follows:

2. Segment information (continued)

	Mannitol	New Drug Development	Corporate	Total
Half-year 2020	**$'000**	**$'000**	**$'000**	**$'000**
Total segment revenue	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**
Half-year 2019				
Total segment revenue	3,269	259	263	3,791
Expenses from ordinary activities				
Employee costs	(3,037)	(1,529)	(901)	(5,467)
Administration & corporate	(188)	(87)	(878)	(1,153)
Rent, occupancy & utilities	(386)	(37)	(60)	(483)
Clinical trials	98	(1,167)	-	(1,069)
Drug development	-	(1,311)	-	(1,311)
Sales, marketing & distribution	(668)	-	-	(668)
Safety, medical and regulatory affairs	(487)	-	-	(487)
Manufacturing purchases	(746)	-	-	(746)
Other	(124)	(157)	(125)	(406)
	(5,538)	(4,288)	(1,964)	(11,790)
Adjusted EBITDA	(2,269)	(4,029)	(1,701)	(7,999)

The senior management committee uses the adjusted EBITDA as a measure to assess performance of the segments. This excludes the effects of material non-recurring expenditure such as partnering agreement legal expenses and patent impairments when the impairment is the result of an isolated, non-recurring event. It also excludes the effects of equity-settled share-based payments and unrealised gains/losses on financial instruments.

2. Segment information (continued)

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

	31 December 2020 $'000	31 December 2019 $'000
Adjusted EBITDA	**713**	(7,999)
Interest revenue	**36**	230
Finance costs - lease liability charges	**(252)**	(307)
Unrealised/realised net foreign exchange gains/(losses)	**1,549**	(89)
Depreciation and amortisation expense	**(1,589)**	(1,616)
Share-based payment expenses	**(411)**	(538)
Profit / (loss) before income tax	**46**	(10,319)

3. Revenue

Sales revenue		
Sale of goods	**3,086**	3,259
Other revenue		
Chiesi US FDA approval milestone	**9,949**	-
Interest	**36**	230
Other	**137**	-
	10,122	230

4. Other income

R&D tax incentive income	**148**	259
Government COVID-19 cash flow boost	**50**	-
BTB grant	**98**	-
Other income	**183**	273
	479	532

5. Contributed equity

	Parent entity		Parent entity	
	31 December 2020	30 June 2020	**31 December 2020**	30 June 2020
	Shares	Shares	**$'000**	$'000
(a) Share capital				
Ordinary shares				
Fully paid	**397,179,798**	395,249,198	**367,301**	367,301

Movements in ordinary share capital:

Details	**Number of shares**	**Issue price**	**$'000**
Opening balance as at 1 July 2020	395,249,198		367,301
Exercise of employee options	1,393,800	$ - (1)	-
Employee Share Plan	536,800	$ - (2)	-
Closing Balance at 31 December 2020	397,179,798		367,301

(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 2020 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 2020 had a total deposits of $0.9 million (2019: $0.9 million) covering a rental bond and corporate credit card facility.

7. Events occurring after the end of the reporting period

On 8 February 2021 the Company shipped commercial launch stock of Bronchitol to its US partner Chiesi thereby earning a US$3 million milestone.

Except for the above no circumstance have arisen since 31 December 2020 that has 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.

8. Earnings per share

	31 December 2020 Cents	31 December 2019 Cents
(a) Basic earnings per share		
Profit / (loss) attributable to the ordinary owners of the Company	**0.00**	(0.03)
(b) Diluted earnings per share		
Profit / (loss) attributable to the ordinary owners of the company	**0.00**	(0.03)
(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	**396,233,387**	394,566,595
Weighted average number of ordinary shares used as the denominator in calculating diluted earnings / (loss) per share	**407,481,112**	405,059,345

(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 2020

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 2020 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 2021

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 2020, 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 2020 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 our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Material uncertainty related to going concern

We draw attention to Note 1 in the financial report, which states that the:

- Group generated an operating profit after tax of $0.05 million and net operating cash inflows of $5 million during the half-year ended 31 December 2020
- Group has cash and cash equivalents of $18.2 million at 31 December 2020
- 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/or secure additional sources of funding including milestones and/or capital.

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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.

Responsibility 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 responsibility 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 2020 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

Mark Dow
Partner

Sydney
10 February 2021