ABN 75 082 811 630

# ASX Half year report – 31 December 2014

# 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 2014 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

Results for announcement to the market (Appendix 4D item 2)	2
Other Appendix 4D information (Appendix 4D items 3 to 9)	2
Half year report	3

ABN 75 082 811 630

# Reporting period: Half year ended 31 December 2014 (Previous corresponding period: Half year ended 31 December 2013)

# Results for announcement to the market

				<u>A\$'000</u>
Revenue from sale of goods	Up	27.6%	to	3,040
Other revenue from ordinary activities	Up	216.6%	to	<u>9,498</u>
Total revenue from ordinary activities	Up	133.0%	to	<u>12,538</u>
Loss from ordinary activities after tax	Down	68.2%	to	(6,572)
Net loss for the year attributable to members	Down	68.2%	to	(6,572)

# Dividends

It is not proposed to pay a dividend.

# Other Appendix 4D information

	<u>31</u> <u>December</u> 2014	<u>31</u> <u>December</u> <u>2013</u>
Net tangible assets per ordinary share	\$ 0.036	\$ 0.12

# Pharmaxis Ltd Half-Year Report - 31 December 2014

# Contents

	Page
Directors' report	2
Auditor's independence declaration	7
Consolidated income statement	8
Consolidated statement of comprehensive income	9
Consolidated balance sheet	10
Consolidated statement of changes in equity	11
Consolidated statement of cash flows	12
Notes to the consolidated financial statements	13
Directors' declaration	18
Independent auditor's review report to the members	19

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, Australia 2086

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 2014 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 26<sup>th</sup> February 2015. 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 2014

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 2014.

### Directors

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

Malcolm McComas (Chairman) Gary Phillips (Chief Executive Officer) William Delaat Simon Buckingham

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

#### Overview

Pharmaxis is a specialty pharmaceutical Company with a portfolio of products at various stages of development and approval. It's respiratory product's Bronchitol<sup>®</sup> and Aridol<sup>®</sup> have each been approved and are currently being sold in a number of major pharmaceutical markets. The Company also has an active research program advancing several products of interest to large pharmaceutical companies through the drug discovery and development process.

The Company's current major objective is to create a new, simplified and sustainable Pharmaxis business model built around the existing product portfolio whereby:

- Bronchitol sales and marketing infrastructure outside of Australia is provided by capable partners and distributors with specialist cystic fibrosis experience
- Funding of the phase 3 clinical trial of Bronchitol in CF required for accessing the US CF market is provided by a US partner, with Pharmaxis receiving payments on commercial launch and achievement of significant sales milestones, as well as an ongoing share of US Bronchitol sales revenue
- Partners and collaborators enable Pharmaxis to rapidly advance its drug discovery and development programs to meaningful value enhancing milestones that provide additional research funds to the Company
- Aridol continues to be sold to international markets
- The simplified business model allows for further reductions in the Pharmaxis cost base.

As previously reported, the challenges facing the Company were significantly compounded in July 2014 when a financier alleged a breach of a financing agreement thereby necessitating renegotiations with a prospective US Bronchitol partner to fill the funding gap created by the financiers action as well as renegotiation of the financing agreement.

On 24 December 2014 the Company announced it had entered into an exclusive distribution and supply agreement with global pharmaceutical company Chiesi Farmaceutici SpA (Chiesi) for the commercialisation of Bronchitol® in the United States, and as a precursor to that agreement the Company had also settled its dispute with its financier. Under the terms of the commercialisation agreement, Chiesi will fund up to US\$22 million of the cost of the phase 3 clinical trial of Bronchitol which, subject to approval in the United States, will be sold as part of Chiesi's portfolio of cystic fibrosis products. Milestones totalling up to US\$25 million are payable tied to the launch of Bronchitol, and on achieving certain annual sales levels. In addition, Pharmaxis will manufacture and supply Bronchitol on commercial terms but should it be independently sourced by Chiesi in the future, Pharmaxis will still receive an ongoing share of sales revenue.

Under the terms of the amended financing agreement, the Company's financier will receive reduced financial terms (i.e., a reduced share of Bronchitol revenue in the US and EU) on its existing US\$20 million investment with no further investment to be made.

During the period the Company continued to work on partnering activities for the Bronchitol business in the EU and the drug discovery programs. Ongoing discussions are well advanced.

### Bronchitol

Bronchitol is designed to restore normal lung hydration, improve lung function and to help relieve the mucus burden in the lungs of patients suffering from chronic respiratory conditions, including cystic fibrosis. Pharmaxis has to date received marketing approval for Bronchitol for the treatment of cystic fibrosis in Australia, the European Union and Israel, and has marketing approval applications under review by regulators in Brazil and Russia. Bronchitol is currently being sold in Australia, Germany, the United Kingdom, Austria, Denmark, Greece, Turkey and Ireland. The Company is currently progressing pricing approvals in Ireland, Italy and Israel in an economic environment that is proving hostile to all new drug applications. During the period the Company was successful in its application in Denmark to broaden the prescription status of Bronchitol. In the Netherlands however, despite representations by CF clinicians and patient representatives to both the government and regulator, the pricing approval application was rejected.

### **Directors' Report**

For the half-year ended 31 December 2014

During the period the Company announced that it had enrolled the first subject in its international phase 3 clinical trial evaluating Bronchitol in adults with cystic fibrosis (CF303). The trial is being conducted in accordance with the requirements of the US Food and Drug Administration (FDA) to gain approval for Bronchitol to treat cystic fibrosis in the United States. As guided by the FDA, the clinical study protocol closely follows the design of the two large scale clinical trials already undertaken by Pharmaxis. The trial will enrol between 350 and 440 cystic fibrosis patients aged 18 years and older, and will assess improvements in lung function, pulmonary exacerbations and safety. Management of the trial is outsourced to a global contract research organisation with significant experience running international trials in the cystic fibrosis community. More than 100 sites across 19 countries are participating in the study and recruitment is expected to take twelve months to complete.

Sales of Bronchitol 14 day packs for the period increased 36% to 4,461 compared to the period ending 31 December 2013. At the individual country level unit sales in Australia grew by 57%. In the UK, despite a relatively weak December quarter, sales for the half year period grew 89% compared to the period ending 31 December 2013. German unit sales were flat, while initial sales were made into Greece and Turkey.

### 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.

Pharmaxis has received marketing approval of Aridol in Australia, South Korea and a number of European countries where it is currently selling the product. The Company has also received marketing approval in the United States and several countries in South East Asia where it is not currently selling the product.

Sales of Aridol kits for the period increased 24% to 36,695 compared to the period ending 31 December 2013. Korea now represents over 75% of unit sales and increased by 40% compared to the comparative period. EU sales increased by 25%, while US sales in the comparative period of 2,030 kits reduced to nil subsequent to the 2014 decision to discontinue supplying that market as discussed in the 2014 annual report.

### Drug discovery and development programs

The Company has been conducting a comprehensive process to partner or otherwise fund it's early discovery programs since the beginning of the 2014 financial year, with particular attention to the LOXL2 and SSAO programs.

The LOXL2 program is focussing in an area of significant interest to large pharmaceutical companies, and based on discussions with these companies Pharmaxis believes it's approach is unique and potentially first in class. LOXL2 plays a role in several fibrotic diseases and some cancers. However, while the level of interest from potential partners has been very encouraging, the current lead optimisation phase of the program is still early. The Company has therefore pursued research collaborations that appropriately share the risks and rewards of advancing the development program to a point of greater value. Research collaboration discussions are currently at the term sheet negotiation stage.

Interest in the SSAO target and also the Company's SSAO inhibitor (PXS4728A) has emerged over the last twelve months. Pharmaxis has made considerable progress in developing PXS4728A over this period. In August the Company announced it had completed the preclinical development PXS4728A clearing the way for the drug to commence human clinical phase 1 studies which occurred in January 2015. Large pharmaceutical companies are interested in the SSAO enzyme for its role in various inflammatory diseases such as non-alcoholic steatohepatitis (NASH) and chronic obstructive pulmonary disease (COPD). Term sheets have been received and the Company is currently at the contract negotiation stage.

# **Revised Business Plan**

The cost reductions outlined in the revised business plan were achieved during the 2014 financial year. The now completed US partnering of Bronchitol was a major step in simplifying the Pharmaxis business model and reduced the Company's requirement for full time internal capability. Also during the period the Company completely closed its US office. Successful completion of the EU partnering currently being negotiated will again simplify the business model and permit further reduction in the Pharmaxis cost base. Several senior management positions including Chief Medical Officer, Head of Regulatory Affairs and Project Management were made redundant at the end of the period. The partnership with Chiesi will investigate leveraging Chiesi's experience and capability to reduce manufacturing costs over the medium term.

#### **Financial Highlights**

#### Revenue from sale of goods

Sales for the half year ended 31 December of \$3.0 million reflect the growing contribution by Bronchitol which increased from \$1.5 million in 2013 to \$2.1 million in 2014, an increase of 39%. In addition to sales in Germany, the United Kingdom, Austria, Denmark and Australia, initial sales were made into new markets of Greece and Turkey via distributors.

The group shipped Aridol to customers in Europe, Australia and Asia during the period. Sales of Aridol in the half-year ended 31 December 2014 were \$951,000, an increase of 6% over the half year ended 31 December 2013. This increase reflected higher sales in South Korea and Europe, offset by no sales revenue in the United States as a result of the Group's exit from that market. Sales in the US were \$168,000 in the half year ended 31 December 2013.

Overall gross margin was 68% of sales for the half-year ended 31 December 2014 (2013: 63%), reflecting a change in sales mix between products (Aridol vs. Bronchitol) and sales channel mix (distributor vs. direct).

#### Interest

The decrease in interest income was driven by a lower average balance of cash and cash equivalents available for investment during the period.

#### Other income

Other income includes an amount of \$8.5 million representing the initial R&D cost reimbursement pursuant to the commercialisation agreement with Chiesi as discussed above. The amount reimburses Pharmaxis for the clinical trial costs directly incurred up to 31 December 2014 with the clinical research organisation managing the Company's US Phase III pivotal clinical trial in cystic fibrosis adults aged 18 years and over.

Other income also includes an adjustment which increased the R&D tax incentive credits actually received by the Company for the year ended 30 June 2014. The R&D Tax Incentive scheme in Australia enables a 43.5 per cent refundable tax offset to eligible entities with an aggregated turnover of less than \$20 million per annum. The Company is forecast to book revenue in excess of the \$20 million cap for the 2015 fiscal year including the clinical trial reimbursements under the commercialisation agreement with Chiesi. Accordingly, no R&D tax incentive credits for the half year period to 31 December 2014 have been accounted for, compared to the \$1.9 million booked in the half year ended 31 December 2013.

#### **Employee costs**

Employee related expenses were \$7.5 million in the half-year ended 31 December 2014 compared to \$10.2 million in the half-year ended 31 December 2013. Employee costs include share based payments (non-cash) totalling \$0.1 million in the 2014 period, compared to \$1.0 million in the corresponding 2013 period. Employee costs are progressively reducing as the Company simplifies its business model as discussed above. At 31 December 2014 the Company employed 90 full time equivalents of whom approximately 41% were engaged in production, quality and engineering, 25% were engaged in sales and marketing, predominantly in Europe, 11% in drug discovery, 10% in clinical trials and 13% across administration, medical affairs and safety. As discussed above the Company is pursuing further cost reductions as the business model is simplified and intends to fund its drug discovery expenses including employee costs from partnering and collaboration agreements.

#### Administration & corporate

Administration and corporate expenses include accounting & IT, legal & compliance, public company costs, patent portfolio and insurance costs. Administration expenses were \$1.8 million in the 2014 half-year period and \$1.7 million in 2013. The increase of \$61,000 reflects an increase in legal fees of \$0.5 million related to financing and business development activities, offset by a reduction in other administration and corporate costs as the general business complexity is rationalised.

#### **Clinical trials**

Clinical trials expenses were \$5.4 million in the half-year ended 31 December 2014 compared to \$1.4 million in the half-year ended 31 December 2013, an increase of \$4.0 million. The clinical trials expenses relate to the external costs incurred and are predominately driven by fees paid to the clinical research organisations contracted to manage the trials in multiple jurisdictions, and costs paid to participating site investigators. The increase is the result of the commencement of the Phase 3 clinical trial of Bronchitol for the treatment of CF in adults aged 18 years and over which enrolled its first subject on 30 October 2014. The outsourced costs incurred for the period for this Phase 3 clinical trial totalled \$3.3 million and are subject to reimbursement under the terms of the commercialisation agreement with Chiesi. The Company continues to progress the substantially smaller Phase 2 European paediatric clinical trial evaluating Bronchitol in cystic fibrosis.

#### Drug development

Drug development expenses were \$0.5 million in both the half-years ended 31 December 2014 and ended 31 December 2013. The drug development expenses relate to the external costs incurred in running the Company's research laboratory (excluding any allocation of lease and utilities), selecting and then progressing drug candidates through the pre-clinical development path. The amount of resources allocated to this group has remained constrained pending completion of external funding arrangements.

#### Sales, marketing & distribution

Sales & marketing expenses are primarily focussed on external costs incurred in developing and delivering the commercial strategy and capability to sell Bronchitol globally. Limited resources are directed at the sale of Aridol. Sales & marketing expenses for the current half-year were \$1.3 million, compared to \$1.9 million in the half-year ended 31 December 2013. The expenses in both periods include costs associated in applying for pricing reimbursements and the decrease in sales & marketing expenses reflects a more tailored and targeted approach in markets, in line with sales performance and growth.

#### Safety, medical and regulatory affairs expenses

Safety, medical and regulatory affairs expenses relate to external costs directed at monitoring and reporting product safety to regulatory agencies, reviewing material provided to clinicians and patients by the Company and obtaining and maintaining product approvals. Expenses for the current half-year were \$0.8 million which was in line with the 2013 half year spend. The level of expenditure is consistent and from a regulatory perspective primarily related to routine licence maintenance. The main cost relates to satisfying the Company's EU Bronchitol approval to undertake a prospective observational safety study of Bronchitol in adult cystic fibrosis patients over a 5 year period. The costs of this study totalled \$0.4 million (2013: \$0.4 million).

### Manufacturing purchases

Manufacturing purchases were \$1.2 million in the half-year ended 31 December 2014 compared to \$1.0 million in the half-year ended 31 December 2013, an increase of \$0.2 million. 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. In addition to manufacture and supply of commercial product, purchases also related to the manufacture of clinical trial material for the Phase 3 clinical trial in cystic fibrosis which commenced dosing subjects during the period.

#### Other

Other expenses were \$0.8 million in the half-year ended 31 December 2014 compared to \$0.4 million in the half-year ended 31 December 2013, representing an increase of \$0.4 million. This category encompasses corporate travel related costs, shared office administration costs, and other costs.

Also included are royalty costs payable to the Sydney Local Health District, or SLHD, based on gross profit on product sales for products incorporating the licensed technology. The Pharmaxis products Aridol and Bronchitol fall within the scope of the SLHD license. During the 2014 half-year royalties were payable on sales of both Aridol and Bronchitol totalling \$0.1 million (2013: \$0.1 million).

#### **Depreciation & amortisation**

Depreciation and amortisation expense was \$1.7 million in the half-year ended 31 December 2014 compared to \$2.5 million in the half-year ended 31 December 2013. The decrease in expense reflects the write down of certain intangible assets in the second half of the 2014 financial year.

#### Finance expenses

Finance expenses were in credit totalling \$3.0 million in the 2014 half-year period compared to an expense of \$4.7 million in 2013. There are two components to this group of expenses.

- 1. Finance charges associated with the capitalised finance lease of our corporate manufacturing facility at French's Forest, Sydney totalling \$0.4 million (2013: \$0.4 million).
- 2. Accrued finance costs up to 31 December 2014 in relation to the NovaQuest financing agreement. As outlined in the Review of Operations above, the Company settled its dispute with NovaQuest Pharma Opportunities Fund III (NovaQuest) on 23 December 2014 and entered an Amended and Restated Financing Agreement. Under the terms of the amended financing agreement, NovaQuest will receive reduced financial terms on its existing US\$20 million investment and no further investment by NovaQuest is required.

### Directors' Report

For the half-year ended 31 December 2014

In accordance with Australian Accounting Standards the Company had been accruing for finance costs from the commencement of the original contract term, being 31 January 2013, on the original anticipated full investment amount of US\$40 million which the Company had elected to drawdown.

As a consequence of the new financial terms and reduced investment balance, the financial liability required restatement which resulted in a net credit to the income statement in the half year period of \$3.4 million. Movements in the exchange rate between the US and Australian dollar are also reflected in this adjustment. The financial liability recorded on the balance sheet at 31 December 2014 is the Australian dollar equivalent of the US\$20 million investment by NovaQuest plus accrued net finance costs to date of US\$14,808 minus payments made to date of US\$187,009.

#### Impairment expenses

Restructure and impairment expenses were \$0.3 million in the 2014 half-year period compared to \$Nil in 2013. The 2014 half year charge relates to the write down of several patent families following a re-assessment of their recoverability.

#### Income tax expense

Income tax expense relates to tax on the income generated by the group's subsidiaries which are currently reimbursed for their R&D and sales and marketing expenditures on a cost plus basis, upon which tax is payable.

### **Balance Sheet**

The group ended the half-year with \$19.8 million in cash and cash deposits. In addition, the Company is currently due to receive \$8.5 million under its agreement with Chiesi as a reimbursement of prior expenditure in relation to the Phase 3 clinical trial of cystic fibrosis.

### Events occurring after the end of the reporting period

The Company announced on 21 January 2015 that it has commenced a Phase 1 clinical trial of its Semicarbazide-Sensitive Amine Oxidase/Vascular Adhesion Protein-1 (SSAO/VAP-1) Inhibitor (PXS4728A) investigating its potential to treat inflammatory diseases. PXS4728 is a highly selective small molecule inhibitor of SSAO that can be administered orally and has already demonstrated acceptable pharmacological properties during pre-clinical development. The initial stage of the trial is a single ascending dose study being conducted in 48 subjects at an Australian Phase 1 clinical trial centre. If these results are positive, the Company will proceed to a multiple ascending dose study in 24 subjects. The trial is expected to report in the third quarter of 2015 and cost approximately \$2 million.

No other matters or circumstance have arisen since 31 December 2014 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.

# 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 7.

#### Rounding of amounts

The Company is of a kind referred to in Class Order 98/100, issued by the Australian Securities & Investments Commission, relating to the "rounding off" of amounts in the directors' report and financial statements. Amounts in the directors' report and financial statements have been rounded off to the nearest thousand dollars in accordance with that Class Order.

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

Gary J Phillips Director 26<sup>th</sup> February 2015



# Auditor's Independence Declaration

As lead auditor for the review of Pharmaxis Ltd for the half-year ended 31 December 2014, 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.

Edda Wilkie

Eddie Wilkie Partner PricewaterhouseCoopers

Sydney 26 February 2015

7 **PricewaterhouseCoopers, ABN 52 780 433 757** Darling Park Tower 2, 201 Sussex Street, GPO BOX 2650, SYDNEY NSW 1171 T: +61 2 8266 0000, F: +61 2 8266 9999, www.pwc.com.au

### **Consolidated income statement**

For the half-year ended 31 December 2014

<b>Revenue from continuing operations</b> Revenue from sale of goods Other revenue Other income	Notes 3 3 4	31 December 2014 \$'000 3,040 403 9,095 12,538	31 December 2013 \$'000 2,382 1,010 1,990 5,382
		,	-,
Expenses from ordinary activities Employee costs Administration & corporate Rent, occupancy & utilities Clinical trials Drug development Sales, marketing & distribution Safety, medical and regulatory affairs Manufacturing purchases Other Depreciation & amortisation Finance costs Impairment expenses		(7,483) (1,797) (813) (5,371) (533) (1,326) (758) (1,182) (816) (1,704) 3,045 (277)	(10,248) (1,736) (917) (1,370) (454) (1,900) (803) (1,023) (415) (2,472) (4,681)
		(19,015)	(26,019)
Loss before income tax		(6,477)	(20,637)
Income tax expense Loss for the period		<u>(95)</u> (6,572)	(61)
<b>Earnings per share:</b> Basic earnings / (loss) per share Diluted earnings / (loss) per share	8 8	Cents (0.02) (0.02)	Cents (6.7) (6.7)

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

# Consolidated statement of comprehensive income

For the half-year ended 31 December 2014

	31 December 2014	31 December 2013
	\$'000	\$'000
Loss for the period	(6,572)	(20,698)
Other comprehensive income		
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	41	78
Other comprehensive loss for the period, net of tax	41	78
Total comprehensive loss for the period	(6,531)	(20,620)
Total comprehensive income for the period is attributable to:		
Owners of Pharmaxis Ltd	(6,531)	(20,620)

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 2014

	Notes	31 December 2014 \$'000	30 June 2014 \$'000
ASSETS			
Current assets			
Cash and cash equivalents		19,814	34,182
Trade and other receivables		9,903	4,563
Inventories		1,989	2,150
Total current assets		31,706	40,895
Non-current assets		2 1 4 0	2.146
Receivables		2,140 21,144	2,146
Property, plant and equipment Intangible assets		555	22,448 1,258
Total non-current assets		23,839	25,852
Total assets		55,545	66,747
LIABILITIES Current liabilities Trade and other payables		5,256	5,659
Borrowings		725	679
Other liabilities		699	1,018
Provisions		437	800
Current tax liabilities		231	126
Total current liabilities		7,348	8,282
Non-current liabilities			
Borrowings		10,523	10,893
Other liabilities		25,748	29,182
Provisions		300	323
Total non-current liabilities		36,571	40,398
Total liabilities		43,919	48,680
Net assets		11,626	18,067
EQUITY			
Contributed equity	5 (a)	344,623	344,623
Reserves		17,846	17,715
Accumulated losses		(350,843)	(344,271)
Total equity		11,626	18,067

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

# Consolidated statement of changes in equity

For the half-year ended 31 December 2014

	Contributed equity	Reserves	Accumulated losses	Total
	\$'000	\$'000	\$'000	\$'000
Balance at 30 June 2013	344,623	15,725	(292,453)	67,895
Loss for the period	-	-	(20,698)	(20,698)
Other comprehensive income	-	78	-	78
Total comprehensive income/(loss) for the half year	-	78	(20,698)	(20,620)
Transactions with owners in their capacity as owners				
Employee share options	-	1,029	-	1,029
	-	1,029	-	1,029
Balance at 31 December 2013	344,623	16,832	(313,151)	48,304
Balance at 30 June 2014	344,623	17,715	(344,271)	18,067
Loss for the period	-	-	(6,572)	(6,572)
Other comprehensive income	-	41	-	41
Total comprehensive income/(loss) for the half year	-	41	(6,572)	(6,531)
Transactions with owners in their capacity as owners				
Employee share options	-	90	-	90
		90	-	90
Balance at 31 December 2014	344,623	17,846	(350,843)	11,626

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

# Consolidated statement of cash flows

For the half-year ended 31 December 2014

Cash flows from operating activitiesReceipts from customers (inclusive of goods and services tax)4,0492,583Payments to suppliers and employees (inclusive of goods and services tax)(21,272)(21,120)(17,223)(18,537)(17,223)(18,537)R&D tax incentive3,3644,9114031,010Income taxes refunded-13Net cash outflow from operating activities(13,456)(12,603)Cash flows from investing activities(13,456)(12,603)Payments for plant and equipment(88)(56)Proceeds from disposal of plant & equipment(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Payments for intangible assets(19)(35)Net cash outflow from financing activities(107)(80)Financia gareement payments(215)-Net cash outflow from financing activities(913)(676)Financing agreement payments(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the bealance of cash held in foreign currencies108101Cash and cash equivalents at the bealance of cash held in foreign currencies108101		31 December 2014 \$'000	31 December 2013 \$'000
goods and services tax)4,0492,583Payments to suppliers and employees (inclusive of goods and services tax)(21,272) (21,120)(21,20)(17,223)(18,537)R&D tax incentive3,3644,911Interest received4031,010Income taxes refunded-13Net cash outflow from operating activities(13,456)(12,603)Cash flows from investing activities(13,456)(12,603)Payments for plant and equipment(88)(56)Proceeds from disposal of plant & equipment-11Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Cash flows from financing activities(11,476)(13,359)Cash and cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the108101Cash and cash equivalents at the108101	Cash flows from operating activities		
(inclusive of goods and services tax)(21,272)(21,120)(IT,223)(18,537)R&D tax incentive3,3644,911Interest received4031,010Income taxes refunded-13Net cash outflow from operating activities(13,456)(12,603)Cash flows from investing activities(13,456)(12,603)Payments for plant and equipment equipment-11Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Cash flows from financing activities(107)(80)Cash flows from financing activities(113,359)(215)Net cash outflow from financing activities(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the belance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,655		4,049	2,583
R&D tax incentive3,3644,911Interest received4031,010Income taxes refunded-13Net cash outflow from operating activities(13,456)(12,603)Cash flows from investing activities(13,456)(12,603)Payments for plant and equipment(88)(56)Proceeds from disposal of plant & equipment-11Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Finance lease payments(698)(676)Financing agreement payments(215)-Net cash outflow from financing activities(913)(676)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the beginning of the financial period50,655		(21,272)	(21,120)
Interest received4031,010Income taxes refunded-13Net cash outflow from operating activities(13,456)(12,603)Cash flows from investing activities(13,456)(12,603)Payments for plant and equipment(88)(56)Proceeds from disposal of plant & equipment-11Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Finance lease payments(215)-Net cash outflow from financing activities(913)(676)Finance lease payments(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the beginning of the financial period108101		(17,223)	(18,537)
Income taxes refunded-13Net cash outflow from operating activities(13,456)(12,603)Cash flows from investing activities(13,456)(12,603)Payments for plant and equipment(88)(56)Proceeds from disposal of plant & equipment-11Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Finance lease payments(698)(676)Financing agreement payments(215)-Net cash outflow from financing activities(913)(676)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the beginning of the financial period108101	R&D tax incentive	3,364	4,911
Net cash outflow from operating activities(13,456)(12,603)Cash flows from investing activitiesPayments for plant and equipment(88)(56)Proceeds from disposal of plant & equipment-11Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Cash flows from financing activities(698)(676)Finance lease payments(698)(676)Financing agreement payments(215)-Net cash outflow from financing activities(913)(676)Net cash outflow from financing activities(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685	Interest received	403	1,010
activities(13,456)(12,603)Cash flows from investing activitiesPayments for plant and equipment(88)(56)Proceeds from disposal of plant & equipment-11Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Finance lease payments(698)(676)Financing agreement payments(215)-Net cash outflow from financing activities(913)(676)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the beginning of the financial period50,685	Income taxes refunded	-	13
Payments for plant and equipment(88)(56)Proceeds from disposal of plant & equipment-11Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Finance lease payments(698)(676)Financing agreement payments(215)-Net cash outflow from financing activities(913)(676)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the beginning of the financial period50,68550,685		(13,456)	(12,603)
Payments for intangible assets(19)(35)Net cash outflow from investing activities(107)(80)Cash flows from financing activities(107)(80)Finance lease payments(698)(676)Financing agreement payments(215)-Net cash outflow from financing activities(913)(676)Net cash outflow from financing activities(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685	Payments for plant and equipment Proceeds from disposal of plant &	(88)	(56)
Net cash outflow from investing activities(107)(80)Cash flows from financing activities(698)(676)Financie lease payments(215)-Net cash outflow from financing activities(913)(676)Net cash outflow from financing activities(14,476)(13,359)Cash and cash equivalents at the 		-	
activities(107)(80)Cash flows from financing activities(698)(676)Finance lease payments(215)-Net cash outflow from financing activities(913)(676)Net cash outflow from financing activities(14,476)(13,359)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685	Payments for intangible assets	(19)	(35)
Finance lease payments(698)(676)Financing agreement payments(215)-Net cash outflow from financing activities(913)(676)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685	-	(107)	(80)
Financing agreement payments(215)-Net cash outflow from financing activities(913)(676)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685	Cash flows from financing activities		
Net cash outflow from financing activities(913)(676)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685	Finance lease payments	(698)	(676)
activities(913)(676)Net decrease in cash and cash equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685	Financing agreement payments	(215)	-
equivalents(14,476)(13,359)Cash and cash equivalents at the beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685	-	(913)	(676)
beginning of the financial period34,18263,943Effects of exchange rate changes on the balance of cash held in foreign currencies108101Cash and cash equivalents at the19,81450,685		(14,476)	(13,359)
balance of cash held in foreign currencies108101Cash and cash equivalents at the19 81450 685		34,182	63,943
		108	101
		19,814	50,685

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 2014 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 2014 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.

### Presentation of financial statements

The group has decided to change its presentation of expenses in its income statement to a classification based on the nature of the expenses as opposed to their function within the entity. In accordance with *AASB101: Presentation of financial statements* the change in presentation is considered to provide information that is more relevant to users of the financial statements and follows a significant change in the nature of the entity's operations as discussed in the 'Review of Operations' in the Directors' report. The comparative information has been reclassified accordingly.

#### New accounting standards and interpretations

Certain new accounting standards and interpretations have been published that are not mandatory for 31 December 2014 reporting periods and the Group is finishing their assessment of these. At this stage the Group does not believe that the impact of these new standards and interpretations will be significant.

# 2. Segment information

#### (a) Description of segments

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

- 1. Bronchitol and Aridol business covering the ongoing clinical development, manufacture and sale of the 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 new series of inflammatory and respiratory drug candidates.

The corporate head office related costs of the group's business are not regarded as a segment but 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 2014 is as follows:

Pharmaxis Ltd Notes to the consolidated financial statements For the half-year ended 31 December 2014

# 2. Segment information (continued)

	Bronchitol & Aridol	New Drug Development	Corporate	Total
Half-year 2014	\$'000	\$'000	\$'000	\$'000
Total segment revenue	11,918	-	217	12,135
Expenses from ordinary activities				
Employee costs	(5,493)	(653)	(1,130)	(7,276)
Administration & corporate	(457)	(53)	(536)	(1,046)
Rent, occupancy & utilities	(468)	(41)	(304)	(813)
Clinical trials	(4,946)	(425)	-	(5,371)
Drug development	-	(533)	-	(533)
Sales, marketing & distribution	(1,326)	-	-	(1,326)
Safety, medical and regulatory affairs	(758)	-	-	(758)
Manufacturing purchases	(1,182)	-	-	(1,182)
Other	(580)	(28)	(208)	(816)
	(15,210)	(1,733)	(2,178)	(19,121)
Adjusted EBITDA	(3,292)	(1,733)	(1,961)	(6,986)
Half-year 2013				
Total segment revenue	3,717	579	76	4,372
Expenses from ordinary activities				
Employee costs	(7,056)	(699)	(1,464)	(9,219)
Administration & corporate	(456)	(51)	(1,192)	(1,699)
Rent, occupancy & utilities	(522)	(47)	(348)	(917)
Clinical trials	(1,370)	-	-	(1,370)
Drug development		(454)		
Drug de reiephient	-	(454)	-	(454)
Sales, marketing & distribution	- (1,900)	(434)	-	(454) (1,900)
	- (1,900) (803)			
Sales, marketing & distribution				(1,900)
Sales, marketing & distribution Safety, medical and regulatory affairs	(803)	-	-	(1,900) (803)
Sales, marketing & distribution Safety, medical and regulatory affairs Manufacturing purchases	(803) (1,023)	-	- -	(1,900) (803) (1,023)

The senior management committee uses the adjusted EBITDA as a measure to assess performance of the segments. This excludes the effects of non-recurring expenditure such as redundancy costs, partnering and financing agreement legal expenses, business development 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.

Pharmaxis Ltd Notes to the consolidated financial statements

# For the half-year ended 31 December 2014

# 2. Segment information (continued)

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

	31 December	31 December
	2014	2013
	\$'000	\$'000
Adjusted EBITDA	(6,986)	(13,428)
Interest revenue	403	1,010
Finance costs		
Financing agreement credits/(charges) <sup>(1)</sup>	3,419	(4,291)
Finance lease charges	(374)	(390)
Depreciation and amortisation expense	(1,704)	(2,472)
Impairment of patents and other assets	(277)	-
Redundancy expenses	(117)	-
Non recurring legal and business development expenses	(751)	(37)
Share-based payment expenses	(90)	(1,029)
Loss before income tax	(6,477)	(20,637)

(1) As outlined in the Directors' Report, the Company entered an Amended and Restated Financing Agreement with NovaQuest. As a consequence of the new financial terms and reduced investment balance, the financial liability required restatement which resulted in a net credit to the income statement in the half year period of \$3.4 million. Movements in the exchange rate between the US and Australian dollar are also reflected in this adjustment.

# 3. Revenue

Sales revenue		
Sale of goods	3,040	2,382
Other revenue		
Interest	403	1,010
R&D cost reimbursements from Chiesi	8,500	-
R&D cost reimbursements from Chiesi	8,500	-
Licence income	214	-
R&D tax credits	164	1,914
Other income	217	76

Pharmaxis Ltd Notes to the consolidated financial statements For the half-year ended 31 December 2014

# 5. Contributed equity

		Parent entity		Parent entity			
		31 December	30 June	31 December	30 June		
		2014	2014	2014	2014		
		Shares	Shares	\$'000	\$'000		
(a) S	Share capital						
Ordina	ary shares						
F	Fully paid	310,265,349	309,514,849	344,623	344,623		
Movements in ordinary share capital:							
Details		Number of shares	s Issue price \$'000				
Opening balance as at 1 July 2014		309,514,84		344,623			
Exercise of employee options		750,5	00 \$ - (1)	-			
(	Closing Balance at	31 December 2014	310,265,34	49	344,623		

(1) These related to options issued under the Performance Rights Plan, which are issued with a zero grant price and zero exercise 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 2014 in respect of:

#### Guarantees

The Company's bankers have issued bank guarantees of \$892,035 in relation to rental bond deposits for which no provision has been made in the accounts. The rental bond deposits cover the leased building which has been accounted for as a finance lease and other leased premises accounted for as operating leases. These bank guarantees are secured by security deposits held at the bank.

The Company's bankers have provided a corporate credit card facility which is secured by a deposit held at the bank totalling \$30,000.

The Company's bankers have issued a bank guarantee of GBP180,000 in relation to corporate credit card and local payment clearing house facilities provided by an overseas affiliate of the banker to Pharmaxis Pharmaceuticals Limited. The Company's bankers have also issued a bank guarantee of GBP140,000 in relation to a UK Customs Duty Deferment facility provided by an overseas affiliate of the banker to Pharmaxis Ltd. These bank guarantees are secured by a deposit held at the bank.

The Company's bankers have issued a bank guarantee of USD120,000 in relation to corporate credit card and local payment clearing house facilities provided by an overseas affiliate of the banker to Pharmaxis, Inc. This bank guarantee is secured by a deposit held at the bank.

# 7. Events occurring after the end of the reporting period

The Company announced on 21 January 2015 that it has commenced a Phase 1 clinical trial of its Semicarbazide-Sensitive Amine Oxidase/Vascular Adhesion Protein-1 (SSAO/VAP-1) Inhibitor (PXS4728A) investigating its potential to treat inflammatory diseases. PXS4728 is a highly selective small molecule inhibitor of SSAO that can be administered orally and has already demonstrated acceptable pharmacological properties during pre-clinical development. The initial stage of the trial is a single ascending dose study being conducted in 48 subjects at an Australian Phase 1 clinical trial centre. If these results are positive, the Company will proceed to a multiple ascending dose study in 24 subjects. The trial is expected to report in the third quarter of 2015 and cost approximately \$2 million.

No other matters or circumstance have arisen since 31 December 2014 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	31 December
		2014	2013
		Cents	Cents
(a)	Basic earnings per share		
	Loss attributable to the ordinary owners of the Company	(0.02)	(6.7)
(b)	Diluted earnings per share		
	Loss attributable to the ordinary owners of the company	(0.02)	(6.7)
(c)	Weighted average number of shares used as the denominator		
	Weighted average number of ordinary shares used as the denominator in calculating basic and diluted earnings / (loss) per share	309,725,145	308,698,335
(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. Given the entity is currently loss making, the potential ordinary shares are anti-dilutive and have therefore not been included in the diluted earnings per share calculation.

#### Pharmaxis Ltd Directors' declaration 31 December 2014

In the directors' opinion:

- (a) the financial statements and notes set out on pages 8 to 17 are in accordance with the *Corporations Act* 2001, including:
  - (i) complying with Accounting Standards, 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 2014 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 26<sup>th</sup> February 2015



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

# **Report on the Half-Year Financial Report**

We have reviewed the accompanying half-year financial report of Pharmaxis Ltd (the Company), which comprises the consolidated balance sheet as at 31 December 2014, the consolidated income statement, consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, selected explanatory notes and the directors' declaration for the Pharmaxis Group (the consolidated entity). The consolidated entity comprises the company and the entities it controlled during that half-year.

# Directors' responsibility 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 (including the Australian Accounting Interpretations) 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 is free from material misstatement whether due to fraud or error.

# Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Australian Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2014 and 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*. As the auditor of Pharmaxis Ltd, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

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.

# Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

19 **PricewaterhouseCoopers, ABN 52 780 433 757** Darling Park Tower 2, 201 Sussex Street, GPO BOX 2650, SYDNEY NSW 1171 T: +61 2 8266 0000, F: +61 2 8266 9999, www.pwc.com.au



# Conclusion

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

- a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2014 and of its performance for the half-year ended on that date;
- b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

ricewaterhouse Coopers

PricewaterhouseCoopers

Eddie Milkie

Eddie Wilkie Partner

Sydney 26 February 2015