# Pharmaxis Ltd

ABN 75 082 811 630

## ASX Half year report – 31 December 2015

## 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 2015 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 2015

**(Previous corresponding period: Half year ended 31 December 2014)**

**Results for announcement to the market**

| | | | | **A$'000** |
|---|---|---|---|---|
| **Revenue** from sale of goods | **Up** | **23%** | to | **3,727** |
| **Other revenue** from ordinary activities | **Down** | **41%** | to | **5,645** |
| **Total revenue** from ordinary activities | **Down** | **25%** | to | **9,372** |
| **Loss** from ordinary activities after tax | **Up** | **70%** | to | **(11,185)** |
| **Net loss** for the year attributable to members | **Up** | **70%** | to | **(11,185)** |

**Dividends**

It is not proposed to pay a dividend.

**Other Appendix 4D information**

| | **31 December 2015** | 31 December 2014 |
|---|---|---|
| Net tangible assets per ordinary share | **$ 0.079** | $ 0.036 |

# Pharmaxis Ltd
# Half-Year Report - 31 December 2015

## 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, 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 2015 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 25th February 2016. 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 2015**

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 2015.

**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 specialist pharmaceutical company with a portfolio of products at various stages of development and approval including two drug discoveries approved in various world markets and a research pipeline focused on areas of high unmet clinical need.

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 and includes Semicarbazide-Sensitive Amine Oxidase (SSAO) inhibitors for Non-alcoholic Steatohepatitis (NASH) and inflammatory diseases including kidney fibrosis and Chronic Obstructive Pulmonary Disease (COPD), and Lysyl Oxidase (LOX) inhibitors targeting fibrotic diseases including NASH, pulmonary fibrosis and some cancers. Pharmaxis' acknowledged expertise in amine oxide chemistry has attracted interest from leading pharmaceutical companies looking to make acquisitions or partner in this rapidly expanding growth area of scientific research. In May 2015, Boehringer Ingelheim (Boehringer) acquired the Pharmaxis phase 1 investigational drug PXS4728A, to develop it for the treatment of the diabetes and liver-related condition NASH.

Pharmaxis manufacturers and exports it's approved products from a purpose built high-tech manufacturing facility in Sydney.

- Bronchitol®, an inhaled dry powder for the treatment of cystic fibrosis (CF), has been the subject of two large scale global clinical trials conducted by Pharmaxis. The product is marketed in Europe and Australia and a third large multicentre clinical trial is currently underway aiming to secure approval in the United States.
- Aridol® a lung function test for asthma is approved and sold in Europe, Australia and Asia.

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

Drug discovery

During the current half year the Company moved quickly to build on the transformational deal completed in May 2015 with Boehringer Ingelheim for the Pharmaxis drug discovery PXS-4728A.

- In September 2015 Pharmaxis announced positive results for all primary and secondary endpoints from the phase 1 clinical trial of PXS-4728A. Boehringer is developing PXS-4728A as a treatment for cardiometabolic diseases such as NASH. PXS-4728A is a highly selective inhibitor of an enzyme and adhesion protein which reduces inflammation and oxidative stress. Pharmaxis had a commitment to complete the phase 1 study as a part of the agreement with Boehringer and earlier in the year reported positive results from the initial phase 1a single ascending dose stage of this clinical trial. Once daily oral dosing of PXS-4728A for 14 days at doses between 3 and 10 mg was found to be safe and well tolerated. The data confirmed the high oral bioavailability of PXS-4728A and most importantly, showed these low doses are efficacious in inhibiting the enzyme and cause a long lasting inhibition. PXS-4728A is therefore ideally suited for potential use as a chronic treatment; a once a day tablet that causes 24 hour inhibition of the target enzyme at low doses. Importantly, these positive phase 1 results enable Boehringer Ingelheim to proceed with further development of the program. Under the agreement, Boehringer is responsible for all development, regulatory, manufacturing and commercialisation activities, and Pharmaxis is entitled to total potential future milestones of €390 million (~A$523 million) to approval for 2 indications plus sales milestones and earn out payments at a high single digit percentage of sales. Boehringer is currently designing and preparing for the phase 2 clinical trial. The Company expects the phase 2 trial to commence by the first quarter of 2017.
- In August 2015 Pharmaxis announced a research collaboration with UK biotechnology company Synairgen plc (LSE: SNG) to develop a selective inhibitor to the Lysyl Oxidase Type 2 enzyme (LOXL2) to treat the fatal lung disease idiopathic pulmonary fibrosis (IPF). IPF affects approximately 100,000 people in the US. Whilst current products are expected to produce global revenues in excess of $1.1 billion by 2017 there remains a clear need for new treatments. This was evidenced recently when Bristol Myers Squibb announced an agreement to acquire a phase 2 drug for the

treatment of IPF and myelofibrosis with total potential payments of US$1.25 billion. Pharmaxis is targeting the LOXL2 enzyme because it is known to promote scar tissue which hardens and irreparably damages the lungs of IPF patients. It is hoped that the inhibition of LOXL2 will slow the build-up of scar tissue and improve survival rates that are worse than many cancers. Under the terms of the agreement Synairgen will fund further activity of the program, use its BioBank and in vitro lung model platform, and collaborate with the IPF research team at the University of Southampton in the UK to complete pre-clinical and early clinical development. The IPF program is managed by a joint steering committee through to the end of phase 1 or phase 2a clinical trials, at which time the collaboration will seek a license partner. Pharmaxis and Synairgen will share any licensing revenues in accordance with the ratio of total investment by the two companies at that time. The share of licensing revenues is expected to be approximately equal for a compound licensed for IPF after early clinical development. The significant interest among leading clinicians and pharmaceutical companies in the role of LOXL2 in a number of different diseases highlighted the need for Pharmaxis to collaborate for selected indications in order to fully exploit the potential value of the Company's intellectual property. Synairgen has a demonstrated excellence in respiratory drug development, having successfully licensed its inhaled IFN-beta Phase 2 program to AstraZeneca. By collaborating with Synairgen, Pharmaxis aims to accelerate the development of a highly competitive once a day oral treatment for patients with IPF while continuing to independently develop LOXL2 inhibitors for other potential indications. Synairgen and Pharmaxis have quickly identified a likely candidate and are working towards formal preclinical testing over the next six months.

- The Synairgen collaboration was the main priority of the drug discovery team over the half year with activity in other programs based around the Company's amine oxidase chemistry platform expected to increase in the next half year with the objective of moving one or more programs into preclinical development over the next twelve months.

Approved products - Bronchitol for cystic fibrosis

Bronchitol is an inhaled dry powder for the treatment of cystic fibrosis and has been the subject of two large scale global clinical trials conducted by Pharmaxis. The product is approved and marketed in Europe and Australia and a third large multicentre clinical trial is currently underway aiming to secure approval in the United States.

- In the US Pharmaxis has partnered with Chiesi Farmaceutici SpA which is funding (up to US$22 million) the international phase 3 clinical trial designed to meet the remaining clinical requirements of the US Food and Drug Administration (FDA). Under the terms of the agreement and following a positive outcome of the trial, Chiesi will have responsibility for completing the New Drug Application with the FDA and the commercialisation of Bronchitol in the United States. The Company continues to work closely with Chiesi on all aspects of securing US marketing approval for Bronchitol. The clinical trial (CF303) commenced recruitment in October 2014 and is being conducted in over 120 sites across more than 20 countries. At 31 December 2015, 299 patients had been recruited into the trial, which has a targeted full recruitment of up to 440 patients. The trial is taking longer to recruit than initially scheduled and the Company is extending the trial into additional countries to support recruitment efforts. Our current expectation is that CF303 will be fully recruited by mid 2016 and will cost approximately US$25 million, of which Chiesi is reimbursing the first US$22 million.

- In the EU, Pharmaxis appointed Chiesi as its exclusive distributor for the currently launched markets of the UK and Germany from 1 June 2015. Chiesi is an experienced and respected partner in key global markets and sells Bronchitol as part of its cystic fibrosis portfolio. Unit sales of Bronchitol by Pharmaxis and/or Chiesi in the UK and Germany for the six months to 31 December 2015 were 2% lower than the six months to 31 December 2014. This is a satisfactory outcome given the change in distribution to Chiesi and Pharmaxis looks forward to a return to growth in both the UK and Germany as Chiesi sales and marketing initiatives build momentum.

- In December 2015 Pharmaxis reported positive results for its phase 2 trial of Bronchitol in children and adolescents with cystic fibrosis (CF204). The trial, conducted across 39 global centres, met its primary endpoint and confirms that Bronchitol is efficacious in young patients, regardless of whether patients are taking dornase alfa. During the Bronchitol treatment period patients had a statistically significant improvement in lung function compared to placebo showing an absolute improvement of 3.42% (p=0.004) in FEV1 (% predicted) which equates to a relative change in FEV1 (% predicted) of 4.97% (p=0.005). This treatment improvement in the primary endpoint occurred irrespective of whether patients were taking dornase alfa. Secondary endpoints in the trial included absolute change in FEF25-75 (% predicted) which is thought to have particular significance in younger patients. Bronchitol produced an absolute improvement of 5.75% (p=0.005) in FEF25-75 equating to a relative improvement of 10.5%. In other secondary endpoints, treatment induced sputum weight was significantly increased (p=0.012) and a positive trend was seen in FVC. Although not recorded as a formal endpoint, patients on Bronchitol experienced approximately 25% fewer lung infections and exacerbations of CF which support the improvements seen in earlier studies despite the short duration of this study. The trial utilised a number of different design features to overcome some of the issues seen in this age group in the earlier phase 3 studies; in particular the European Medicines Agency (EMEA) agreed to the use of large particle size non-respirable mannitol as the placebo rather than a smaller dose of the active drug as used in the phase 3 trials. As a result the placebo effect seen in this study is minimal and it has therefore not only provided important and reassuring additional evidence on the benefit of Bronchitol in the paediatric and adolescent population but also highlighted that the results of the earlier phase 3 studies, where a control effect was seen in younger patients, may have been understated. In the trial subjects, Bronchitol was well-tolerated overall and had a favourable safety profile. There was no difference in the rate of adverse events or serious adverse events between the treatment groups. The most common adverse event was cough, which was mild to moderate in most cases and similar between the treatment arms. Three patients

experienced haemoptysis on Bronchitol and two on placebo. All haemoptysis events were categorised as either scant or mild and the overall level was below background rates reported in other comparable studies. The trial was designed in consultation with the EMEA as a condition of the marketing authorisation granted for Bronchitol for treating adult cystic fibrosis patients in Europe. To meet the condition in full Pharmaxis will submit a detailed study report to the EMEA in 2016. Pharmaxis is currently considering an application to extend the European Union marketing authorisation to include children and adolescents but it is not yet known if the trial results alone will be sufficient to gain an approval.

- Approval and reimbursement applications continue to progress in various countries including Eastern Europe, the Middle East and Brazil. Russian and Brazilian approvals are expected over the next few months.

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 Australia, South Korea and a number of European countries.

Sales of Aridol kits for the period increased 6% for both Australia and Europe, and decreased by 20% for South Korea.

**Financial Highlights**

**Revenue from sale of goods**

Sales for the half year ended 31 December of $3.7 million reflect the growing contribution by Bronchitol which increased from $2.1 million in 2014 to $2.8 million in 2015, an increase of 34%. Sales were made in Germany, the United Kingdom, Austria, Denmark, Sweden and Australia. In the EU, Pharmaxis appointed Chiesi as its exclusive distributor for the currently launched markets of the UK and Germany from 1 June 2015. Bronchitol sales in Germany and the United Kingdom represent approximately 80% of total Bronchitol sales. For the six months ended 31 December 2014 Bronchitol was sold directly to pharmacies in these markets by Pharmaxis. For the six months ended 31 December 2015 Bronchitol was sold to Chiesi. While Pharmaxis sales in the current period for Germany and the UK have been at a lower unit price to allow for distributor margins, volume of sales by Pharmaxis to Chiesi has increased as they have built inventory. Unit sales to pharmacies of Bronchitol in the UK and Germany for the six months to 31 December 2015 were 2% lower than the six months to 31 December 2014.

The group sold Aridol to customers in Europe, Australia and Asia during the period. Sales of Aridol in the half-year ended 31 December 2015 were $960,000, an increase of 9% over the half year ended 31 December 2014. This increase reflected higher sales in Europe offset by weaker sales in South Korea.

**Interest**

The increase in interest income was driven by an increase of cash and cash equivalents following the sale of the PXS-4728A compound to Boehringer Ingelhiem in May 2015.

**Other income**

Other income includes an amount of $4.4 million (2014: $8.5 million) representing the recognition of R&D cost reimbursements for the half-year ended 31 December 2015 pursuant to the commercialisation agreement with Chiesi. The amount reimburses Pharmaxis for the clinical trial costs from the clinical research organisation managing the Company's US Phase III pivotal clinical trial in cystic fibrosis adults aged 18 years and over, up to a maximum of US$22.0 million. The revenue recognised each period is reduced by a revenue deferral designed to recognise Pharmaxis' expected funding requirement at the end of the trial (currently US$ 3 million) over the term of the trial. The total deferred revenue at 31 December 2015 is A$2.4 million, of which A$ 1.4 million was deferred in the half-year ended December 2015.

Other income includes an amount of $420,000 charged to Synairgen under our research collaboration agreement for drug discovery services that was announced in August 2015.

The remaining component of other income includes an amount of $173,000 representing the sub-leasing part of the Company's Frenchs Forest premises.

**Employee costs**

Employee related expenses were $5.2 million in the half-year ended 31 December 2015 compared to $7.5 million in the half-year ended 31 December 2014. Employee costs include share based payments (non-cash) totalling $0.4 million in the 2015 period, compared to $0.1 million in the corresponding 2014 period. Employee costs have progressively reduced as the Company simplified its business model. At 31 December 2015 the Company employed 64 full time equivalents of whom 34 were engaged in production, quality and engineering, 12 in drug discovery, 10 across administration, medical affairs and safety, 6 in clinical trials and 2 were engaged in sales and marketing in Europe.

**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 2015 half-year period and $1.8 million in 2014. The decrease of $644,000 reflects a decrease in legal fees of $0.45 million relating to the financing and business development activities that occurred in the half-year ended 31st December 2014. The remaining decrease relates to a reduction in other administration and corporate costs as the general business complexity was rationalised.

**Clinical trials**

Clinical trials expenses were $6.4 million in the half-year ended 31 December 2015 compared to $5.4 million in the half-year ended 31 December 2014, an increase of $1.0 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 scale up of the Phase 3 clinical trial of Bronchitol for the treatment of CF in adults aged 18 years. The outsourced costs incurred for the period for this Phase 3 clinical trial totalled $5.7 million (2014: $3.3m) and are reimbursed under the terms of the commercialisation agreement with Chiesi. The smaller Phase 2 European paediatric clinical trial evaluating Bronchitol in cystic fibrosis concluded in December 2015.

**Drug development**

Drug development expenses were $1.2 million for the half-year ended 31 December 2015 compared to $0.5 million in the half-year ended 31 December 2014. 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. Following the sale of the compound PXS-4728A to Boehringer the Company has been able to increase investment in the drug development pipeline..

**Sales, marketing & distribution**

Sales & marketing expenses are external costs incurred in obtaining marketing and pricing approvals and selling Bronchitol globally, primarily through distributors. Limited resources are directed at the sale of Aridol. Sales & marketing expenses for the current half-year were $0.6 million, compared to $1.3 million in the half-year ended 31 December 2014. The expenses in both periods include costs associated in applying for pricing reimbursements and the decrease in sales & marketing expenses reflects the appointment of Chiesi as an exclusive distributor for the main European markets where Bronchitol is currently sold and the subsequent closure of the Company's European commercial infrastructure in May 2015.

**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 $0.9 million which was in line with the 2014 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 (to December 2017). The costs of this study for the six months ended 31 December 2015 totalled $0.4 million (2014: $0.4 million).

**Manufacturing purchases**

Manufacturing purchases were $0.9 million in the half-year ended 31 December 2015 compared to $1.2 million in the half-year ended 31 December 2014, a decrease of $0.3 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.

**Other**

Other expenses were $1.7 million in the half-year ended 31 December 2015 compared to $0.8 million in the half-year ended 31 December 2014, representing an increase of $0.9 million. This category encompasses corporate travel related costs, shared office administration costs, foreign exchange losses ($1.0 million) and other costs.

The foreign exchange losses of $1.0 million is largely made up of the $1.3 million loss on the USD denominated NovaQuest finance agreement.

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 2015 half-year royalties were payable on sales of both Aridol and Bronchitol totalling $0.1 million (2014: $0.1 million).

**Depreciation & amortisation**

Depreciation and amortisation expense was $1.5 million in the half-year ended 31 December 2015 compared to $1.7 million in the half-year ended 31 December 2014. The decrease in expense reflects the write down of certain intangible assets in the first half of the 2015 financial year.

**Finance expenses**

Finance expenses were $0.3 million in the 2015 half-year period compared to an credit of $3.0 million in 2014. 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 $0.3 million (2014: $0.4 million).
2. Accrued finance costs in relation to the NovaQuest financing agreement. The Company settled its dispute with NovaQuest Pharma Opportunities Fund III (NovaQuest) on 23 December 2014 and entered an Amended and Restated Financing Agreement. As a consequence of the new financial terms and reduced potential 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.

**Impairment expenses**

Restructure and impairment expenses were $Nil in the 2015 half-year period compared to $0.3 million in 2014. 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 in the 2014 half year relates to tax on the income generated by the group's subsidiaries which was reimbursed for their R&D and sales and marketing expenditures on a cost plus basis, upon which tax was payable. The group's overseas subsidiaries are currently dormant.

**Balance Sheet**

The group ended the half-year with $46 million in cash and cash deposits.

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

No matters or circumstance have arisen since 31 December 2015 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 8.

**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
25th February 2016

# Auditor's Independence Declaration

As lead auditor for the review of Pharmaxis Ltd for the half-year ended 31 December 2015, 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.

Eddie Wilkie
Partner
PricewaterhouseCoopers

Sydney
25 February 2016

**Pharmaxis Ltd**

**Consolidated income statement**

For the half-year ended 31 December 2015

| | Notes | **31 December 2015 $'000** | 31 December 2014 $'000 |
|---|---|---|---|
| **Revenue from continuing operations** | | | |
| Revenue from sale of goods | 3 | **3,727** | 3,040 |
| Other revenue | 3 | **658** | 403 |
| Other income | 4 | **4,987** | 9,095 |
| | | **9,372** | 12,538 |
| Expenses from ordinary activities | | | |
| Employee costs | | **(5,233)** | (7,483) |
| Administration & corporate | | **(1,153)** | (1,797) |
| Rent, occupancy & utilities | | **(624)** | (813) |
| Clinical trials | | **(6,375)** | (5,371) |
| Drug development | | **(1,180)** | (533) |
| Sales, marketing & distribution | | **(635)** | (1,326) |
| Safety, medical and regulatory affairs | | **(913)** | (758) |
| Manufacturing purchases | | **(900)** | (1,182) |
| Other | | **(1,674)** | (816) |
| Depreciation & amortisation | | **(1,516)** | (1,704) |
| Finance costs | | **(347)** | 3,045 |
| Impairment expenses | | **-** | (277) |
| | | **(20,550)** | (19,015) |
| **Loss before income tax** | | **(11,178)** | (6,477) |
| Income tax expense | | **(7)** | (95) |
| **Loss for the period** | | **(11,185)** | (6,572) |
| **Earnings per share:** | | **Cents** | Cents |
| Basic earnings / (loss) per share | 8 | **(0.04)** | (0.02) |
| Diluted earnings / (loss) per share | 8 | **(0.04)** | (0.02) |

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

**Pharmaxis Ltd**

**Consolidated statement of comprehensive income**

For the half-year ended 31 December 2015

| | **31 December 2015** | 31 December 2014 |
|---|---|---|
| | **$'000** | $'000 |
| **Loss for the period** | **(11,185)** | (6,572) |
| **Other comprehensive income** | | |
| Items that may be reclassified subsequently to profit or loss | | |
| Exchange differences on translation of foreign operations | **18** | 41 |
| **Other comprehensive loss for the period, net of tax** | **18** | 41 |
| **Total comprehensive loss for the period** | **(11,167)** | (6,531) |
| Total comprehensive loss for the period is attributable to: | | |
| Owners of Pharmaxis Ltd | **(11,167)** | (6,531) |

*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 2015

| | Notes | **31 December 2015 $'000** | 30 June 2015 $'000 |
|---|---|---|---|
| **ASSETS** | | | |
| **Current assets** | | | |
| Cash and cash equivalents | | **45,936** | 54,138 |
| Trade and other receivables | | **4,363** | 5,827 |
| Inventories | | **1,391** | 1,575 |
| Total current assets | | **51,690** | 61,540 |
| **Non-current assets** | | | |
| Receivables | | **1,031** | 1,021 |
| Property, plant and equipment | | **19,113** | 19,634 |
| Intangible assets | | **342** | 363 |
| Total non-current assets | | **20,486** | 21,018 |
| **Total assets** | | **72,176** | 82,558 |
| **LIABILITIES** | | | |
| **Current liabilities** | | | |
| Trade and other payables | | **4,140** | 5,796 |
| Borrowings | | **821** | 772 |
| Other liabilities | | **755** | 1,070 |
| Provisions | | **480** | 494 |
| Current tax liabilities | | **-** | 16 |
| Total current liabilities | | **6,196** | 8,148 |
| **Non-current liabilities** | | | |
| Borrowings | | **9,699** | 10,121 |
| Other liabilities | | **30,474** | 27,690 |
| Provisions | | **295** | 278 |
| Total non-current liabilities | | **40,468** | 38,089 |
| **Total liabilities** | | **46,664** | 46,237 |
| **Net assets** | | **25,512** | 36,321 |
| **EQUITY** | | | |
| Contributed equity | 5 (a) | **344,623** | 344,623 |
| Reserves | | **17,879** | 17,503 |
| Accumulated losses | | **(336,990)** | (325,805) |
| **Total equity** | | **25,512** | 36,321 |

*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 2015

| | Contributed equity | Reserves | Accumulated losses | Total |
|---|---|---|---|---|
| | $'000 | $'000 | $'000 | $'000 |
| **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 |
| **Balance at 30 June 2015** | **344,623** | **17,503** | **(325,805)** | **36,321** |
| Loss for the period | **-** | **-** | **(11,185)** | **(11,185)** |
| Other comprehensive income | **-** | **18** | **-** | **18** |
| **Total comprehensive income/(loss) for the half year** | **-** | **18** | **(11,185)** | **(11,167)** |
| **Transactions with owners in their capacity as owners** | | | | |
| Employee share options | **-** | **358** | **-** | **358** |
| | **-** | **358** | **-** | **358** |
| **Balance at 31 December 2015** | **344,623** | **17,879** | **(336,990)** | **25,512** |

*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 2015

| | **31 December 2015 $'000** | 31 December 2014 $'000 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Receipts from customers (inclusive of goods and services tax) | **11,316** | 4,049 |
| Payments to suppliers and employees (inclusive of goods and services tax) | **(18,378)** | (21,272) |
| | **(7,062)** | (17,223) |
| R&D tax incentive | **-** | 3,364 |
| Interest received | **658** | 403 |
| Income taxes refunded (paid) | **(22)** | **-** |
| **Net cash outflow from operating activities** | **(6,426)** | (13,456) |
| **Cash flows from investing activities** | | |
| Payments for plant and equipment | **(1,087)** | (88) |
| Proceeds from disposal of plant & equipment | **2** | **-** |
| Payments for intangible assets | **(7)** | (19) |
| **Net cash outflow from investing activities** | **(1,092)** | (107) |
| **Cash flows from financing activities** | | |
| Finance lease payments | **(720)** | (698) |
| Financing agreement payments | **(152)** | (215) |
| **Net cash outflow from financing activities** | **(872)** | (913) |
| **Net decrease in cash and cash equivalents** | **(8,390)** | (14,476) |
| Cash and cash equivalents at the beginning of the financial period | **54,138** | 34,182 |
| Effects of exchange rate changes on the balance of cash held in foreign currencies | **188** | 108 |
| **Cash and cash equivalents at the end of the financial period** | **45,936** | 19,814 |

*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 2015 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 2015 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.

### New accounting standards and interpretations

Certain new accounting standards and interpretations have been published that are not mandatory for 31 December 2015 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, 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. 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 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 2015 is as follows:

## 2. Segment information (continued)

| | Bronchitol & Aridol | New Drug Development | Corporate | Total |
|---|---|---|---|---|
| **Half-year 2015** | **$'000** | **$'000** | **$'000** | **$'000** |
| Total segment revenue | 8,121 | 420 | 173 | 8,714 |
| Expenses from ordinary activities | | | | |
| Employee costs | (2,816) | (828) | (1,102) | (4,746) |
| Administration & corporate | (261) | (53) | (751) | (1,065) |
| Rent, occupancy & utilities | (306) | (38) | (280) | (624) |
| Clinical trials | (6,278) | (97) | - | (6,375) |
| Drug development | - | (1,180) | - | (1,180) |
| Sales, marketing & distribution | (635) | - | - | (635) |
| Safety, medical and regulatory affairs | (913) | - | - | (913) |
| Manufacturing purchases | (900) | - | - | (900) |
| Other | (497) | (71) | 207 | (361) |
| | (12,606) | (2,267) | (1,926) | (16,799) |
| **Adjusted EBITDA** | **(4,485)** | **(1,847)** | **(1,753)** | **(8,085)** |
| **Half-year 2014** | | | | |
| 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)** |

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.

## 2. Segment information (continued)

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

| | **31 December 2015 $'000** | 31 December 2014 $'000 |
|---|---|---|
| Adjusted EBITDA | **(8,085)** | (6,986) |
| Interest revenue | **658** | 403 |
| Finance costs | | |
| Unrealised (gains) / losses on financial instruments [(1)] | **(1,313)** | 3,419 |
| Finance lease charges | **(347)** | (374) |
| Depreciation and amortisation expense | **(1,516)** | (1,704) |
| Impairment of patents and other assets | **-** | (277) |
| Redundancy expenses | **(129)** | (117) |
| Non recurring legal and business development expenses | **(88)** | (751) |
| Share-based payment expenses | **(358)** | (90) |
| **Loss before income tax** | **(11,178)** | (6,477) |

(1) Outlined in the Directors' Report for 31st December 2014 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 as for 31st December 2015.

## 3. Revenue

| | | |
|---|---|---|
| *Sales revenue* | | |
| Sale of goods | **3,727** | 3,040 |
| *Other revenue* | | |
| Interest | **658** | 403 |

## 4. Other income

| | | |
|---|---|---|
| R&D cost reimbursements from Chiesi | **4,394** | 8,500 |
| Drug Discovery service fees | **420** | - |
| Licence income | **-** | 214 |
| R&D tax credits | **-** | 164 |
| Other income | **173** | 217 |
| | **4,987** | 9,095 |

## 5. Contributed equity

| | Parent entity | | Parent entity | |
|---|---|---|---|---|
| | **31 December 2015** | 30 June 2015 | **31 December 2015** | 30 June 2015 |
| | **Shares** | Shares | **$'000** | $'000 |
| **(a) Share capital** | | | | |
| Ordinary shares | | | | |
| Fully paid | **317,126,457** | 314,813,957 | **344,623** | 344,623 |

**Movements in ordinary share capital:**

| **Details** | **Number of shares** | **Issue price** | **$'000** |
|---|---|---|---|
| Opening balance as at 1 July 2015 | 314,813,957 | | 344,623 |
| Exercise of employee options | 2,104,500 | $ - (1) | - |
| Employee Share Plan | 208,000 | $ - (2) | - |
| Closing Balance at 31 December 2015 | 317,126,457 | | 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.

(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 2015 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 31st December 2015 had a total deposits of $1.9 million (2014: $1.8 million) covering a rental bond, corporate credit card and payment clearing house facilities, and a UK Customs Duty Deferment facility.

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

No matters or circumstance have arisen since 31 December 2015 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 2015** | 31 December 2014 |
|---|---|---|
| | **Cents** | Cents |
| **(a) Basic earnings per share** | | |
| Loss attributable to the ordinary owners of the Company | **(0.04)** | (0.02) |
| **(b) Diluted earnings per share** | | |
| Loss attributable to the ordinary owners of the Company | **(0.04)** | (0.02) |
| **(c) Weighted average number of shares used as the denominator** | | |
| Weighted average number of ordinary shares used as the denominator in calculating basic and diluted earnings / (loss) per share | **316,712,722** | 309,725,145 |

**(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 2015

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 2015 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
25th February 2016

# 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 2015, 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 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 half-year 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 2015 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*.

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## *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 2015 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*.

## *Matters relating to the electronic presentation of the reviewed half-year financial report*

This review report relates to the half-year financial report of the company for the half-year ended 31 December 2015 included on Pharmaxis Ltd's web site. The company's directors are responsible for the integrity of the Pharmaxis Ltd web site. We have not been engaged to report on the integrity of this web site. The review report refers only to the statements named above. It does not provide an opinion on any other information which may have been hyperlinked to/from these statements. If users of this report are concerned with the inherent risks arising from electronic data communications they are advised to refer to the hard copy of the reviewed half-year financial report to confirm the information included in the reviewed half-year financial report presented on this web site.

PricewaterhouseCoopers

Eddie Wilkie

Eddie Wilkie
Partner

Sydney
25 February 2016