



## **Pharmaxis Ltd**

ABN 75 082 811 630

### **ASX Half year report – 31 December 2008**

#### **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 2008 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.

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## Pharmaxis Ltd

ABN 75 082 811 630

**Reporting period: Half year ended 31<sup>st</sup> December 2008**

**(Previous corresponding period: Half year ended 31<sup>st</sup> December 2007)**

### Results for announcement to the market

				<u>A\$'000</u>
Revenue from ordinary activities	Up	22%	to	3,966
Profit(loss) from ordinary activities after tax	Up	45%	to	(15,394)
Net profit(loss) for the half year attributable to members	Up	45%	to	(15,394)

### **Dividends**

It is not proposed to pay a dividend

### Other Appendix 4D information

	<u>31 December</u> <u>2008</u>	<u>31 December</u> <u>2007</u>
Net tangible assets per ordinary share	\$ 0.53	\$ 0.65

# Pharmaxis Ltd

## Half-Year Report - 31 December 2008

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This half-year report covers both Pharmaxis Ltd as an individual entity and the consolidated entity consisting of Pharmaxis Ltd and its subsidiaries. The financial report is 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  
Unit 2, 10 Rodborough Road  
Frenchs Forest, Australia 2086

This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the financial statements for the year ended 30 June 2008 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 this financial report.

The half-year report was authorised for issue by the directors on 5<sup>th</sup> February 2009. The company has the power to amend and reissue the financial report.

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 reports and other information are available on our website: [www.pharmaxis.com.au](http://www.pharmaxis.com.au).

**Pharmaxis Ltd**  
**Directors' Report**

For the half-year ended 31 December 2008

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 2008.

**Directors**

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

Denis Hanley (Chairman)  
Alan Robertson (Chief Executive Officer)  
William Delaat  
Peter Farrell  
Malcolm McComas  
John Villiger

**Review of operations**

**Overview**

Pharmaxis is a specialty pharmaceutical company with activities spanning product research and development through to manufacture, sales and marketing. The group is producing human healthcare products to treat and manage respiratory diseases.

Bronchitol

The group is developing Bronchitol for the management of chronic obstructive lung diseases including cystic fibrosis, bronchiectasis and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patient's clear mucus more effectively.

Major milestones achieved during the first half of fiscal 2009 included:

- Release of successful clinical data from the group's Phase II Bronchitol dosing trial in patients with cystic fibrosis. The lung function of trial participants improved by 8.6% when treated with 400mg Bronchitol
- Completion of enrolment of the group's first global Phase III clinical trial in patients with cystic fibrosis. A total of 325 participants joined the trial with the last patient scheduled to complete the study in the first quarter of 2009. A positive result from the trial should allow the group to file a marketing application throughout Europe.
- Commencement of enrolment in the group's second Phase III clinical trial in patients with cystic fibrosis. This trial is required in order for the group to submit a marketing application in the U.S
- Release of positive long-term safety data from the group's first Phase III clinical trial of Bronchitol in people living with bronchiectasis
- Filing of a marketing application with the Australian regulatory agency for Bronchitol for the treatment of bronchiectasis.

Aridol

Aridol is the group's first approved product. It is a simple-to-use airways inflammation test administered as a dry powder in a hand-held inhaler. Doctors can use the results of this test to identify airway hyper-responsiveness – a hallmark of asthma. During the first half of fiscal 2009 the group received approvals to market Aridol in Spain, France and Switzerland. Aridol is now available in 13 European countries as well as South Korea and Australia. Initial sales to a number of countries occurred during the half.

Other

Construction of the new purpose built group headquarters progressed on plan. Fit out of the base building has commenced with first occupancy scheduled for the second quarter of 2009.

**Pharmaxis Ltd**  
**Directors' Report**

For the half-year ended 31 December 2008

<b>Financial Highlights</b>	<b>31 December 2008 \$'000</b>	31 December 2007 \$'000
<b>Revenue from sale of goods</b>	<b>309</b>	193
Cost of sales	<b>(77)</b>	(51)
<b>Gross profit</b>	<b>232</b>	142
Interest income	<b>3,657</b>	3,061
Other income	<b>144</b>	235
Other expenses from ordinary activities		
Research & development expenses	<b>(13,587)</b>	(9,640)
Administration expenses	<b>(2,922)</b>	(2,464)
Commercial expenses	<b>(2,890)</b>	(1,951)
<b>Loss before income tax</b>	<b>(15,366)</b>	(10,617)
Income tax expense	<b>(28)</b>	(16)
<b>Loss for the period</b>	<b>(15,394)</b>	(10,633)
<b>Cash and cash equivalents</b>	<b>93,970</b>	120,844
<b>Net assets</b>	<b>104,902</b>	127,139

***Revenue from sale of goods:***

The group shipped Aridol to customers in Europe, Australia and Asia during the period, including \$42,893 to pharmaceutical companies for use in their clinical trials. Sales of Aridol in the half-year ended 31 December 2008 were 60% greater than sales in the half-year ended 31 December 2007. Overall gross margin was 75% of sales for the half-year ended 31 December 2008 (2007: 74%).

***Interest:***

The increase in interest income is attributable to the greater level of funds invested during the current half-year as a result of a share placement in October 2007. This is slightly offset by a general decrease in interest rates.

***Other income:***

Other income includes fees charged for the group's UK and Australian sales force promoting other pharmaceutical company's products to respiratory specialists, as well as grant income.

***Research & development expenses:***

Research & development expenses increased by approximately \$4.0 million in the first half of fiscal 2009 compared to the first half of fiscal 2008. There are four major components to research & development expenses:

1. The drug discovery unit based at North Ryde. This unit accounted for approximately 7 percent of the total research and development expenditure in the current half-year. It is focused on inflammatory and respiratory drug discovery. Expenditure decreased by approximately \$200,000 compared to the half-year ended 31 December 2007 reflecting a decreased requirement for outside research consultants at the current stage of development work.
2. The preclinical development unit located at our Frenchs Forest facility accounted for approximately 4 percent of the total research and development expenditure in the current half-year and decreased by approximately \$180,000 compared to the half-year ended 31 December 2007. In the 31 December 2007 half-year the group was managing outsourced safety/toxicology studies of PXS25. In the current half-year the unit was not engaged in safety studies of a similar size or cost.
3. The clinical unit located at our Frenchs Forest facility accounted for approximately 67 percent of the total research and development expenditure in the current half-year and increased by approximately \$4.4 million compared to the half-year ended 31 December 2007. The clinical unit designs and monitors the clinical trials run by the group and are responsible for regulatory agency filings. The majority of the expenditures of this unit are directed at hospitals

**Pharmaxis Ltd**  
**Directors' Report**

For the half-year ended 31 December 2008

and other services related to the conduct and analysis of clinical trials. This increase in expenditure reflects the increased number of clinical trials in the active dosing phase during the current half-year as well as costs associated with achieved and proposed regulatory filings of Aridol and Bronchitol. As the group's largest area of research, the increase of expenditure by the clinical unit was the predominant cause of the overall increase of research and development expenditure during the current half-year.

4. **Manufacturing.** The GMP manufacturing facility at Frenchs Forest is focused on producing material for clinical trials and regulatory filing related studies, and developing enhanced manufacturing processes. All costs associated with this work are classified as a research and development expenditure. Costs associated with the Aridol product sold are classified as cost of sales. Manufacturing accounted for approximately 22 percent of our total research and development expenditure in the current half-year and increased by approximately \$343,000 compared to the half-year ended 31 December 2007 predominantly because of the completion of outsourced stability studies before the commencement of the current half.

**Administration expenses:**

Administration expenses include accounting, administration, recruitment and public company costs. Administration expenses for the current half-year were \$2.9 million, compared to \$2.5 million in the half-year ended 31 December 2007 and \$2.8 million in the half-year ended 30 June 2008. The increase in administration expenses in the current half-year is mainly attributable to additional costs associated with expanding the group both domestically and internationally, and costs to support the expanding clinical program.

**Commercial expenses:**

The commercial expenses are focussed on developing and delivering the commercial strategy and capability to sell Aridol and Bronchitol globally. Commercial expenses for the current half-year were \$2.9 million, compared to \$2.0 million in the half-year ended December 2007 and \$2.6 million in the half-year ended 30 June 2008. The increase in commercial expenses is predominantly attributable to the establishment of US commercial operations in the second half of the 2007 financial year.

**Income tax expense:**

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

**Balance Sheet:**

The group ended the half-year with \$94 million in cash, cash deposits and bank accepted commercial bills.

Capital expenditure during the period predominantly related to the new manufacturing facility.

Shareholders are advised that additional information concerning the group's progress in the quarter ended 31 December 2008 is contained in the December 2008 Quarterly Report to Shareholders, available on the Pharmaxis website.

**Auditors' independence declaration**

A copy of the auditors' independence declaration as required under section 307C of the *Corporations Act 2001* is set out on page 5.

**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 report. Amounts in the directors' report and financial report 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.



Alan D Robertson  
Director

5<sup>th</sup> February 2009

## Auditors' Independence Declaration

As lead auditor for the review of Pharmaxis Ltd for the half year ended 31 December 2008, I declare that to the best of my knowledge and belief, there have been:

- a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- b) no contraventions of any applicable code of professional conduct in relation to the review.

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



Mark Dow  
Partner  
PricewaterhouseCoopers

Sydney  
5 February 2009

**Pharmaxis Ltd****Consolidated income statement**

For the half-year ended 31 December 2008

		<b>31 December 2008</b>	31 December 2007
	Notes	<b>\$'000</b>	\$'000
<b>Revenue from continuing operations</b>			
Revenue from sale of goods	2	<b>309</b>	193
Cost of sales		<b>(77)</b>	(51)
<b>Gross profit</b>		<b>232</b>	142
Other revenue	2	<b>3,657</b>	3,061
Other income	3	<b>144</b>	235
Other expenses from ordinary activities	4		
Research & development expenses		<b>(13,587)</b>	(9,640)
Administration expenses		<b>(2,922)</b>	(2,464)
Commercial expenses		<b>(2,890)</b>	(1,951)
<b>Loss before income tax</b>		<b>(15,366)</b>	(10,617)
Income tax expense		<b>(28)</b>	(16)
<b>Loss for the period</b>		<b>(15,394)</b>	(10,633)
<b>Earnings per share:</b>			
		<b>Cents</b>	Cents
Basic earnings / (loss) per share	9	<b>(7.9)</b>	(5.8)
Diluted earnings / (loss) per share	9	<b>(7.9)</b>	(5.8)

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



**Pharmaxis Ltd**  
**Consolidated balance sheet**  
As at 31 December 2008

	Notes	31 December 2008 \$'000	30 June 2008 \$'000
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents		93,970	111,842
Trade and other receivables		7,406	6,651
Inventories		123	96
Total current assets		<b>101,499</b>	118,589
<b>Non-current assets</b>			
Receivables		2,099	1,526
Other financial assets		-	39
Plant and equipment		7,858	3,668
Intangible assets		1,258	1,227
Total non-current assets		<b>11,215</b>	6,460
<b>Total assets</b>		<b>112,714</b>	125,049
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables		7,563	5,709
Other liabilities		-	-
Current tax liabilities		61	31
Total current liabilities		<b>7,624</b>	5,740
<b>Non-current liabilities</b>			
Provisions		188	188
Total non-current liabilities		<b>188</b>	188
<b>Total liabilities</b>		<b>7,812</b>	5,928
<b>Net assets</b>		<b>104,902</b>	119,121
<b>EQUITY</b>			
Contributed equity	5 (a)	194,691	194,680
Reserves		8,603	7,439
Accumulated losses		(98,392)	(82,998)
<b>Total equity</b>		<b>104,902</b>	119,121

*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 2008

	<b>31 December 2008</b>	31 December 2007
	<b>\$'000</b>	\$'000
<b>Total equity at the beginning of the financial year</b>	<b>119,121</b>	76,559
Exchange differences on translation of foreign operations	<b>14</b>	(8)
<b>Net income recognised directly in equity</b>	<b>14</b>	(8)
<b>Loss for the period</b>	<b>(15,394)</b>	(10,633)
<b>Transactions with equity holders in their capacity as equity holders</b>		
Contributions of equity, net of transaction costs	5 (a) <b>11</b>	59,540
Employee share options	<b>1,150</b>	1,681
<b>Total equity at the end of the financial period</b>	<b>104,902</b>	127,139

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

**Pharmaxis Ltd****Consolidated cash flow statement**

For the half-year ended 31 December 2008

	<b>31 December 2008 \$'000</b>	31 December 2007 \$'000
<b>Cash flows from operating activities</b>		
Receipts from customers (inclusive of goods and services tax)	408	54
Payments to suppliers and employees (inclusive of goods and services tax)	<b>(16,200)</b>	(16,003)
	<b>(15,792)</b>	(15,949)
Research grant receipts from government	298	472
Other income	66	117
Interest received	3,657	3,061
Income taxes paid	<b>(56)</b>	(12)
<b>Net cash outflow from operating activities</b>	<b>(11,827)</b>	(12,311)
<b>Cash flows from investing activities</b>		
Payments for plant and equipment	<b>(4,595)</b>	(2,506)
Instalment payments to acquire plant and equipment	<b>(1,363)</b>	-
Proceeds from disposal of plant & equipment	-	1
Payments for intangible assets	<b>(129)</b>	(46)
<b>Net cash outflow from investing activities</b>	<b>(6,087)</b>	(2,551)
<b>Cash flows from financing activities</b>		
Proceeds from issues of shares	11	62,061
Share issue transaction costs	-	(2,521)
<b>Net cash inflow from financing activities</b>	11	59,540
<b>Net (decrease) / increase in cash and cash equivalents</b>	<b>(17,903)</b>	44,678
Cash and cash equivalents at the beginning of the financial year	<b>111,842</b>	76,182
Effects of exchange rate changes on the balance of cash held in foreign currencies	<b>31</b>	(16)
<b>Cash and cash equivalents at the end of the financial period</b>	<b>93,970</b>	120,844

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

## 1. Basis of preparation of half-year report

This general purpose financial report for the interim half-year reporting period ended 31 December 2008 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2008 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.

## 2. Revenue

	<b>31 December 2008 \$'000</b>	31 December 2007 \$'000
<i>Sales revenue</i>		
Sale of goods	<b>309</b>	193
<i>Other revenue</i>		
Interest	<b>3,657</b>	3,061

## 3. Other income

Government grants	<b>(52)</b>	128
Income from sale force agreements	<b>196</b>	107
	<b>144</b>	235

Government grants comprised the following:

- i. R&D START program grants of \$Nil (2007: \$5,584).
- ii. Australian Government's Pharmaceuticals Partnerships Program ("P3") grants of \$(51,663) (2007: \$52,302).
- iii. Export Market Development Grant of \$Nil (2007: \$70,000).

## 4. Expenses

	<b>31 December 2008 \$'000</b>	31 December 2007 \$'000
<b>Loss before income tax includes the following specific expenses:</b>		
Depreciation		
Plant and equipment	<b>278</b>	321
Computer equipment	<b>87</b>	71
Leasehold improvements	<b>54</b>	46
Total depreciation	<b>419</b>	438
Amortisation		
Patents	<b>48</b>	47
Trademarks	<b>3</b>	1
Software	<b>47</b>	33
Total amortisation	<b>98</b>	81

#### 4. Expenses (continued)

	31 December 2008 \$'000	31 December 2007 \$'000
Net loss on disposal of plant and equipment	-	5
Rental expense relating to operating leases	365	316
Net foreign exchange (gains) / losses	(79)	40
Employee benefits expense		
Defined contribution superannuation expense	352	292
Other employee benefits expenses	6,810	5,915

#### 5. Equity and reserves

	Parent entity		Parent entity	
	31 December 2008 Shares	30 June 2008 Shares	31 December 2008 \$'000	30 June 2008 \$'000
<b>(a) Share capital</b>				
Ordinary shares				
Fully paid	194,537,262	194,514,762	194,691	194,680

##### Movements in ordinary share capital:

Date	Details	Number of shares	Issue price	\$'000
1 July 2008	Opening balance	194,514,762		194,680
	Exercise of employee options	22,500	\$ 0.5080	11
31 December 2008	Balance	194,537,262		194,691

##### (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 parent entity and group had contingent liabilities at 31 December 2008 in respect of:

##### *Government grants*

The group has received three separate Australian Government research grants under the R&D START Program, all three of which have been completed. The Government may require the group to repay all or some of the amount of a particular grant together with interest in either of the following circumstances:

- a) the company fails to use its best endeavours to commercialise the relevant grant project within a reasonable time of completion of the project; or
- b) upon termination of a grant due to breach of agreement or insolvency.

The group continues the development and commercialisation of all three projects funded by the START Program. The total amount received under the START Program at 31 December 2008 was \$4,707,817.

The group recognised \$(51,663) (2007: \$52,302) under the Australian Government's Pharmaceuticals Partnerships

**Pharmaxis Ltd****Notes to the financial statements**

For the half-year ended 31 December 2008

(continued)

Program ("P3") during the financial period. The Government may require the group to repay all or some of the amount of the grant together with interest in any of the following circumstances:

- a) the Government determines that expenditure claimed on research projects do not meet the P3 guidelines; or
- b) upon termination of the grant due to breach of agreement, change in control of the group or insolvency.

*Guarantees*

The company's bankers have issued bank guarantees of \$1,115,203 in relation to rental bond deposits for which no provision has been made in the accounts. These bank guarantees are secured by security deposits held at the bank.

The company's bankers have issued a bank guarantee of GBP70,000 in relation to corporate credit card facilities provided by an overseas affiliate of the banker to Pharmaxis Pharmaceuticals Limited. This bank guarantee is secured by a deposit held at the bank.

The company's bankers have issued a bank guarantee of USD100,000 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 balance sheet date**

No matter or circumstance has arisen since 31 December 2008 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. Financial reporting by segments**

The group operates predominantly in one industry. The principal activities of the group are the research, development and commercialisation of pharmaceutical products.

The group operates predominantly in one geographical area, being Australia.

**9. Earnings per share**

	<b>31 December 2008</b>	31 December 2007
	<b>Cents</b>	Cents
<b>(a) Basic earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	<b>(7.9)</b>	(5.8)
<b>(b) Diluted earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	<b>(7.9)</b>	(5.8)
<b>(c) Weighted average number of shares used as the denominator</b>		
Weighted average number of ordinary shares used as the denominator in calculating basic and diluted earnings / (loss) per share	<b>194,532,615</b>	184,226,939

**(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. The options have not been included in the determination of basic earnings per share. 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 2008

In the directors' opinion:

- (a) the financial statements and notes set out on pages 6 to 12 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 2008 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.



Alan D Robertson

Director

Sydney  
5<sup>th</sup> February 2009

# Pharmaxis Ltd

## Half-Year Report - 31 December 2008

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Pharmaxis Ltd  
Unit 2, 10 Rodborough Road  
Frenchs Forest, Australia 2086

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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 this financial report.

The half-year report was authorised for issue by the directors on 5<sup>th</sup> February 2009. The company has the power to amend and reissue the financial report.

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 reports and other information are available on our website: [www.pharmaxis.com.au](http://www.pharmaxis.com.au).



**Pharmaxis Ltd**  
**Directors' Report**

For the half-year ended 31 December 2008

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 2008.

**Directors**

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

Denis Hanley (Chairman)  
Alan Robertson (Chief Executive Officer)  
William Delaat  
Peter Farrell  
Malcolm McComas  
John Villiger

**Review of operations**

**Overview**

Pharmaxis is a specialty pharmaceutical company with activities spanning product research and development through to manufacture, sales and marketing. The group is producing human healthcare products to treat and manage respiratory diseases.

Bronchitol

The group is developing Bronchitol for the management of chronic obstructive lung diseases including cystic fibrosis, bronchiectasis and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patient's clear mucus more effectively.

Major milestones achieved during the first half of fiscal 2009 included:

- Release of successful clinical data from the group's Phase II Bronchitol dosing trial in patients with cystic fibrosis. The lung function of trial participants improved by 8.6% when treated with 400mg Bronchitol
- Completion of enrolment of the group's first global Phase III clinical trial in patients with cystic fibrosis. A total of 325 participants joined the trial with the last patient scheduled to complete the study in the first quarter of 2009. A positive result from the trial should allow the group to file a marketing application throughout Europe.
- Commencement of enrolment in the group's second Phase III clinical trial in patients with cystic fibrosis. This trial is required in order for the group to submit a marketing application in the U.S
- Release of positive long-term safety data from the group's first Phase III clinical trial of Bronchitol in people living with bronchiectasis
- Filing of a marketing application with the Australian regulatory agency for Bronchitol for the treatment of bronchiectasis.

Aridol

Aridol is the group's first approved product. It is a simple-to-use airways inflammation test administered as a dry powder in a hand-held inhaler. Doctors can use the results of this test to identify airway hyper-responsiveness – a hallmark of asthma. During the first half of fiscal 2009 the group received approvals to market Aridol in Spain, France and Switzerland. Aridol is now available in 13 European countries as well as South Korea and Australia. Initial sales to a number of countries occurred during the half.

Other

Construction of the new purpose built group headquarters progressed on plan. Fit out of the base building has commenced with first occupancy scheduled for the second quarter of 2009.

**Pharmaxis Ltd**  
**Directors' Report**

For the half-year ended 31 December 2008

<b>Financial Highlights</b>	<b>31 December 2008</b>	31 December 2007
	<b>\$'000</b>	\$'000
<b>Revenue from sale of goods</b>	<b>309</b>	193
Cost of sales	<b>(77)</b>	(51)
<b>Gross profit</b>	<b>232</b>	142
Interest income	<b>3,657</b>	3,061
Other income	<b>144</b>	235
Other expenses from ordinary activities		
Research & development expenses	<b>(13,587)</b>	(9,640)
Administration expenses	<b>(2,922)</b>	(2,464)
Commercial expenses	<b>(2,890)</b>	(1,951)
<b>Loss before income tax</b>	<b>(15,366)</b>	(10,617)
Income tax expense	<b>(28)</b>	(16)
<b>Loss for the period</b>	<b>(15,394)</b>	(10,633)
<b>Cash and cash equivalents</b>	<b>93,970</b>	120,844
<b>Net assets</b>	<b>104,902</b>	127,139

**Revenue from sale of goods:**

The group shipped Aridol to customers in Europe, Australia and Asia during the period, including \$42,893 to pharmaceutical companies for use in their clinical trials. Sales of Aridol in the half-year ended 31 December 2008 were 60% greater than sales in the half-year ended 31 December 2007. Overall gross margin was 75% of sales for the half-year ended 31 December 2008 (2007: 74%).

**Interest:**

The increase in interest income is attributable to the greater level of funds invested during the current half-year as a result of a share placement in October 2007. This is slightly offset by a general decrease in interest rates.

**Other income:**

Other income includes fees charged for the group's UK and Australian sales force promoting other pharmaceutical company's products to respiratory specialists, as well as grant income.

**Research & development expenses:**

Research & development expenses increased by approximately \$4.0 million in the first half of fiscal 2009 compared to the first half of fiscal 2008. There are four major components to research & development expenses:

1. The drug discovery unit based at North Ryde. This unit accounted for approximately 7 percent of the total research and development expenditure in the current half-year. It is focused on inflammatory and respiratory drug discovery. Expenditure decreased by approximately \$200,000 compared to the half-year ended 31 December 2007 reflecting a decreased requirement for outside research consultants at the current stage of development work.
2. The preclinical development unit located at our Frenchs Forest facility accounted for approximately 4 percent of the total research and development expenditure in the current half-year and decreased by approximately \$180,000 compared to the half-year ended 31 December 2007. In the 31 December 2007 half-year the group was managing outsourced safety/toxicology studies of PXS25. In the current half-year the unit was not engaged in safety studies of a similar size or cost.
3. The clinical unit located at our Frenchs Forest facility accounted for approximately 67 percent of the total research and development expenditure in the current half-year and increased by approximately \$4.4 million compared to the half-year ended 31 December 2007. The clinical unit designs and monitors the clinical trials run by the group and are responsible for regulatory agency filings. The majority of the expenditures of this unit are directed at hospitals

**Pharmaxis Ltd**  
**Directors' Report**

For the half-year ended 31 December 2008

and other services related to the conduct and analysis of clinical trials. This increase in expenditure reflects the increased number of clinical trials in the active dosing phase during the current half-year as well as costs associated with achieved and proposed regulatory filings of Aridol and Bronchitol. As the group's largest area of research, the increase of expenditure by the clinical unit was the predominant cause of the overall increase of research and development expenditure during the current half-year.

4. **Manufacturing.** The GMP manufacturing facility at Frenchs Forest is focused on producing material for clinical trials and regulatory filing related studies, and developing enhanced manufacturing processes. All costs associated with this work are classified as a research and development expenditure. Costs associated with the Aridol product sold are classified as cost of sales. Manufacturing accounted for approximately 22 percent of our total research and development expenditure in the current half-year and increased by approximately \$343,000 compared to the half-year ended 31 December 2007 predominantly because of the completion of outsourced stability studies before the commencement of the current half.

**Administration expenses:**

Administration expenses include accounting, administration, recruitment and public company costs. Administration expenses for the current half-year were \$2.9 million, compared to \$2.5 million in the half-year ended 31 December 2007 and \$2.8 million in the half-year ended 30 June 2008. The increase in administration expenses in the current half-year is mainly attributable to additional costs associated with expanding the group both domestically and internationally, and costs to support the expanding clinical program.

**Commercial expenses:**

The commercial expenses are focussed on developing and delivering the commercial strategy and capability to sell Aridol and Bronchitol globally. Commercial expenses for the current half-year were \$2.9 million, compared to \$2.0 million in the half-year ended December 2007 and \$2.6 million in the half-year ended 30 June 2008. The increase in commercial expenses is predominantly attributable to the establishment of US commercial operations in the second half of the 2007 financial year.

**Income tax expense:**

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

**Balance Sheet:**

The group ended the half-year with \$94 million in cash, cash deposits and bank accepted commercial bills.

Capital expenditure during the period predominantly related to the new manufacturing facility.

Shareholders are advised that additional information concerning the group's progress in the quarter ended 31 December 2008 is contained in the December 2008 Quarterly Report to Shareholders, available on the Pharmaxis website.

**Auditors' independence declaration**

A copy of the auditors' independence declaration as required under section 307C of the *Corporations Act 2001* is set out on page 5.

**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 report. Amounts in the directors' report and financial report 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.



Alan D Robertson  
Director

5<sup>th</sup> February 2009

## Auditors' Independence Declaration

As lead auditor for the review of Pharmaxis Ltd for the half year ended 31 December 2008, I declare that to the best of my knowledge and belief, there have been:

- a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- b) no contraventions of any applicable code of professional conduct in relation to the review.

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



Mark Dow  
Partner  
PricewaterhouseCoopers

Sydney  
5 February 2009

**Pharmaxis Ltd****Consolidated income statement**

For the half-year ended 31 December 2008

	Notes	31 December 2008 \$'000	31 December 2007 \$'000
<b>Revenue from continuing operations</b>			
Revenue from sale of goods	2	309	193
Cost of sales		(77)	(51)
<b>Gross profit</b>		<b>232</b>	<b>142</b>
Other revenue	2	3,657	3,061
Other income	3	144	235
Other expenses from ordinary activities	4		
Research & development expenses		(13,587)	(9,640)
Administration expenses		(2,922)	(2,464)
Commercial expenses		(2,890)	(1,951)
<b>Loss before income tax</b>		<b>(15,366)</b>	<b>(10,617)</b>
Income tax expense		(28)	(16)
<b>Loss for the period</b>		<b>(15,394)</b>	<b>(10,633)</b>
<b>Earnings per share:</b>			
Basic earnings / (loss) per share	9	(7.9)	(5.8)
Diluted earnings / (loss) per share	9	(7.9)	(5.8)

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

**Pharmaxis Ltd**  
**Consolidated balance sheet**  
As at 31 December 2008

	Notes	31 December 2008 \$'000	30 June 2008 \$'000
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents		93,970	111,842
Trade and other receivables		7,406	6,651
Inventories		123	96
Total current assets		<b>101,499</b>	118,589
<b>Non-current assets</b>			
Receivables		2,099	1,526
Other financial assets		-	39
Plant and equipment		7,858	3,668
Intangible assets		1,258	1,227
Total non-current assets		<b>11,215</b>	6,460
<b>Total assets</b>		<b>112,714</b>	125,049
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables		7,563	5,709
Other liabilities		-	-
Current tax liabilities		61	31
Total current liabilities		<b>7,624</b>	5,740
<b>Non-current liabilities</b>			
Provisions		188	188
Total non-current liabilities		<b>188</b>	188
<b>Total liabilities</b>		<b>7,812</b>	5,928
<b>Net assets</b>		<b>104,902</b>	119,121
<b>EQUITY</b>			
Contributed equity	5 (a)	194,691	194,680
Reserves		8,603	7,439
Accumulated losses		<b>(98,392)</b>	(82,998)
<b>Total equity</b>		<b>104,902</b>	119,121

*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 2008

	<b>31 December 2008 \$'000</b>	31 December 2007 \$'000
<b>Total equity at the beginning of the financial year</b>	<b>119,121</b>	76,559
Exchange differences on translation of foreign operations	<b>14</b>	(8)
<b>Net income recognised directly in equity</b>	<b>14</b>	(8)
<b>Loss for the period</b>	<b>(15,394)</b>	(10,633)
<b>Transactions with equity holders in their capacity as equity holders</b>		
Contributions of equity, net of transaction costs	<b>11</b>	59,540
Employee share options	<b>1,150</b>	1,681
<b>Total equity at the end of the financial period</b>	<b>104,902</b>	127,139

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

**Pharmaxis Ltd****Consolidated cash flow statement**

For the half-year ended 31 December 2008

	<b>31 December 2008 \$'000</b>	31 December 2007 \$'000
<b>Cash flows from operating activities</b>		
Receipts from customers (inclusive of goods and services tax)	408	54
Payments to suppliers and employees (inclusive of goods and services tax)	<b>(16,200)</b>	(16,003)
	<b>(15,792)</b>	(15,949)
Research grant receipts from government	298	472
Other income	66	117
Interest received	3,657	3,061
Income taxes paid	<b>(56)</b>	(12)
<b>Net cash outflow from operating activities</b>	<b>(11,827)</b>	(12,311)
<b>Cash flows from investing activities</b>		
Payments for plant and equipment	<b>(4,595)</b>	(2,506)
Instalment payments to acquire plant and equipment	<b>(1,363)</b>	-
Proceeds from disposal of plant & equipment	-	1
Payments for intangible assets	<b>(129)</b>	(46)
<b>Net cash outflow from investing activities</b>	<b>(6,087)</b>	(2,551)
<b>Cash flows from financing activities</b>		
Proceeds from issues of shares	11	62,061
Share issue transaction costs	-	(2,521)
<b>Net cash inflow from financing activities</b>	11	59,540
<b>Net (decrease) / increase in cash and cash equivalents</b>	<b>(17,903)</b>	44,678
Cash and cash equivalents at the beginning of the financial year	111,842	76,182
Effects of exchange rate changes on the balance of cash held in foreign currencies	31	(16)
<b>Cash and cash equivalents at the end of the financial period</b>	<b>93,970</b>	120,844

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



## 1. Basis of preparation of half-year report

This general purpose financial report for the interim half-year reporting period ended 31 December 2008 has been prepared in accordance with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2008 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.

## 2. Revenue

	<b>31 December 2008 \$'000</b>	31 December 2007 \$'000
<i>Sales revenue</i>		
Sale of goods	<b>309</b>	193
<i>Other revenue</i>		
Interest	<b>3,657</b>	3,061

## 3. Other income

Government grants	<b>(52)</b>	128
Income from sale force agreements	<b>196</b>	107
	<b>144</b>	235

Government grants comprised the following:

- i. R&D START program grants of \$Nil (2007: \$5,584).
- ii. Australian Government's Pharmaceuticals Partnerships Program ("P3") grants of \$(51,663) (2007: \$52,302).
- iii. Export Market Development Grant of \$Nil (2007: \$70,000).

## 4. Expenses

	<b>31 December 2008 \$'000</b>	31 December 2007 \$'000
<b>Loss before income tax includes the following specific expenses:</b>		
Depreciation		
Plant and equipment	<b>278</b>	321
Computer equipment	<b>87</b>	71
Leasehold improvements	<b>54</b>	46
Total depreciation	<b>419</b>	438
Amortisation		
Patents	<b>48</b>	47
Trademarks	<b>3</b>	1
Software	<b>47</b>	33
Total amortisation	<b>98</b>	81

#### 4. Expenses (continued)

	31 December 2008 \$'000	31 December 2007 \$'000
Net loss on disposal of plant and equipment	-	5
Rental expense relating to operating leases	365	316
Net foreign exchange (gains) / losses	(79)	40
Employee benefits expense		
Defined contribution superannuation expense	352	292
Other employee benefits expenses	6,810	5,915

#### 5. Equity and reserves

	Parent entity		Parent entity	
	31 December 2008 Shares	30 June 2008 Shares	31 December 2008 \$'000	30 June 2008 \$'000
<b>(a) Share capital</b>				
Ordinary shares				
Fully paid	194,537,262	194,514,762	194,691	194,680

##### Movements in ordinary share capital:

Date	Details	Number of shares	Issue price	\$'000
1 July 2008	Opening balance	194,514,762		194,680
	Exercise of employee options	22,500	\$ 0.5080	11
31 December 2008	Balance	194,537,262		194,691

##### (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 parent entity and group had contingent liabilities at 31 December 2008 in respect of:

##### *Government grants*

The group has received three separate Australian Government research grants under the R&D START Program, all three of which have been completed. The Government may require the group to repay all or some of the amount of a particular grant together with interest in either of the following circumstances:

- a) the company fails to use its best endeavours to commercialise the relevant grant project within a reasonable time of completion of the project; or
- b) upon termination of a grant due to breach of agreement or insolvency.

The group continues the development and commercialisation of all three projects funded by the START Program. The total amount received under the START Program at 31 December 2008 was \$4,707,817.

The group recognised \$(51,663) (2007: \$52,302) under the Australian Government's Pharmaceuticals Partnerships

**Pharmaxis Ltd****Notes to the financial statements**

For the half-year ended 31 December 2008

(continued)

Program ("P3") during the financial period. The Government may require the group to repay all or some of the amount of the grant together with interest in any of the following circumstances:

- a) the Government determines that expenditure claimed on research projects do not meet the P3 guidelines; or
- b) upon termination of the grant due to breach of agreement, change in control of the group or insolvency.

*Guarantees*

The company's bankers have issued bank guarantees of \$1,115,203 in relation to rental bond deposits for which no provision has been made in the accounts. These bank guarantees are secured by security deposits held at the bank.

The company's bankers have issued a bank guarantee of GBP70,000 in relation to corporate credit card facilities provided by an overseas affiliate of the banker to Pharmaxis Pharmaceuticals Limited. This bank guarantee is secured by a deposit held at the bank.

The company's bankers have issued a bank guarantee of USD100,000 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 balance sheet date**

No matter or circumstance has arisen since 31 December 2008 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. Financial reporting by segments**

The group operates predominantly in one industry. The principal activities of the group are the research, development and commercialisation of pharmaceutical products.

The group operates predominantly in one geographical area, being Australia.

**9. Earnings per share**

	<b>31 December 2008</b>	31 December 2007
	<b>Cents</b>	Cents
<b>(a) Basic earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	<b>(7.9)</b>	(5.8)
<b>(b) Diluted earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	<b>(7.9)</b>	(5.8)
<b>(c) Weighted average number of shares used as the denominator</b>		
Weighted average number of ordinary shares used as the denominator in calculating basic and diluted earnings / (loss) per share	<b>194,532,615</b>	184,226,939
<b>(d) Information concerning the classification of securities</b>		

*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. The options have not been included in the determination of basic earnings per share. 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 2008

In the directors' opinion:

- (a) the financial statements and notes set out on pages 6 to 12 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 2008 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.



Alan D Robertson

Director

Sydney  
5<sup>th</sup> February 2009

## INDEPENDENT AUDITOR'S REVIEW REPORT

to the members of Pharmaxis Limited

### Report on the Half-Year Financial Report

We have reviewed the accompanying half-year financial report of Pharmaxis Ltd, which comprises the balance sheet as at 31 December 2008, and the income statement, statement of changes in equity and cash flow statement for the half-year ended on that date, other selected explanatory notes and the directors' declaration for the Pharmaxis Ltd Group (the consolidated entity). The consolidated entity comprises both Pharmaxis Ltd (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 and fair presentation of the half-year financial report in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001*. This responsibility includes establishing and maintaining internal control relevant to the preparation and fair presentation of the half-year financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

#### *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 Auditing Standard on Review Engagements ASRE 2410 *Review of an Interim 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 2008 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. It also includes reading the other information included with the financial report to determine whether it contains any material inconsistencies with the financial report. 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.

For further explanation of a review, visit our website <http://www.pwc.com/au/financialstatementaudit>.

While we considered the effectiveness of management's internal controls over financial reporting when determining the nature and extent of our procedures, our review was not designed to provide assurance on internal controls.

Our review did not involve an analysis of the prudence of business decisions made by directors or management.

*Matters relating to the electronic presentation of the reviewed financial report*

This review report relates to the financial report of Pharmaxis Ltd (the Company) for the half-year ended 31 December 2008 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 financial report identified above. It does not provide an opinion on any other information which may have been hyperlinked to/from the financial report. 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 financial report to confirm the information included in the reviewed financial report presented on this web site.

*Independence*

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

*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 2008 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 Interim Financial Reporting and Corporations Regulations 2001.



PricewaterhouseCoopers



Mark Dow  
Partner

Sydney  
5 February 2009