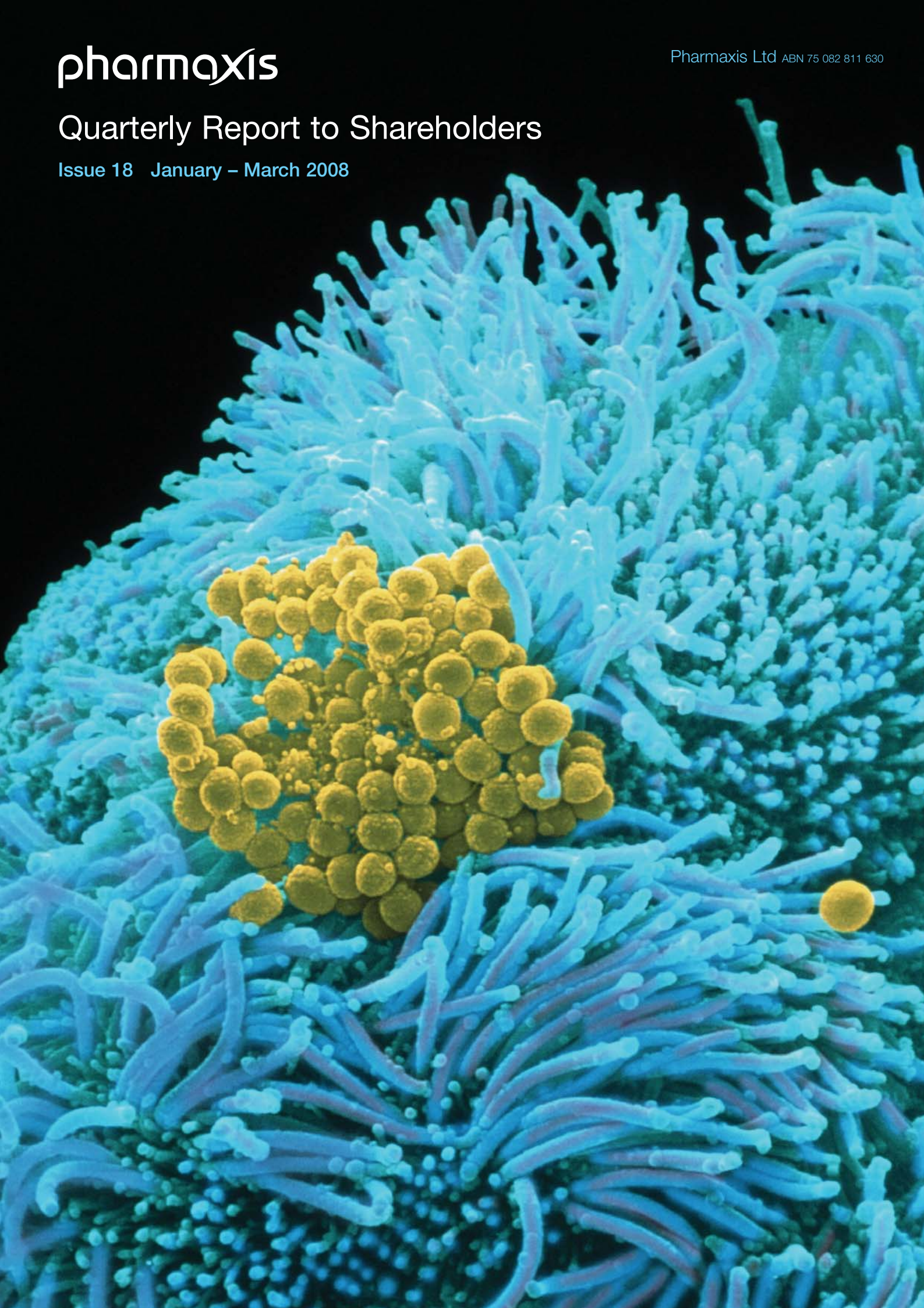
pharmaxis

Pharmaxis Ltd ABN 75 082 811 630

Quarterly Report to Shareholders

Issue 18 January – March 2008



Producing human healthcare products to treat and manage respiratory and immune diseases

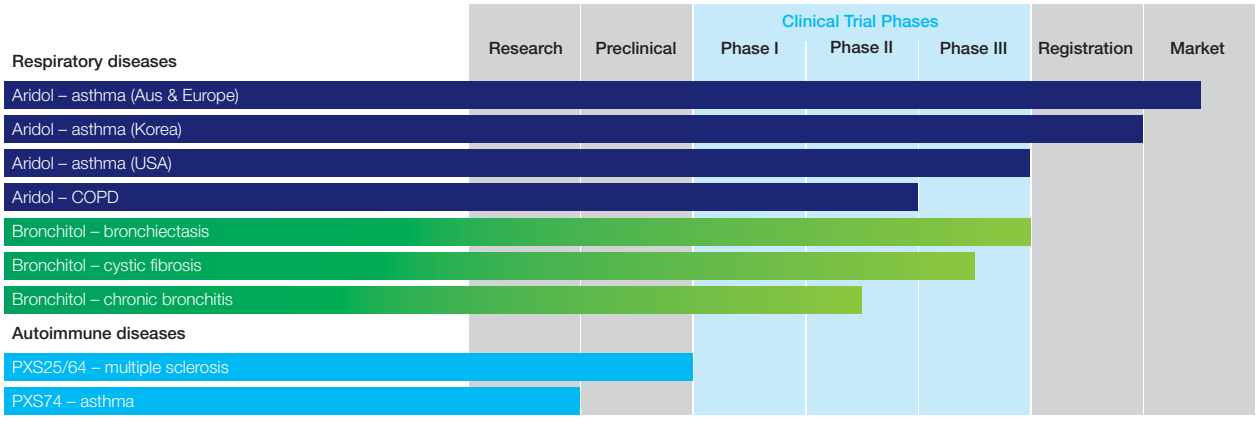
Overview

Pharmaxis is a specialty pharmaceutical company with activities spanning product research & development through to manufacture, sales and marketing.

Our therapeutic interests include lung diseases such as cystic fibrosis, asthma, bronchiectasis and chronic obstructive pulmonary disease; and diseases of the immune system such as multiple sclerosis and rheumatoid arthritis.

Our first product, Aridol, is now registered for sale in Australia, Europe and parts of Asia and is designed to assist in the management of both asthma and chronic ob-structive pulmonary disease. Our second product, Bronchitol, is in final clinical trials as a new treatment for cystic fibrosis and chronic obstructive pulmonary diseases such as bronchiectasis and chronic bronchitis.

Pharmaxis Product Development at March 2008



COPD = Chronic Obstructive Pulmonary Disease – a fatal disease of the lungs, related to smoking.

Front cover: A microscopic view of a colony of Staphylococcus bacteria on a human lung. The lungs are lined with cilia (hair like projections) which help keep them free of dust and other irritants. These bacteria are a major problem for people with cystic fibrosis and bronchiectasis, colonizing the lung and resulting in excessive mucus production that makes breathing difficult. *(JUERGEN BERGER/SCIENCE PHOTO LIBRARY)*

CEO Report

We have made steady progress on all fronts of the business, however this quarter has been dominated by our interaction with the various regulatory agencies worldwide. A meeting to discuss the marketing application of Aridol was hosted by the FDA, which involved a comprehensive discussion of the data we have gathered to date. Agreement has been reached on the marketing application filing plan and we will submit the application shortly.

We have also reached agreement from the Australian regulatory authorities on the marketing application filing plan for Bronchitol in the treatment of bronchiectasis. An Australian approval also gives us an opportunity to reach into other countries in South East Asia. The European regulatory agencies have asked us to consider conducting a second trial in patients with bronchiectasis and the U.S. FDA has provided us with advice on the bronchiectasis trial and regulatory path to a marketing approval. We are now close to aligning the very detailed responses from the two different agencies.

The Bronchitol Phase III clinical trial in adults and children with cystic fibrosis follows a different regulatory path to bronchiectasis, where a pre-trial agreement to market has been reached with the European Agency and the FDA.

I hope you enjoy reading about our positive progress during the quarter.

Alan D Robertson, Chief Executive Officer

First Quarter Highlights

Inroads into Asia

- Aridol gains approval in Korea
- China accepts Bronchitol clinical trial application dossier for review
- U.S. FDA meeting confirms Aridol marketing submission plans
- Australian TGA meeting confirms Bronchitol marketing application plans
- Cystic fibrosis trial in children returns positive results with Bronchitol
- Aridol for elite athletes accepted by Olympic Committee

Coming Events

Aridol for US market

- File New Drug Application for Aridol with US FDA
- File Marketing Application for Bronchitol with Australian TGA
- Complete enrollment in international Phase III cystic fibrosis study
- Commence dosing in US Phase III cystic fibrosis study
- Bronchitol cystic fibrosis dose relationship to report

Corporate News

New factory on track

Progress continues on the new Pharmaxis headquarters and factory in Frenchs Forest, Sydney. The building is on schedule, with the excavation finished and half the footings poured. The 7,000 square metre facility is expected to be completed by early next year.

Foundations being laid for new factory

China office opens

Pharmaxis' representative office in Shanghai was formally registered and approved by the State Administration for Industry and Commerce of the People's Republic of China.

Current Regulatory Activities

Aridol – Europe

Approvable advice from Switzerland

Marketing Authorisation Certificates for Aridol have been received from Denmark, Sweden, The Netherlands, Ireland and The United Kingdom.

We are hopeful that most of the rest of the European Union will provide us with the necessary certificates during the June 2008 quarter.

For those countries where marketing certificates have been granted, we are working through hospital formulary submissions, pricing applications and reimbursement issues.

An approvable letter was received from Switzerland in March after a lengthy review process. The final marketing authorisation is expected to be received during Q3 2008.

Aridol – USA

Positive meeting with US FDA

A Pre-New Drug Application (NDA) meeting was held with the U.S. FDA in March to discuss Aridol. The meeting was positive and helpful and no unresolved problems or issues were uncovered.

As a result, we are now in a position to file our New Drug Application. The submission will include data from two Phase III clinical trials involving 1,200 subjects. We plan to submit the NDA during the June quarter following completion of extensive stability studies.

New Bronchitol trials planned

Bronchitol (bronchiectasis) – Europe

A Scientific Advice meeting was held with the European Medicines Agency (EMEA) to discuss the path forward on the clinical development program for Bronchitol for the treatment of bronchiectasis. Formal advice was received from the Agency following the meeting. In summary, the EMEA advice is to conduct a further clinical trial of six months' duration with two primary efficacy measures: the number of exacerbations requiring antibiotic treatment and quality of life.

Bronchitol (bronchiectasis) – USA

A second Phase III protocol was submitted to the FDA under the Special Protocol Assessment route and the formal response has been received. The FDA has advised us to conduct a further clinical trial of at least 12 months' duration with one primary efficacy measure: reduction in pulmonary exacerbations. With no universally accepted definition of exacerbation in bronchiectasis, we are continuing to work with the FDA on a mutually acceptable definition. Bronchitol has US Orphan Drug designation for this condition.

Australian application in Q3

Bronchitol (bronchiectasis) – Australia

Fruitful discussions with the Australian Therapeutic Goods Administration (TGA) have provided a path forward for bringing Bronchitol to market in Australia.

It has been agreed to file a marketing application for Bronchitol in bronchiectasis once the ongoing 12 month safety component of the trial is complete. This is expected to be mid-2008 and, therefore, the target date for submission of the marketing application is Q3 2008. Bronchiectasis affects more than 20,000 Australians.

First steps into China

Bronchitol (bronchiectasis) – China

A clinical trial application for Bronchitol to treat bronchiectasis has been accepted for evaluation by China's State Food and Drug Administration (SFDA). All pharmaceutical companies are required to undertake a study in a Chinese population to support their marketing approval application. Final approval of the clinical trial application is expected in the fourth quarter.

The number of Chinese who suffer from bronchiectasis is more than double that of the rest of the world. A number of leading Chinese respiratory physicians have indicated they wish to conduct bronchiectasis studies, and have confirmed there is a large unmet need for new treatments for bronchiectatic patients.

Europe CF trial recruiting underway

Bronchitol (cystic fibrosis) – Europe

Some time ago, a Phase III clinical trial design was agreed with the EMEA under their protocol assistance process and the trial is now well into its recruitment phase with over 180 subjects out of the 250 enrolled. This trial will be sufficient to seek approval for Bronchitol in cystic fibrosis in Europe, and the EMEA has confirmed that Bronchitol is eligible for submission through the centralised Community procedure.

This requires a single application, a single evaluation and a single authorization, allowing direct access to the entire market of the European Union. Bronchitol has Orphan drug designation for cystic fibrosis in Europe, which affords Bronchitol 10 years' market exclusivity within the European Union.

Bronchitol (cystic fibrosis) – USA

Late last year, the FDA agreed to a Phase III clinical trial of Bronchitol for cystic fibrosis. This will form the primary basis of an efficacy claim in support of a New Drug Application, conducted under the Special Protocol Assessment scheme. The agreement covers the study design, trial size, clinical endpoints and data analyses. This clinical trial is now in the establishment phase with the assistance of the US cystic fibrosis foundation. Bronchitol has Orphan Drug designation and Fast Track status for cystic fibrosis in the U.S.

Current Medical Activities

Bodes well for Phase III trial

Phase II trial in children delivers positive results

A Phase II clinical trial in children with cystic fibrosis demonstrated excellent lung function improvement following three months treatment with Bronchitol.

Bronchitol matched the results achieved by the current marketed product rhDnase. The improvement in lung function after three months on Bronchitol reflects that seen in a previous study following two weeks of treatment.

The study was an independent investigator initiated study conducted in the United Kingdom. While not on the regulatory approval path, this is the first time we have had an opportunity to measure the performance of Bronchitol following three months' continuous treatment. The results bode well for the pivotal six month Phase III trial currently in progress.

Current Marketing Activities

Strong Korean opportunity

Aridol gains first Asian approval

In January the Korean regulatory agency granted marketing approval for our asthma management product, Aridol. This is the first Asian approval of Aridol.

Korea is an important base from which to launch and grow Aridol in Asia. There are an estimated 2.5 million asthma sufferers and yet only 160,000 bronchial challenge tests are performed annually to assist with asthma diagnosis and management. The existing broad acceptance of lung function challenge tests presents a firm opportunity for marketing Aridol.

Olympic athletes to use Aridol

IOC Medical Commission's Independent Panel approves Aridol

The International Olympic Committee Medical Commission's Independent Panel has included Aridol as an approved test.

The approval was contained in the IOC Consensus Statement on Asthma in Elite Athletes, for athletes competing in the Beijing Olympics.

The IOC Medical Commission is concerned that athletes competing at the Olympics are diagnosed correctly and receive the most appropriate therapy. An estimated 20% of Olympic athletes are asthmatic.

The Commission recommends that in diagnosing asthma in Olympians, a bronchial provocation test such as Aridol be used to establish the presence of airway hyper-responsiveness.

Aridol sparks international debate

World experts discuss Aridol

Pharmaxis was represented at the recent American Academy of Asthma Allergy & Immunology (AAAAI) meeting held in Philadelphia, USA.

Aridol featured in several scientific posters and presentations and was the subject of a high-profile debate between two world leaders in bronchial provocation testing, which drew a large audience and had a very favourable result for Aridol.

Various U.S. clinicians, researchers and key bodies expressed a keen interest in Aridol at the meeting and look forward to being involved with and following its progress in this important market.

Pharmaxis also hosted a stand at the annual 2008 Thoracic Society of Australia and New Zealand Annual Meeting in March. More than 1,000 respiratory physicians and thoracic specialists attended the event.

Current Research Activities

Phase I clinical trial nears

PXS25

PXS25 is being developed to treat inflammatory lung diseases such as asthma and chronic obstructive pulmonary disease. Our research, clinical and regulatory teams are preparing the necessary documents to submit a clinical trial application to regulatory authorities. The Phase I clinical study will be conducted in Australia and will focus on safety and the pharmacokinetic profile of PXS25.

In another research project, our drug discovery team has now designed advanced leads which inhibit the protein SSAO/VAP-1. This protein plays a key role in the inflammatory process and its inhibition is expected to lead to new therapies for diseases such as rheumatoid arthritis and multiple sclerosis. We have selected a preferred development candidate and have commenced the scale up manufacture and pre-clinical safety studies necessary to evaluate the compound in human studies.

Intellectual Property Portfolio

There has been no material change to the patent portfolio this quarter.

Financial Overview of the Quarter

At the end of March 2008 the cash position was A$116 million, sufficient to advance our clinical program and expand our manufacturing capacity.

Aridol sales increases

Revenue

Aridol sales for the March 2008 quarter of A$136,000 were 230% greater than the March 2007 quarter. Sales were made to customers in Australia (43%), Europe (14%) and for clinical trial use (43%). Australian sales were 67% greater than March 2007 and 12% greater than December 2007.

The increase in interest income over the prior comparable quarter reflects the increase in invested cash as well as generally higher interest rates received on the bank accepted bills in which the majority of funds are invested.

Grant income relates predominantly to the Pharmaceuticals Partnerships Program.

Research & development expenditure

Expenditure

Research and development expenditure of A$4.4 million for the March 2008 quarter compares to A$5.2 million in the March 2007 quarter, and A$4.6 million in the December 2007 quarter.

Clinical expenses accounted for 65% of R&D expenditure, an increase of around 28% from the March 2007 quarter due to greater clinical trial activity.

Our drug discovery unit accounted for 13% of R&D expenditure – a rise of 43% over the March 2007 quarter but unchanged from the December 2007 quarter.

Preclinical expenses for the quarter were minimal, with one project completing its preclinical development and another set to commence.

Manufacturing R&D expenses accounted for 22% of R&D expenditure – a decrease of close to 44% from expenditure in the March 2007 quarter. Manufacturing R&D remains focused on the supply of product to clinical trials and to long term stability studies required for the Aridol marketing application in the U.S.

Commercial expenses

Commercial expenditure of A$1,154,000 compares to A$846,000 in the March 2007 quarter and A$1,053,000 in the December 2007 quarter. The predominant reason for the increase is higher (non cash) costs in relation to employee share options. Expenditure in the current quarter also include costs associated with the U.S. office and European market research.

Administration expenditure of A$1,321,000 compares to A$1,325,000 in the March 2007 quarter and A$1,411,000 in the December 2007 quarter.

Cash Flow

Investing activities for the March 2008 quarter of A$276,000 included expenditure for the new manufacturing facility and additional computer infrastructure.

International Financial Reporting Standards

(Unaudited)
('000 except per share data)

Income Statement

	Three months ended			Year-to-date		
	31-Mar-08	31-Mar-07	31-Mar-08	31-Mar-08	31-Mar-07	31-Mar-08
	A$	A$	US$[1]	A$	A$	US$[1]
Revenue from sale of goods	136	41	124	330	159	301
Cost of sales	(30)	(10)	(27)	(82)	(39)	(75)
Gross profit	106	31	97	248	120	226
Other income						
Interest	2,108	1,283	1,925	5,169	4,059	4,720
Grant income	668	396	610	796	1,583	727
Other	21	–	19	127	–	116
			–			–
Expenses			–			–
Research & development	4,370	5,212	3,991	14,010	18,984	12,794
Commercial	1,154	846	1,054	3,105	2,462	2,835
Administration	1,321	1,325	1,206	3,785	3,258	3,456
Total expenses	6,845	7,383	6,251	20,900	24,704	19,086
Net loss before tax	(3,942)	(5,673)	(3,600)	(14,560)	(18,942)	(13,296)
Income tax expense	2	4	2	18	12	16
Net loss after tax	(3,944)	(5,677)	(3,602)	(14,578)	(18,954)	(13,313)
Basic and diluted earnings (loss) per share – $	(0.020)	(0.032)	(0.019)	(0.078)	(0.107)	(0.071)
Depreciation & amortisation	253	239	231	772	693	705
Fair value of options issued under employee plan	923	462	843	2,604	1,091	2,378

	As at		
	31-Mar-08	30-Jun-07	31-Mar-08
	A$	A$	US$[1]
Cash and cash equivalents	116,224	76,182	106,136
Plant & equipment	5,570	3,509	5,087
Intangible assets	1,239	1,229	1,131
Total assets	127,264	82,648	116,217
Total liabilities	(3,120)	(6,089)	(2,849)
Total shareholders' equity	124,144	76,559	113,368

Cash Flow Data

	Three months ended			Year-to-date		
	31-Mar-08	31-Mar-07	31-Mar-08	31-Mar-08	31-Mar-07	31-Mar-08
	A$	A$	US$[1]	A$	A$	US$[1]
Cash flows from operating activities	(4,363)	(6,018)	(3,984)	(16,674)	(17,089)	(15,227)
Cash flows from investing activities	(275)	(151)	(251)	(2,826)	(1,027)	(2,581)
Cash flows from financing activities	31	13	28	59,571	192	54,400
Net increase (decrease) in cash held	(4,607)	(6,156)	(4,207)	40,071	(17,924)	36,593

Share Data

	Ordinary Shares As at		American Depositary Shares As at	
	31-Mar-08	30-Jun-07	31-Mar-08	30-Jun-07
Ordinary shares on issue	194,515	177,949	12,968	11,863
Options over ordinary shares outstanding	11,524	9,836	768	656

(1) Convenience translation into U.S. dollars from Australian dollars based upon rate on March 31, 2008

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Contact Details

Further information on Pharmaxis can be obtained from www.pharmaxis.com.au or by contacting David McGarvey, Chief Financial Officer.

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