pharmaxis

Pharmaxis Ltd ABN 75 082 811 630

Quarterly Report to Shareholders

Issue 19 April – June 2008

Producing human healthcare products to treat and manage respiratory diseases

Overview

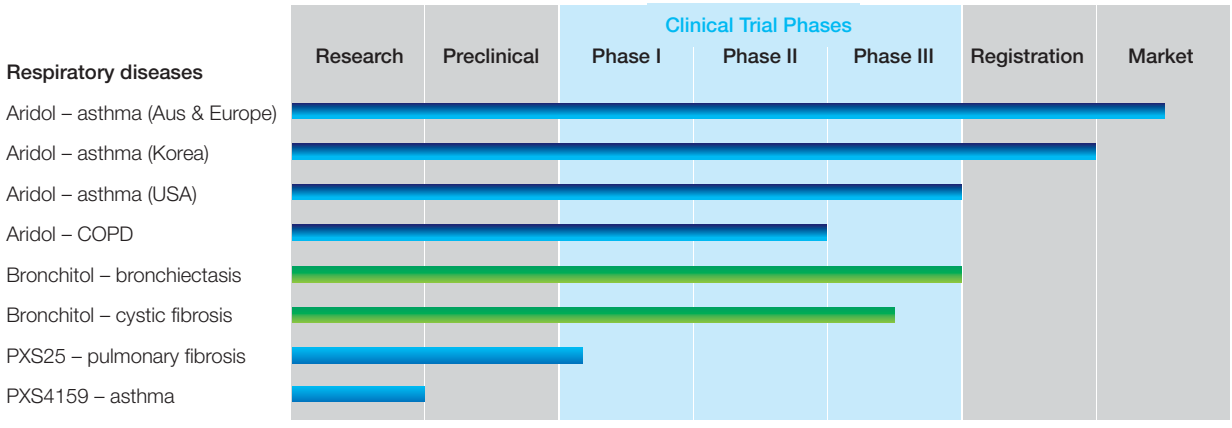
Pharmaxis is a specialty pharmaceutical company with activities spanning product research & development through to manufacture, sales and marketing.

Our therapeutic interests include lung diseases such as cystic fibrosis, asthma, bronchiectasis and chronic obstructive pulmonary disease.

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 obstructive 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.

Our research group is developing two new potential therapies for chronic and debilitating lung conditions such as asthma and pulmonary fibrosis.

Pharmaxis Product Development at June 2008



COPD: Chronic Obstructive Pulmonary Disease – a fatal disease of the lungs, related to smoking.
Pulmonary fibrosis: excessive fibrous connective tissue in the lungs.

Front cover: Twelve-year-old Harry Coffey is the first person in the world to complete the Phase 3 trial of Bronchitol in cystic fibrosis. Read about his experience with the medicine on page 5.

Photo courtesy of Justine McCullagh-Beasy, *The Guardian*, Swan Hill.

CEO Report

I am pleased to report that we are making good progress on all facets of the business, from the early stage research projects through to our marketed product, Aridol. While obtaining the necessary European Aridol marketing certificates has been frustratingly slow, most of these are now in place and we are working with our EU distributors to give Aridol the best possible opportunity of making a solid start in Europe. The Aridol marketing application for the USA has involved considerable effort, particularly on the manufacturing and stability aspects of the product, and will be filed with the Food and Drug Administration shortly.

Bronchitol has finished a long term Phase 3 safety and efficacy trial in bronchiectasis and this will form the basis of our first Bronchitol marketing application, to be filed in Australia this year. In Europe, cystic fibrosis will be the first indication for which we file a marketing application early next year.

Generating revenue from Aridol and Bronchitol is critical for our future and the correct clinical, regulatory and reimbursement strategies are paramount to the success of both products. This report contains details of our progress in the first two areas.

Alan D Robertson, Chief Executive Officer

Bronchitol for CF progressing

Second Quarter Highlights

- Recruitment milestone reached in Phase 3 CF trial
- First patient finishes global Phase 3 CF trial
- Phase 2 CF dosing study completes
- Agreement reached with FDA on pivotal Phase 3 bronchiectasis trial
- Long-term safety study of Bronchitol for bronchiectasis closes
- Pharmaxis establishes global compassionate use program for Bronchitol
- Aridol approved for marketing in four more EU countries
- New Pharmaxis board appointment

FDA drug application nears completion

Coming Events

- File marketing application for Aridol with US FDA
- File marketing application for Bronchitol with Australian TGA
- Results of long-term safety study of Bronchitol in bronchiectatic patients
- Reporting of Phase 2 CF dosing study
- PXS4159 moves to preclinical development for asthma

Corporate News

Construction gears up on new premises

Walls going up on new factory

The new Pharmaxis company headquarters and manufacturing facility at 20 Rodborough Road, Frenchs Forest in Sydney are beginning to take shape.

The factory floor has now been laid and the warehouse walls are in the process of being erected. The new state-of-the-art premises are on track to be completed early next year, housing all of Pharmaxis' Australian employees.

Pharma industry leader joins Pharmaxis board

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Senior Australian pharmaceutical executive Will Delaat has joined the Pharmaxis board of directors.

Mr Delaat has 35 years experience in the global pharmaceutical industry, most recently as the managing director of the Australian subsidiary of Merck & Co., a position he held from 1997 until his recent retirement.

During his career Mr Delaat has held executive positions in both Europe and Australia for Merck and AstraZeneca. Mr Delaat is experienced in sales and marketing and has been responsible for international product launches and commercialisation of respiratory products.

He also serves the pharmaceutical industry in important representative roles. He is chairman of the Australian pharmaceutical industry's peak body, Medicines Australia, and is chairman of the Pharmaceuticals Industry Council.

Will Delaat is considered one of Australia's pharmaceutical industry leaders. The Pharmaxis board will benefit from his unique skills and experience.

Industry honour for Pharmaxis CEO

Alan Robertson named CEO of the Year

Pharmaxis CEO Dr Alan Robertson has been named CEO of 2007 at the Australian Excellence in Biotechnology in Investment Awards.

Held in Sydney in April, the award was made in recognition of Alan's work in developing Pharmaxis.

Current Medical Activities

CF trial close to full recruitment

Recruitment milestone reached in Phase 3 CF trial

The first Phase 3 Bronchitol trial in subjects with cystic fibrosis reached its initial protocol target of 250 patients in June 2008. Over 50 subjects are now in the open label phase of the trial and 14 subjects have completed the study (see story below). The trial will close recruitment shortly and the headline data will be available during the first quarter of 2009. The trial design was completed with advice from the European Committee for Orphan Medicinal Products and positive data will allow us to file a marketing application in Europe during the second quarter of 2009.

Bronchitol helps Harry live life to the full

First patient in world completes Phase 3 CF trial

Harry Coffey is breathing easier on the football field, after being treated with Bronchitol for his cystic fibrosis.

The 12-year-old Swan Hill midfielder is the first patient in the world to complete the year-long Phase 3 trial of Bronchitol in cystic fibrosis sufferers.

The young sportsman battles to clear his lungs of heavy mucus every day, a problem that has affected his ability to breathe, particularly when running for the ball. But for the past six months while on the trial, Harry has been finding breathing much easier.

"It tastes better than other medications and it's quicker in the mornings," he explains. "I can breathe it in over about five minutes in the morning and it isn't as boring as the old medication either."

Harry's mother says Bronchitol has helped her son get rid of more mucus more often, reducing the persistent cough that can hold him back from doing the things he likes best. Expelling the sticky mucus also reduces the chance of developing a serious lung infection.

Harry's doctor, Professor Phil Robinson of the Royal Children's Hospital in Melbourne, says if proven effective, Bronchitol has the potential to improve people's lives dramatically.
(Story courtesy of The Age, 2 May 2008, p.5)

Second CF Phase 3 trial to commence

Second Phase 3 CF clinical trial

A second Phase 3 clinical trial in patients with cystic fibrosis required for a U.S. marketing application will begin enrolment shortly. Site centre agreements have been signed, ethics applications granted, investigational drug shipped and the protocol completed with the assistance of the FDA through their Special Protocol Assistance scheme. The trial aims to enrol approximately 250 subjects and is expected to be fully recruited by mid 2009.

The principal objective of the trial is to determine the effect of Bronchitol on the lung function of patients with cystic fibrosis.

Study will confirm optimal dosage

Phase 2 CF dosing study completes

A Phase 2 dosing study of Bronchitol in patients with cystic fibrosis has completed with the last patient having their last visit in June 2008.

A total of 48 patients from 13 sites across Argentina and Canada were tested on a range of doses to find the optimum level for treating their condition. Bronchitol was administered twice daily at doses of 40mg, 120mg, 240mg and 400mg. The data from this trial is undergoing analysis and will be released in the third quarter of 2008.

Australian Bronchitol marketing application

Long-term safety study in Bronchitol due to report

A 12 month Phase 3 clinical trial evaluating the safety of Bronchitol in over 100 subjects with bronchiectasis completed in June.

This study was an open label extension to a three month efficacy trial which has already reported, showing that Bronchitol improved quality of life and mucus clearance.

The objective of the open label extension is to determine the adverse event profile of Bronchitol following prolonged use. Following statistical analysis, the results from this second phase of the trial will be reported in the next quarter.

After receiving the study report, Pharmaxis intends filing its first marketing application in Australia for Bronchitol.

Global compassionate use program launched

Bronchitol available worldwide to patients in need

Pharmaxis has appointed a respected international agency to manage and provide Bronchitol to patients with no alternative clinical options and in need of the medicine.

Overseas patients with severe bronchiectasis and cystic fibrosis who are unable to take part in current Pharmaxis clinical trials and for whom no satisfactory authorised treatment exists can now apply through their doctors to purchase Bronchitol via IDIS Limited.

IDIS provides medicines on an individual named patient basis in over 100 countries around the world. Through IDIS, post-trial supply of Bronchitol can be arranged for those overseas patients who still need the therapy.

We are receiving frequent requests from ex-trial patients and those with serious conditions to receive Bronchitol, and the appointment of IDIS will ensure they are responded to quickly and professionally.

Pharmaxis has been providing medicines on a compassionate basis in Australia and New Zealand for several years.

Current Regulatory Activities

Trial protocol agreed with FDA

FDA progress on Bronchitol Phase 3 trial

Pharmaxis and the U.S. Food and Drug Administration have concluded the Special Protocol Assessment process for the Phase 3 registration trial of Bronchitol for bronchiectasis.

The SPA process allows the FDA to evaluate a clinical trial protocol supporting a New Drug Application, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA.

This one trial will also support a European marketing application. The Phase 3 trial has been designed in collaboration with internationally renowned experts in the field of bronchiectasis and will be a randomized investigation of Bronchitol twice daily in 350 adults worldwide. A clinical trial application (CTA) to begin this trial was approved in the UK in June.

Participants will be treated for 52 weeks and the primary endpoints are reduction in frequency of exacerbations and improvement in quality of life. This trial will be the second Phase 3 study to be undertaken for Bronchitol in bronchiectasis and follows the completion of a successful shorter trial reported last year.

More European approvals

Four more European countries have granted Pharmaxis marketing approval for Aridol. The approvals by Germany, Norway, Greece and Finland bring the number of European countries where Aridol can be sold to 10. The lung function test is also available in South Korea and Australia.

In Germany a total of 660,000 lung function tests are conducted annually, of which 90% are conducted by office-based physicians and the remainder in the major hospitals. To enter the market, Pharmaxis will first negotiate with insurance companies that cover

Aridol now available in 12 countries

Countries where Aridol is approved for sale

the office-based physician market before launching with a local distributor. These latest approvals help position Aridol as the worldwide standard for detecting sensitive airways in people with conditions like asthma.

Current Marketing Activities

International specialists enthusiastic about Aridol

Aridol was highlighted at the May meeting of the American Thoracic Society, which attracted over 13,000 global delegates from all facets of respiratory science and medicine.

Global experts discuss Aridol

Aridol featured in several presentations and poster sessions, prompting valuable discussion and raising awareness of the product among key physicians and scientists.

Meanwhile, the first worldwide presentation of data from the pivotal Phase 3 Aridol trial was unveiled at the Aspen Lung Conference, held during the quarter. US allergists attending the forum showed strong interest in the trial results, which will form the basis of our U.S. marketing application.

Current Research Activities

PXS25 and PXS4159

PXS25 targets lung diseases

While our clinical and regulatory teams prepare the necessary documents to submit a clinical trial application with the aim to develop PXS25 to treat inflammatory lung diseases, our research scientists continue to evaluate the mechanism of this compound in cellular and animal models. We plan to conduct the Phase 1 clinical study in Australia, focussing on safety and the pharmacokinetic profile of PXS25.

PXS4159 moves to preclinical development

The SSAO/VAP-1 protein plays a key role in the inflammatory process and its inhibition is expected to lead to new therapies for lung diseases like asthma. To target this protein, we have developed new clinical candidate PXS4159 and begun the scale up manufacture and pre-clinical safety studies needed to evaluate it in human studies. In parallel, we continue basic research to explore its other potential clinical uses.

Publications and Presentations

Three new papers & posters

More than 60 papers about Aridol, Bronchitol or mannitol for inhalation have now been published in peer-reviewed journals. New publications and presentations this past quarter include:

1. E. Daviskas et al., Effect of increasing doses of mannitol on mucus clearance in patients with bronchiectasis. European Respiratory Journal 2008; 31: 765–772.

2. A. Jaques et al., Inhaled Mannitol Improves Lung Function in Cystic Fibrosis. Chest 2008; 133:1388–1396.

3. S. Spector et al., Mannitol Inhalational Challenge: Will it replace methacholine or histamine? Presented at the Thomas L. Petty Aspen Lung Conference, Golden Anniversary Meeting on "Asthma: Insights and Expectations," June 4-7, 2008.

Intellectual Property Portfolio

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

Financial Overview of the Quarter

We completed the year with cash of A$112 million, a strong position from which to progress our business in the coming year.

Revenue

Aridol sales for the June 2008 quarter of A$197,000 compared to A$46,000 in the June 2007 quarter and A$136,000 in the March 2008 quarter. Sales for the year of A$527,000 were 156% greater than in 2007. Australian sales for the quarter were 49% greater than June 2007 while Australian sales for the year were 82% greater than in 2007.

Aridol sales for year more than double 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 Australian government Pharmaceuticals Partnerships Program.

Expenditure

Research and development expenditure of A$6.0 million for the June 2008 quarter compares to A$4.9 million in the June 2007 quarter, and A$4.4 million in the March 2008 quarter. The largest increases were in clinical and manufacturing.

Clinical and manufacturing spending rises

Clinical expenses accounted for 59% of R&D expenditure and increased by approximately 42% from the June 2007 quarter and 24% from the March 2008 quarter, reflecting an increase in the number of subjects enrolled in clinical trials.

Manufacturing R&D expenses accounted for approximately 35% of R&D expenditure, and increased by approximately 24% from the June 2007 quarter and 112% from the March 2008 quarter. Manufacturing R&D provides drug to our increasing clinical trials while also completing analysis of long term stability studies required for the U.S. Aridol marketing application.

Our drug discovery unit accounted for approximately 6% of R&D expenditure and preclinical expenses for the quarter were minimal with one project having completed its preclinical development and another about to commence.

Commercial expenditure of A$1,452,000 compare to A$778,000 in the June 2007 quarter and A$1,154,000 in the March 2008 quarter. Commercial expenses increased due to increased (non cash) costs in relation to employee share options and an increase in commercial activity and headcount in the U.S., Europe and Australia associated with both Aridol and Bronchitol.

Administration expenditure of A$1,446,000 compares to A$1,409,000 in the June 2007 quarter and A$1,321,000 in the March 2008 quarter.

Financial Statement Data
(International Financial Reporting Standards)

(Unaudited)
('000 except per share data)

Income Statement

	Three months ended			Year ended		
	30-Jun-08	30-Jun-07	30-Jun-08	30-Jun-08	30-Jun-07	30-Jun-08
	A$	A$	US$[1]	A$	A$	US$[1]
Revenue from sale of goods	197	46	188	527	205	504
Cost of sales	(47)	(10)	(45)	(129)	(49)	(123)
Gross profit	150	36	143	398	156	381
Other income						
Interest	2,233	1,219	2,135	7,402	5,278	7,078
Grant income	562	569	537	1,358	2,152	1,299
Other	91	–	87	218	–	208
Expenses						
Research & development	5,986	4,856	5,724	19,996	23,840	19,120
Commercial	1,452	778	1,388	4,557	3,240	4,357
Administration	1,446	1,409	1,383	5,231	4,666	5,002
Total expenses	8,884	7,043	8,495	29,784	31,746	28,479
Net loss before tax	(5,848)	(5,219)	(5,593)	(20,408)	(24,160)	(19,513)
Income tax expense	14	7	13	32	19	31
Net loss after tax	(5,862)	(5,226)	(5,606)	(20,440)	(24,179)	(19,544)
Basic and diluted earnings (loss) per share – $	(0.030)	(0.029)	(0.029)	(0.108)	(0.136)	(0.103)
Depreciation & amortisation	252	246	241	1,024	939	979
Fair value of options issued under employee plan	830	397	794	3,434	1,488	3,284

Balance Sheet Data

	As at		
	30-Jun-08	30-Jun-07	30-Jun-08
	A$	A$	US$[1]
Cash and cash equivalents	111,842	76,182	106,943
Plant & equipment	3,668	3,521	3,507
Intangible assets	1,227	1,239	1,173
Total assets	125,049	82,648	119,572
Total liabilities	(5,928)	(6,089)	(5,668)
Total shareholders' equity	119,121	76,559	113,904

Cash Flow Data

	Three months ended			Year ended		
	30-Jun-08	30-Jun-07	30-Jun-08	30-Jun-08	30-Jun-07	30-Jun-08
	A$	A$	US$[1]	A$	A$	US$[1]
Cash flows from operating activities	(3,673)	(3,608)	(3,512)	(18,850)	(20,697)	(18,024)
Cash flows from investing activities	(736)	(295)	(704)	(5,059)	(1,322)	(4,837)
Cash flows from financing activities	1	171	1	59,572	363	56,963
Net increase (decrease) in cash held	(4,408)	(3,732)	(4,215)	35,663	(21,656)	34,102

Share Data

	Ordinary Shares[2]	
	As at	
	30-Jun-08	30-Jun-07
Ordinary shares on issue	194,515	177,949
Options over ordinary shares outstanding	11,536	9,836

Notes:

(1) Convenience translation into U.S. dollars from Australian dollars based upon rate on 30 June 2008.

(2) Pharmaxis ordinary shares are traded on the Australian Securities Exchange (PXS) and our ADRs are traded on the Nasdaq Global Market (PXSL). One Pharmaxis ADR represents 15 Pharmaxis ordinary shares.

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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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