pharmaxis

Pharmaxis Ltd ABN 75 082 811 630

Quarterly Report to Shareholders

Issue 20 July – September 2008

Producing human healthcare products to treat and manage respiratory diseases

Overview

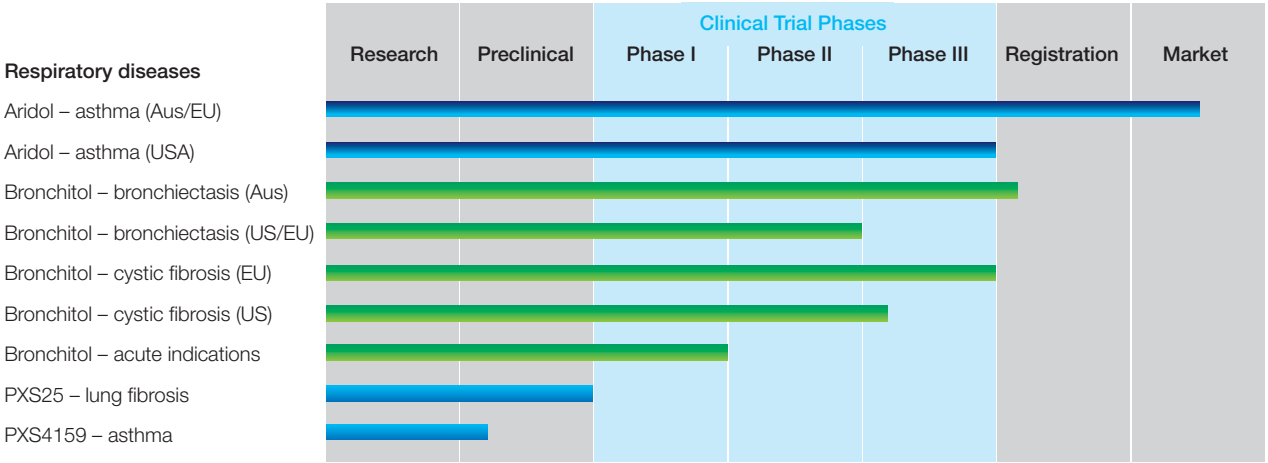
Pharmaxis is a specialty pharmaceutical company with activities spanning product research & development through to manufacture, sales and marketing.

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 September 2008



Front cover: In Australia, 15% of children are reported to have asthma and it is a frequent reason for hospitalization of children, especially boys.

CEO Report

In what has been a very difficult few months for the capital markets, we have made solid progress in a number of key areas of the business. We are fortunate to have a healthy cash position that allows us to continue the development of our various products for international and domestic healthcare markets in spite of the global financial crisis that is having widespread ramifications.

Work on cystic fibrosis dominated the quarter with the very satisfying results from one trial being presented, one Phase 3 trial closing to recruitment and one Phase 3 trial opening to recruitment. Currently, there are only two approved treatments for cystic fibrosis and, while life expectancy is increasing, there is no cure and no new drugs have been developed for over 11 years. We are hopeful that Bronchitol will impact the progression of the disease and be the first disease modifying drug ever approved for cystic fibrosis.

The other big event for us was the filing of an Australian marketing application of Bronchitol for the treatment of bronchiectasis. This is the first drug ever to be developed for this patient group and we are looking forward to working with the Therapeutic Goods Administration during the review process.

Generating revenue from Aridol and Bronchitol remains a key focus as we navigate our way through the clinical, regulatory and re-imbursement landscape. This report contains details of our progress this quarter.

Alan D Robertson, Chief Executive Officer

Third Quarter Highlights

Bronchitol marketing application submitted

- Phase 2 cystic fibrosis dosing trial returns positive data
- 1st global Phase 3 cystic fibrosis trial completes enrolment
- 1st Phase 3 bronchiectasis trial reports positive long term safety data
- 2nd global Phase 3 cystic fibrosis trial commences enrolment
- 1st worldwide marketing application filed for Bronchitol
- Aridol available throughout major European countries

Coming Events

Early stage pipeline moving ahead

- File marketing application for Aridol with US FDA
- PX4159 to enter regulatory safety testing program
- PXS25 to enter Phase 1 clinical testing program
- 2nd Bronchitol Phase 3 trial to commence

Corporate News

Construction of new premises on track

Roof construction on new factory

The construction of the new purpose built Pharmaxis company headquarters at 20 Rodborough Road, Frenchs Forest in Sydney is progressing on schedule and when complete will house all Australian employees and will have initial capacity to manufacture more than 72,000 Bronchitol doses per year.

The roof of the building is being constructed and base building completion is expected by the end of 2008.

New website and annual report

Complete website revision

An extensive revision and upgrade of the Pharmaxis website has been completed. The website has a number of new features, is easier to navigate for those interested in learning about the company and contains a number of important links for patients and physicians seeking information on our products.

The launch of the new website coincides with a new annual reporting format to shareholders. For the first time, we have completed a web based statutory annual report that combines both U.S. and Australian reporting requirements and a second, printed document that provides a comprehensive, but brief, review of the year.

The statutory annual report can be accessed from the website and paper copies are available to those shareholders who specifically request to receive a copy. The Annual Review is mailed to all shareholders unless they have specifically elected not to receive a copy. This new reporting format is designed to give shareholders the information they require in a level of detail chosen by them. It also saves the company on printing and mailing costs and contributes to reducing our environmental impact.

Annual General Meeting in October

Annual General Meeting

The Annual General Meeting will be held in Sydney on 23 October 2008 and all shareholders and interested parties are invited to attend. The notice of the meeting was mailed to shareholders on 16 September and further details can be sourced from the Pharmaxis website.

Clinical and Medical News

1st CF trial closes recruitment

Enrolment closed in landmark Phase 3 CF trial

The 1st Phase 3 Bronchitol trial in people living with cystic fibrosis closed with a total of 325 participants electing to join the trial. Over 100 subjects are now in the open label phase of the trial and more than 50 have completed the full trial protocol. The headline data is expected to 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 throughout the world excluding the U.S. This trial explores the effects of restoring airway surface liquid in people with moderate to severe cystic fibrosis and holds out the promise of being the first therapeutic advance to come to the market with this mechanism. By improving lung hygiene and restoring normal lung defence and clearance, we hope that Bronchitol will be the first medicine to alter the progression of the disease.

2nd CF trial commences recruitment

Enrolment commenced in second Phase 3 CF trial

The U.S. Food and Drug Administration (FDA) has indicated that a total of two Phase 3 trials in cystic fibrosis will be sufficient clinical proof of effectiveness to submit a marketing application for the U.S. This trial is the second of the two requested trials and commenced enrolment during the quarter. The trial has been designed with the assistance of the FDA through their Special Protocol Assessment scheme and is expected to be fully enrolled by the middle of 2009.

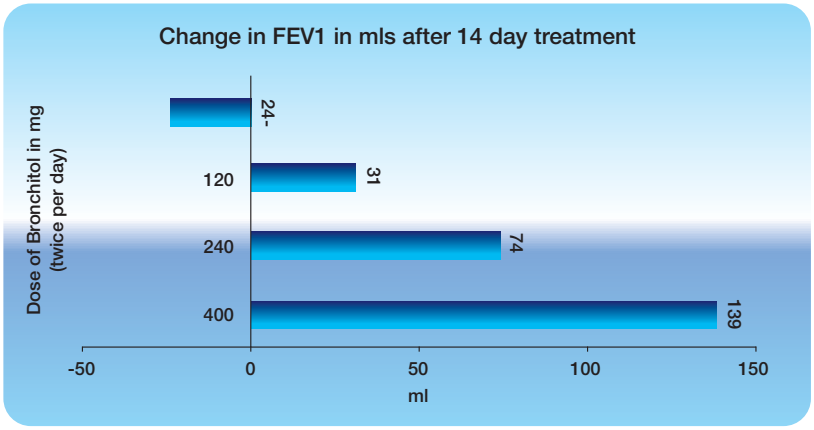
Bronchitol has been granted fast track designation by the FDA which allows Pharmaxis to submit parts of the marketing application ahead of completing the clinical study.

Cystic fibrosis dosing trial

A successful dosing study of Bronchitol in patients with cystic fibrosis has reported with the last patient completing the study in June 2008.

48 patients from 12 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 in a crossover design at doses of 40mg, 120mg, 240mg and 400mg. 38 subjects completed the protocol and the first data was presented in August. The lung function of trial participants improved by 139ml or 8.6% when treated with 400mg Bronchitol.

Study confirms optimal dose



First long-term Phase 3 clinical study in Bronchitol
A Phase 3 clinical trial evaluating the safety and efficacy of Bronchitol in people living with bronchiectasis completed in June and reported in August 2008.

First bronchiectasis Phase 3 trial completes

This trial was an open label safety extension to an initial three month efficacy component which has already reported, showing that in 360 subjects, Bronchitol improved quality of life and mucus clearance. A total of 123 subjects started the open label component taking 320mg Bronchitol twice per day and 99 subjects completed the full 12 months. Of the 24 withdrawals, only 7 were a result of adverse events (3 related to lung infections and 2 related to cough).

Reported adverse events related to treatment were infrequent, mild in severity, and in most cases were a consequence of the underlying disease. The trial demonstrated that Bronchitol was effective and safe when administered to people for twelve months.

This trial represents the first ever successful Phase 3 clinical trial in this patient group.

Second Phase 3 trial in participants affected by bronchiectasis
A second Phase 3 trial in bronchiectasis, examining the effects of twice daily treatment of Bronchitol on the frequency of infectious episodes over twelve months, is currently in the set up phase. The first approval to commence the trial has been received from the UK regulatory authorities.

Second Phase 3 bronchiectasis trial at set up

The trial protocol has been developed with the assistance of the U.S. FDA and the European regulatory agency, the EMEA. The trial will take place at centres throughout the U.S. and Europe.

Regulatory Activities

First Bronchitol marketing application submitted
A marketing application seeking approval to market Bronchitol for the treatment of bronchiectasis has been filed with the Australian regulatory authority, the TGA. The basis for the marketing application was the first Phase 3 clinical trial described above and represents the first ever targeted therapy for patients living with bronchiectasis.

Bronchitol marketing application submitted

After being accepted for evaluation, the TGA has 255 working days to review the application.

Aridol available for marketing in Europe
During the quarter, approvals to market Aridol were received from Spain and France, bringing the number of European countries where Aridol can be sold to 12. The lung function test is also available in South Korea and Australia.

Aridol marketing application in the USA
A New Drug Application (NDA) is being assembled with a view to seeking a marketing application for Aridol in the U.S.. The clinical basis for the application centres around two Phase 3 clinical trials involving over 1,200 subjects. The application is being coordinated by our regulatory affairs group in Philadelphia and will be submitted as soon as possible.

Current Marketing Activities

Aridol

Aridol introduction to the European market is being coordinated by our offices in the UK. Marketing, sales and distribution outside the UK are being handled by a network of commercial partners and within the UK by Pharmaxis. Launch stock for some of our partners was shipped during the quarter to coincide with the European Respiratory Society meeting in Berlin.

Aridol now available throughout Europe

Current Research Activities

PXS25 and PXS4159

PXS25 inhibits a key enzyme involved in the conversion of inactive Tissue Growth Factor (TGF) to active TGF. TGF is a key mediator in the development of fibrotic disorders and we anticipate PXS25 to have therapeutic potential in the development of fibrosis. Our initial interest is in interstitial lung fibrosis; a fatal condition of the lung of unknown origin and with few treatment options. We plan to conduct the first Phase 1 clinical study of PXS25 in Australia, focusing on safety and the pharmacokinetic profile.

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 such as asthma. PXS4159 is a potent inhibitor of this protein. Initial scale up manufacture has been completed and pre-clinical safety studies are being initiated as we continue basic research on other potential clinical uses.

Financial Overview of the Quarter

We completed the quarter with A$106 million in cash.

Revenue

Aridol sales for the September 2008 quarter of A$106,000 compared to A$47,000 in 2007 and were evenly divided between customers in Australia and Europe. Interest income of $2.1 million was earned on commercial bills issued or accepted by the four larger Australian banks.

Expenditure

Expenditure dominated by clinical research

Research and development expenditure of A$6.0 million for the September 2008 quarter compare to A$5.0 million in the September 2007 quarter, and A$6.0 million in the June 2008 quarter. 70% of R&D expenditure was accounted for by the clinical group which increased by 70% from the September 2007 quarter and 18% from the June 2008 quarter, reflecting an increase in the number of clinical trials in the active dosing stage.

Commercial expenditure of A$1,371,000 compare to A$899,000 in the September 2007 quarter and A$1,452,000 in the June 2008 quarter. Commercial expenses are focused on developing the commercial strategy and capability to sell Bronchitol and Aridol globally.

Administration expenditure of A$1,283,000 compares to A$1,053,000 in the September 2007 quarter and A$1,446,000 in the June 2008 quarter. In addition to administrative, finance and public company costs, this group supports the company's international clinical and commercial efforts.

Cash Flow

Investing activities for the September 2008 quarter predominantly relates to the new manufacturing facility.

Financial Statement Data – Unaudited (International Financial Reporting Standards

('000 except per share data)

Income Statement Data

	Three months ended		
	30-Sep-08	30-Sep-07	30-Sep-08
	A$	A$	US$[1]
Revenue from sale of goods	106	47	84
Cost of sales	(28)	(16)	(22)
Gross profit	78	31	62
Interest	2,076	1,152	1,641
Other income	3	345	2
Expenses			
Research & development	(5,960)	(5,033)	(4,711)
Commercial	(1,371)	(899)	(1,084)
Administration	(1,283)	(1,053)	(1,014)
Total expenses	8,614	6,985	6,809
Loss before income tax	(6,457)	(5,457)	(5,104)
Income tax expense	(6)	(8)	(5)
Loss for the period	(6,463)	(5,465)	(5,109)
Basic and diluted earnings (loss) per share – $	(0.033)	(0.031)	(0.026)
Depreciation & amortisation	252	259	199
Fair value of options issued under employee plan	611	639	483

Balance Sheet Data

	As at		
	30-Sep-08	30-Jun-08	30-Sep-08
	A$	A$	US$[1]
Cash and cash equivalents	105,552	111,842	83,428
Plant & equipment	4,193	3,668	3,314
Total assets	118,678	125,049	93,803
Net assets	113,281	119,121	89,537

Cash Flow Data

	Three months ended		
	30-Sep-08	30-Sep-07	30-Sep-08
	A$	A$	US$[1]
Cash flows from operating activities	(4,877)	(7,723)	(3,855)
Cash flows from investing activities	(1,430)	(1,082)	(1,130)
Cash flows from financing activities	11	43	9
Net increase (decrease) in cash held	(6,296)	(8,762)	(4,976)

Share Data

	Ordinary Shares[2] as at	
	30-Sep-08	30-Jun-08
Ordinary shares on issue	194,537	194,515
Options over ordinary shares outstanding	12,949	11,536

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