pharmaxis

Quarterly Report to Shareholders

Issue 21 | September – December 2008

Asthma is the commonest chronic disease of childhood, affecting nearly 5 million children in the United States. In children, asthma causes 3 million physician visits and 200,000 hospitalisations every year.

Pharmaxis Ltd ABN 75 082 811 630

pharmaxis

Producing human healthcare products to treat and manage respiratory diseases

Overview

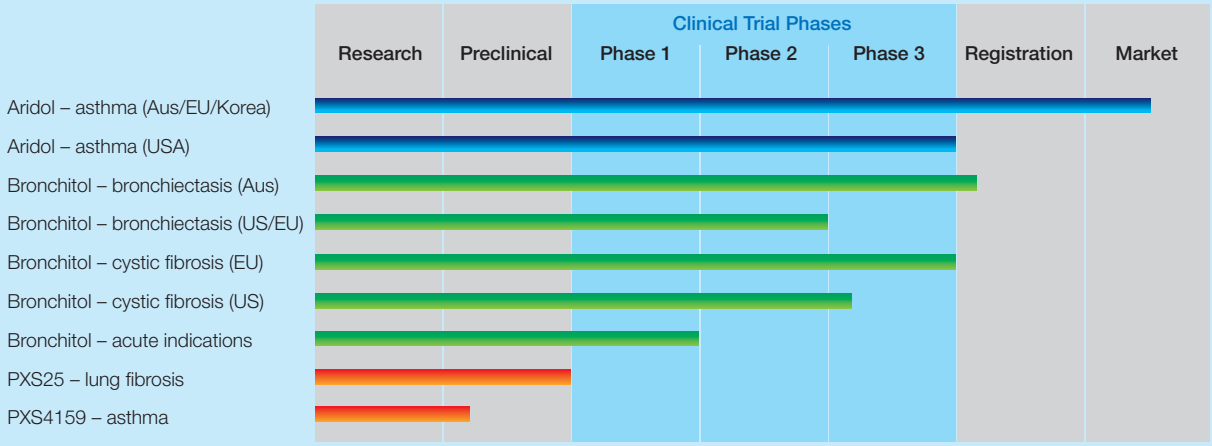
Pharmaxis is a specialty pharmaceutical company with activities spanning product research & development through to manufacture, sales and marketing.

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 December 2008



CEO Report

2008 has come to a close and many of us will look back on the financial aspects of the year with little fondness. This is certainly true for those working in the capital markets and those owning shares in just about any company on any securities exchange.

At Pharmaxis, we have focused firmly on the tasks at hand and have completed a solid year of progress that takes us closer to getting our products on to the global stage. Completing enrolment for our first of two Bronchitol Phase 3 clinical trials in cystic fibrosis required a great effort, co-ordination and commitment from our clinical department. Similarly, completing the open label phase of our bronchiectasis Phase 3 clinical trial and filing the first marketing application for Bronchitol in Australia was a significant event.

The corporate objective remains the same: to build a profitable research based pharmaceutical company. Shorter term, our objective is to generate revenue from our lung function test (Aridol) through opening up new markets and developing existing markets. In Australia, where we have most information, sales continue to grow consistently across all States. We are finalising pricing and reimbursement in Europe and commenced our marketing push at the European Respiratory Society meeting in October 2008. Preparing for the filing of the Aridol U.S. marketing application has been a major project during the last quarter. Medium term, we are working to ensure we have Bronchitol approved for marketing as efficiently as possible.

This report contains details for our progress for the last quarter of 2008.

Alan D Robertson, Chief Executive Officer

2008 fourth quarter highlights

Bronchitol marketing application accepted for review

- Bronchitol marketing application for bronchiectasis accepted for review by Australian regulator
- 12 clinical presentations on Aridol and Bronchitol at international meetings
- Aridol approved for marketing in Switzerland
- First patient receives Bronchitol in Europe through compassionate use program
- Aridol Spanish pricing application approved
- Bronchitol Intensive Care Unit study receives first regulatory approvals
- PXS4159 enters formal pre-clinical safety testing programme

Forthcoming Events

PXS25 to begin Phase 1

- First Phase 3 cystic fibrosis clinical trial to report (Bronchitol)
- PXS25 to enter Phase 1 clinical testing program (lung fibrosis)
- Second Bronchitol Phase 3 trial in bronchiectasis to commence dosing

Corporate News

Installation of spray drier for new factory

Spray drier lifted into position

Construction on schedule

The construction of the new purpose built Pharmaxis factory and 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 capacity to manufacture more than 30 million Bronchitol doses per year.

The equipment necessary to manufacture both Aridol and Bronchitol on an industrial scale is now being installed and the full fit-out of the building is planned to be complete during the second quarter of 2009.

The factory is being built to our specification and we have signed a 15 year lease with options to further extend the lease.

Facilities

The employees of the company are spread across three sites in Sydney with our drug discovery and development laboratories located in North Ryde— some distance from Frenchs Forest. Additionally, we have offices in Shanghai in China, Philadelphia in the U.S. and Luton in the United Kingdom.

The regional offices are headed by experienced pharmaceutical executives with extensive experience in sales, marketing and business development.

Shareholders reappoint directors

Annual General Meeting

The Annual General Meeting was held in Sydney on 23 October 2008. All resolutions were passed and Mr Denis Hanley was reappointed as Chairman of the Board of Directors and Mr Will Delaat was reappointed as an independent non-executive director.

Clinical and Medical News

First CF trial close to the finish

Enrolment closed in landmark Phase 3 CF trial

The first Phase 3 Bronchitol trial in people living with cystic fibrosis closed with a total of 325 participants. The last patients are going through the clinical trial protocol and as they finish the trial, we are making the product available to those eligible through an individual named patient program. This program is administered by Pharmaxis in Australia and New Zealand and by our partner, IDIS, throughout the rest of the world. This will be the largest clinical trial to report in cystic fibrosis this year and the result will attract a great deal of attention. The headline data is expected to be available during the second quarter of 2009.

The main purpose of the trial is to determine if Bronchitol provides an improvement in lung function when measured against an inactive placebo following administration to a subject twice a day for 6 months. For people living with cystic fibrosis, the insidious loss of lung function is one of the most difficult consequences of the disease.

Bronchitol has been developed as a dry powder for inhalation and is designed to evenly disperse throughout the lungs to help improve lung hygiene. It does this by restoring the surface liquid lining the lungs and strengthening the ability of the lungs to resist recurrent infections and colonisation by adventitious bacteria. In earlier clinical trials, mucus and mucus plugs were loosened, the patients ability to breathe was improved along with lung function.

Marketing application through central procedure

A positive improvement in lung function and an absence of serious adverse events should allow us to file a marketing application throughout Europe based on this trial.

We have been given approval by the EMEA to file the marketing application through what is known as the centralised procedure. The main advantage of this procedure is that Bronchitol can be made available to all European residents at the same time once marketing authorisation has been granted. The centralised procedure also leads to greater efficiency in Europe, as only one or two member states are asked to produce assessment reports.

Enrolment commenced in second Phase 3 CF trial

A second Phase 3 trial is being run because the U.S. FDA advised us that two clinical trial are required before Bronchitol can be considered for a marketing application in the US. This trial is essentially identical to the first clinical trial and has the same primary objective of demonstrating that lung function is improved when subjects are receiving Bronchitol. The trial is seeking to recruit over 300 volunteers and involves more than 60 hospitals in Argentina, the USA, France, Belgium, Canada and Germany.

Second P3 CF trial in recruitment

The trial is well into its recruitment phase an our objective is to have the recruitment finished by the end of the second quarter 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.

Both the FDA and the EMEA have granted Bronchitol periods of market exclusivity through their respective Orphan Drug Acts. In the case of the US the market exclusivity is seven years from launch of the product and in the case of the EMEA it is 10 years.

First Bronchitol marketing application submitted

First long-term Phase 3 clinical study in Bronchitol

Bronchiectasis is a chronic infection of the airways that leads to abnormal and permanent stretching and enlarging of the medium and smaller airways. In a healthy lung, these airways are usually kept mucus-free by the cilia, which push mucus to the upper airways where it is released by coughing. However, when the airways becomes dilated, and the cilia don't function properly, the mucus becomes stuck, accumulates and forms plugs. The blockage can subsequently become infected, which leads to further weakening and widening of the airways. Weakened respiratory passages become scarred and deformed, allowing more mucus and bacteria to accumulate. The result is a cycle of repeated lung infections and blocked airways.

There are no treatments available to help with this condition.

A Phase 3 clinical trial evaluating the safety and efficacy of Bronchitol in people living with bronchiectasis completed in June of 2008 and reported in August 2008. This trial was the first ever successful trial of this nature and size in people with bronchiectasis. As a result, a marketing application was filed with the Australian regulatory authority (the TGA) in September 2008. Subsequently, the application was accepted for review by the TGA which has 255 working days to complete the review of the application.

Second Phase 3 bronchiectasis trial to begin

Australia has over 18,000 people living with bronchiectasis and indigenous children in Central Australia have the highest rates of bronchiectasis in the world.

If approved, Bronchitol will represent the first ever new medicine to be developed specifically for this clinical condition.

Second Phase 3 trial in participants affected by bronchiectasis

A second Phase 3 trial in bronchiectasis is in the set up phase. This trial will examine the effects of Bronchitol following twelve months of treatment. The trial has the necessary regulatory approvals to commence and clinical trial centre selection and preparation is well advanced. Bronchiectasis sufferers have chronic infections but can become acutely unwell and may require hospitalisation. This clinical trial aims to prove that people treated with Bronchitol will have fewer periods of acute sickness and require less hospitalisation than people not taking Bronchitol.

The trial protocol has been developed with the assistance of the U.S. FDA under their Special Protocol Assessment (SPA) scheme and the European regulatory agency, the EMEA. The trial is taking place at centres throughout the U.S. and Europe.

Bronchitol in a ventilator

Bronchitol in ventilated patients

Mucus retention and immobility in patients breathing with the aid of a respirator is a serious but rarely studied clinical problem. As normal mucus clearance is impaired it provides a source of infection and increases the risk of the patient developing serious lung infections such as pneumonia. Each year in the U.S., there are more than 200,000 cases of ventilator-assisted pneumonia (VAP). Each case prolongs patients' hospital stays by at least four to nine days, at a total cost of more than $1 billion a year. Pneumonia is a primary or contributing factor in over 30,000 U.S. hospital deaths each year.

A small pilot trial is being conducted to determine the effects of Bronchitol on mucus retention and immobility when it is added to the inspired air of the ventilated patient. Initial data from this trial is expected during the second half of 2009.

Marketing and Regulatory Activities

Aridol was shipped to four new European countries in October 2008 and an additional three new countries are to be supplied this quarter.

Aridol supplied to new European countries

We have now a healthy level of key opinion leading support in the U.S. and the marketing application will be filed with the FDA as soon as possible. U.S. Aridol sales are dependent on a favourable review from the FDA but will not commence until 2010.

Aridol has been approved for marketing in Korea and the first batches to be shipped have been approved for sale following testing by the Korean FDA. The reimbursement process is in train and is expected to be finalised this quarter. As soon as this is finalized we will be in a position to ship the first batches to the distributor.

Current Research Activities

PXS25 inhibits a key enzyme involved in the conversion of inactive Tissue Growth Factor (TGF) to active TGF. TGF is critical for the development of fibrotic disorders and our clinical focus is the lung. The preclinical safety studies have been completed and Phase 1 clinical studies of PXS25 will be undertaken in Australia.

PXS4159 moves to preclinical development

PXS4159 is a powerful inhibitor of a protein known as SSAO/VAP-1. This protein plays a key role in inflammation and its inhibition should lead to new therapies for lung diseases such as asthma. The large scale manufacture has been completed and preclinical safety studies are well underway.

Financial Overview of the Quarter

The cash position at the end of the quarter was A$94 million.

Aridol sales for the December 2008 quarter of A$203,000 compared to A$146,000 in 2007 and were divided between customers in Australia (32 percent), Europe (47 percent) and sales to pharmaceutical companies (21 percent). Interest income of $1.6 million was earned on commercial bills issued or accepted by larger Australian banks.

Expenditure again dominated by clinical research

Research and development expenditure of A$7.6 million for the December 2008 quarter compares to A$4.6 million in the December 2007 quarter, and A$6.0 million in the September 2008 quarter. The largest component of research and development expenditure was the clinical group accounting for 66 percent of R&D expenditure, an increase of 130 percent from the December 2007 quarter and 27 percent from the September 2008 quarter, reflecting an increase in the level of clinical trial activity.

Commercial expenditure of A$1.5 million compares to A$1.1 million in the December 2007 quarter and A$1.4 million in the September 2008 quarter. Commercial expenses are focused on developing the commercial strategy and capability to sell Bronchitol and Aridol globally.

Administration expenditure of A$1.6 million compares to A$1.4 million in the December 2007 quarter and A$1.3 million in the September 2008 quarter. In addition to finance and public company costs, the finance and administration department supports the company's global clinical and commercial efforts.

Investing activities during the quarter of A$4.7 million related almost exclusively to the fit-out and additional capacity being installed in the new factory.

Financial Statement Data – Unaudited
(International Financial Reporting Standards)

('000 except per share data)

Income Statement Data

	Three months ended			Six months ended		
	31-Dec-08	31-Dec-07	31-Dec-08	31-Dec-08	31-Dec-07	31-Dec-08
	A$	A$	US$[1]	A$	A$	US$[1]
Revenue from sale of goods	203	146	142	309	193	216
Cost of sales	(48)	(35)	(34)	(77)	(51)	(54)
Gross profit	155	111	108	232	142	162
Interest	1,581	1,909	1,104	3,657	3,061	2,554
Other income	141	(110)	98	144	235	101
Expenses						
Research & development	(7,626)	(4,607)	(5,325)	(13,586)	(9,640)	(9,487)
Commercial	(1,519)	(1,053)	(1,061)	(2,890)	(1,951)	(2,018)
Administration	(1,639)	(1,411)	(1,145)	(2,922)	(2,464)	(2,040)
Total expenses	(10,784)	(7,071)	(7,531)	(19,398)	(14,055)	(13,545)
Loss before income tax	(8,907)	(5,161)	(6,221)	(15,365)	(10,617)	(10,728)
Income tax expense	(22)	(9)	(15)	(28)	(16)	(20)
Loss for the period	(8,929)	(5,170)	(6,236)	(15,393)	(10,633)	(10,748)
Basic and diluted earnings (loss) per share – $	(0.046)	(0.027)	(0.032)	(0.079)	(0.058)	(0.055)
Depreciation & amortisation	265	260	185	518	519	362
Fair value of options issued under employee plan	539	1,042	376	1,151	1,681	804

Balance Sheet Data

	As at		
	31-Dec-08	30-Jun-08	31-Dec-08
	A$	A$	US$[1]
Cash and cash equivalents	93,970	111,842	65,619
Plant & equipment	7,857	5,878	4,718
Intangible assets	1,258	1,222	878
Total assets	112,714	125,049	78,708
Net assets	104,902	119,121	73,253

Cash Flow Data

	Three months ended			Six months ended		
	31-Dec-08	31-Dec-07	31-Dec-08	31-Dec-08	31-Dec-07	31-Dec-08
	A$	A$	US$[1]	A$	A$	US$[1]
Cash flows from operating activities	(6,951)	(4,588)	(4,100)	(11,828)	(12,311)	(8,259)
Cash flows from investing activities	(4,657)	(1,469)	(3,985)	(6,087)	(2,551)	(4,251)
Cash flows from financing activities	–	59,497	–	11	59,540	8
Net increase (decrease) in cash held	(11,608)	53,440	(8,085)	(17,904)	44,678	(12,502)

Share Data

	Ordinary Shares[2] As at	
	31-Dec-08	30-Jun-08
Ordinary shares on issue	194,537	194,515
Options over ordinary shares outstanding	13,499	11,536

Notes:

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