

Pharmaxis Ltd ABN 75 082 811 630

Quarterly Report to Shareholders

Issue 16 July – September 2007



pharmaxis



Developing human healthcare products to treat and manage respiratory and immune diseases.

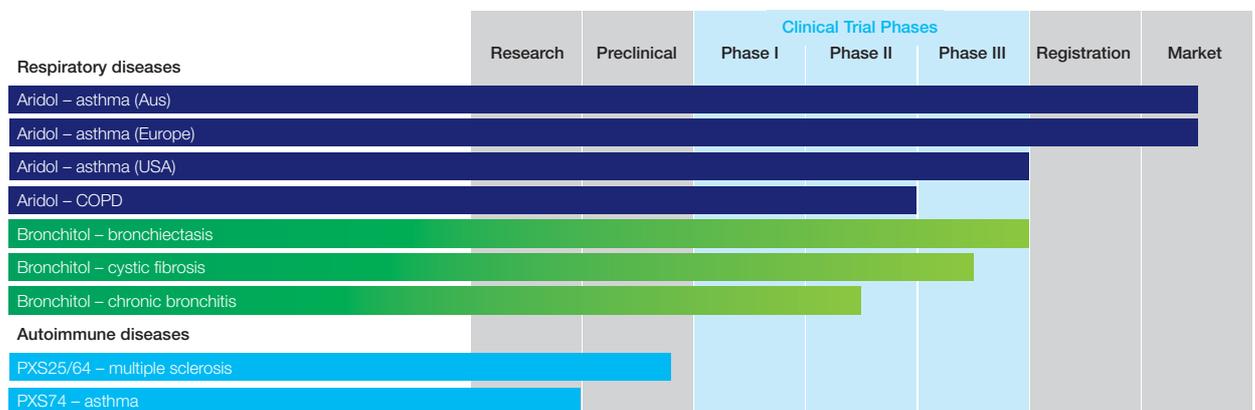
Overview

Pharmaxis is a specialty pharmaceutical company with activities spanning product research and 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 and Europe to diagnose asthma through an airways function test. Aridol 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 and chronic bronchitis.

Pharmaxis Product Development at September 2007



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



CEO Report

This quarter, we were able to report the results of a large Phase III clinical trial in people with bronchiectasis. This trial was the largest ever undertaken in this patient group and we were very pleased with the outcome. We demonstrated unequivocally that Bronchitol improves patients' quality of life, is very efficient at clearing mucus from congested lungs and is not associated with any significant side effects. We are working hard at bringing this important new medicine to patients and believe that extended treatment with Bronchitol will improve the whole clinical picture for the patient. People with bronchiectasis have had very few therapeutic options until now and we supply Bronchitol through a compassionate use programme that allows patients access to drugs before formal regulatory approval. The feedback from patients on this programme has been very encouraging for all of us at Pharmaxis working to get Bronchitol more widely available.

I hope you find this summary useful and interesting, and that it improves your understanding of the work we do here at Pharmaxis.

Alan D Robertson, Chief Executive Officer

Bronchitol phase III trial meets end points

- Release of positive headline clinical data on the Phase III Bronchitol trial in patients with bronchiectasis
- Release of the Annual Report for the 2007 financial year
- Filing of an Aridol marketing application dossier with the Korean regulatory authorities

Recent Highlights Subsequent to Quarter End

- The placement of shares to institutional investors was completed in early October and the offering of shares to private individuals through a share purchase plan under the same terms is expected to conclude in November.

Two US phase III studies to commence

Forthcoming Events

- Completion of a Phase II trial in subjects with cystic fibrosis. The study is designed to demonstrate a dose response relationship with Bronchitol.
- Completion of a pilot clinical trial with Bronchitol in patients with COPD.
- Completion of clinical trial design discussions with the U.S. FDA, allowing commencement of a U.S. Phase III trial in cystic fibrosis.
- Completion of clinical trial design discussions with the U.S. FDA, allowing commencement of a U.S. Phase III trial in bronchiectasis.

Aridol markets opening up gradually

Current Regulatory Activities

Aridol EU National approvals slow but steady

Following the recent successful completion of the European Mutual Recognition Procedure, we have received marketing authorizations for Aridol from Denmark, Sweden and the Netherlands. We continue to work with the other individual countries within the European Union to finalise the process as efficiently as possible.

The Aridol marketing application was filed in early July with the Korean FDA and we are anticipating an approval during the first quarter of 2008.

For Switzerland, we are well into the review process which can be somewhat more protracted than in other parts of the world. We are anticipating a decision from the Swiss agency around the middle of 2008.

For the USA, we are completing some additional stability studies on Aridol and plan to file the marketing application during the first quarter of 2008

Current Marketing Activities

Aridol launched in Europe

European Launch of Aridol at ERS 2007

Aridol was presented to the European community at the European Respiratory Society (ERS) annual congress, a highly influential meeting held during September and attended by 17,000 respiratory healthcare professionals from around the world. Pharmaxis staff worked a busy booth in the exhibition hall and later held meetings with key opinion leaders. A further highlight for European respiratory physicians was the lecture tour given by the inventor of Aridol, Dr Sandra Anderson, who sits on our scientific advisory board. Dr Anderson spoke to groups of interested physicians in Denmark, Switzerland, the Netherlands, Spain and the UK.

Aridol a valid marker in clinical studies

Interest from pharma companies

Aridol continues to make inroads as a simple, validated test to measure the efficacy of the next generation of asthma drugs. We have been approached by several large multinational companies since Aridol was first registered more than a year ago, and the ERS opened additional doors. The latest company to choose Aridol is Cambridge Antibody Technology, now part of MedImmune, the global biologics unit of Astra Zeneca. The study has multiple centres in several European countries and in Australia.

Korean distributor appointed

Korean distributor for Aridol appointed

Following the lodging of the regulatory submission in July, we have contracted BL&H to market and distribute Aridol in Korea. Korea has one of the highest rates of asthma in Asia. Coupled with its already established use of challenge tests as a diagnostic tool, we are looking forward to introducing Aridol to respiratory specialists in this large and growing market.

Current Clinical Activities

Bronchitol, is being tested as a new treatment for bronchiectasis, cystic fibrosis and acute exacerbations of chronic bronchitis. Bronchitol improves mucus clearance and is in a number of Phase III clinical trials. There are no approved products available to help bronchiectasis patients clear their lungs of excess mucus with the main treatment, physiotherapy, having limited effectiveness.

US Phase III trials to commence

Bronchitol for bronchiectasis

In late August, we released the preliminary results from a large Phase III clinical trial in people with bronchiectasis. The subjects were given either an inactive comparator or Bronchitol. The primary efficacy measures were quality of life and mucus clearance and on both measures Bronchitol produced a statistically significant change and a clinical improvement in the subjects.

Quality of life was measured using a Patient Reported Outcome, where the subjects are asked to respond to a series of questions. A Patient Reported Outcome instrument is defined as any measure of a patient's health status that comes directly from the patient and assesses how a patient 'feels or functions with respect to his or her health condition'

Bronchitol meets primary end points in bronchiectasis trial

Mucus clearance was measured over a 24 hour period at defined intervals throughout the study. For those patients taking Bronchitol, there was a 30% improvement in mucus clearance versus those patients taking a placebo.

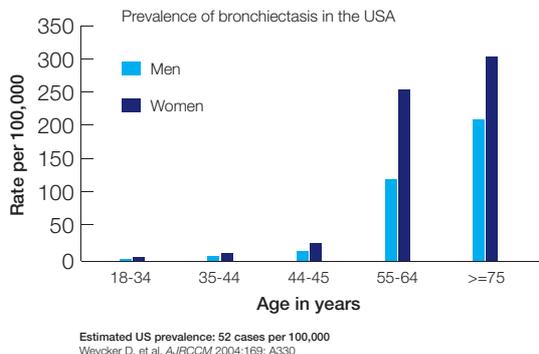
The primary data analysis has additionally shown Bronchitol to be safe after 12 weeks treatment: in the trial the numbers of adverse events for both Bronchitol and placebo were low and they were similar in nature.

Trial extension continues

At the end of the 12 week treatment period, patients elected to participate in an extension of the study where they would take Bronchitol for a total of 52 weeks. This component of the study is proceeding well and will provide us with very valuable safety data on long term use of Bronchitol.

We are finalizing with the FDA the clinical trial design for a Phase III trial to be conducted in 2008 in the USA.

Prevalence of bronchiectasis



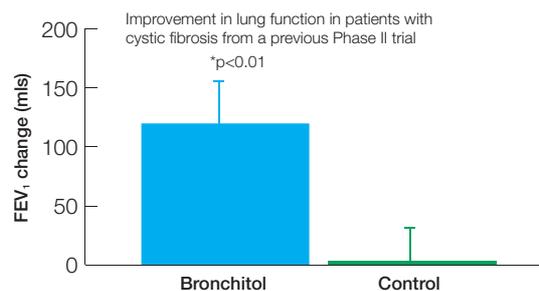
Bronchitol for cystic fibrosis

Cystic fibrosis is a genetic disease characterized by extremely thick bodily secretions in the digestive and pulmonary systems. Sticky, tenacious secretions in the lungs lead to frequent, debilitating infections, subsequent irreversible lung damage, and a shortening of life due to respiratory failure.

Bronchitol has been designed to improve lung hygiene by restoring the surface liquid lining of the lung that is depleted in people with cystic fibrosis. By doing this, we expect to reduce the number of debilitating lung infections and to improve mucus flow and clearance.

Early clinical trials with Bronchitol have shown a marked improvement in lung function and we are now completing the clinical development for Bronchitol for cystic fibrosis.

Bronchitol improves CF lung function



Phase III CF trial well underway

The Phase III European/Australian trial for Bronchitol in cystic fibrosis (CF301) is being conducted in 40 hospitals across Australia, New Zealand, Ireland, the United Kingdom and Germany. It is recruiting well, and so far we have enrolled more than one third of the required subjects.

The trial is being conducted after special Protocol Assistance was received from the European Medicines Agency. Bronchitol has Orphan Drug Designation in the European Union and a successful result from this study will allow us to submit a marketing application in Europe and elsewhere.

The trial includes an initial six month period where the treatment is unknown (ie Bronchitol or placebo), followed by an extended treatment period when all patients receive Bronchitol. The first patients are now entering this extension component of the trial.

**US Phase III trial
being finalized with
the FDA**

Plans for a second Phase III trial in the USA are almost complete. We are finalizing the clinical trial protocol with the FDA, have met with the U.S. Cystic Fibrosis Foundation and appointed a contract research organization to assist with the study. We anticipate commencing this trial during Q1 2008.

We are conducting a Phase II trial in patients with cystic fibrosis to ensure we fully understand the effects of different doses of Bronchitol on the lung functions of the patients. We anticipate that we will be able to close this study by the end of 2007.

**Research
activities
bearing fruit**

Current Research Activities

The focus of our new drug discovery research team is on finding treatments for immune system related disorders such as asthma, multiple sclerosis and rheumatoid arthritis.

PXS25 is a product of this research and we have developed improved procedures for its preparation to ensure consistency of supply. PXS25 has shown to be effective in models of multiple sclerosis and is currently being studied in models of asthma. The pre-clinical safety testing is now coming to an end and we anticipate commencing our first clinical trial with this compound in early 2008.

An earlier research programme is discovering new inhibitors of a protein that has recently been implicated in a number of inflammatory diseases, including asthma. While still at an early stage, highly potent inhibitors have been discovered and these are undergoing refinement to ensure they meet the demands of a new pharmaceutical.

**New equipment
ordered to
expand capacity**

Manufacturing Expansion

In anticipation of the demand for Bronchitol, we have ordered a new spray drier that will expand our manufacturing capacity by more than 20 fold. Successful design specification has been completed by the manufacturer and it will be installed in a clean room designed to meet the various demands of the regulatory agencies worldwide. We anticipate that the facility will be ready to produce Bronchitol under the appropriate certifications by early 2009.

**Three new
scientific articles
published**

Publications and Presentations

More than 50 papers about Aridol, Bronchitol or mannitol for inhalation have now been published in peer-reviewed journals. New publications this past quarter include:

- 1 Daviskas E, et al. Inhaled mannitol changes the sputum properties in asthmatics with mucus hypersecretion. *Respirology* 2007. doi 10.1111/j1440-1843.2007.01107
- 2 Glover J, et al. Effect of particle size of dry powder mannitol on the lung deposition in healthy volunteers. *Int J Pharm* 2007 doi 10.106/j.ijpharm, 2007.08.013
- 3 Brannan J, et al. Monitoring asthma therapy using indirect provocation tests. *Clin J Respir* 2007. doi10.1111/j/1752-699x.2007.00004x
- 4 National Heart Lung and Blood Institute (NHLBI): Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma, Section 3, page 65

**1st appearance
in NHLBI
guidelines**

Financial Overview for the First Quarter

At the end of the quarter we had cash and cash equivalents of A\$67 million. This was increased in early October by a successful \$50 million placement to institutions and professional investors. Our balance sheet is now in a strong position as we continue our series of international Phase III clinical trials and embark on the expansion of our Sydney manufacturing operations.

Aridol sales in Australia for the September 2007 quarter were A\$47,000. We continue to see quarterly improvement in Australian sales while consistent international sales await the issue of marketing certificates in a number of European countries.

The decrease in interest income over the prior comparable quarter reflects the decrease in invested cash funds.

Grant income is derived from the Pharmaceuticals Partnerships Program which was awarded to us in 2004 and concludes in the current financial year.

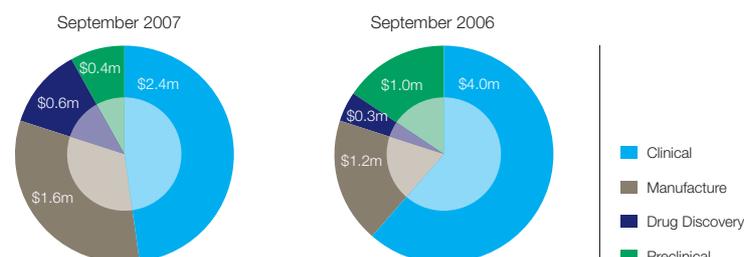
Research and development expenses of A\$5.0 million for the September 2007 quarter compare to A\$6.5 million in the September 2006, and A\$4.9 million in the June 2007 quarter.

Clinical expenses reduced significantly in the September 2007 quarter over September 2006, reflecting the high level of activity in 2006 related to our recently completed Phase III trial in bronchiectasis. The September 2007 level of expenditure is similar to the June 2007 quarter, but is expected to increase as our European Phase III clinical trial in cystic fibrosis continues to recruit and as two U.S. Phase II clinical trials commence in 2008.

Our recently established drug discovery group is now close to full strength and takes over from the research previously contracted to the Australian National University.

Preclinical efforts in the September 2007 quarter related to safety studies required for PXS25 to commence Phase I studies, while in September 2006 our preclinical expenditures were focused on long safety studies required to commence Phase III Bronchitol trials in the U.S.

Research and Development expenditure



Manufacturing R&D expenditure has increased as we supply product to clinical trials and to continue long term stability studies required for the Aridol marketing application in the U.S.

Commercial expenses in the September 2007 quarter of A\$898,000 compare to A\$697,000 in September 2006. The increased expenditure includes consulting in relation to establishing a Pharmaxis operation in the USA.

Administration expense for the September 2007 quarter of A\$1,053,000 was 10% higher than the September 2006 quarter, the majority of which relates to an increase in the calculated employee share option expense.

Income tax expense relates to income generated by our UK subsidiary which is reimbursed for its expenditure on a cost plus basis. Cash flow used in operating activities for the September 2007 quarter of A\$7.7 million includes the payment of clinical trial liabilities booked at 30 June 2007 in relation to the Phase III bronchiectasis study. Investing activities for the September 2007 quarter of A\$1.1 million include the first installments for the new spray drying equipment on which the Danish supplier has commenced manufacture.

Contact Details

Further information on Pharmaxis can be obtained from www.pharmaxis.com.au or by contacting Jane Sugden, Investor Relations.

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Australian Generally Accepted Accounting Principles

(Unaudited)
(’000 except per share data)

Income Statement

	Three months ended	
	30-Sep-07	30-Sep-06
	A\$	A\$
Revenue from sale of goods	47	49
Cost of sales	(17)	(9)
Gross profit	30	40
Other income		
Interest	1,152	1,410
Grant income	300	499
Other	45	-
Expenses		
Research & development	5,033	6,521
Commercial	898	697
Administration	1,053	960
Total expenses	6,984	8,178
Net loss before tax	(5,457)	(6,229)
Income tax expense	8	2
Net loss after tax	(5,465)	(6,231)
Basic and diluted earnings (loss) per share – \$	(0.031)	(0.035)
Depreciation & amortisation	259	217
Fair value of options issued under employee plan	639	321

Balance Sheet Data

	As at	
	30-Sep-07	30-Jun-07
Cash and cash equivalents	67,411	76,182
Plant & equipment	4,367	3,521
Intangible assets	1,204	1,239
Total assets	75,972	82,648
Total liabilities	(4,200)	(6,089)
Total shareholders' equity	71,773	76,559

Cash Flow Data

	Three months ended	
	30-Sep-07	30-Sep-06
Cash flows from operating activities	(7,723)	(6,516)
Cash flows from investing activities	(1,082)	(427)
Cash flows from financing activities	43	23
Net increase (decrease) in cash held	(8,762)	(6,920)

Balance Sheet Data

	As at	
	30-Sep-07	30-Jun-07
Ordinary shares on issue	178,032	177,949
Options over ordinary shares outstanding	11,374	9,836

US Generally Accepted Accounting Principles

(Unaudited)
(’000 except per share data)

Statement of Operations

	Three months ended		
	Sep-30-06	Sep-30-07	Sep-30-07
	A\$	A\$	US\$(1)
Revenue from sale of goods	49	47	41
Cost of sales	(9)	(17)	(14)
Gross profit	40	30	27
Operating expenses			
Research & development	5,853	4,378	3,876
Commercial	630	777	688
General and administrative	791	849	752
Amortization of intangible assets	24	24	22
Fair value of stock options issued to employees			
Research & development	145	332	294
Commercial	67	121	106
General and administrative	109	186	165
Total operating expenses	7,619	6,667	5,903
Loss from operations	(7,579)	(6,637)	(5,876)
Interest income	1,410	1,152	1,020
Other income	-	45	40
Foreign exchange gains(losses)	(60)	(17)	(15)
Net loss before tax	(6,229)	(5,457)	(4,831)
Income tax expense	(2)	(8)	(7)
Net loss	(6,231)	(5,465)	(4,838)
Basic and diluted net loss per ADS	(0.528)	(0.460)	(0.408)
Depreciation & amortisation	205	253	224

Balance Sheet Data

	As at		
	Jun-30-07	Sep-30-07	Sep-30-07
	A\$	A\$	US\$(1)
Cash and cash equivalents	76,182	67,411	59,693
Plant & equipment	3,752	4,592	4,066
Intangible assets	1,002	979	867
Total assets	82,642	75,972	67,273
Total liabilities	(6,083)	(4,200)	(3,719)
Total shareholders' equity	76,559	71,773	63,555

Cash Flow Data

	Three months ended		
	Sep-30-06	Sep-30-07	Sep-30-07
	A\$	A\$	US\$(1)
Net cash used in operating activities	(6,516)	(7,723)	(6,838)
Net cash used in investing activities	(427)	(1,082)	(958)
Net cash provided by financing activities	23	43	38
Net increase in cash and cash equivalents	(6,920)	(8,762)	(7,758)

American Depository Share Data

	As at	
	Sep-30-07	Sep-30-07
Equivalent ADSs on issue	11,863	11,869
Equivalent Options over ADSs outstanding	656	758

(1) Convenience translation into U.S. dollars from Australian dollars based upon rate on September 30, 2007