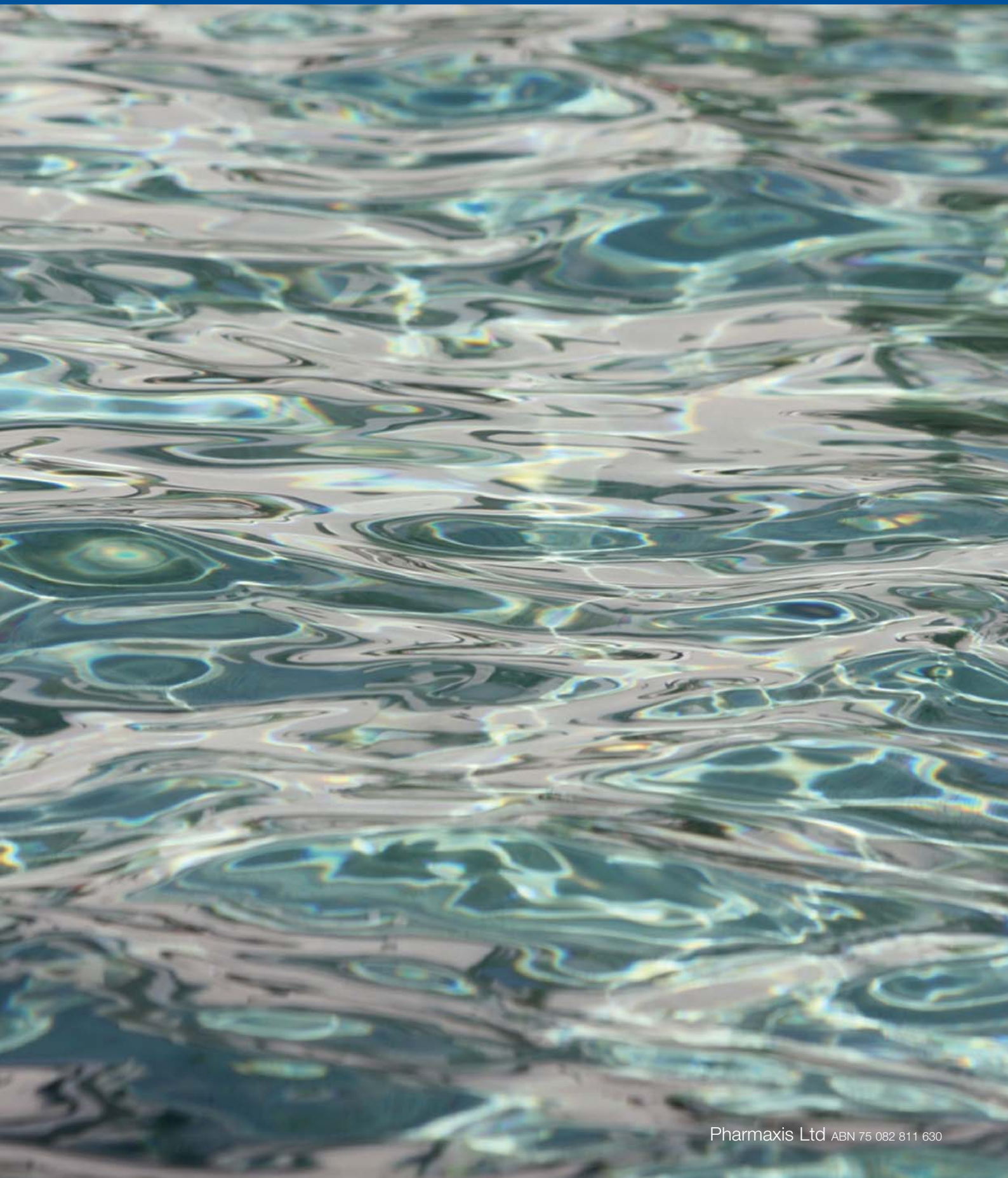
pharmaxis

Quarterly Report to Shareholders

Issue 29 | October – December 2010



Pharmaxis Ltd ABN 75 082 811 630

Producing human healthcare products to treat and manage respiratory diseases

Overview of Pharmaxis

The Business
Pharmaxis is a specialty pharmaceutical company with activities spanning product research & development through to manufacture, sales and marketing. The company's therapeutic interests include lung diseases such as cystic fibrosis, asthma, bronchiectasis and chronic obstructive pulmonary disease.

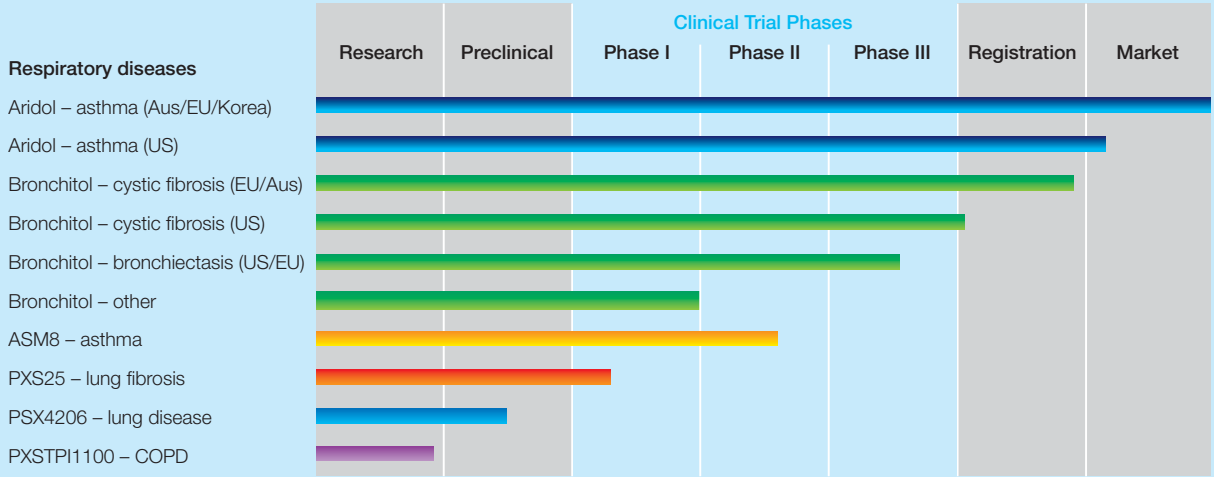
Based in Sydney, Australia, Pharmaxis manufactures its two lead products for commercial sale,clinical trials and for compassionate use.

Aridol
The first product, Aridol™ (mannitol bronchial challenge test) is registered for sale and marketing in Australia, Europe, South Korea and the United States. Aridol is designed to assist in the detection of hyper-responsive, or twitchy airways, which is one of the hallmarks of asthma. Aridol's approvals followed the completion of two large Phase III trials involving over 1,100 participants.

Bronchitol
The second product, Bronchitol™ has completed two regulatory Phase III trials for cystic fibrosis and we are currently seeking marketing approval for Bronchitol in Europe, Australia and shortly the United States. An additional Phase III trial in bronchiectasis is underway.

Other Products
The drug discovery group is located in Sydney and uses rational design to discover new potential therapies as drugs of the future. This group has been responsible for discovering PXS25 and PXS4206 – both targeting lung disease where there are currently no treatment options. ASM8 is an inhaled drug for asthma that was originally discovered and developed in Canada.

Pharmaxis Product Development at December 2010



First new drug for CF mucus in 15 years

CEO Report

The close of the last Quarter of 2010 gives cause to reflect on an eventful year for Pharmaxis – a year of significant challenge and a year that establishes a firm foundation for the future. After 10 years of effort, we are finally on the cusp of bringing Bronchitol to the market place and for all those involved, over all those years, this will be a great achievement. To bring a new drug to the international arena is no mean feat and we should be very proud of what we have achieved so far. But this is only the end of the beginning; now we have to turn that endeavour into revenue by ensuring Bronchitol is a global success – a drug that benefits the lives of thousands of families around the world.

Chronic diseases such as cystic fibrosis or bronchiectasis are particularly challenging areas in which to develop new drugs. This is evident if you look at the success rate. In the case of cystic fibrosis, the last drug to help with mucus clearance was approved over 15 years ago and no drug has ever been approved specifically for bronchiectasis. The slow insidious nature of the diseases present difficulties for the drug developer and it can often be a challenge to demonstrate success in a clinical trial that lasts a few months in a disease that lasts many years.

In Bronchitol, we are convinced we have a drug that provides significant benefit to patients and while we still have some way to go through the regulatory review processes around the world, the first plank is in place following a recommendation that Bronchitol be approved for cystic fibrosis in Australia by the Advisory Committee on Prescription Medicine (ACPM).

As we look ahead to the forthcoming year, Pharmaxis will be concentrating on generating Aridol revenue from the United States following its approval by the FDA and in generating Bronchitol revenue once approved in Australia and Europe. Our expectation is that additional marketing approvals will be received in due course and we are well prepared for that eventuality.

Finally, I am very pleased to be back to full health following a period of illness and look forward to 2011 with great enthusiasm. I owe a debt of gratitude to the Pharmaxis team and, in particular, Gary Phillips for stepping in and assuming the CEO role during my recuperation.

Alan D Robertson, Chief Executive Officer

Fourth Quarter Highlights

Pre-NDA concluded with FDA

- Australian advisory group (ACPM) recommends Bronchitol for approval
- Bronchitol provides sustained benefit in cystic fibrosis after 12 months treatment
- Pre-NDA meeting concluded with the US FDA for Bronchitol
- Bronchitol data presented at the North American CF Foundation annual meeting
- ASM8 commences clinical trial in asthma
- PXS25 completes additional preclinical study

Forthcoming Events

- Response from EMA on Bronchitol marketing application for Europe
- Response to the Australian marketing application for Bronchitol

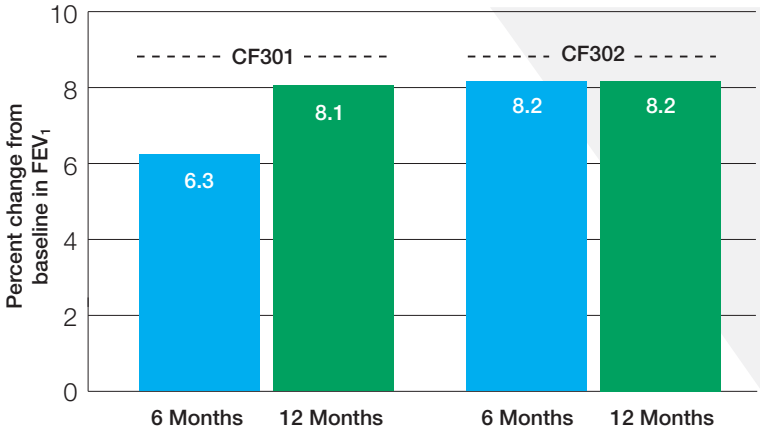
Bronchitol for Cystic Fibrosis

Bronchitol has been precision formulated as a dry powder inhalation agent to help restore normal lung clearance mechanisms and hence prevent ongoing bacterial infection and colonization of lungs. It is particularly suited to patients with cystic fibrosis and bronchiectasis but we believe it may also be useful for other diseases where mucus retention in the lung is a problem such as chronic obstructive pulmonary disease, or COPD.

Pharmaxis has completed two Phase III trials around the world in patients with cystic fibrosis and has seen remarkably consistent results between the two trials. The two trials involved around 600 patients – 300 in each trial, and looked at the changes in lung function over time. This is particularly important because people with cystic fibrosis, for example, lose lung function over time and most people with the disease will die from respiratory failure. Today, in the United States, the actual average survival for someone with CF is only 26 years, so there is a pressing need for new medicines that help arrest the decline in lung function.

The two trials both had a blinded phase where neither the clinician nor the patient were aware of whether they were taking Bronchitol or a control and an open label phase where both the clinician and the patient were aware they were taking Bronchitol. The trials lasted 12 months in total with both phases lasting for 6 months. The first trial was called CF301 and took place in Australia, New Zealand and Europe and the second trial was called CF302 and took place in South America, North America and Europe.

Lung function changes at 6 and 12 months following Bronchitol treatment



Complete CF data set now available

At the end of the two trials the lung function improvement from baseline after 12 months treatment with Bronchitol was remarkably consistent at just over 8%. An individual with cystic fibrosis may experience a loss of 1-2% of lung function annually – as measured by Forced Expiratory Volume in 1 second (FEV_1). So, improvement in lung function is one metric that is important, but the real value in Bronchitol may be in its ability to prevent the normal loss of lung function. This loss of lung function is the main cause of early death for people with cystic fibrosis.

Late last year, we received notification that the Australian Bronchitol marketing submission had been recommended for approval by the Advisory Committee on Prescription Medicines. This committee gives advice and makes non-binding recommendations to the TGA on prescription medicines including the inclusion of prescription medicines on the Australian Register of Therapeutic Goods.

Bronchitol for CF in Europe

Marketing plans well advanced in Europe

During the quarter, Pharmaxis continued to work with the European Medicines Agency on the marketing application for Bronchitol to treat cystic fibrosis. The original marketing application was submitted in October 2009 and we are hopeful that the process will conclude during the first half of 2011.

In the meantime, the head of the German marketing and sales operation has been appointed and the UK group is making preparations for the Bronchitol launch, including detailed pre-marketing efforts. The Quintiles organisation has been contracted to provide the sales force to promote Bronchitol in mainland Europe and, additionally, to provide expert assistance on health economic modelling and pricing and reimbursement issues.

Bronchitol for CF in the USA

Pharmaxis to seek approval in the USA

For the US market, two clinical trials have been conducted and significant support was received from the US Cystic Fibrosis Foundation to help with one of those studies. That trial (CF302) was conducted in 53 hospitals across the United States, and elsewhere, and the data has been discussed previously. In order to gain approval for marketing Bronchitol in the United States, a comprehensive package of information is assembled and reviewed by the US regulatory agency, the Food and Drug Administration. This process has commenced, the first step of which was a pre-NDA meeting with the FDA held in mid-December. The New Drug Application (NDA) for Bronchitol to treat cystic fibrosis is planned for submission to the FDA during the first half of 2011.

Bronchitol for bronchiectasis

Bronchiectasis is a disease of the lung that results in irreversible dilation of the bronchial tree that then becomes weak, inflamed and prone to collapse resulting in airflow obstruction and impaired clearance of lung secretions. For people affected by the condition, breathlessness, excessive mucus production and constant coughing are typical symptoms.

Expanding Bronchitol's application

Pharmaxis has completed one clinical trial in over 300 people and demonstrated that Bronchitol was able to improve quality of life and mucus production when patients were treated for 3 months. A second Phase III trial is underway where people are treated for 12 months and, in addition to quality of life and mucus production, exacerbation rate frequency is a key outcome. An exacerbation is an episode where the condition gets much worse and those patients treated with Bronchitol are expected to have fewer exacerbations than the control group of patients.

This trial, B305, is a major clinical trial to extend the use of Bronchitol beyond cystic fibrosis. This trial commenced dosing in October 2009 and full recruitment is scheduled for completion in the first half of 2011. The trial is being conducted in over 90 sites in 9 countries and is approximately half way towards the target recruitment of 474 subjects. This is an important trial and amongst the largest ever conducted in this patient group and it will form a key part of the marketing applications for Bronchitol to treat bronchiectasis.

Bronchitol to the world

Bronchitol is now the subject of 21 separate peer reviewed publications and, in addition, the results from the recent Phase III cystic fibrosis trials were presented at the 24th Annual North American Cystic Fibrosis Conference in Baltimore in October last year.

Aridol

Aridol launch in the USA

Aridol is a lung function test designed to help doctors diagnose and manage asthma by detecting active airway inflammation through measuring airway hyperresponsiveness. Anti-inflammatory drugs are the mainstay of asthma treatment and lead to a reduction in airway-hyperresponsiveness through reducing inflammation. Aridol is simple and easy to use and suitable for use in hospital outpatient clinics and specialist physician's offices.

Pharmaxis has undertaken to market Aridol through education, recognising that it will not command the sort of marketing resources that will be directed to Bronchitol. Last year, there were 22 new publications on Aridol as well as multiple presentations at international scientific meetings. There are now over 100 publications in total and with approvals in Europe and the USA, Aridol is on its way to becoming the globally accepted standard for bronchial challenge testing.

The US launch of Aridol is scheduled for the first quarter of 2011 and ahead of the launch significant effort has gone into training and understanding the reimbursement process. Aridol will be reimbursed by US payors under existing procedure codes. Our objective is to make sure the US clinicians have a positive experience when using Aridol and that they are appropriately reimbursed for conducting a test. The existing market for bronchial challenge tests is small in the US but Aridol overcomes many of the drawbacks of the existing challenge tests and represents an exciting opportunity to grow this market.

ASM8

New drug for allergic asthma

ASM8 is a new inhaled drug designed to treat those allergic asthmatics that are inadequately controlled with existing medication. This represents about 10% of the asthma community and affects children and adults alike. For these people there is very little recourse, although one drug (omalizumab) has been developed and approved to assist this group. This drug is a monoclonal antibody and is given by an injection administered by a healthcare provider once every two to four weeks. When approved, ASM8 will compete against this product which has annual sales of approximately $1 billion.

Some of the earlier clinical trials have already reported and a further Phase II trial has begun. In this trial, patients with allergic asthma are treated for 14 days after which they are exposed to the allergen that causes their asthma. If ASM8 is effective, the response and their asthma trigger should be blunted. This trial is well underway, and is expected to report during the second half of 2011.

PXS25

PXS25 prevents loss of lung condition

PXS25 is a new antithrombotic agent being developed to treat pulmonary fibrosis. Idiopathic Pulmonary Fibrosis is a disease of unknown origin that involves the deposition of collagen in the walls of the alveoli the consequence of which is a lung that loses elasticity and function and causes shortness of breath and dry cough. In preclinical studies conducted in collaboration with the Mayo clinic in the US, PXS25 prevents the deposition of collagen and the loss of elasticity in models of pulmonary fibrosis. The first Phase I trial has been completed and PXS25 was shown to be safe and well tolerated and to have a suitable profile in humans for a new pharmaceutical.

Further studies are being organised to commence during the first half of 2011.

Corporate News

Pharmaxis presents at international meetings

An important part of drug development is presentation of the clinical trial data in scientific meetings that allows participants an opportunity to review the data and to question the results. In this regard, we presented the results of our work at the following major meetings in 2010:

- The European Respiratory Society meeting in Barcelona, Spain
- The European Cystic Fibrosis meeting in Valencia, Spain
- The American Academy of Allergy, Asthma & Immunology, New Orleans, USA
- The American Thoracic Society, New Orleans, USA
- The North American Cystic Fibrosis meeting, Baltimore, USA

The majority of the presentations concerned Aridol and Bronchitol, but we also presented the Phase II clinical trial with ASM8 and some preclinical work on PXS25.

Financial Overview of the Quarter

Pharmaxis finished the quarter with $67 million in cash.

Clinical trial costs dominate R&D expenditure

For the December 2010 quarter, sales of A$156,000 compared to A$171,000 in 2009 and A$202,000 in the September 2010 quarter.

Research and development expenses of A$9.0 million for the December 2010 quarter compares to A$9.2 million in the December 2009 quarter, and A$8.8 million in the September 2010 quarter. The mix of research and development expenditure is similar to that of the September 2010 quarter, with clinical trial costs and manufacturing research and development continuing to account for the major part of the expenditure – 62 percent.

Commercial expenses of A$2.2 million compares to A$1.2 million in the December 2009 quarter and A$1.5 million in the September 2010 quarter. Expenditures have increased as the company prepares for the commercial launch of Bronchitol in Europe and Australia, and Aridol in the US.

Administration expenditure of A$1.6 million compares to A$1.8 million in the December 2009 quarter and A$1.2 million in the September 2010 quarter. The effect of changes in exchange rates on foreign currency denominated assets and liabilities accounts for part of the changes in expenditure between quarters as does the amount and timing of certain professional consulting fees.

Finance costs represent the ongoing finance charge component of the capitalized finance lease for our facility at Frenchs Forest.

Operating activities used cash of A$8.4 million compared to A$10.3 million in December 2009 and A$8.8 million in the September 2010 quarter. Investing activities used cash of A$0.4 million compared to A$0.9 million in December 2009 and $0.4 million in the September 2010 quarter.

Financial Statement Data – Unaudited
(International Financial Reporting Standards)

('000 except per share data)

Income Statement Data

	Three months ended		Six months ended	
	31-Dec-10	31-Dec-09	31-Dec-10	31-Dec-09
	A$	A$	A$	A$
Revenue from sale of goods	157	171	359	354
Cost of sales	(48)	(60)	(117)	(107)
Gross profit	109	111	242	247
Interest	834	978	1,771	1,930
Other income	75	77	250	165
Expenses				
Research & development	(8,952)	(9,184)	(17,720)	(17,296)
Commercial	(2,193)	(1,213)	(3,662)	(2,465)
Administration	(1,596)	(1,813)	(2,793)	(3,534)
Finance expenses	(143)	(222)	(433)	(508)
Total expenses	(12,884)	(12,432)	(24,608)	(23,803)
Loss before income tax	(11,866)	(11,266)	(22,345)	(21,461)
Income tax expense	–	(32)	(7)	(43)
Loss for the period	(11,866)	(11,298)	(22,352)	(21,504)
Basic and diluted earnings (loss) per share – $	(0.053)	(0.052)	(0.099)	(0.099)
Depreciation & amortisation	1,217	641	2,406	1,146
Fair value of securities issued under employee plans	390	549	830	1,154

Balance Sheet Data

	As at	
	31-Dec-10	30-Jun-10
	A$	A$
Cash and cash equivalents	66,997	85,787
Property, plant & equipment	31,668	32,537
Intangible assets	16,829	17,702
Total assets	118,810	140,767
Total liabilities	(25,501)	(25,751)
Net assets	93,309	115,016

Cash Flow Data

	Three months ended		Six months ended	
	31-Dec-10	31-Dec-09	31-Dec-10	31-Dec-09
	A$	A$	A$	A$
Cash flows from operating activities	(8,426)	(10,316)	(17,221)	(20,344)
Cash flows from investing activities	(410)	(909)	(843)	(2,233)
Cash flows from financing activities	29	(122)	(259)	(311)
Impact of foreign exchange rate movements on cash	(27)	(4)	(467)	(24)
Net increase (decrease) in cash held	(8,834)	(11,351)	(18,790)	(22,912)

Share Data

	Ordinary Shares as at	
	31-Dec-10	30-Jun-10
Ordinary shares on issue	226,126	225,410
Options over ordinary shares outstanding	12,903	13,155

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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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