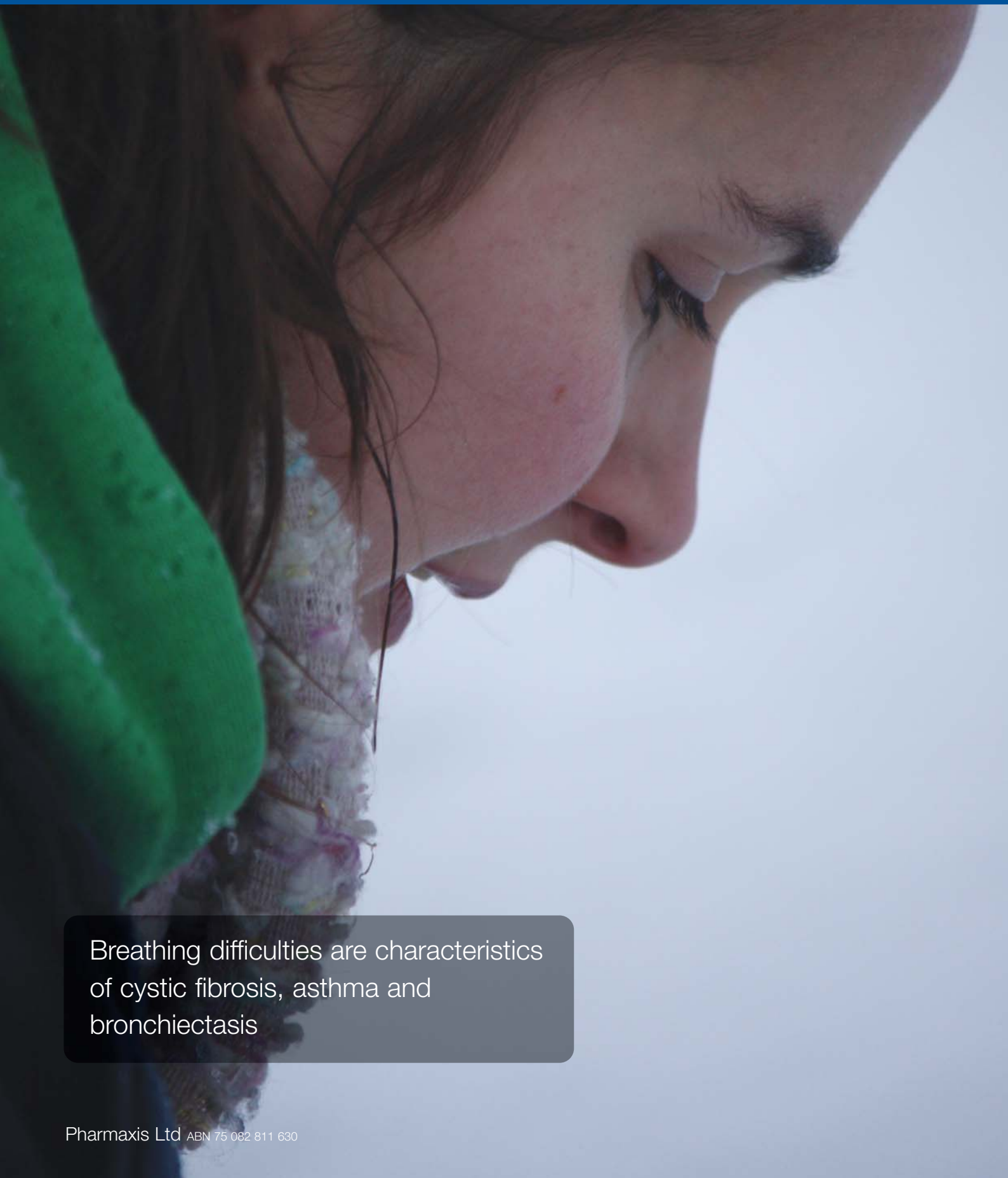
pharmaxis

Quarterly Report to Shareholders

Issue 26 | January – March 2010



Breathing difficulties are characteristics of cystic fibrosis, asthma and bronchiectasis

Pharmaxis Ltd ABN 75 082 811 630

Producing human healthcare products to treat and manage respiratory diseases

Overview of Pharmaxis

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.

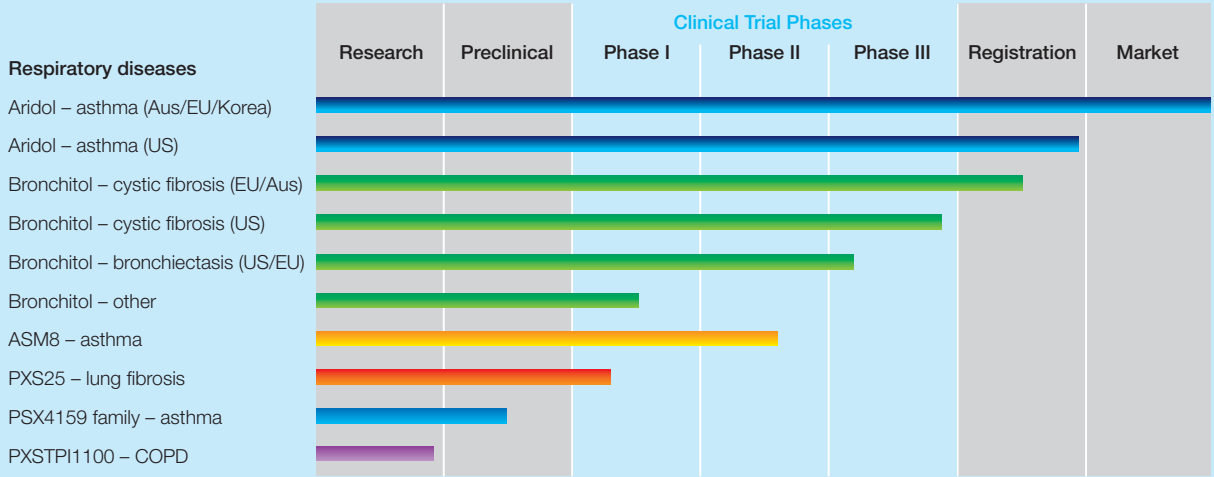
Based in Sydney, Australia, Pharmaxis manufactures its two lead products for commercial sale, clinical trials and for compassionate use.

Our first product, Aridol™ (mannitol bronchial challenge test) is registered for sale and marketing in Australia, Europe and South Korea and a marketing approval is being sought from the FDA in 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 Australian and European approvals followed the completion of two large Phase 3 trials involving over 1,100 participants.

Our second product, Bronchitol™, has completed the first regulatory Phase 3 trial for cystic fibrosis and is currently seeking approval for marketing in Europe and Australia. Additional Phase 3 trials in cystic fibrosis and bronchiectasis are underway.

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

Pharmaxis Product Development at March 2010



CEO Report

Breathing is something most of us take for granted. When something goes wrong with our breathing it has a sudden and immediate impact. The key function of the lung is to exchange gases in our blood — supply oxygen and remove carbon dioxide. Any disease that inhibits this process impacts a person's overall health by reducing the oxygen levels in the blood and causing breathing to increase. Severe cases of lung disease may impair breathing enough to cause abnormally low levels of oxygen and high levels of carbon dioxide in the blood. This situation is known as respiratory failure and if something is not done immediately, the consequences are usually fatal.

Cystic fibrosis, bronchiectasis, pulmonary fibrosis and chronic obstructive pulmonary disease (COPD) can all lead to respiratory failure.

Asthma is not a well managed disease for some

Asthma is a condition in which the airways narrow, usually reversibly, in response to a stimulus. Asthma is a common disease and its frequency sometimes detracts from its potential seriousness and some experts believe that severe asthma should be considered as a different disease than asthma. Only 5-10% of asthmatics have severe asthma and yet these individuals carry a substantial proportion of the cost and run the highest risk of exacerbations and death. It is these patients who do not respond well to conventional treatments and it these patients we are targeting with ASM8.

Pharmaxis now has Aridol on the market for assisting with asthma management and additional products at various stages of development for cystic fibrosis, bronchiectasis, asthma, COPD and pulmonary fibrosis as indicated in the chart opposite.

Our goal remains consistent: to bring new medicines to people with respiratory disease and help them to breathe more easily.

This quarterly report charts our progress.

Alan D Robertson, Chief Executive Officer

First Quarter Highlights

Cystic fibrosis trial closed

- Subjects in the first Phase 3 cystic fibrosis trial reach 18 months on treatment
- Acquisition of Topigen completed
- ASM8 posts an impressive result in a Phase 2 trial of asthma patients
- PXS25 completes Phase 1 clinical trial in healthy volunteers

Coming Events

Major milestones in coming months

- Second Phase 3 trial of Bronchitol for cystic fibrosis to report primary outcome
- Finalisation of Aridol NDA with the U.S. FDA

New Research Activities

Outstanding results from early trials of new asthma therapy

Asthma patients' breathing was improved by an outstanding 32-49% in Phase 2 clinical trials of Pharmaxis' new anti-inflammatory agent ASM8.

Effective therapy for asthma

The new molecule was obtained by Pharmaxis in its recent acquisition of the Canadian company Topigen Pharmaceuticals.

Tested on patients with allergic asthma, the Phase 2a dosage study found inhalation of 8mg of ASM8 reduced bronchoconstriction by 32% during the early phase of an allergen challenge, and by 49% during the late phase of the response compared to control. Inflammation of the lungs was also reduced by 49% 7 hours later, and by 57% 24 hours after the allergen challenge.

The results indicate ASM8 could be a potent new therapy in treating severe asthma, which is significantly undertreated by current medicines and currently affects more than three million people in the U.S., Europe and Japan.

As a once-a-day inhaled medicine with a strong safety profile, ASM8 is already showing clear advantages over many of its in-market competitors, which require injections, intravenous transfusion, are expensive or have significant side-effects.

A second Phase II trial of longer duration will begin recruiting later this year.

Gene silencing approach

Diagram: ASM8 takes a distinctly new approach to controlling lung inflammation by switching off the genes responsible for manufacture of the proteins that cause airway inflammation.

ASM8 is being developed to control asthma in patients who have severe or persistent asthma that is poorly treated by existing medications.

PXS25 passes its first clinical hurdle

First Phase 1 trial completed

The first Phase 1 trial of Pharmaxis' new antifibrotic agent PXS25 has delivered encouraging results.

Designed to determine the tolerance and pharmaceutical properties of PXS25 following intravenous administration, the trial found the drug to be safe, well tolerated and with an excellent pharmacokinetic profile in healthy volunteers.

PXS25 is being developed as a potential new treatment for pulmonary fibrosis, which affects over 500,000 people in the major pharmaceutical markets.

Additional Phase 1 trials will be completed before PXS25 is evaluated in patients with lung disease.

Cystic Fibrosis

The clinical manifestations of cystic fibrosis were first recognised in the 1930's, however, it was not until the gene responsible was identified in 1989 that scientists began to understand the complex nature of the disease. Although cystic fibrosis affects a number of organs in the body, it is the effects on the lung that are most devastating. Difficulty breathing, excessive mucus production, continuous lung infections and lung damage are hallmarks of the disease.

Modifying the course of cystic fibrosis

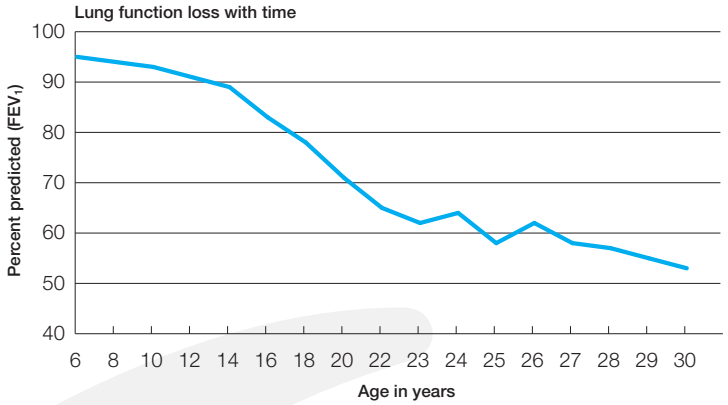


Chart: For a person living with cystic fibrosis, lung function will typically drop by around 2% per year

Source: Cystic Fibrosis Foundation Patient registry, 2004

Bronchitol for Cystic Fibrosis

In a Phase 3 clinical trial in cystic fibrosis reported last year, we showed that Bronchitol was able to arrest the fall in lung function and by 6 months, lung function had improved by 7% and at 12 months by 8%.

Lung function improves 8% in a year

This trial has now reached 18 months duration and the last patients had their final visits in March 2010. The results from this extended treatment trial are therefore due during the April to June quarter.

Data from the trial including other lung function parameters and effects on exacerbation will be presented at a special symposium at the European CF meeting in Valencia in June this year.

The important second Phase 3 trial being run with the assistance of the U.S. Cystic Fibrosis Foundation is nearing the end of its 6 month blinded phase. 305 patients with CF started the trial which is being conducted at hospitals in Argentina, the USA, Canada, Germany, France, The Netherlands and Belgium. The data from this trial will form part of the marketing submission to the U.S. FDA and will be available during the forthcoming April to June quarter.

Marketing approvals for Bronchitol in Europe and Australia

Marketing applications seeking approval for Bronchitol to treat people with cystic fibrosis were filed last year with the Australian and European regulatory authorities.

Marketing applications proceeding

The European review of the marketing application is well underway and has included an audit of some of the clinical centres involved in the pivotal Phase 3 trial. The review is going through the centralised procedure which affords access to all European Union member states. The outcome of the review should be known during the second half of 2010.

The Australian marketing application for Bronchitol was submitted to the Therapeutic Goods Administration (TGA) in December 2009. The TGA advised in mid-February 2010 that the marketing application has been accepted for review. The TGA must then complete the evaluation and make a decision on registration of Bronchitol within a further 255 working days. A final decision on the marketing application is expected in the first half of 2011.

Bronchitol for Bronchiectasis

Major bronchiectasis trial enrolling

Phase 3 bronchiectasis trial in progress

We have demonstrated in a number of clinical trials that Bronchitol brings clear and measurable benefits to people with bronchiectasis and many of these studies have now been published. On the basis of the earlier trials we embarked on a major international trial with the regulatory assistance of both the EMA and the FDA. This trial will evaluate the effects of Bronchitol over 12 months compared to an inactive placebo. The trial is now actively recruiting at 49 centres in the U.S., Argentina, Australia, New Zealand and Germany.

The aim of the trial is to show a reduction in the rates of exacerbations when treated with Bronchitol and the trial is planned to close recruitment later this year.

Breathing difficulties

Bronchiectasis is often thought of as the poor cousin of cystic fibrosis and yet, as far as the respiratory tract is concerned, many of the clinical features are similar with heavy mucus production and breathing difficulties most common. Many people born with cystic fibrosis will almost inevitably go on to develop bronchiectasis. The usual cause of bronchiectasis is severe or repeated respiratory infections and most people develop a chronic non-productive cough.

The two drugs that are recommended for treating patients with cystic fibrosis have not benefited patients with bronchiectasis and the unmet clinical need is acute. Our objective with this program is to bring Bronchitol to clinical practice for both cystic fibrosis and bronchiectasis.

Aridol

U.S. marketing application progress

Pharmaxis is actively working with the U.S. FDA to finalise its New Drug Application (NDA) for Aridol. On 24 December 2009, Pharmaxis received a Complete Response Letter, which high-lighted some outstanding matters in relation to subcontract testing and packing, labeling revision and post marketing requirements. Significant progress has been made on all fronts as we get closer to bringing this marketing application to a conclusion.

Pharmaxis filed the NDA for Aridol in February 2009 and is requesting approval to market Aridol in the USA for the assessment of bronchial hyper-responsiveness to aid in the diagnosis of patients with signs and symptoms of asthma.

In late October Pharmaxis presented to the Pulmonary and Allergy Advisory Committee of the U.S. FDA in Washington and responded to questions from the committee. At the conclusion of the meeting, the committee recommended that Aridol should be approved by the FDA on the basis of the clinical evidence.

Operations

Factory operational

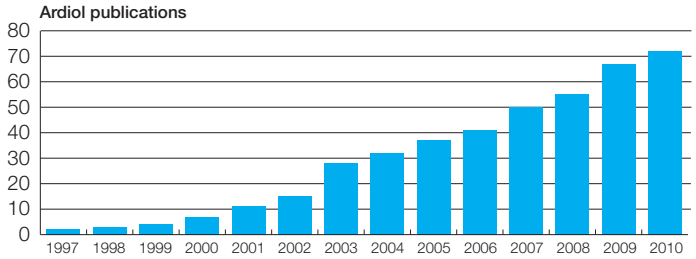
The new manufacturing plant in Rodborough Road, Frenchs Forest is now operational and the qualification work on the new equipment is essentially complete. The spray drier operates well and has produced a number of batches of both Bronchitol and Aridol within our specification. Further fine tuning is being concluded before the validation process commences and ahead of an inspection by the relevant regulatory authority.

The spray drier has capacity to produce enough Bronchitol to treat 40,000 patients a year.

International interest in Aridol

Aridol Citations

The awareness of Aridol as a viable lung function test continues to grow. In the first quarter of this year, there has been an additional four publications concerning the use of Aridol in various clinical situations. To date more than 70 peer reviewed scientific articles have been published on Aridol and, when approved in the USA, it is set to become the global standard for lung function testing.



Corporate News

Topigen becomes part of Pharmaxis

Acquisition of Topigen completed

In early February Pharmaxis completed its acquisition of Canadian biopharmaceutical company Topigen. A total of 3.2 million shares were issued on closing and a further 3.0 million shares on achievement of a clinical milestone, with a further 2 million shares to be paid when remaining milestones are achieved.

The Topigen portfolio of therapeutic candidates is an exciting adjunct to Pharmaxis' pipeline of products, with ASM8 in particular showing great promise in treating asthma. Topigen's activities and staff are being integrated into Pharmaxis operations

Financial Overview of the Quarter

Pharmaxis finished the quarter with $96 million in cash.

For the March 2010 quarter, Aridol sales of A$282,000 compared to A$144,000 in 2009 and A$171,000 in the December 2009 quarter.

Research and development expenses of A$9.0 million for the March 2010 quarter compares to A$7.2 million in the March 2009 quarter, and A$9.2 million in the December 2009 quarter. Expenditure on clinical trials, manufacturing development, device development and drug discovery accounted equally for the change. Commercial expenses of A$1.3 million compares to A$1.4 million in the March 2009 quarter and A$1.2 million in the December 2009 quarter.

R&D dominates expenditure

Commercial expenditure is directed at preparing for the commercial launch of Bronchitol in Europe and the US, preparing for the sale of Aridol in the US and the costs of selling Aridol in Europe and Asia Pacific.

Administration expenditure of A$4.6 million compares to A$1.3 million in the March 2009 quarter and A$1.8 million in the December 2009 quarter. The current quarter expenditure includes approximately $3.1 million in relation to the integration of the Topigen acquisition. The business was acquired with sufficient working capital to fund both its next clinical milestone and the integration.

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

Operating activities used cash of A$11.6 million compared to A$4.5 million in March 2009 and A$10.3 million in the December 2009 quarter. This cash usage includes approximately $2.0 million in relation to the integration of Topigen. As a consequence of the Topigen acquisition including cash of A$5.7 million, investing activities generated net cash of $5.5 million for the quarter. This compares to a cash usage of A$3.7 million in March 2009 and A$0.9 million in the December 2009 quarter.

Financial Statement Data – Unaudited
(International Financial Reporting Standards)

('000 except per share data)

Income Statement Data

	Three months ended		Nine months ended	
	31-Mar-10	31-Mar-09	31-Mar-10	31-Mar-09
	A$	A$	A$	A$
Revenue from sale of goods	282	144	636	453
Cost of sales	(125)	(35)	(232)	(113)
Gross profit	157	109	404	340
Interest	1,003	927	2,933	4,584
Other income	123	132	288	276
Expenses				
Research & development	(8,991)	(7,193)	(26,287)	(20,780)
Commercial	(1,261)	(1,449)	(3,725)	(4,339)
Administration	(4,631)	(1,336)	(8,165)	(4,258)
Finance expenses	(148)	–	(656)	–
Total expenses	(15,031)	(9,978)	(38,833)	(29,377)
Loss before income tax	(13,748)	(8,810)	(35,208)	(24,177)
Income tax expense	–	1	(42)	(27)
Loss for the period	(13,748)	(8,809)	(35,250)	(24,204)
Basic and diluted earnings (loss) per share – $	(0.063)	(0.045)	(0.162)	(0.124)
Depreciation & amortisation	689	271	1,836	789
Fair value of options issued under employee plan	719	650	1,872	1,801

Balance Sheet Data

	As at	
	31-Mar-10	30-Jun-09
	A$	A$
Cash and cash equivalents	95,904	124,993
Property, plant & equipment	32,934	32,698
Intangible assets	12,594	1,193
Total assets	148,152	163,997
Total liabilities	(28,821)	(26,306)
Net assets	119,331	137,691

Cash Flow Data

	Three months ended		Nine months ended	
	31-Mar-10	31-Mar-09	31-Mar-10	31-Mar-09
	A$	A$	A$	A$
Cash flows from operating activities	(11,554)	(4,515)	(31,898)	(16,343)
Cash flows from investing activities	5,515	(3,655)	3,282	(9,742)
Cash flows from financing activities	(181)	–	(492)	11
Net increase (decrease) in cash held	(6,220)	(8,170)	(29,108)	(26,074)

Share Data

	Ordinary Shares as at	
	31-Mar-10	30-Jun-09
Ordinary shares on issue	225,324	217,659
Options over ordinary shares outstanding	13,405	15,075

pharmaxis

Contact Details

Further information on Pharmaxis can be obtained from www.pharmaxis.com.au or by contacting David McGarvey, Chief Financial Officer:

Telephone: +612 9454 7200
david.mcgarvey@pharmaxis.com.au

Pharmaxis Ltd
ABN 75 082 811 630
20 Rodborough Road
Frenchs Forest NSW 2086