pharmaxis

Quarterly Report to Shareholders

Issue 30 | January – March 2011

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.

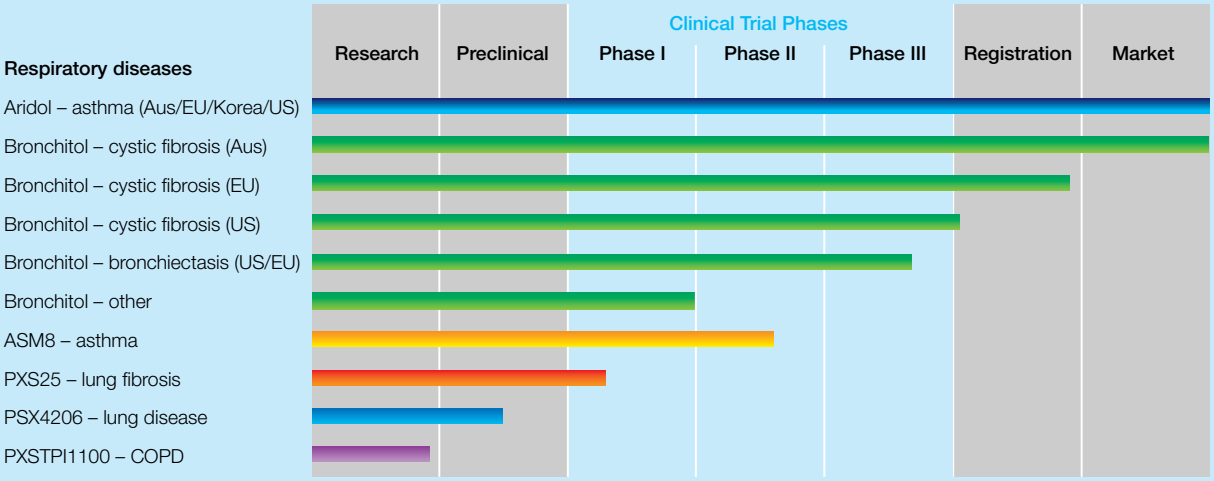
Aridol
The first product, Aridol™ (mannitol bronchial challenge test) is registered for sale and marketing in Australia, Europe, South Korea and the United States. Aridol is designed to assist in the detection of hyper-responsive, or twitchy airways, which is one of the hallmarks of asthma. Aridol's 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 involving 600 patients and has been approved for marketing in Australia and is in marketing approval review in Europe.
An additional Phase III trial in bronchiectasis is underway.

ASM8
This new drug for the treatment of asthma has completed a number of clinical trials in people affected by allergic asthma and it is currently in an expansive Phase II clinical trial.

PXS25
This drug has been developed for the treatment of lung fibrosis and is currently in Phase I clinical trials.

Pharmaxis Product Development at March 2011



Front cover: In recent years, there has been a worldwide increase in childhood asthma.

CEO Report

The first quarter of 2011 is now well behind us and the challenges facing the developer of new pharmaceutical products are no easier today than they ever were, in spite of great advances in our understanding of human diseases. A great deal of effort has to be expended to show that a new medicine is both effective at treating the target disease and is safe. The challenges are particularly difficult for developers of new drugs to treat serious, life long diseases such as cystic fibrosis, where the drugs may have to be taken for 20 or 30 years. Under this scenario new drugs must be extremely safe. I am very pleased to say that Bronchitol has now been approved to treat cystic fibrosis in its first market, Australia, and so becomes the first new medicine to treat this disease for 18 years. The apparent poor record in delivering new drugs for cystic fibrosis is not due to lack of effort but highlights the difficulties in developing medicines for this disease. As we have been developing Bronchitol over the last few years, we have seen competitors fall at one of the many clinical development hurdles – being deemed either not effective enough or not safe. Bronchitol is a very rare thing indeed, a new drug shown to be both safe and effective.

Bronchitol becomes the second product developed by Pharmaxis from the same base technology and our plan is to broaden the application of Bronchitol beyond cystic fibrosis by investing in new clinical indications and new delivery technologies. In a similar vein, as we look out beyond Bronchitol and Aridol, it is appropriate that we continue to research and develop new drugs of the future.

First new drug for CF in 18 years

We must do this – while staying focused on our firm and clear goal to reach a positive cash flow position. The company is now at a turning point in its evolution as it moves from a clinically and regulatory focused organization to an operating business concerned with product supply, inventory, customers and, importantly, receipts.

The future for the business has not looked brighter and we look forward to engaging in the transformation of the company with a great deal of enthusiasm.

Alan D Robertson, Chief Executive Officer

First Quarter Highlights

EU marketing application for Bronchitol

- The Australian TGA approves Bronchitol for cystic fibrosis
- The Bronchitol market launch for CF occurs in Perth
- Aridol is formally launched in the USA

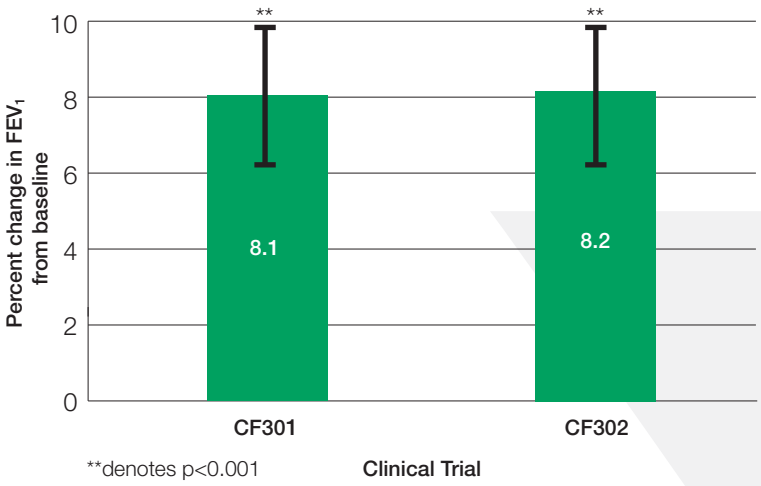
Forthcoming Events

- The European marketing application for Bronchitol concludes
- The US marketing application for Bronchitol is submitted to the FDA

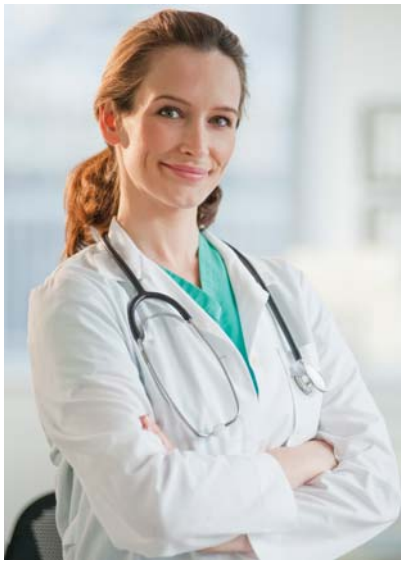
Bronchitol for cystic fibrosis

Cystic fibrosis is a challenging disease to live with and involves extensive and intensive treatment regimes for the patients and their families. It is a disease from birth and the major cause of debilitation for the patient is mucus build up in the lungs. Excessive mucus on the lungs causes a cycle of infection and excessive lung secretions that is difficult to break. Over the years therapies have been developed to help with mucus clearance (dornase alpha) and with infection (antibiotics) and these products have been commercially successful and have produced significant benefit for the patient. However, people with cystic fibrosis have a much shorter life expectancy than people without cystic fibrosis and the main problem is an irreversible loss of lung function. It is now generally accepted, although not definitively proven, that loss of lung function in cystic fibrosis is due to loss of water from the surface lining of the lung—impairing normal lung clearance. If it were possible to restore normal lung defence and normal lung clearance then the patient with CF should suffer much less from the cycle of infection and mucus build up that leads to loss of lung function. Bronchitol has been designed to restore normal lung hydration and, we believe, when that is achieved normal lung defence and normal lung clearance is restored.

Change in lung function after 12 months Bronchitol treatment



Complete CF data set now available



Bronchitol has been the subject of extensive clinical trials and its performance has been remarkably consistent. In two major clinical trials, run in different hospitals, in different countries, at different times, Bronchitol improved lung function by 8.1% in one instance and 8.2% in the second instance. Bronchitol achieved this feat in patients that were being treated with the latest drugs and subject to the latest techniques for keeping their lungs clear. It is important to bear in mind that patients with cystic fibrosis will normally lose 1-2% of their lung function annually. This data and this consistency of performance gives us hope that Bronchitol will change the course of the disease over time and less people will succumb to the ravages of the disease early in life.

Bronchitol has now been approved for sale in Australia following an extensive review by the Therapeutic Goods Administration and Pharmaxis has applied to have Bronchitol listed on the Pharmaceutical Benefits Scheme (PBS). In the meantime, Bronchitol has been launched to the cystic fibrosis community and is now available to eligible patients who wish to use it. It is indicated for the treatment of cystic fibrosis in both paediatric and adult populations six years and above, as either an add on therapy to dornase alfa, or in patients intolerant to, or inadequately responsive to dornase alfa.

Dornase alfa is marketed as Pulmozyme and has been part of the cystic fibrosis treatment regimen for 18 years. In the clinical trials, dornase alfa was used by 65% of the patients.

Bronchitol for CF in Europe

Marketing plans well advanced in Europe

The marketing application for Bronchitol in Europe has been the subject of an exhaustive review by the European regulatory agencies. The application has gone through what is known as the centralised procedure which, if successful, gives access to all 27 member states of the European Union. The process is now nearing its end and is scheduled to conclude during the June quarter. Bronchitol will be made available first in Germany and the United Kingdom and launches will be held as soon as the marketing certificates have been received—normally a month or so after approval.

There are 40,000 people affected by cystic fibrosis in Western Europe which represents a major market for the company. Pharmaxis has established a subsidiary in the UK that will take responsibility for the local sales of Bronchitol. There are currently 11 staff in this office with responsibility for sales, marketing and product support. In the UK, there are 8,000 patients with cystic fibrosis treated through 55 specialist CF centres that provide services for both adults and children.

Germany and the UK first markets

For the principal European countries outside the UK we have engaged the Quintiles organisation to provide market access personnel. The first appointment has been made to help reach into the German market and additional people will be added following receipt of the market authorisation. In Germany, there are 111 CF centres and the nine largest hospitals care for 36% of the 8,000 German CF patients. Market research shows that today, even before the product is approved, over 80% of the German CF physicians are aware of Bronchitol through either direct, first hand, experience or through company presentations at international scientific meetings.

After Germany and the UK, the product will be introduced progressively throughout the rest of Europe.

Bronchitol for CF in the USA

The United States represents the largest national market for Bronchitol for cystic fibrosis with over 30,000 patients managed through 150 specialist centres. To access this market, two clinical trials have been conducted in 600 patients in 93 hospitals. The data from all the trials undertaken with Bronchitol during its development have been presented to the FDA and the marketing application is now being assembled. It is anticipated that this process will conclude during 2012.

NDA in preparation

Access to the United States will be driven by our subsidiary in Philadelphia. In this office, there are now 18 people concerned with regulatory affairs and various product support activities. In addition and while the Bronchitol marketing application is being progressed, this group is overseeing the sales and marketing of Aridol throughout the USA.

Although the number of patients is small the clinical need in CF remains real and compelling. Even with the introduction of new antibiotics and extensive physiotherapy, the average age at which a cystic fibrosis patient loses their life is in the mid-20's.

Bronchitol for bronchiectasis

Bronchiectasis is a serious condition of the lung affecting as many as 600,000 people in the US and Europe. Pharmaxis has conducted one large Phase 3 trial demonstrating that Bronchitol can improve quality of life and we are now completing a second Phase 3 trial looking at reducing the incidence of serious, life threatening exacerbations. The trial results are due mid-2012.

Aridol

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.

During the quarter the results from two important clinical trials with Aridol were reported at the annual meeting of the American Association of Allergy, Asthma and Inflammation in San Francisco.

The first trial (Respir Med. 2011 Apr;105(4):558-65) was run in the United Kingdom and was conducted in 119 asthmatics and was designed to determine if supervised step-down of inhaled steroid treatment had any effect on inflammation. This is important because current asthma guidelines recommend step-down of inhaled steroids and yet determining the minimum effective dose can be problematic. The conclusion from this trial was that a significant reduction in inhaled steroid dose can be achieved in a community setting using Aridol, without any worsening of airway inflammation, or lung function, and with an associated improvement in quality of life.

New publications on Aridol use

In a second trial (Respir Med. 2011 May;105(5):691-7) conducted in children aged 12-17 years in the Netherlands, researchers were able to show that children with clinically stable asthma, controlled by a combination product of a long acting bronchodilator and an anti-inflammatory drug can have the long acting bronchodilator removed from treatment without any loss of asthma control or change to the Aridol response. The importance of this clinical study directly relates to the current debate surrounding the safety of long acting bronchodilator treatment – particularly in children.

These two trials position Aridol as a valuable agent for improving health outcomes for those people with persistent asthma. The trials (described in brief above) and additional presentations at international symposium are bringing Aridol to the attention of the respiratory scientific community. This should translate to increased sales of Aridol and improved health outcomes for those people with asthma.

Aridol was launched in the US in February of this year.

ASM8

ASM8 in trial

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. A Phase II trial with ASM8 is in recruitment and is expected to report during the second half of 2011.

PXS25

PXS25 is a drug being developed to treat pulmonary fibrosis—a disease of unknown origin that involves the deposition of collagen in the walls of the lung. 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 further studies are being organised to commence later in 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 have received acceptance of four papers to be presented at the forthcoming European Cystic Fibrosis Society meeting in Hamburg, Germany. We are anticipating that this meeting will coincide with the German launch of Bronchitol.

In addition to presentations at symposia, a scientific paper has been accepted for publication concerning the first cystic fibrosis Phase 3 clinical trial with Professor D Bilton as the leading author and further scientific papers concerning the role of Bronchitol in combined clinical data from the Phase 3 clinical trials are in preparation. Quality scientific articles in peer reviewed journals are vital for the commercial success of Bronchitol.

The new factory in Sydney is now well established with additional ancillary equipment being installed in recent months. The factory has been inspected by the TGA and is appropriately certified for the manufacture of both Aridol and Bronchitol for clinical trial use.

Financial Overview of the Quarter

Pharmaxis finished the quarter with $56 million in cash.

Aridol revenue increased

For the March 2011 quarter, sales of $318,000 compared to $282,000 in 2010 and $157,000 in the December 2010 quarter.

Research and development expenses of $7.8 million for the March 2011 quarter compares to $9.0 million in both the March 2010 and the December 2010 quarter. Clinical trials and manufacturing development each account for approximately 30% of expenditure in the current quarter. The decrease in current quarter expenditure is mainly attributable to clinical trials (decreased by approximately 60%), partially offset by a small increase in device development.

Commercial expenses of $2.7 million compares to $1.3 million in the March 2010 quarter and $2.2 million in the December 2010 quarter. Expenditures have increased as the company launched Aridol in the US and Bronchitol in Australia, and as it prepares for the launch of Bronchitol in Europe.

Administration expenditure of $1.2 million compares to $4.6 million in the March 2010 quarter and $1.6 million in the December 2010 quarter. The comparative quarter included approximately $3.1 million in relation to the integration of the Topigen acquisition.

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

Operating activities used cash of $10.2 million compared to $11.5 million in March 2010 and $8.4 million in the December 2010 quarter. Integration of the Topigen acquisition accounted for approximately $2.0 million of cash usage in March 2010. Investing activities used cash of $0.3 million compared to the generation of $5.5 million cash in March 2010 and use of $0.4 million cash in the December 2010 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-11	31-Mar-10	31-Mar-11	31-Mar-10
	A$	A$	A$	A$
Revenue from sale of goods	318	282	677	636
Cost of sales	(148)	(125)	(266)	(232)
Gross profit	170	157	411	404
Interest	697	1,003	2,468	2,933
Other income	82	123	332	288
Expenses				
Research & development	(7,832)	(8,991)	(25,552)	(26,287)
Commercial	(2,668)	(1,261)	(6,329)	(3,725)
Administration	(1,206)	(4,631)	(3,999)	(8,165)
Finance expenses	(215)	(148)	(648)	(656)
Total expenses	(11,921)	(15,031)	(36,528)	(38,833)
Loss before income tax	(10,972)	(13,748)	(33,317)	(35,208)
Income tax expense	(58)	–	(65)	(42)
Loss for the period	(11,030)	(13,748)	(33,382)	(35,250)
Basic and diluted earnings (loss) per share – $	(0.048)	(0.063)	(0.147)	(0.162)
Depreciation & amortisation	1,167	689	3,573	1,836
Fair value of securities issued under employee plans	352	719	1,182	1,872

Balance Sheet Data

	As at	
	31-Mar-11	30-Jun-10
	A$	A$
Cash and cash equivalents	56,284	85,787
Property, plant & equipment	31,244	32,537
Intangible assets	16,401	17,702
Total assets	107,420	140,767
Total liabilities	(24,718)	(25,751)
Net assets	82,702	115,016

Cash Flow Data

	Three months ended		Nine months ended	
	31-Mar-11	31-Mar-10	31-Mar-11	31-Mar-10
	A$	A$	A$	A$
Cash flows from operating activities	(10,174)	(11,543)	(27,395)	(31,863)
Cash flows from investing activities	(297)	5,515	(1,140)	3,282
Cash flows from financing activities	(304)	(181)	(563)	(492)
Impact of foreign exchange rate movements on cash	62	(11)	(405)	(35)
Net increase (decrease) in cash held	(10,713)	(6,220)	(29,503)	(29,108)

Share Data

	Ordinary Shares as at	
	31-Mar-11	30-Jun-10
Ordinary shares on issue	228,128	225,410
Options over ordinary shares outstanding	12,882	13,155

pharmaxis

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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