pharmaxis

Quarterly Report to Shareholders

Issue 27 | April – June 2010

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.

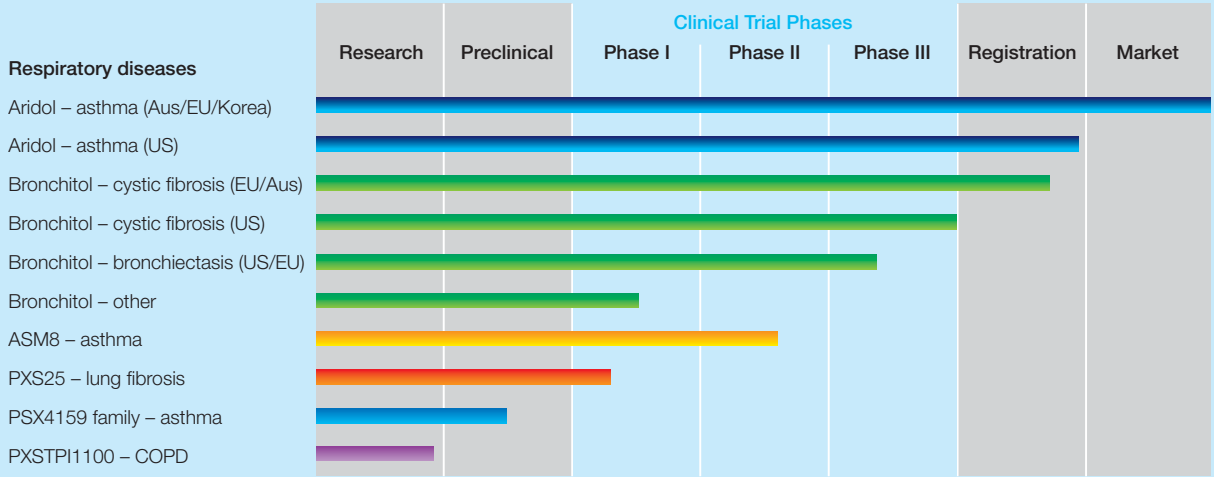
Based in Sydney, Australia, Pharmaxis manufactures its two lead products for commercial sale, clinical trials and for compassionate use.

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 III trials involving over 1,100 participants.

Our second product, Bronchitol, has completed two Phase 3 regulatory trials for cystic fibrosis and is currently seeking approval for marketing in Europe, Australia and soon the United States. An additional Phase III trial in bronchiectasis is 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 June 2010



CEO Report

Welcome to our 27th Quarterly Report. Since Pharmaxis first listed in 2003 these reports have been written by our Chief Executive Officer Alan Robertson. Unfortunately Alan had to undergo a medical procedure in June and is still recovering. I am pleased to report that Alan is now at home and he has asked me to pass on his thanks for the many messages of support he has received from those of you who have followed our progress over the years.

The Board has appointed me to the position of Acting CEO while Alan recovers. I have been with Pharmaxis since the first day we listed on the ASX in 2003 but previously worked in the pharmaceutical industry for over 20 years. Half that time was spent as CEO of country operations for a large pharmaceutical company in Europe, Asia and Australia. As Chief Operating Officer of Pharmaxis I am already very familiar with all aspects of the company's business. We have a strong and experienced management team here and we look forward to welcoming Alan back when he is fully recovered.

We remain confident in our overall clinical program

This quarter was again a busy one. We have made good progress across the business. However much of this report will focus on cystic fibrosis and the results of CF302, our second large Phase III clinical trial of Bronchitol in cystic fibrosis. In this trial, Bronchitol yet again demonstrated that patients taking it can expect an early improvement in lung function that is sustained over six months. The control group in this study had a bigger improvement than in our earlier study (CF301) but there was more variability in the data which lead to the trial narrowly missing its primary endpoint. Shareholders have asked what this result means for our European and US cystic fibrosis marketing submissions.

We will address these questions in this report but to summarise: our EU submission remains on track and is supported by CF302, which confirms that Bronchitol has an acceptable safety profile. Preparation of our FDA submission is ongoing as planned and we remain confident that the overall clinical program will support a positive outcome. Almost 1% of all diagnosed cystic fibrosis patients in the world have now been trialled on Bronchitol. We have a compelling body of evidence to support our US submission, which we look forward to discussing with the FDA later this year.

Gary Phillips, Acting Chief Executive Officer

Second Quarter Highlights

- Results of second Phase III trial of Bronchitol in cystic fibrosis patients (CF302)
- EU marketing application progressing
- New facility receives initial accreditation by TGA

Coming Events

EU decision expected this year

- Pre-NDA meeting with US FDA to discuss Bronchitol marketing submission for CF
- EU decision on marketing Bronchitol for cystic fibrosis
- US FDA to complete review of Aridol NDA

Bronchitol for Cystic Fibrosis

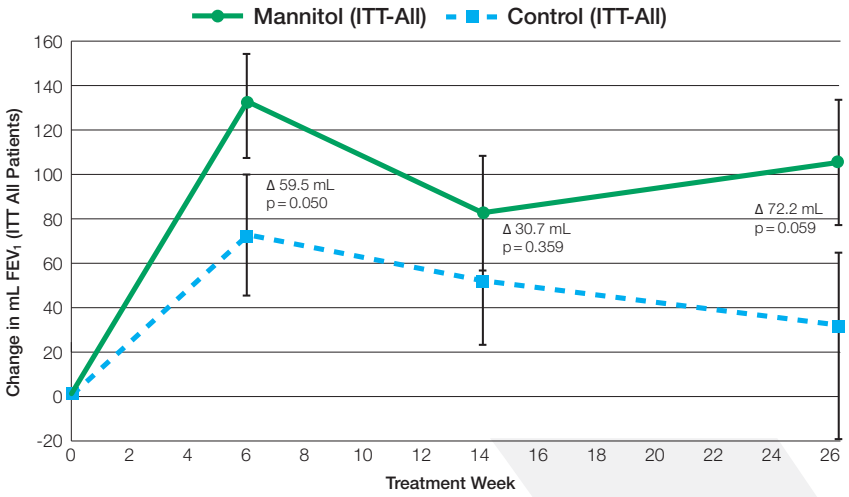
CF302 results explained

The results of Pharmaxis' second large-scale global Phase III trial (CF302) of Bronchitol in patients with cystic fibrosis reported in June 2010 are very encouraging, despite narrowly missing the primary endpoint.

Lung function improved 8.2%

Patients receiving Bronchitol showed an average 8.2% (p<0.001) improvement in lung function over the course of the study compared to baseline. This compares to a 6.3% improvement demonstrated in the earlier trial (CF301) reported in May 2009. Similar to the results of CF301, trial patients receiving Bronchitol experienced early and sustained lung function improvement, as shown below:

Sustained improvement



The greatest cause of death for cystic fibrosis patients is declining lung function, reducing their life expectancy to around 40 years of age. People living with CF on average lose between 1/2% to 2% of their lung function every year.

Primary endpoint narrowly misses statistical significance

The primary endpoint of the clinical trial agreed with regulators was to compare the improvement in the volume of air subjects taking Bronchitol can expel from their lungs in one second (Forced Expiratory Volume/FEV_1) to a control group over the 26 weeks. The trial result (p=0.059) fell fractionally short of statistical significance (p=0.05).

Comprehensive analysis of the trial data has now commenced, and will be presented at the North American CF meeting in October. On initial review the primary end point result reflects two factors – increased variability in the range of lung function results and performance of the control which was higher than expected at week 6 and week 14. Nevertheless, the same FEV_1 data when analysed by percent change (rather than actual mLs in the primary end point) was significant (p=0.029).

Similarly, when patient growth over the 26 weeks is taken into account using the standard measure of FEV_1 percent predicted, Bronchitol was significantly superior to control at week 26 (p=0.029).

FDA submission planning underway

We are confident the total body of evidence from this and the previous trial shows Bronchitol to be a safe and effective drug. After Pharmaxis completes further analysis of the results, the next step is to hold a meeting with the US Food and Drug Administration (FDA) to plan the submission of a New Drug Application (NDA) for Bronchitol.

Safety reinforced

Bronchitol appeared to be safe and well-tolerated overall, demonstrating a similar rate of adverse events across treatment groups.

Pleasingly, the withdrawal rate during the study was only 15% – half that of CF301 and less than what we had forecast in this patient population.

Diverse patient group for widest market approval

To demonstrate that Bronchitol is effective across a broad population of CF sufferers, both CF301 and CF302 recruited patients ranging from children to adults and patients who were already receiving current best standard of care including existing medication (e.g. rhDNase and inhaled antibiotics). In CF302 a total of 318 patients were enrolled in the US and six other countries.

We are grateful to the U.S. Cystic Fibrosis Foundation Therapeutics Development Network, the investigators, healthcare staff and patients who took part in CF302.

European approval supported by CF302

European review progressing

Bronchitol is currently being reviewed for marketing approval by the European regulatory authority, the EMA. The EMA has requested the safety data from CF302 as part of its review process.

Given the reassuring safety result in CF302, we believe this trial has enhanced our existing application with the EMA. Over the next few weeks Pharmaxis will submit its response to all questions raised by the EMA in the review process and therefore remains on track to receive a response from the EMA later this year.

EU commercialisation strategy

Preparations for EU launch

In preparing for the anticipated approval of Bronchitol for CF in Europe, Pharmaxis has finalized its European sales and marketing model.

Pharmaxis will sell directly to Western European markets using the highly respected Quintiles organization to manage a contract Pharmaxis sales force outside of the UK. In the UK, our existing operation will promote the product.

The Pharmaxis contract sales representatives will be supported and managed by the Quintiles organization throughout Western Europe while marketing and market support will be managed by Pharmaxis office in the UK. This will allow faster access to each of these countries markets, access to the considerable local experience of the Quintiles organization and provide Pharmaxis with a centralised approach to pricing. The first product launches are planned for the UK and Germany in the first quarter of 2011, pending approval.

Central and Eastern European countries will be managed by a distributor who will take full responsibility for sales and marketing.

Presenting the research to the CF community

Pharmaxis at global CF forums

Data from CF302 is widely anticipated by CF patients groups worldwide, and detailed analysis will be presented at the upcoming North American Cystic Fibrosis Conference in Baltimore, Maryland on 21 – 23 October, 2010.

Pharmaxis was centre stage at another global conference last month, when it hosted a symposium at the 2010 annual meeting of the European Cystic Fibrosis Society in Valencia, Spain.

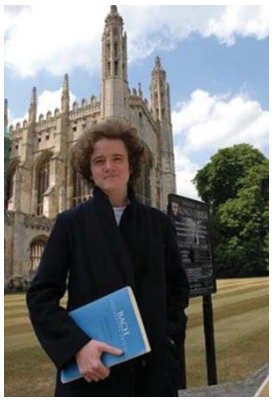
Discussing recent advances in respiratory disease treatments, the forum was addressed by several world experts, including the UK's Professor Di Bilton, who commented on a survey completed by healthcare professionals and CF patient groups prior to the symposium. When asked 'What is the most important goal we are seeking to achieve?' both groups ranked enhanced quality of life highest, followed by improved lung function. When considering drug treatment, the most important aspect was effectiveness and a need to reduce the number of drugs taken on a daily basis. Professor Bilton concluded that determining which treatments are suitable for individual patients is now a central issue.

Sustained benefit

Long term Bronchitol treatment

Pharmaxis first Phase III trial in cystic fibrosis (CF301) included a second phase in which eligible patients were all offered Bronchitol for 12 months following completion of the 6 months placebo controlled blinded phase. During the quarter we reported headline results for patients who had been treated with Bronchitol for 18 months. The statistically significant result ($p<0.01$) showed an improvement of 7.9% relative to their lung function on entering the trial. This compares to 6.5% after 6 months and 8.1% after 52 weeks. The sustained benefit following long term treatment holds out the promise that Bronchitol may slow the progression of the disease.

A boy called Alex



Every so often we learn about people suffering from cystic fibrosis who inspire us at Pharmaxis to redouble our efforts to bring Bronchitol to patients worldwide. Alex Stobbs is one such person.

Aged 19, Alex is a musical prodigy known to millions of people worldwide after starring in a television documentary (that recently aired on ABC) about his resolve to become a classical musician. Studying at Cambridge University in the UK, Alex has written a book about his determination to live as a normal teenager in the face of a crippling illness which means each day could be his last.

In this extract from his book, Alex describes the fine line he treads daily between life and death, highlighting the desperate need for new therapies like Bronchitol…

"...my body is getting weaker."

'(In) September 2008 I had a spate of coughing that lasted three hours. By dawn my sheets were soaked in blood. A lung haemorrhage means a major infection. Not good. They started me immediately on up to 20 syringes a day of antibiotics.

'The antibiotics went through my port-a-cath – the permanent opening in my upper left chest. But the medical team also needed to give me intravenous fluids through a line into my arm... they tried to get the needle in 15 times in different places on my arms; my veins are collapsing and can't take the needles any more.

'My lung capacity was down to 29 per cent, and the doctors apparently told my mother it could go either way. I knew I was not in good shape. CF is degenerative, and each time I go back into hospital my lungs are a little worse. I'm not under any illusion; as well as my battered lungs, my liver is enlarged, my bones are thinning and my digestive system is not good. I know my body is getting gradually weaker.

'I was in hospital for three weeks and three days this time. In hospital I see so many forlorn little faces among the children with CF, and I try to show them that it's better not to be scared. Of course, I get frightened, too.

'The possibility that an infection will not be fought off is always there. Mostly I don't give in to those fears – I love life too much. When I'm listening to beautiful music, I can't think about dying. And once I'm up and busy, I don't give grim thoughts any room.'

Story courtesy of the *Daily Mail, UK. A Passion For Living: The Amazing Story Of A Boy Who Makes Every Day Matter* by Alexander Stobbs (Hodder).

TGA Licence received

Operations

At the end of the quarter the first step in the formal regulatory approval process of the new manufacturing facility at 20 Rodborough Road was completed with the Australian Therapeutic Goods Administration granting a license for the manufacture of inhalation product for clinical trial purposes. A license for manufacture of product for commercial sale will be sought after process validation is completed later in the year.

Aridol US Marketing Application

During the quarter Pharmaxis resubmitted its New Drug Application (NDA) for Aridol™ (mannitol inhalation powder), following a complete response letter received from the FDA in December 2009. The resubmission included a safety information update, revised labeling and further information regarding the Chemistry Manufacturing and Control. The company believes the resubmission fully addresses all of the issues raised by the FDA. The matter is scheduled to complete in the fourth quarter.

Financial Overview of the Quarter

Pharmaxis finished the quarter with $86 million in cash.

For the June 2010 quarter, Aridol sales of A$192,000 compared to A$141,000 in 2009 and A$282,000 in the March 2010 quarter.

Research and development expenses of A$8.9 million for the June 2010 quarter compares to A$8.5 million in the June 2009 quarter, and A$9.1 million in the March 2010 quarter. The relative mix of expenditure on the components of R&D was consistent with prior comparable quarters.

Commercial expenses of A$1.9 million compares to A$1.9 million in the June 2009 quarter and A$1.3 million in the March 2010 quarter. The increase in commercial expenditure over the prior period relates to preparation for the commercial launch of Bronchitol in Europe and Aridol in the US.

Administration expenditure of A$1.6 million compares to A$1.5 million in the June 2009 quarter and A$4.6 million in the March 2010 quarter. The March 2010 quarter expenditure includes 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 A$7.7 million compared to A$10.1 million in June 2009 and A$11.6 million in the March 2010 quarter. The March 2010 quarter includes approximately $2.0 million in relation to the integration of Topigen. Investing activities used cash of A$2.1 million compared to A$1.8 million in June 2009 and the generation of $5.5 million net cash in the March 2010 quarter, the latter as a consequence of the Topigen acquisition including cash of A$5.7 million. The current quarter investing activities included A$1.7 million to purchase a suite of early stage inhalation device intellectual property owned by a UK company.

Financial Statement Data – Unaudited
(International Financial Reporting Standards)

('000 except per share data)

Income Statement Data

	Three months ended		Twelve months ended	
	30-Jun-10	30-Jun-09	30-Jun-10	30-Jun-09
	A$	A$	A$	A$
Revenue from sale of goods	192	141	828	595
Cost of sales	(75)	(35)	(307)	(153)
Gross profit	117	106	521	442
Interest	1,002	763	3,935	5,347
Other income	328	246	616	523
Expenses				
Research & development	(8,853)	(8,531)	(35,140)	(29,308)
Commercial	(1,932)	(1,865)	(5,657)	(6,202)
Administration	(1,550)	(1,541)	(9,715)	(5,800)
Finance expenses	(198)	(122)	(854)	(122)
Total expenses	(12,533)	(12,059)	(51,366)	(41,432)
Loss before income tax	(11,086)	(10,944)	(46,294)	(35,120)
Income tax expense	(9)	(24)	(51)	(51)
Loss for the period	(11,095)	(10,968)	(46,345)	(35,171)
Basic and diluted earnings (loss) per share – $	(0.049)	(0.055)	(0.210)	(0.180)
Depreciation & amortisation	1,185	475	3,021	1,265
Fair value of options issued under employee plan	623	631	2,495	2,432

Balance Sheet Data

	As at	
	30-Jun-10	30-Jun-09
	A$	A$
Cash and cash equivalents	85,787	124,993
Property, plant & equipment	32,537	32,698
Intangible assets	17,702	1,193
Total assets	140,767	163,997
Total liabilities	(25,751)	(26,306)
Net assets	115,016	137,691

Cash Flow Data

	Three months ended		Twelve months ended	
	30-Jun-10	30-Jun-09	30-Jun-10	30-Jun-09
	A$	A$	A$	A$
Cash flows from operating activities	(7,678)	(10,143)	(39,576)	(26,422)
Cash flows from investing activities	(2,140)	(1,800)	1,142	(11,542)
Cash flows from financing activities	(280)	51,104	(772)	51,115
Net increase (decrease) in cash held	(10,098)	39,161	(39,206)	13,151

Share Data

	Ordinary Shares as at	
	30-Jun-10	30-Jun-09
Ordinary shares on issue	225,410	217,659
Options over ordinary shares outstanding	13,155	15,075

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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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