pharmaxis

Quarterly Report to Shareholders

Issue 35 | April – Jun 2012

Pharmaxis Ltd ABN 75 082 811 630

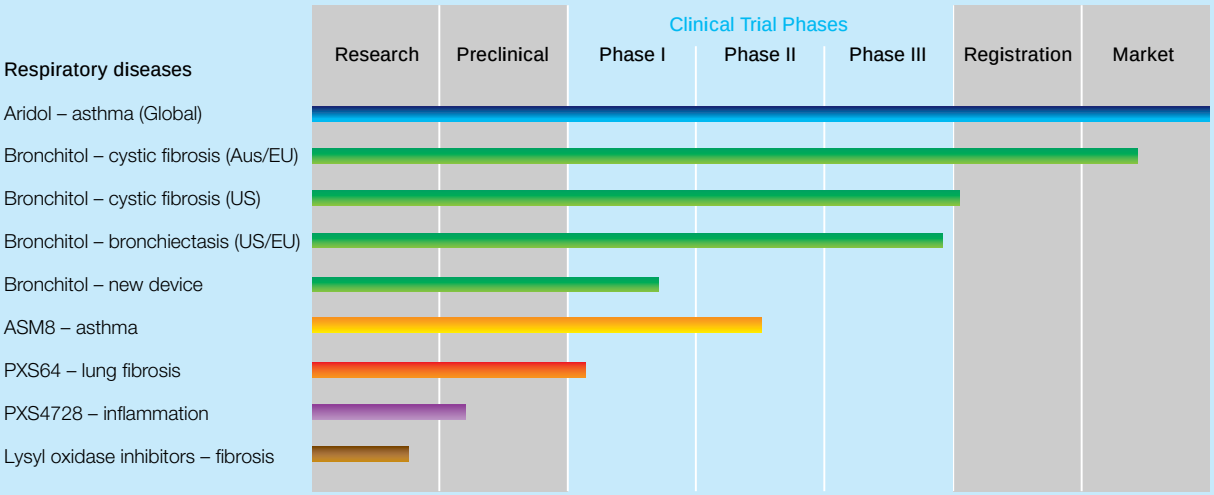
Overview of Pharmaxis

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 asthma, bronchiectasis and chronic obstructive pulmonary disease (COPD) and the genetic disorder, cystic fibrosis.

Based in Sydney, Pharmaxis manufactures its two lead products for commercial sale, clinical trials and for compassionate use and has offices in Exton, Pennsylvania and Slough in the UK.

Pharmaxis Product Development at June 2012



Aridol

Aridol® is a bronchial challenge test and is being sold and marketed 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.

Bronchitol

Bronchitol® has been designed to assist with lung clearance and lung defence for people with cystic fibrosis and bronchiectasis. The drug is now approved for marketing in Europe and Australia and an NDA has been submitted in the USA. A Phase III clinical trial in bronchiectasis is close to completion.

ASM8

ASM8 is an anti-inflammatory drug delivered to the airways, designed to treat allergic asthma and is for people not responsive to currently approved asthma medications.

PXS64

PXS64 is an anti-fibrotic drug that inhibits the function of TGFβ and is extremely effective in preclinical models of fibrosis. The drug is targeting fibrosis of the lungs.

PXS4728

PXS4728A is an anti-inflammatory drug with a variety of clinical opportunities. It is delivered once per day and is scheduled for Phase I clinical trials in early 2013.

CEO address to staff

New Chairman of the Board

Bronchitol launched in Dublin, Ireland

PXS4728 enters pre-clinical development

CEO Report

This report to shareholders covers the three months to end June 2012.

On the 30th April, 2012, Denis Hanley retired from his position as Chairman of the Board of Directors. Denis started working with Pharmaxis when it was a small venture operating from a research lab in the John Curtin School of Medical research in Canberra and left the company as a well capitalised business with operations in three continents and a number of products approved in multiple jurisdictions around the world. During his tenure, Pharmaxis completed a number of important clinical trials and secured marketing approval for our products Aridol and Bronchitol. In respect of Bronchitol, we have developed a product that now fundamentally impacts the way in which people with cystic fibrosis can manage their disease. It is a rare thing to be part of a new drug discovery effort and to see that idea become a fully fledged commercial product. Denis has been at the forefront of the development of Bronchitol and his contribution as Chairman of the Board has been significant. Personally, I am indebted to Denis for his guidance and, while I will miss his formal contribution, I know he will be unable to resist providing me with informal advice.

The company is now on solid ground after the unexpected difficulties we experienced last year and in Malcolm McComas we have a Chairman who is not only familiar with the business but well equipped to help move Pharmaxis into its next phase of growth.

Establishing and growing a new pharmaceutical company takes time and there are few opportunities to accelerate the process. Each new drug has to be carefully selected and carefully tested to make sure it is safe when introduced to patients. The Bronchitol clinical program has seen a rigorous series of tests undertaken to establish that the drug is safe and effective and it is exciting to be introducing it to the world.

Aridol was our first product for people with asthma, Bronchitol is our second product and it has initially been developed for cystic fibrosis. Behind those two we have a number of other products that represent business opportunities and drugs of the future. For example, PXS4728A was formally accepted into development during the quarter and a provisional patent application, specifically nominating PXS4728A was lodged with the U.S. Patent office on 02 May 2012. This drug is designed to be given as an oral tablet once a day and has potential applications in fibrosis, cancer, eye disease, and complications associated with diabetes. PXS4728A is scheduled for human trials early next year.

Pharmaxis is now an operating business dealing with the manufacture of new drugs and their supply to multiple countries of the world. We are committed to building revenue from the investment in innovation undertaken over the last few years. For now, Bronchitol is a critical part of that endeavour and we look forward to reporting its progress over the coming quarters.

Alan D Robertson, Chief Executive Officer

Forthcoming Events

- The FDA acceptance of Bronchitol U.S. marketing application
- The commercial introduction of Bronchitol in Australia

Bronchitol for Cystic Fibrosis in Europe

Bronchitol stand at ECFS, Dublin, Ireland

Bronchitol introduced to European CF community

On the 20th April, 2012, Pharmaxis was notified by the European Medicines Agency that Bronchitol was approved for marketing throughout the 27 countries of the European Union. Bronchitol is indicated for the treatment of cystic fibrosis in people aged 18 years and over.

On the 6-9th June, 2012 in Dublin, Ireland, the European Cystic Fibrosis Society (ECFS) held its annual meeting to discuss new advances in cystic fibrosis and to present latest research findings. It was during this meeting that Pharmaxis formally launched Bronchitol in front of 600 delegates at a special symposium.

Attendees were addressed by four key opinion leading physicians from the UK, Germany and Belgium. Of most interest was identifying for which patients Bronchitol would be most suitable and this issue was covered in an engaging and educational manner by Dr Ian Ketchell from the All Wales Adult Cystic Fibrosis Centre, University Hospital, Cardiff, Wales.

Following the meeting in Dublin, Bronchitol was introduced in Germany, Austria and the UK and will shortly be introduced in Denmark. Germany represents the largest single market in Europe and just under half the German CF centres have been visited by Pharmaxis representatives since launch and, of those, over half have been trained on how to correctly administer Bronchitol. The Bronchitol initiation training is going well and we are experiencing a high level of interest. Bronchitol has been ordered by more than 60 pharmacies in Germany and we are already seeing repeat orders from some. The first orders from Austria have also been received.

Bronchitol symposium at ECFS, Ireland

For the UK and Ireland, well over half the adult CF centres have been visited and half of those have been trained on how to administer Bronchitol. The review by the National Institute of Health and Clinical Excellence (NICE) remains an outstanding issue that is not expected to conclude until the fourth quarter of the year. Despite this, a number of hospitals are considering including Bronchitol and, in addition, independent funding sources are being followed. NICE provides health economic advice to clinicians and patients and a response has been submitted to its initial technology appraisal. It is expected that an additional meeting will be held by NICE in the UK during the third quarter of the year and the matter will be finalised during the fourth quarter. NICE exists to ensure that people across England and Wales have equal access to new and existing medicines that are deemed clinically and cost effective.

France represents one of the larger markets in Europe and an application for reimbursement has been submitted. This is expected to conclude during the fourth quarter.

The awareness of Bronchitol is high amongst patients and clinicians and the consistent feedback indicates a clear clinical requirement for Bronchitol.

Bronchitol

Bronchitol for cystic fibrosis in Australia

Australian reimbursement date finalised

On the 25 June, 2012, the Australian government announced that Bronchitol was to be listed on the Pharmaceutical Benefits Scheme. This was welcome news for Pharmaxis and the thousands of people dealing with cystic fibrosis in Australia. David Jack, the CEO of Cystic Fibrosis Australia also welcomed the news and pointed out that there remains an unmet clinical need for people with cystic fibrosis.

The company has since been advised by the Department of Health and Ageing that Bronchitol will be made available as a pharmaceutical benefit through the Highly Specialised Drugs Program and that reimbursement will take effect from the 1st of August 2012. It has been given a 'Streamlined Authority' code that will make access to the drug less burdensome for the prescribing physician.

Bronchitol is approved for marketing in Australia for people with cystic fibrosis aged 6 and over.

Bronchitol for cystic fibrosis in the United States

Bronchitol NDA submitted

On the 21st May, 2012, Pharmaxis submitted to the FDA a New Drug Application (NDA) requesting approval to market Bronchitol in the United States for the management of cystic fibrosis in patients 6 years and older to improve pulmonary function. This represents a major milestone for the company as the largest market for Bronchitol by value is in the United States.

The submission was supported by two Pivotal Phase III trials of 12 months duration in 600 patients involving 90 hospitals in 10 countries. In addition to the Phase III trials there were a number of Phase II trials supporting the submission including detailed pharmacokinetic trials in children and adults.

An NDA is an extensive submission that documents the work done in manufacturing Bronchitol, in assessing it's pre-clinical safety and the outcome of the clinical trial program. Cystic fibrosis is a disease affecting a relatively small number of patients and Bronchitol has been granted orphan drug status for cystic fibrosis by the FDA. The advantage of orphan drug status is a period of market exclusivity, a waiver of the filing fees for the NDA and assistance with the clinical development program.

The NDA review is expected to take 10 months and it is highly likely that the FDA will convene an expert advisory panel to discuss the application before it makes a final determination. Accordingly, we expect the NDA to have a standard review period, and to therefore conclude sometime around March 2013.

Bronchitol for bronchiectasis

Bronchiectasis Phase 3 trial nears completion

The development of Bronchitol for the treatment of bronchiectasis has presented a number of challenges, in spite of the fact that it has made a dramatic and immediate improvement on their lives of some people. The complexities involved in developing new drugs for bronchiectasis are consistent with the fact that no new drugs have been specifically developed for this indication. Designing a clinical trial that will provide the endpoints necessary to garner approval around the world has involved extensive discussion with the regulatory authorities in Europe and the USA.

On the 13th December, 2011 the recruitment target was reached for the pivotal Phase III trial with Bronchitol in bronchiectasis. The trial has involved 485 subjects in close to 100 hospitals all around the world. Subjects who enter the trial are treated for 12 months and the principle objective is to show that Bronchitol can reduce infectious episodes for people with bronchiectasis. There are a number of additional outcomes that will be measured including lung function and sputum production. The last patient should finish the trial in early 2013 and the data will be available shortly thereafter.

Bronchiectasis Phase 3 trial on track

Bronchiectasis affects as many as 600,000 people in the established pharmaceutical markets and many more in the emerging markets and for some people it is an extremely debilitating condition involving breathlessness, constant coughing and poor quality of life. Pharmaxis expects that Bronchitol will make a clear and demonstrable difference to the lives of people affected by this condition.

We look forward to completing this trial and to the opportunity to make Bronchitol available to patients living with this difficult condition.

Additional data for Bronchitol for cystic fibrosis

On the 8th June, 2012, Pharmaxis released additional data concerning the reduction in risk of having an infectious episode (exacerbation) following treatment with Bronchitol. For adults with cystic fibrosis that showed a response to Bronchitol compared to those who had no improvement as measured by lung function, the risk of experiencing a life threatening exacerbation is reduced by 60%.

ASM8 for asthma

ASM8 study results released

On the 17th April, 2012, Pharmaxis released the results of an exploratory Phase II trial with ASM8 – a drug to treat severe asthma that is uncontrolled by existing medications. A situation that affects as many as 10% of people with asthma or around 5 million patients globally.

The study was designed as a three way crossover trial that meant that each subject was treated with two different doses of drug, or a placebo, in a randomised fashion. There is good reason to structure the trial this way and the great advantage is that every subject acts as their own control, and that enables the research clinicians to tease apart more information from a smaller number of subjects. Patients with severe allergic asthma were admitted into the study and the baseline response to their allergy trigger was measured. After being treated for 14 days, their response to the allergy trigger was measured and compared to the response at the start of the trial. As expected, ASM8, at both doses tested, produced a profound blunting of the response, to the extent that trial participants were effectively no longer responding to their allergy trigger. This was the outcome that had been predicted at the outset of the trial. What had not been predicted was that when participants were given placebo, they would also experience a blunting of their response to the allergy trigger. When the trial data was analysed closely it became apparent that this response to the placebo only occurred when participants were given the placebo after they had been given ASM8. In other words, it appears that ASM8 has led to a desensitisation of the patients response to their allergy trigger. This was an unexpected and positive surprise from the trial and indicates that ASM8 may have wider application in treating asthma than first contemplated.

ASM8 reduces sensitivity to allergy triggers

From this trial, it can be concluded that a 4 mg dose is as effective as an 8 mg dose and this has important implications for safety and for the cost of goods. It can also be concluded that both doses are safe and suitable for further studies. The consequences of carry over effects need to be considered in subsequent trials.

Additional studies being planned

The next trial with ASM8 is under development but is likely to consist of patients with severe, non-responsive allergic asthma and they will be treated for 14 days or longer and the design may consist of two doses and a placebo dose run in a parallel fashion. The main endpoints in a trial of this nature will be lung function.

PXS 64

PXS64 shows promise as a unique small molecule that is well suited for treating and, perhaps, reversing idiopathic pulmonary fibrosis (IPF) – a condition of the lung that leads to the early death of the patient. IPF affects as many as 500,000 people in the major pharmaceutical markets of the world and, so far, only one drug has been approved for marketing in certain countries. Preclinical safety evaluation of PXS64 is in progress.

PXS 4728

Potential new drug with broad utility

PXS4728A is designed to be delivered as an oral tablet given once a day. PXS4728A has been shown in preclinical studies to have potential applications in inflammatory lung diseases such as asthma and COPD, inflammatory eye disease such as macular degeneration, fibrosis – particularly of the liver following cirrhosis and complications associated with diabetes. In addition, studies are in progress to determine its potential in treating certain forms of cancer. PXS4728A has entered formal preclinical safety testing with a view to commencing a Phase I trial in healthy volunteers next year.

Lysyl Oxidase inhibitors

Aridol sales continue to show positive double digit growth

A program of work aimed at discovering lysyl oxidase inhibitors with therapeutic potential has been running for some time and has now delivered a family of selective inhibitors that are being prepared for preclinical evaluation. These inhibitors, such as PXS4820, are expected to have broad applicability in fibrotic diseases such as idiopathic pulmonary fibrosis and also in treating cancer.

Aridol

Aridol is a test for twitchy or hyper-responsive lungs that is now sold and marketed throughout Europe, Australia, parts of Asia and the USA. The commercial investment in this product is contained as most effort is going into education, training and awareness.

Aridol is now one of the standard tests to help with asthma management in the respiratory labs and this aspect is the current focus of the commercial team. However, there is an increasing awareness of its potential to assist with determining appropriate inhaled steroid use. While there have been some conflicting studies in this area, in the March issue of the Primary Care Respiratory Journal, an editorial entitled: 'Asthma monitoring in primary care: time to gather more robust evidence' helps point the way of the future (Prim Care Respir J. 2012 Mar;21(1):4-5).

In comparison to the previous quarter, and taking all countries together, sales of Aridol improved by 25%, with a solid contribution coming from Korea. Institutional clinics in the U.S. are now fully reimbursed for Aridol. It is anticipated that Aridol will be included in a number of professional guidelines to be published in the next 6-8 months. Reorders have reached 60 percent of total sales in the U.S. and a new webinar program is allowing access to more customers. The U.S. army has now drafted an Aridol protocol which is expected to be published by the end of the year and this should support the efforts in the military channel.

Financial Overview of the Quarter

Pharmaxis finished the quarter with $82 million in cash.

Research and development dominate expenses

For the June 2012 quarter, sales of $373,000 compared to $233,000 in 2011 and $298,000 in the March 2012 quarter. Bronchitol was launched in Europe during June and sales for the remaining weeks of the quarter were $16,000.

Research and development expenses of $7.4 million for the June 2012 quarter compares to $9.1 million in the June 2011 quarter and $6.5 million in the March 2012 quarter. Clinical trials and manufacturing development account for 29% and 32% respectively of expenditure in the current quarter. The decreased expenditure in the current quarter primarily reflects reduced clinical trial expenditure.

Commercial expenses of $3.7 million compares to $2.8 million in the June 2011 and $3.0 million in the March 2012 quarters. The increase reflects the launch of Bronchitol in Europe and pricing reimbursement applications in various countries.

Administration expenditure of $1.4 million compares to $1.2 million in the June 2011 quarter and $1.4 million in the March 2012 quarter.

Operating activities used cash of $10.0 million compared to $10.0 million in June 2011 and $9.1 million in the March 2012 quarter. Investing activities used cash of $85,000 compared to $1.7 million in June 2011 and $130,000 in the March 2012 quarter. Investing activities in the June 2011 quarter included the a payment of $1.5 million for the purchase of a suite of early stage inhalation device intellectual property.

Financial Statement Data – Unaudited

('000 except per share data)

Income Statement Data

	Three months ended		Twelve months ended	
	30-Jun-12	30-Jun-11	30-Jun-12	30-Jun-11
	A$	A$	A$	A$
Revenue from sale of goods	373	233	1,331	910
Cost of sales	(157)	(65)	(522)	(342)
Gross profit	216	168	809	568
Interest	968	615	3,049	3,083
Other income	1,441	134	3,874	465
Expenses				
Research & development	(7,402)	(9,096)	(29,222)	(34,632)
Commercial	(3,716)	(2,834)	(11,073)	(9,163)
Administration	(1,389)	(1,167)	(5,387)	(5,171)
Finance expenses	(201)	(212)	(768)	(859)
Total expenses	(12,708)	(13,309)	(46,450)	(49,825)
Loss before income tax	(10,083)	(12,392)	(38,718)	(45,709)
Income tax expense	(50)	16	74	(49)
Loss for the period	(10,133)	(12,376)	(38,644)	(45,758)
Basic and diluted earnings (loss) per share – $	(0.033)	(0.054)	(0.142)	(0.202)
Depreciation & amortisation	1,393	1,453	4,904	5,026
Fair value of securities issued under employee plans	201	385	957	1,567

Balance Sheet Data

	As at	
	30-Jun-12	30-Jun-11
	A$	A$
Cash and cash equivalents	81,475	44,343
Property, plant & equipment	27,683	30,570
Intangible assets	14,143	15,954
Total assets	131,700	94,572
Total liabilities	(21,897)	(23,742)
Net assets	109,803	70,830

Cash Flow Data

	Three months ended		Twelve months ended	
	30-Jun-12	30-Jun-11	30-Jun-12	30-Jun-11
	A$	A$	A$	A$
Cash flows from operating activities	(9,979)	(9,971)	(38,142)	(37,366)
Cash flows from investing activities	(85)	(1,743)	(169)	(2,883)
Cash flows from financing activities	(18)	(195)	75,426	(758)
Impact of foreign exchange rate movements on cash	7	(32)	17	(437)
Net increase (decrease) in cash held	(10,075)	(11,941)	37,132	(41,444)

Share Data

	Ordinary Shares as at	
	30-Jun-12	30-Jun-11
Ordinary shares on issue	307,631	228,290
Options over ordinary shares outstanding	11,902	13,297

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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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