pharmaxis

Quarterly Report to Shareholders

Issue 28 | July – September 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.

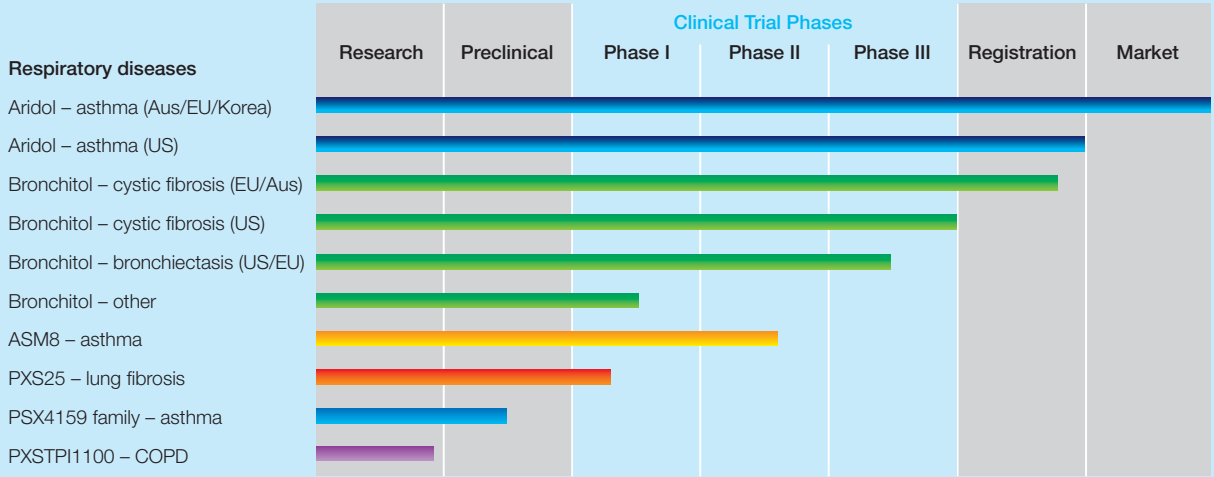
Our first product, Aridol™ (mannitol bronchial challenge test) is registered for sale and marketing in Australia, Europe, South Korea and the United States.

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.

Our 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 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 September 2010



CEO Report

Quarter 3 2010 has seen Pharmaxis enter an important and exciting phase in the development of the business as we gear up for the European launch of Bronchitol for cystic fibrosis and the filing of a marketing application for Bronchitol in the USA.

Sales and marketing arrangements are in place for European countries and planning is well advanced for a pre-NDA meeting with the US Food and Drug Administration (FDA). Our regulatory and clinical teams are working hard on preparing a New Drug Application dossier for the US centred on data from our two international Phase III clinical trials of Bronchitol.

A considerable amount of work has also gone in to preparation for an important upcoming CF meeting in North America where, for the first time, the complete data set gathered in the two global trials will be presented. This is a much anticipated event, not only for everyone at Pharmaxis, but for the healthcare professionals, patients and other stakeholders in the cystic fibrosis community.

Preparing for Bronchitol launch in EU

This quarter has also seen a notable milestone with the FDA approving a marketing application for our lung function test Aridol in the United States. An FDA submission is a complex task requiring involvement from almost all divisions of the company and the approval was a great outcome for everyone who worked so hard for so long. The FDA decision is an important step in the growth of Pharmaxis and means we are operating as a global pharmaceutical company with a presence in key world markets including Asia, Europe, Australia and now the USA.

Preparing for Aridol launch in USA

Finally, it is with pleasure that I report that Alan Robertson has returned to work at Pharmaxis after recovering from surgery and will soon be resuming the CEO's chair.

Gary Phillips, Acting Chief Executive Officer

Third Quarter Highlights

- FDA approves Aridol
- Agreement with Quintiles for European marketing of Bronchitol
- CEO returns

Forthcoming Events

- Complete clinical trial data on Bronchitol to be presented at North American CF meeting
- Response from EMA on Bronchitol for Europe
- Meet with FDA to discuss filing NDA for Bronchitol
- Response from TGA on Bronchitol for Australia

Bronchitol for Cystic Fibrosis

Pharmaxis continues to lay the foundations for the commercial launch of Bronchitol for cystic fibrosis (CF) in Europe and Australia. We are awaiting responses to submissions from the European agency (EMA) and the Therapeutic Goods Administration (TGA) in Australia.

More than 600 cystic fibrosis patients, or nearly one per cent of the world's CF population, have completed involvement in two large international Phase III clinical trials of Bronchitol.

In June this year, Pharmaxis announced results of its second Phase III trial (CF302) for Bronchitol in cystic fibrosis patients, demonstrating an early and sustained improvement in lung function and adding support to the results of the first Phase III trial (CF301).

In CF302, patients treated with Bronchitol had an 8.2 % (107mL) improvement in lung function (FEV1) compared to baseline over the 26 weeks of the study which was highly significant ($p<0.001$) and similar to the 6.3% improvement seen in the earlier study (CF301). For CF302, Bronchitol narrowly missed achieving statistical significance over control ($p=0.059$) due, in part, to a positive response from the control group. By comparison, in CF301, statistical significance was easily achieved over the control group ($p<0.001$). This topic was fully discussed in the last Quarterly Report.

Complete CF data set to be presented

Additional data from the clinical trials, together with the combined data, will be presented at the 24th Annual North American Cystic Fibrosis Conference (NACFC), to be held from 21st to 23rd October 2010 in Baltimore, Maryland. The NACFC is the largest gathering of cystic fibrosis professionals in the world and provides the latest medical education and a multi-disciplinary approach to the advancement of CF research, treatments and care. It gathers everyone with an interest in cystic fibrosis including physicians, research scientists, nurses, social workers, nutritionists, dieticians, physical therapists, respiratory therapists, pharmacists, psychologists, psychiatrists and research coordinators. The 2010 NACFC will offer more than 70 educational and scientific sessions. The Bronchitol data presentation will be made by the principal investigator from the CF302 trial Dr Moira Aitken from the Division of Pulmonary and Critical Care at the University of Washington Medical Centre.

Pharmaxis is due to meet with the US Food and Drug Administration (FDA) shortly to discuss the submission of a New Drug Application (NDA) for Bronchitol. Bronchitol has orphan drug designation in both the US and EU.

European launch of Bronchitol

Marketing plans locked in for Bronchitol

During the quarter, Pharmaxis announced finalization of an agreement with the Quintiles group to provide the sales force to promote Bronchitol to the respiratory clinical community in Europe.

The arrangement was put in place in advance of anticipated marketing approval and a planned launch in early 2011 and ensures we have the infrastructure locked in to move quickly and efficiently into the European market.

Quintiles is a leading pharmaceutical contract services provider with 23,000 employees in 60 countries and has been involved in developing or commercializing the world's 30 best-selling drugs. Quintiles will provide us with dedicated sales representatives and market access managers, the management of that field force and back office support on a cost-plus basis. Pharmaxis will maintain control of pricing, marketing, medical and regulatory support from our Sydney headquarters and from the Pharmaxis UK office.

Under the six-year agreement, Quintiles will support Pharmaxis in a comprehensive roll-out across Western Europe, initially in Germany during the first quarter of 2011. Austria, Belgium, France, Italy, Luxemburg, Portugal, Scandinavia, Spain and Switzerland will follow.

Quintiles is respected for the depth of experience in the complex European market and is recognised for its expertise in market access, field sales and product promotion.

A first step in the Quintiles arrangement has been the appointment of a person to head the German sales operation. Meanwhile the Pharmaxis UK office is preparing for the UK Bronchitol launch with intensive pre marketing efforts and will shortly commence recruitment of additional market access managers.

Australian launch of Bronchitol

TGA considers Bronchitol

Pre-marketing activities are underway for an Australian launch of Bronchitol in the first half of 2011. Pharmaxis lodged an application with the Therapeutic Goods Administration (TGA) in February 2010 and is continuing to build relationships with the Australian cystic fibrosis communities. New therapies are much needed and developments keenly watched by clinician and patient groups alike.

Key activities during the quarter included projects to further enhance engagement with important cystic fibrosis stakeholder groups: nurses, physiotherapists, physicians and patient and carer advocacy groups. Pharmaxis has been prominent at Australian CF-specific clinical meetings, as well as programs aimed at further understanding the multidisciplinary nature of modern CF care.

Bronchitol for bronchiectasis

B305 is a clinical trial to extend the use of Bronchitol to patients with bronchiectasis. A major trial commenced dosing in October last year and full recruitment is scheduled for completion in the first half of 2011. The trial is being conducted in 89 sites in 9 countries. Increased recruitment over the past two quarters sees us approaching the half way point of our recruitment target. An additional 9 sites were activated during the quarter with the remaining 24 sites to be activated over the next few months.

Aridol

FDA approves Aridol

On 6th October 2010 Pharmaxis received news that it had become one of the first Australian companies to successfully navigate a path for a new drug through the approval process of the US Food and Drug Administration (FDA).

The decision came after comprehensive analysis of the results of two major phase three clinical trials involving more than a thousand people. Aridol is now approved in more markets than any of its competitors and we anticipate it will become the world standard for bronchial challenge testing.

Following its approval by the FDA for the assessment of bronchial hyperresponsiveness we anticipate Aridol becoming a valuable tool that physicians will use in their overall assessment of asthma. The US represents one of the world's largest markets for bronchial challenge tests. Asthma affects 23 million people in the US and is the cause of over 13 million visits to physicians and almost 500,000 hospital admissions. The large number of medical publications and conference presentations on Aridol have raised awareness and expectations amongst US physicians.

Pharmaxis' US office will launch Aridol in Quarter 1 2011. Preparations for the launch are now well advanced and will make use of telemarketing and peer group advocacy to ensure efficient sales and training activity. Aridol will be reimbursed by US payors under pre existing procedure codes.

In other news on Aridol, there are ongoing investigation initiated studies to explore the expanded utility of the product in managing reactive airway diseases such as asthma and COPD and a number of these are due to report shortly.

ASM8

ASM8 is a new inhaled drug being tested to prevent the response an asthmatic experiences when exposed to the allergen that triggers their asthma. It aims to fill a need for new disease modifying anti-inflammatory drugs for the severe asthma sufferers who currently have limited treatment alternatives.

More detail on the previously reported phase II clinical trial was presented at the European Respiratory Society (ERS) meeting in Barcelona in September 2010 and places ASM8 at the forefront of potential new asthma medications under development.

A second phase II clinical trial that involves treating the patients for 14 days is set to commence before the end of the year.

PXS25

PXS25 is being developed as a potential new treatment for pulmonary fibrosis. The first Phase I clinical trial in healthy volunteers has been completed and PXS25 was found to be safe and well tolerated. PXS25 is a first in class anti-fibrotic agent and additional Phase I/II trials are currently being organised to commence during the first half of 2011.

Corporate News

Upcoming AGM

Pharmaxis' 2010 Annual Review of its operations and Statutory Annual Report were released in September. The Annual Review is a concise report which includes highlights of the year's progress, an update of our products in development, an overview of operations and summary financial data. The Statutory Annual Report is a comprehensive document detailing all of Pharmaxis' statutory annual reporting and disclosure requirements. Both documents can be found online at: www.pharmaxis.com.au/annual-reports

The Pharmaxis Annual General Meeting with be held at 2:30 pm on Wednesday, 20th October 2010 at the Intercontinental Hotel, corner Bridge and Phillip Streets, Sydney. A notice of the meeting was issued to all shareholders in September. Two directors, Malcolm McComas and John Villiger are due to retire by rotation and will be seeking re-election at this meeting.

Financial Overview of the Quarter

Pharmaxis finished the quarter with $76 million in cash.

For the September 2010 quarter, Aridol sales of A$202,000 compared to A$183,000 in 2009 and A$191,000 in the June 2010 quarter.

Research and development expenses of A$8.8 million for the September 2010 quarter compares to A$8.1 million in the September 2009 quarter, and A$8.9 million in the June 2010 quarter. Clinical trial costs decreased by approximately $0.9 million from 2009, and approximately $0.5 million from the June 2010 quarter, while manufacturing research and development costs increased by $0.6 million and $0.3 million for these periods. The Montreal research facility and costs of amortizing the patents acquired on the purchase of Topigen Pharmaceuticals Inc both commenced in the first quarter of 2010 and account for the remainder of the increase in expenses over 2009.

Commercial expenses of A$1.5 million compares to A$1.7 million in the September 2009 quarter and A$1.9 million in the June 2010 quarter. We continue expenditure in relation to the commercial launch of Bronchitol in Europe and Australia and Aridol in the US.

Administration expenses of A$1.2 million compares to A$1.3 million in the September 2009 quarter and A$1.6 million in the June 2010 quarter. While a number of expenses have reduced in the current quarter, the largest contributor to the net decrease has been gains arising between the initial recording and final settlement of foreign currency transactions.

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$8.8 million compared to A$10.0 million in September 2009 and A$7.7 million in the June 2010 quarter. Investing activities used cash of A$0.4 million compared to A$1.3 million in September 2009 and $2.1 million in the June 2010 quarter. Significant foreign exchange rate movements over the quarter had a large impact on the Australian dollar translation of funds we hold in overseas subsidiaries.

Financial Statement Data – Unaudited
(International Financial Reporting Standards)

('000 except per share data)

Income Statement Data

	Three months ended	
	30-Sep-10	30-Sep-09
	A$	A$
Revenue from sale of goods	202	183
Cost of sales	(69)	(47)
Gross profit	133	136
Interest	937	952
Other income	175	88
Expenses		
Research & development	(8,768)	(8,111)
Commercial	(1,469)	(1,251)
Administration	(1,197)	(1,721)
Finance expenses	(290)	(286)
Total expenses	(11,724)	(11,369)
Loss before income tax	(10,479)	(10,193)
Income tax expense	(7)	(11)
Loss for the period	(10,486)	(10,204)
Basic and diluted earnings (loss) per share – $	(0.046)	(0.047)
Depreciation & amortisation	1,189	505
Fair value of securities issued under employee plans	440	604

Balance Sheet Data

	As at	
	30-Sep-10	30-Jun-10
	A$	A$
Cash and cash equivalents	75,831	85,787
Property, plant & equipment	32,026	32,537
Intangible assets	17,255	17,702
Total assets	129,485	140,767
Total liabilities	(24,856)	(25,751)
Net assets	104,629	115,016

	Three months ended	
	30-Sep-10	30-Sep-09
	A$	A$
Cash flows from operating activities	(8,795)	(10,007)
Cash flows from investing activities	(433)	(1,324)
Cash flows from financing activities	(288)	(189)
Impact of foreign exchange rate movements on cash	(440)	(17)
Net increase (decrease) in cash held	(9,956)	(11,537)

Share Data

	Ordinary Shares as at	
	30-Sep-10	30-Jun-10
Ordinary shares on issue	225,765	225,410
Options over ordinary shares outstanding	13,297	13,155

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Contact Details

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