pharmaxis

Quarterly Report to Shareholders

Issue 25 | Oct – Dec 2009

Pharmaxis Ltd ABN 75 082 811 630

pharmaxis

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.

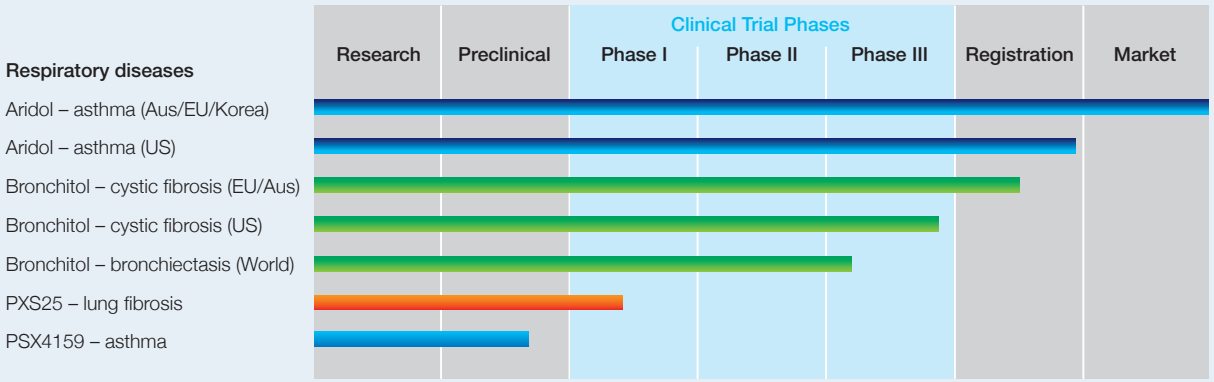
Based in Sydney, Australia, Pharmaxis manufactures its two lead products for commercial sale, clinical trials and for compassionate use.

Our first product, Aridol™ (mannitol bronchial challenge test) is registered for sale and marketing in Australia, Europe and South Korea and a request for marketing approval is being sought 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 European and Australian 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 trials in both cystic fibrosis and bronchiectasis and is currently seeking approval for marketing in cystic fibrosis in Europe and Australia. Additional Phase 3 trials in these conditions 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 December 2009



CEO Report

Welcome to our 25th quarterly report. We have had an extremely busy quarter. We were very pleased to see the results from our twelve month trial with Bronchitol in people with cystic fibrosis. This result emphatically confirmed that Bronchitol has the potential to modify the course of the disease and is a fantastic outcome for those born with cystic fibrosis. We are now working to get Bronchitol approved throughout Europe and this will be a major focus for the year ahead.

The path to new drug approval is never straightforward and requires a huge effort by a lot of people. We were pleased to receive a positive recommendation for Aridol by the U.S. FDA advisory committee following a meeting in Washington. We were disappointed not to be granted the final approval from the FDA on the legislated date but gratified to see that the remainder of the path to final approval had been well laid out and does not contain any unanticipated bumps. All of us involved in progressing the application are looking forward to reaching a satisfactory conclusion before too long.

Bronchitol offers long term clinical benefit

We have signalled our intention to acquire the Canadian biopharmaceutical company, Topigen Pharmaceuticals Inc. Topigen has an exciting group of products targeted at the lung. The first of those, ASM8, is in Phase 2 clinical trials after some years in development. This product will have a very bright future if it lives up to its preclinical and early clinical promise. There have been few new asthma therapies developed in recent years and ASM8 is designed to address the inflammation resulting from a complex interplay between inflammation-causing proteins. The early published clinical data is compelling, the products are a great addition to our armoury and we are looking forward to bringing them through their clinical programs.

Alan D Robertson, Chief Executive Officer

Fourth Quarter Highlights

Marketing applications filed for CF

- European Union and Australian filing of marketing applications for Bronchitol to treat cystic fibrosis
- New Bronchitol data showing sustained benefit for cystic fibrosis patients following 12 months of treatment
- Pivotal Phase 3 bronchiectasis study B305 begins recruitment
- FDA advisory committee recommends Aridol to be approved for marketing in the U.S.
- PXS25 commences a Phase I trial in healthy volunteers

Coming Events

Major milestones in coming months

- Second Phase 3 trial of Bronchitol for cystic fibrosis to report primary outcome
- PXS25 to complete Phase 1A clinical trial
- Finalisation of Aridol NDA with the U.S. FDA

Corporate News

Pharmaxis buying Canadian company

Pharmaxis plans to boost its portfolio of respiratory therapies with the acquisition of the Canadian private biopharmaceutical company Topigen Pharmaceuticals Inc.

In an all-stock deal, Pharmaxis will issue 3.2 million shares on closing the agreement, and pay an additional 5 million shares if Topigen meets development milestones for its anti-asthma drugs.

Topigen has developed a number of potential therapies for respiratory disorders, with the lead drug candidate, TPI ASM8, in Phase 2 dosing trials with the objective of establishing the appropriate dose for further trials in asthma patients with severe unresponsive asthma. TPI ASM8 has completed two Phase I trials and two Phase 2 trials to date. The results from the dose finding study are due in the first half of 2010. A second drug candidate is in preclinical development and targets chronic obstructive pulmonary disease.

ASM8 clinical trial to report first half 2010

The potential new medicines strongly complement Pharmaxis' existing pipeline of respiratory products, reinforcing the company as a growing specialist in undertreated respiratory disorders.

Three million people in the US, Europe and Japan alone are identified as having severe persistent asthma representing a high clinical need.

The acquisition of Topigen is expected to be completed during the first quarter of 2010.

Operations

The last piece of major equipment has been installed in the new manufacturing plant at 20 Rodborough Rd, Frenchs Forest. The automatic capsule filler, or encapsulator, is now in place, with the capacity of filling 50,000 capsules an hour for world markets.

New factory equipment now installed

With all major equipment now installed, the validation process has begun for the spray dryer in preparation for Australian Therapeutic Goods Administration approval. The dryer is already successfully producing powder to required specifications.

Publications

Eleven new peer reviewed scientific papers were published in major journals in recent months.

The papers demonstrate growing scientific curiosity in Bronchitol's development for cystic fibrosis and ongoing worldwide interest in the Aridol challenge test. A list of papers can be found at www.pharmaxis.com.au/scientific-publications.

Patents

The United States Patent Office has granted a patent for Pharmaxis' new molecule in development for pulmonary fibrosis, PXS25.

New patents granted for PXS25 in U.S. and EU

This provides patent life until 2023, and follows a similar patent being granted in Europe in late September.

PXS25 is currently in Phase 1A human testing trials to test its safety and tolerability in healthy volunteers.

Bronchitol for Cystic Fibrosis

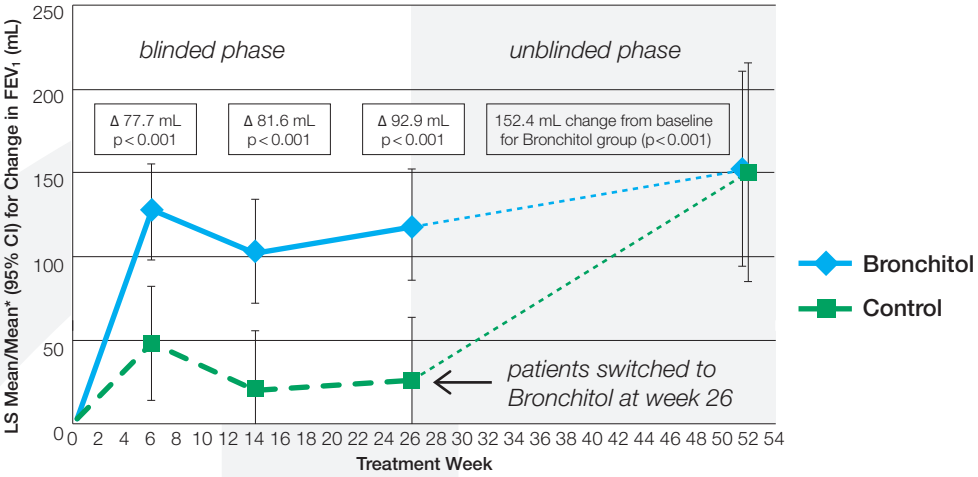
Bronchitol provides sustained benefit in lung function over time

In a major research milestone reported during the quarter, Bronchitol has been found to have a sustained and increasing benefit over time for people with cystic fibrosis.

In the second six month dosing of the international Phase III trial, the lung function of cystic fibrosis patients treated with Bronchitol for a full 12 months improved from 6.5% at six months to 8% ($p<0.001$) at the end of 12 months' treatment. The lung function of patients on placebo for the first six months of the study improved by 10.3% ($p<0.001$) when switched to Bronchitol.

Long term use increases benefit

This clinical trial was the second component of a trial that earlier reported the effects of Bronchitol following six months treatment. Patients treated with placebo during the initial six month blinded phase of the trial were switched to Bronchitol during the subsequent six month open phase. The long term treatment also proved that Bronchitol was safe and well tolerated.



8% lung function improvement at 52 weeks

These results are of significant clinical relevance, particularly given that consistent loss of lung function, averaging 1-2% per year, is the leading cause of death in CF patients.

Additional data from the trial including other lung function parameters and effects on exacerbation will be presented at an upcoming scientific meeting. The data will be used to support marketing applications globally.

CF trial results expected first half of 2010

Meanwhile, a second Phase 3 trial is progressing to support a submission to the U.S. FDA for the approval of Bronchitol for cystic fibrosis. Recruitment of a total of 317 subjects has completed and the headline results will be available during the first half of 2010.

Applications to market Bronchitol in Europe and Australia

Important steps have been made in bringing Bronchitol to the local and world cystic fibrosis communities, with the filing of marketing applications in Australian and Europe.

A submission was lodged to market Bronchitol for the treatment of cystic fibrosis with the European Medicines Agency (EMeA) in October. The EMeA has accepted the submission for review through the European Union's centralized processing procedure. The European review outcome is expected in the second half of this year. Approximately 40,000 Europeans are affected by cystic fibrosis.

The Australian application was submitted to the Therapeutic Goods Administration in December. The TGA will advise by mid February if the marketing application is accepted for evaluation, with a final decision expected in the first half of 2011.

Meeting with influential CF advocates

Keynote presentation at world CF conference
Pharmaxis' latest research results drew a capacity crowd at the world's largest cystic fibrosis conference late last year. The Bronchitol CF301 Phase 3 trial results were presented to the North American Cystic Fibrosis meeting in Minneapolis in October. The conference was attended by 3,500 leading CF specialists and scientists, with Dr Diana Bilton presenting the CF301 data on the first day of the conference. The auditorium was filled to standing room only during her presentation and received strong positive feedback from attendees.

At the same conference, Pharmaxis representatives met with the leadership of the influential North American Cystic Fibrosis Foundation to discuss the company's plans for Bronchitol.

Bronchitol for Bronchiectasis

Pivotal bronchiectasis trial underway
Screening of patients has commenced in a pivotal 12 month Phase 3 trial of Bronchitol for bronchiectasis. This study, B305, has now commenced recruiting and based on our discussions with the FDA and EMEA will support a robust label claim in bronchiectatic patients where there remains a high unmet medical need.

Alignment of bronchiectasis product

The company also moved to streamline its global regulatory and product strategy for this indication. As part of this strategy, Pharmaxis voluntarily withdrew its marketing application to the Therapeutic Goods Administration (TGA) in Australia for the use of Bronchitol to treat bronchiectasis, to ensure one product, one indication and one presentation will be available throughout the world.

Pharmaxis will continue its dialogue with the TGA and resubmit the bronchiectasis indication as soon as possible. In the meantime Bronchitol will continue to be available to bronchiectatic patients in Australia through a special access scheme.

Aridol

US application progressing
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 overwhelmingly that Aridol should be approved by the FDA on the basis of the clinical evidence.

Pharmaxis is actively working with the U.S. FDA now to finalise its New Drug Application (NDA) for Aridol.

This follows the Complete Response Letter received from the FDA in late December advising that the application was not in a position to be approved in its present form. The letter listed matters that had been observed at subcontract testing and packing facilities; the requirement to finalise the revised labelling; and agreement to be reached on post marketing requirements.

Finalising NDA with the U.S. FDA

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

Aridol sales commence in Korea

Aridol launches in Korea

Following formal notification of reimbursement in September, major Korean hospitals have begun formulary listings of Aridol, with first sales orders received by our Korean distributor BL&H in October. Aridol's official launch to the Korean market was held to coincide with the Asia Pacific Society of Respirology (APSR) congress in Seoul, attended by over 1,300 respiratory physicians. APSR was followed by the Korean Academy of Allergy congress in Pusan, where a keynote speech on Aridol was given to over 150 delegates by Dr Celeste Porsbjerg from Denmark.

New Research Activities

With the planned acquisition of Topigen, Pharmaxis will be developing a potential new therapy for severe asthma, called ASM8.

Currently in Phase 2 clinical trials, ASM8 is an inhaled anti-inflammatory specifically designed to reduce the recruitment and persistence of chronic inflammatory cells and the associated release of cytokines – key components causing asthma.

Potential new asthma therapy

ASM8 takes a multi-targeted approach to blocking the synthesis of specific receptors by using RNA-silencing technology. This is expected to have advantages over current medications by providing broader, but specific, pharmacological activity with limited systemic availability, in a convenient, once daily, inhaled formulation.

A second Topigen drug candidate, TPI 1100 is in preclinical development for chronic obstructive pulmonary disease.

Financial Overview of the Quarter

At 31 December 2009, the cash balance was $102 million. For the December 2009 quarter, Aridol sales of A$171,000 compared to A$203,000 in 2008 and A$183,000 in the September 2009 quarter. Interest income of $978,000 earned primarily on commercial bills, compares to $1.6 million in 2008, reflecting significantly lower interest rates.

Research and development expenses of A$9.2 million for the December 2009 quarter compares to A$7.6 million in the December 2008 quarter, and A$8.1 million in the September 2009 quarter. Additional expenditure on clinical trials, regulatory filings and manufacturing development accounted for the changes.

Commercial expenses of A$1.2 million compares to A$1.5 million in the December 2008 quarter and A$1.3 million in the September 2009 quarter. Commercial expenditure includes the costs of preparing for the commercial launch of Bronchitol in Europe and the US, the costs of preparing for the sale of Aridol in the US and the costs of selling Aridol in Europe and Korea.

R&D dominates expenditure

Administration expenditure of A$1.8 million compares to A$1.6 million in the December 2008 quarter and A$1.7 million in the September 2009 quarter. Infrastructure and Topigen acquisition costs are the major components of the changes. Finance costs represent the ongoing charge component of the capitalized finance lease for our new facility at Frenchs Forest.

Operating activities used cash of A$10.3 million compared to A$7.0 million in 2008 and A$10.0 million in the September 2009 quarter. Investing activities used cash of A$0.9 million compared to A$4.7 million in 2008 and A$1.3 million in the September 2009 quarter. Financing activities include the exercise of employee options and the capitalized lease on our headquarters at Frenchs Forest.

Financial Statement Data – Unaudited
(International Financial Reporting Standards)

('000 except per share data)

Income Statement Data

	Three months ended		Six months ended	
	31-Dec-09	31-Dec-08	31-Dec-09	31-Dec-08
	A$	A$	A$	A$
Revenue from sale of goods	171	203	354	309
Cost of sales	(60)	(48)	(107)	(77)
Gross profit	111	155	247	232
Interest	978	1,581	1,930	3,657
Other income	77	141	165	144
Expenses				
Research & development	(9,184)	(7,626)	(17,295)	(13,587)
Commercial	(1,213)	(1,519)	(2,465)	(2,890)
Administration	(1,813)	(1,639)	(3,534)	(2,922)
Finance expenses	(222)	–	(508)	–
Total expenses	(12,432)	(10,784)	(23,802)	(19,399)
Loss before income tax	(11,266)	(8,907)	(21,460)	(15,366)
Income tax expense	(32)	(22)	(43)	(28)
Loss for the period	(11,298)	(8,929)	(21,503)	(15,394)
Basic and diluted earnings (loss) per share – $	(0.052)	(0.046)	(0.099)	(0.079)
Depreciation & amortisation	641	265	1,147	518
Fair value of options issued under employee plan	549	539	1,154	1,151

Balance Sheet Data

	As at	
	31-Dec-09	30-Jun-09
	A$	A$
Cash and cash equivalents	102,081	124,993
Property, plant & equipment	32,801	32,698
Intangible assets	1,144	1,193
Total assets	140,634	163,997
Total liabilities	(22,906)	(26,306)
Net assets	117,728	137,691

Cash Flow Data

	Three months ended		Six months ended	
	31-Dec-09	31-Dec-08	31-Dec-09	31-Dec-08
	A$	A$	A$	A$
Cash flows from operating activities	(10,320)	(6,951)	(20,344)	(11,827)
Cash flows from investing activities	(909)	(4,657)	(2,233)	(6,087)
Cash flows from financing activities	(122)	–	(311)	11
Net decrease in cash held	(11,351)	(11,608)	(22,888)	(17,903)

Share Data

	Ordinary Shares as at	
	31-Dec-09	30-Jun-09
Ordinary shares on issue	219,069	217,659
Options over ordinary shares outstanding	13,480	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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