pharmaxis

Quarterly Report to Shareholders

Issue 22 | January – March 2009

Cystic fibrosis is characterised by a vicious cycle of obstruction, infection and inflammation in the lungs, which is the primary cause of lung function loss and breathing difficulties.

Pharmaxis Ltd ABN 75 082 811 630

pharmaxis

Producing human healthcare products to treat and manage respiratory diseases

Overview

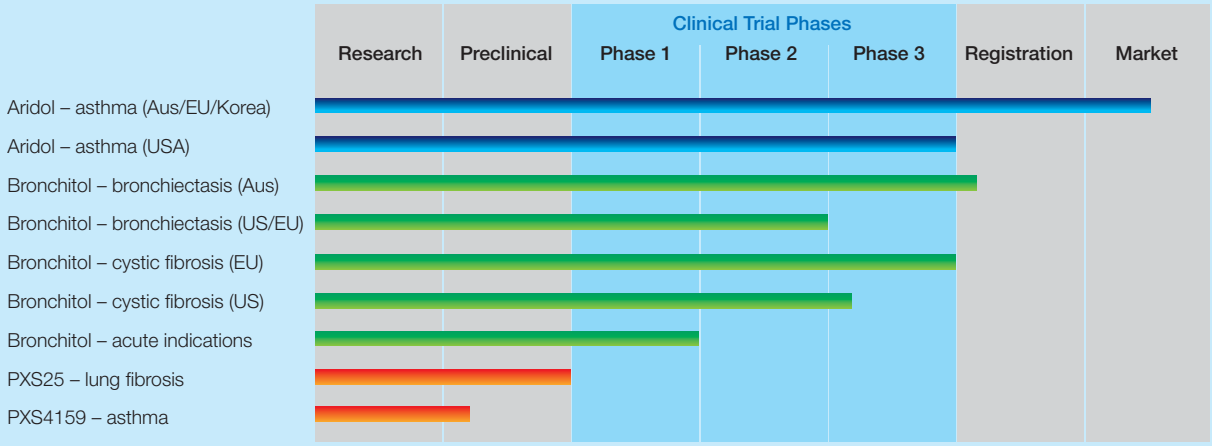
Pharmaxis is a specialty pharmaceutical company with activities spanning product research & development through to manufacture, sales and marketing.

Our therapeutic interests include lung diseases such as cystic fibrosis, asthma, bronchiectasis and chronic obstructive pulmonary disease.

Our first product, Aridol, is now registered for sale in Australia, Europe and parts of Asia and is designed to assist in the management of both asthma and chronic obstructive pulmonary disease. Our second product, Bronchitol, is in final clinical trials as a new treatment for cystic fibrosis and chronic obstructive pulmonary diseases such as bronchiectasis.

Our research group is developing two new potential therapies for chronic and debilitating lung conditions such as asthma and pulmonary fibrosis.

Pharmaxis Product Development at March 2009



CEO Report

Our objective is to build a profitable international pharmaceutical business operating in multiple jurisdictions and we are moving closer to that end. We have always planned to do this through the development of our own products, through innovation, and through collaborative partnerships. In keeping with this goal, we have brought Aridol to international markets and Bronchitol to the point where we have finished large Phase III clinical trials and filed a marketing application in Australia. In Aridol and Bronchitol we have valuable assets unencumbered by third party partnerships. Moreover, we have undertaken the manufacture of both Aridol and Bronchitol and this has allowed us full control of the product and to develop important intellectual property. We believe this is an important aspect of building a sustainable business.

Behind Aridol and Bronchitol we have PXS25 now ready for clinical evaluation and PXS4159 moving through a rigorous set of preclinical safety studies.

Pharmaceutical product development takes time and it can often seem frustratingly slow but it is essential that any product that is going to be administered to people throughout the world and sometimes for many years, is thoroughly evaluated – not only for its effectiveness but also for its safety.

In the immediate term, an important business objective is to generate revenue from Aridol, our lung function test, through opening up new markets and developing existing markets. Additionally we are well placed to complete two Phase III clinical trials with Bronchitol in cystic fibrosis. The first of these trials is due to report shortly, and positive data should allow a marketing application to be submitted to the European Union.

This report contains details for our progress for the first quarter of 2009.

Alan D Robertson, Chief Executive Officer

2009 first quarter highlights

CF clinical trial completed on schedule

- Last subject completes the first part of a Phase III trial into the effects of Bronchitol in adults and children with cystic fibrosis.
- The submission of a New Drug Application to the U.S. FDA seeking approval to market Aridol in the United States.
- Second Phase III trial into the role of Bronchitol in cystic fibrosis recruiting actively.
- Aridol presented to international respiratory community at the American Academy of Allergy, Asthma and Immunology meeting in Washington, DC.

Forthcoming Events

PXS25 to begin Phase I

- Data to be released from the Phase III cystic fibrosis clinical trial with Bronchitol
- PXS25 to enter Phase I clinical testing program
- Second Bronchitol Phase III trial in cystic fibrosis to complete enrolment

Corporate News

Communication

Pharmaxis is moving from a clinically focussed development company to a fully integrated operating business. This move has started with the marketing approvals of Aridol and will continue in more earnest as Bronchitol gets closer to the international marketplace. An important part of the business is communication with local and international stakeholders and interested parties. During the quarter, the science of the company was presented at the Western Society of Allergy, Asthma and Immunology meeting and also at the American Academy of Allergy, Asthma and Immunology meeting in Washington – which included a lively debate on the merits of Aridol versus the existing lung function challenge tests.

International exposure for Pharmaxis

In addition, the business of the company was presented to investors and analysts at the Credit Suisse Global Biotechnology, Biopharmaceuticals and Generics conference in Europe and also at the Cowen and Company Annual Healthcare Conference in the USA.

Facilities

The construction of the new purpose built Pharmaxis factory and company headquarters at 20 Rodborough Road, Frenchs Forest in Sydney is progressing on schedule. We expect the building and its fit out to be completed in April. After the manufacturing equipment has undergone the necessary validation work, Bronchitol manufacturing capacity will be increased to 40,000 patients per year with an option to double this capacity with the installation of additional equipment.

New factory on schedule for April finish

The factory will be the subject of a 15 year lease agreement.

Personnel

The company has over 100 employees and has operations in Sydney, Australia; Philadelphia, in the USA; the midlands of the U.K. and in Shanghai, China.

Recently, Howard Fox joined the company as Chief Medical Officer to join Brett Charlton, the Medical Director. Dr Fox has more than 15 years experience in the international pharmaceutical industry, the last ten of which has been in respiratory product development. He was most recently with Novartis as a Global Brand Medical Director and previously held the positions of Senior Clinical Research Physician and Principle Medical Expert for Novartis.

Medical team strengthened

Board of Directors

The Board of Directors of the company are primarily responsible for strategic oversight. Recently Richard van den Broek joined the Board as an independent non executive Director. Richard is Managing Partner of HSMR Advisors, LLC, an investment fund focused on the biotechnology industry. From 2000 through 2003 he was a Partner at Cooper Hill Partners, LLC, an investment fund focused on the healthcare sector. Before that, Richard had a ten year career as a biotech analyst, starting at Oppenheimer & Co., then Merrill Lynch, and finally at Hambrecht & Quist. Richard is a graduate of Harvard University and is a Chartered Financial Analyst and brings another U.S. perspective to the board.

New Board member appointed

Clinical and Medical News

1st CF trial closes after last patient visit

Last subject completes Phase III CF trial

There are currently only two products approved for the treatment of cystic fibrosis. One of those is an inhaled antibiotic and one is a drug designed to improve the flow properties of mucus in the cystic fibrosis lung. Bronchitol does not compete with either product and would be expected to be used in addition to these approved products. The combined sales of these two products in 2008 were A$1.1 billion (1USD = 1.45AUD).

The Phase III trial involving 325 subjects commenced recruitment in April 2007 and reached its recruitment target in August 2008 and the very last subject had their last clinical visit in April 2009. This trial was designed with the assistance of the European Medicines Agency (EMEA) and Bronchitol has been given orphan drug designation in Europe. The advantages of orphan drug designation is 10 years exclusivity from the date of marketing authorisation and direct access to the centralised procedure for marketing review.

Lung function is the primary determinant

The main purpose of the trial is to determine if Bronchitol provides an improvement in lung function when measured against an inactive placebo following administration to a subject twice a day for 6 months. For people living with cystic fibrosis, the progressive loss of lung function is one of the most difficult consequences of the disease. The trial took place across 40 clinical centres in Australia, New Zealand, the United Kingdom and Ireland and enrolled subjects aged 6 years and older who were variously affected by the disease; from mild through to severely affected.

A positive improvement in lung function and an absence of serious adverse events will allow us to file a marketing application throughout Europe based on this trial. In that case, and with a favourable review, Bronchitol will become only the third new product ever to be approved for cystic fibrosis.

Cystic fibrosis affects over 75,000 people world wide and is the most common life limiting genetic disorder.

Enrolment commenced in second Phase III CF trial

A second Phase III trial is being run to satisfy a U.S. FDA requirement for two pivotal Phase III trials before Bronchitol will be considered for marketing authorization review. The trial is seeking to recruit over 300 volunteers and involves more than 65 clinical centres in Argentina, the USA, France, Belgium, Canada, The Netherlands and Germany.

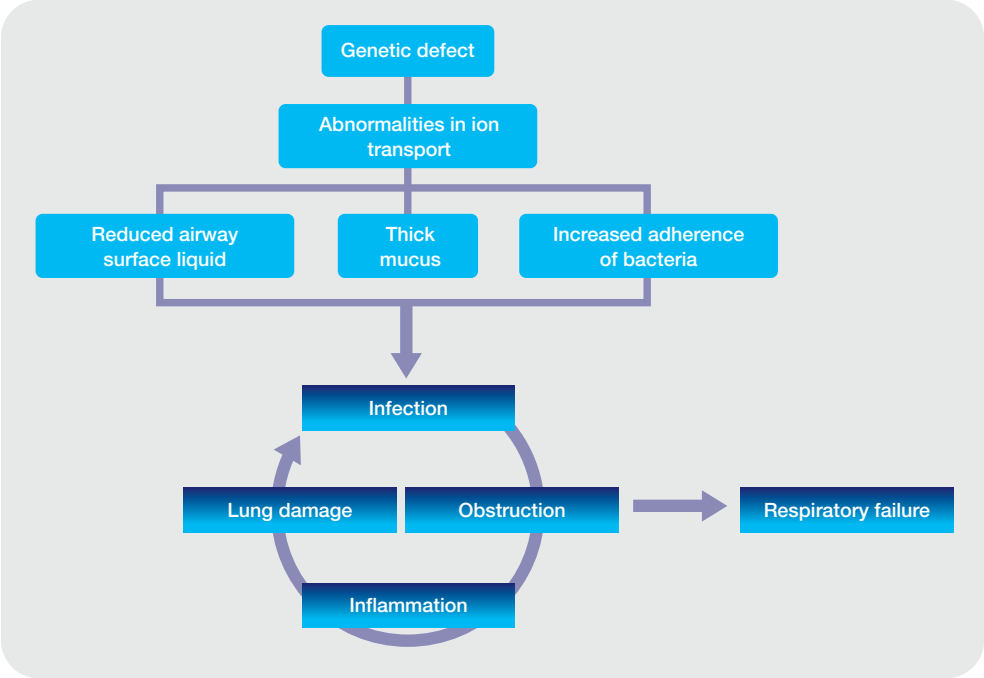
Second PIII CF 30% enrolled

The trial design is similar to the first Phase III trial above with the same primary objective of improving lung function. The trial is well into its recruitment phase and our objective is to have enrolment finished by the middle of 2009 and be in a position to have data from the trial during the first quarter of 2010.

Bronchitol has been granted fast track designation by the FDA. The FDA's Fast Track programs were designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. In addition, the programme allows Pharmaxis to submit parts of the marketing application ahead of completing the full two Phase III clinical studies.

The CF lung deterioration spiral

Several connected mechanisms explain the susceptibility of the CF lung to infection



Bronchitol aims to repair the airway surface liquid and reduce the thickness of the mucus which should result in reduced lung damage, infection rate and obstruction, breaking the cycle that leads to respiratory failure. In addition to effects on lung function, the current clinical trials will examine the effects of Bronchitol on infection rate and inflammation. The ultimate goal, which is beyond the reach of the current clinical trials, is to reduce respiratory failure. That outcome, however, will require many years data collection after the drug is approved.

Bronchitol under TGA review

Bronchitol long-term Phase III clinical trial in bronchiectasis

A Phase III clinical trial evaluating the safety and efficacy of Bronchitol in people living with bronchiectasis completed in June of 2008 and reported in August 2008. In September of 2008 a marketing application was filed with the Australian regulatory authority (the TGA). The submission is now in review, however, the process is not expected to conclude until the third quarter of 2009.

Australia has over 18,000 people living with bronchiectasis and indigenous children in Central Australia have the highest rates of bronchiectasis in the world.

We continue to make the product available through the TGA administered Special Access Scheme and through similar individual named patient schemes throughout the world.

Bronchitol Phase III being set up

Second Bronchitol Phase III trial in bronchiectasis

A second Phase III trial in bronchiectasis is in the set up phase. This trial is designed to examine the effects of Bronchitol following twelve months treatment and has been discussed extensively with the U.S. FDA and the EMEA. This clinical trial aims to prove that people treated with Bronchitol will have fewer periods of acute sickness and require less hospitalisation than people not taking Bronchitol. The trial has been scheduled to commence during the second quarter of 2009.

Marketing and Regulatory Activities

Aridol supplied to new European countries

Aridol is now being marketed in Australia and throughout Scandinavia, Denmark, The Netherlands, Greece, Portugal, Switzerland and the United Kingdoms. We expect to add Spain and Italy to this list during the forthcoming quarter. Aridol is proving to be popular amongst the pulmonary testing labs and the respiratory specialist and we are working to ensure it becomes the test of choice in the future. Our objective now is to stimulate market growth.

The marketing application for the USA was submitted electronically to the FDA at the end of February. By the end of April, the FDA will advise us if the application is in order to permit a substantive review and a timetable for that review.

Following market approval by the Korean FDA, Aridol has been acknowledged by the Health Technology Assessment Committee as a significant new technology and that Aridol is effective for both the diagnosis and management of asthma. This official ruling has been published. A pharmacoeconomic dossier is in the process of being submitted and a decision is expected in June. In the meantime, our distributor is promoting Aridol on a non-reimbursed basis and first sales were recorded this quarter.

Early Stage Research Activities

PXS25 Phase I trials to commence

PXS25 inhibits a key enzyme involved in the conversion of inactive Tissue Growth Factor (TGF) to active TGF. TGF is critical for the development of fibrotic disorders and our clinical focus is the lung.

Phase 1 clinical studies of PXS25 are being scheduled and first exposure to humans will be during the forthcoming quarter.

Financial Overview of the Quarter

At 31 March 2009 Pharmaxis had $86 million in cash.

Expenditure again dominated by clinical research

During the quarter, capital expenditure in relation to our new facility was approximately $3.7 million and we also received a previously negotiated lease rental incentive of $3.6 million as a contribution to the fitout. The remaining $2.5 million of facility related expenditure is expected to be incurred before the end of the financial year.

For the March 2009 quarter, Aridol sales of A$144,000 compared to A$136,000 in 2008. Interest income of $927,000 earned on commercial bills issued or accepted by the four larger Australian banks, compares to $2.1 million in 2008, reflecting lower interest rates and a lower balance of funds invested.

Research and development expenditure of A$7.2 million for the March 2009 quarter compares to A$4.4 million in the March 2008 quarter, and A$7.6 million in the December 2008 quarter. Expenditure on clinical trials and regulatory filings account for the changes.

Commercial expenditure of A$1.4 million compares to A$1.2 million in the March 2008 quarter and A$1.5 million in the December 2008 quarter.

Administration expenditure of A$1.3 million compares to A$1.3 million in the March 2008 quarter and A$1.6 million in the December 2008 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-09	31-Mar-08	31-Mar-09	31-Mar-09	31-Mar-08	31-Mar-09
	A$	A$	US$[1]	A$	A$	US$[1]
Revenue from sale of goods	144	136	99	453	330	311
Cost of sales	(35)	(30)	(24)	(113)	(82)	(78)
Gross profit	109	106	75	340	248	233
Interest	927	2,108	637	4,584	5,169	3,151
Other income	132	689	90	276	923	190
Expenses						
Research & development	7,193	4,370	4,944	20,780	14,010	14,282
Commercial	1,449	1,154	996	4,339	3,105	2,982
Administration	1,336	1,321	918	4,258	3,785	2,927
Total expenses	9,978	6,845	6,858	29,377	20,900	20,191
Loss before income tax	(8,810)	(3,942)	(6,056)	(24,177)	(14,560)	(16,617)
Income tax expense	(1)	2	(1)	27	18	19
Loss for the period	(8,809)	(3,944)	(6,055)	(24,204)	(14,578)	(16,636)
Basic and diluted earnings (loss) per share – $	(0.045)	(0.020)	(0.031)	(0.124)	(0.078)	(0.086)
Depreciation & amortisation	271	253	186	789	772	542
Fair value of options issued under employee plan	650	923	447	1,801	2,604	1,238

Balance Sheet Data

	As at		
	31-Mar-09	30-Jun-08	31-Mar-09
	A$	A$	US$[1]
Cash and cash equivalents	85,832	111,842	58,992
Plant & equipment	18,128	3,668	12,459
Total assets	107,457	125,049	73,855
Net assets	96,767	119,121	66,508

Cash Flow Data

	Three months ended			Nine months ended		
	31-Mar-09	31-Mar-08	31-Mar-09	31-Mar-09	31-Mar-08	31-Mar-09
	A$	A$	US$[1]	A$	A$	US$[1]
Cash flows from operating activities	(4,515)	(4,363)	(3,066)	(16,343)	(16,674)	(11,233)
Cash flows from investing activities	(3,655)	(275)	(2,514)	(9,742)	(2,826)	(6,696)
Cash flows from financing activities	–	31	–	11	59,571	8
Net increase (decrease) in cash held	(8,170)	(4,607)	(5,580)	(26,074)	40,071	(17,921)

Share Data

	Ordinary Shares[2]	
	As at	
	31-Mar-09	30-Jun-08
Ordinary shares on issue	194,537	194,515
Options over ordinary shares outstanding	13,602	11,536

Notes:

(1) Convenience translation into U.S. dollars from Australian dollars based upon rate on 31 March 2009.

(2) Pharmaxis ordinary shares are traded on the Australian Securities Exchange (PXS) and our ADRs are traded on the Nasdaq Global Market (PXSL). One Pharmaxis ADR represents 15 Pharmaxis ordinary shares.

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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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