pharmaxis

Facing a brighter future…

2008 Annual Review

...from today's

This Annual Review

Welcome to Pharmaxis' first Annual Review. It is designed to provide shareholders with an at-a-glance summary of the company's activities for the year. For more detail, the 2008 Statutory Annual Report can be accessed on the Pharmaxis website www.pharmaxis.com.au

Company overview

Pharmaxis is a specialty pharmaceutical company involved in the research, development and commercialisation of new therapies for undertreated respiratory diseases.

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

The company's first product, Aridol, is approved for sale in Australia, 10 European countries and Korea. It is designed to identify lung inflammation and assist in diagnosing and managing asthma. The second product, Bronchitol, is in final clinical trials as a new treatment for the debilitating lung diseases cystic fibrosis and bronchiectasis.

We are committed to bringing our therapeutic advances for respiratory diseases to patients thoughout the world, and to building an internationally successful pharmaceutical business: one that's built to last.

Breathing easy after Aridol test...

Andre Flores is facing a brighter future after bringing his asthma under control. Battling the condition since he was a child, Andre was unable to fulfil his dream of becoming an Army Reservist until he could prove that his asthma was well managed, and that he'd met other Australian Defence Force requirements. After adhering to an asthma management plan and getting fit, Andre undertook an Aridol lung function test, which measures airway hyper-responsiveness – a sign of asthma. The Aridol test showed that his asthma was now under control, opening the door to the Army Reserves, and an exciting future for Andre and his family.

Contents

Notice of Meeting

The 2008 Annual General Meeting of Pharmaxis Ltd will be held at the Sofitel Wentworth Sydney, 61-101 Phillip St, Sydney on Thursday, 23 October, at 2.30pm.

innovations

A year in profile

At Pharmaxis, we are driven by a fundamental desire to make a positive contribution to the world; to brighten the lives of people suffering from untreated diseases by creating innovative medicines.

Our success hinges on our ability to innovate, and over the past year we have made major strides in bringing new ideas to fruition. In doing so, we have entered a new transformational phase in our development.

During 2007/8 we worked hard on our early stage discovery ideas as well as our later stage product development. Our compounds PXS25 and PXS4159 now represent exciting opportunities to become important respiratory medicines of the future.

New therapies must demonstrate strong economic value to the payer and they must do so in a safe, predictable and effective manner. Innovation does not happen by chance and requires specific tools and discipline. Bronchitol is the product of a concept some years ago and we have now completed a number of clinical studies in an effort to demonstrate that it is safe and effective in treating cystic fibrosis and bronchiectasis.

Reducing risk

Innovation involves risk, of course, and we have sought to reduce risk wherever possible as we guide our products through the very complex and cautious regulatory processes involved in bringing a new drug to market today. During the year we concluded discussions with the U.S. Food and Drug Administration on the clinical and regulatory path for marketing Bronchitol in the States for both cystic fibrosis and bronchiectasis. Previously, we had also agreed on a plan for bringing Bronchitol to the European community. Now we can focus on execution.

Delivering on targets

It has been an eventful year for Pharmaxis and one that has seen us deliver on our operational targets. The full completion of the Bronchitol Phase 3 clinical trial for bronchiectasis sufferers was a significant event for us all. It was very rewarding to see that Bronchitol was safe, effective and enjoyed by people participating in the trial. For cystic fibrosis we are involved in two large Phase 3 clinical trials and the first of these should report early in 2009. Our new manufacturing facility is under construction as we prepare to bring Bronchitol to the world.

I am pleased to report that Pharmaxis delivered excellent performance in 2007/8. It is my great pleasure to present our 2008 Annual Review. I thank you for your support and look forward to another year of major progress for the company, creating a brighter future for respiratory disease sufferers throughout the world.

Alan Robertson
Chief Executive Officer

2007/8 Highlights

- Long term Phase 3 trial found Bronchitol safe and effective in bronchiectasis
- Bronchitol 400mg effective in cystic fibrosis
- Bronchitol improved lung function of bronchiectatics following three months' treatment
- Australian TGA confirmed Bronchitol marketing application plans
- International compassionate use program established for Bronchitol
- Construction began on new factory and headquarters in Frenchs Forest
- U.S. headquarters established
- Aridol approved in Korea
- Olympic athletes tested with Aridol
- U.S. FDA confirmed Aridol marketing submission plans
- Completion of $50 million capital raising and $12 million share purchase plan

Product Review

Aridol

Pharmaxis' innovative asthma management test Aridol grew in popularity in 2008 as physicians learned of its benefits.

Doctors currently do not have a rapid, accurate, safe and inexpensive test to evaluate the presence or severity of asthma, and Aridol fills this need. Aridol is simple to use, is administered as a dry power to the lungs in a hand-held inhaler and identifies airway hyper-responsiveness – a hallmark of asthma.

Growing physician recognition

Aridol is now positioned to become the worldwide standard for detecting sensitive airways in people with conditions like asthma. A US independent investigator study found that *'mannitol (Aridol) has many advantages over other indirect challenges as well as direct challenges'*. (Rundell & Slee, US Journal of Allergy and Clinical Immunology, August 2008.)

Aridol also gained prominence at major international scientific congresses during the year. It was highlighted at the May meeting of the American Thoracic Society, which attracted over 13,000 global delegates from all facets of respiratory science and medicine. Aridol also featured at the American Academy of Asthma, Allergy and Immunology meeting; while at the Aspen Lung Conference the detailed results of the pivotal U.S. Phase 3 Aridol trial were unveiled for the first time.

A further fillip occurred when the International Olympic Committee Medical Commission's Independent Panel included Aridol as an approved test. A number of Australian and European Olympians competing in Beijing were tested with Aridol prior to the Games. An independent study of asthmatic Olympic athletes also began in 2008, with more than 300 athletes from eight countries tested using Aridol.

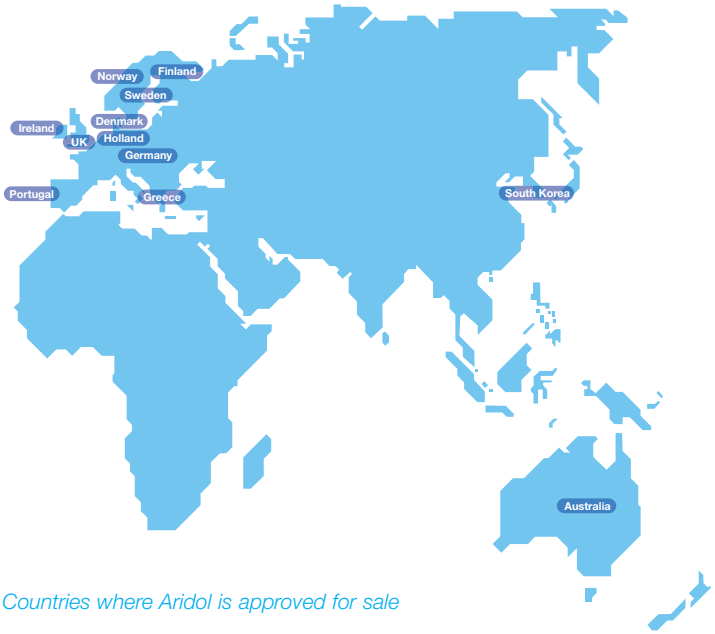
Meantime, revenue from Aridol sales for the year grew 156 per cent from 2007 to $527,000. Australian sales were 82% higher than the previous year.

Global marketing of Aridol

Over the past year, we worked towards finalising individual European Union countries' marketing authorisations. We are now authorised to sell Aridol in Sweden, The Netherlands, Denmark, Ireland, The United Kingdom, Portugal, Germany, Norway, Greece and Finland. At June 2008, only Italy, France, Spain and Belgium were still being processed.

Aridol gained its first Asian marketing approval in January from Korea. Korea is an important base from which to launch and grow Aridol in Asia, with an estimated 2.5 million asthma sufferers and broad acceptance of lung function challenge tests.

Assembly of the data required for an application to market Aridol in the United States progressed during 2008. We have established a new United States office to manage this process and coordinate sales and marketing activities in North America.



Countries where Aridol is approved for sale

Products in

Our research team made significant progress during the year in developing new therapies to treat respiratory diseases.

PXS25 – targeting lung fibrosis

PXS25 has been repositioned during the year and much of the preclinical safety testing has been completed, clearing the way for its first clinical investigation in humans. PXS25 has been designed to inhibit a key receptor involved in scar formation and is expected to find use in conditions such as lung fibrosis.

PXS4159 – promising new candidate for asthma

In another research project, our drug discovery team has designed molecules that inhibit a critical protein that is implicated in the inflammatory response and organ damage associated with chronic immune mediated diseases such as asthma. During 2008 we selected PXS4159 as a development candidate and began the scale up manufacture and pre-clinical safety studies necessary prior to evaluating the compound in human studies.

Bronchitol

The Company's key product in development, Bronchitol, is a drug designed to reduce the amount of mucus build-up in the lungs of patients suffering from a variety of respiratory conditions.

Pharmaxis is developing Bronchitol initially for cystic fibrosis and bronchiectasis, but the applications are potentially much wider than this, covering both acute and chronic conditions of lung congestion.

Bronchitol hydrates the lungs, helps restore normal lung clearance and allows patients to clear mucus more effectively. Clinical studies have shown Bronchitol to be effective and well tolerated, to improve quality of life and mucus flow in people with cystic fibrosis and bronchiectasis.

Cystic fibrosis

Two Phase 3 clinical trials made steady progress during the year for the use of Bronchitol in cystic fibrosis. The first trial is being conducted at centres throughout Australia and Europe, comparing 400mg of Bronchitol twice daily to control.

The 26 week trial is testing the drug's effect on patients' lung function, with results due the first half of 2009. The trial design was completed with advice from the European Committee for Orphan Medicinal Products, and positive data will allow Pharmaxis to file a marketing application mid-2009.

The second Phase 3 clinical trial is in U.S. cystic fibrosis sufferers, required for a U.S. marketing application. During the year, site centre agreements were completed and ethics approvals granted.

This trial is being conducted under the Food and Drug Administration's Special Protocol Assessment (SPA) scheme, and will take place throughout the States, Argentina and Germany. The SPA process ensures the clinical trial protocol is acceptable to the U.S. FDA when the results are submitted to support a marketing application for Bronchitol. Initial data from the trial is expected by the end of 2009.

Pharmaxis is confident the data from both studies will reinforce the positive outcomes from three Phase 2 studies, which resulted in Bronchitol being awarded fast-track status in the U.S., and orphan drug designation in both the U.S. and EU.

Cystic fibrosis is a fatal disease, affecting more than 75,000 people worldwide. There have been no therapeutic advances to help clear their congested lungs for over a decade.

Bronchiectasis

Bronchitol is also being developed for use in bronchiectasis, a progressive lung disease affecting almost 600,000 people worldwide. Bronchiectasis causes significant disruption to sufferers' day-to-day lives. Mucus accumulation affects their ability to breathe, exercise, sleep and lead a normal life – ultimately reducing life expectancy. Bronchitol is the first targeted medication for sufferers in over 20 years.

2008 saw a long-term Phase 3 safety study of more than 360 subjects complete, with no serious adverse events attributable to the drug. These results pave the way for Pharmaxis to submit a marketing application in Australia before the end of 2008.

The results follow an earlier stage of the trial finding that Bronchitol delivered a highly significant improvement in users' quality of life.

The medicine is expected to be approved for bronchiectasis first in Australia, and later in the U.S. and Europe following the completion of a further Phase 3 trial.

The design of this trial was negotiated over the course of the year with the U.S. FDA and the European Medicines Agency. This European and U.S. trial of 300 adults with bronchiectasis is expected to begin recruitment in the second half of 2008, and will form the basis of U.S. and E.U. marketing applications in 2010. Bronchitol has orphan drug status for this indication in the U.S..

In other developments, Pharmaxis appointed an international agency to manage and provide Bronchitol to patients in urgent need of the medicine. Overseas patients with severe bronchiectasis and cystic fibrosis can now apply through their doctors to purchase Bronchitol via IDIS Limited. Pharmaxis has been providing medicines on a compassionate basis to more than 100 patients in Australia and New Zealand for several years.

Development

Operations Overview

Our new manufacturing facility took shape this year, with construction on schedule to be completed in early 2009.

The new facility in Frenchs Forest, Sydney, will house Australia's largest spray dryer for pharmaceutical manufacturing – a state-of-the-art machine from Denmark measuring more than three stories high.

It will be capable of producing 260 million capsules of Bronchitol a year, enabling the company to supply world markets efficiently and rapidly as soon as the product is approved.

International expansion

An important milestone in establishing Pharmaxis' global footprint during 2007/8 was the appointment of marketing, clinical and regulatory capability in the U.S. to coordinate clinical trials locally and to begin commercial operations. We also opened a new office in China to support our entry into Asian markets, bringing our global reach to four continents.

Revamped website

A major review of our website www.pharmaxis.com.au was undertaken in 2008. The updated site reflects the maturing of our business and features regular patient profiles, late-breaking news updates and easy-to-navigate new sections for investors and health professionals.

Board of Directors

During 2008 senior Australian pharmaceutical executive Will Delaat joined the Pharmaxis Board of Directors.

Mr Delaat has 35 years' experience in the global pharmaceutical industry, most recently as the managing director of the Australian subsidiary of Merck & Co. As one of Australia's pharmaceutical industry leaders, he will be a strong addition to our world-class Board of Directors.

Detailed Director biographies can be found on our website www.pharmaxis.com.au and in the 2008 Statutory Annual Report.

L-R: Dennis Hanley (Chairman), Alan D Robertson (CEO), Peter Farrell, John Villiger

Malcolm J McComas, Will Delaat, David M McGarvey (Company Secretary)

Financial History

Pharmaxis completed 2008 with A$112 million of cash, providing a strong position from which to progress our business in the forthcoming year.

Aridol sales in 2008 amounted to A$0.5 million, and were to customers in Australia where the product was launched at the end of 2006 and in Europe where a number of new individual marketing authorisations were received during the year. Additional sales came from pharmaceutical companies for use in clinical trials. Other income is predominantly research grant revenue.

Research & development expenses of $20 million in 2008 includes our drug discovery group which is working on PXS4159 and made up 11 per cent of our 2008 R&D spend; our preclinical group which has completed the work necessary for PXS25 to move into clinical studies and made up three per cent of our 2008 R&D spend; our clinical group which designs and manages our global clinical trial program and made up 56 per cent of our 2008 R&D spend; and our manufacturing operations which produce material for clinical trials and develop production processes, accounting or 30 per cent of our 2008 R&D spend. The decrease in R&D expenses in 2008 is primarily attributable to a reduction in the number and size of clinical trials in the active dosing stage during 2008 compared to 2007.

Commercial expenses of A$4.6 million include the costs of developing our sales and marketing infrastructure and supporting the development and awareness of our products with key respiratory clinicians around the world. Administration expenses of A$5.2 million include our finance, administrative, office, public company and professional service costs. Higher (non cash) costs in relation to employee share options were the major reason for the increase in both commercial and administration expenses in 2008 compared to 2007.

We invested A$5.1 million in 2008 in property, plant and equipment, the majority of which related to the fit-out and installation of manufacturing equipment in the company's new premises.

(prepared in accordance with Australian equivalents to International Financial Reporting Standards)

	Year ended 30 June			
	2008 A$	**2007 A$**	**2006 A$**	**2005 A$**
	(in thousands, except per share data)			
Income Statement Data				
Revenue from sale of goods	527	205	8	–
Cost of sales	(129)	(49)	(2)	–
Gross profit	398	156	6	–
Interest	7,402	5,278	4,282	1,702
Other income	1,576	2,152	1,299	1,219
Expenses				
Research & development	(19,996)	(23,840)	(16,978)	(9,269)
Administration	(5,231)	(4,666)	(4,391)	(3,134)
Commercial	(4,557)	(3,240)	(1,946)	(963)
Loss before income tax	(20,408)	(24,160)	(17,728)	(10,445)
Income tax expense	(32)	(19)	(5)	–
Loss for the year	(20,440)	(24,179)	(17,733)	(10,445)
	Cents	Cents	Cents	Cents
Earnings per share:				
Basic and diluted loss per share	(10.8)	(13.6)	(11.1)	(8.4)

	As at 30 June			
	2008 A$	**2007 A$**	**2006 A$**	**2005 A$**
Balance Sheet Data				
Cash and cash equivalents	111,842	76,182	97,840	33,390
Plant & equipment	3,668	3,521	3,205	2,477
Total assets	125,049	82,648	104,267	37,937
Net assets	119,121	76,559	98,888	35,467
Contributed equity	194,680	135,108	134,745	54,716
Share Data				
Ordinary shares on issue	194,515	177,949	176,904	134,770
Options over ordinary shares on issue	11,536	9,836	9,692	10,914

pharmaxis

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