pharmaxis

Breathe...

2010 Annual Review

This annual review

Pharmaxis' Annual Review provides shareholders with a summary of the company's activities for the year. For more detail, the 2010 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 cystic fibrosis, asthma and bronchiectasis, as well as chronic obstructive pulmonary diseases.

Based in Sydney, Australia and with offices in North America, Europe and China, Pharmaxis manufactures its two lead products – Aridol and Bronchitol – for commercial sale, clinical trials and compassionate use.

Our first commercial product, Aridol, assists in the detection of hyper-responsive airways. It is designed to assist in diagnosing and managing asthma. Aridol is available in Australia, Europe and South Korea, and marketing approval is being sought for the United States.

Our second product, Bronchitol, treats the serious lung disease cystic fibrosis by helping to restore normal lung clearance mechanisms. It has completed two Phase 3 clinical trials and is currently seeking marketing approval in Europe, Australia and soon the United States. An additional Phase 3 trial of Bronchitol in the lung condition bronchiectasis is also underway.

Pharmaxis' pipeline of new medicines is strong, with our researchers developing promising new therapies for severe asthma and the debilitating lung disease pulmonary fibrosis.

Notice of Meeting

The 2010 Annual General Meeting of Pharmaxis Ltd will be held at the Intercontinental Sydney, Corner of Bridge and Phillip Streets, Sydney on Wednesday, 20 October, at 2.30pm.

. . . better

with Pharmaxis

Pharmaxis is bringing fresh hope to people with serious respiratory diseases.

2009/2010 Highlights

- A second Phase 3 Bronchitol trial improves lung function in cystic fibrosis patients
- Potential new asthma treatment ASM8 reduces response to an allergen by up to 49%
- Bronchitol found to be effective over a year and a half in people with cystic fibrosis
- Applications filed in Europe and Australia to market Bronchitol for cystic fibrosis
- Purchase of Canadian pharmaceutical company Topigen Pharmaceuticals Inc
- New Pharmaxis factory and premises fully operational
- Pivotal Phase 3 study of Bronchitol in bronchiectasis commences
- New drug for pulmonary fibrosis, PXS25, successfully completes Phase 1 clinical trial
- US FDA Advisory Committee recommends approval of Aridol
- First Phase 3 trial results of Bronchitol in cystic fibrosis presented at international scientific meetings

CEO's Report

"For breath is life, and if you breathe well you will live long on earth." ~Sanskrit Proverb

This timeless adage has special resonance for people living with respiratory diseases like cystic fibrosis, bronchiectasis and asthma.

While many of us take breathing for granted, breathing is not effortless for people affected by respiratory diseases. For these people, breathing can often be hard and laboured, tingeing much of the person's life with pain and suffering.

Our objective is to bring Pharmaxis' life-changing medicines to people who can't breathe well.

Bronchitol delivers

Bronchitol, our therapy for treating people with the serious lung disease cystic fibrosis, has been the subject of two major worldwide clinical trials involving over 600 participants.

Our second large scale global clinical trial completed this year reinforced our earlier trial outcome – Bronchitol markedly improves the lung function of people with CF. In this second trial, Bronchitol delivered an 8.2%, or 107mL, increase in lung function over the 6 months treatment period.

This improvement is of important clinical relevance given that a person with CF will typically loose 1/2-2% of lung function every year.

With no new therapies approved for marketing to help with mucus clearance in over 15 years, the prospect of modifying the course of the disease with Bronchitol is very real indeed.

The combined body of evidence from this and the previous Phase 3 trial show Bronchitol to be an effective and safe drug. The results will form the basis of an application to market Bronchitol in the United States as soon as possible. Our plans are detailed further in this Review.

EU market for Bronchitol

Meanwhile, this year we have made steady progress in gaining European approval for Bronchitol to treat CF patients. The marketing application was submitted in October 2009 and has been under active review with the European Medicines Agency since then.

We are expecting a positive outcome, and have a robust sales and marketing strategy in place to support the European launch of Bronchitol. We have engaged the highly respected and experienced Quintiles organization to assemble a Pharmaxis contract sales force to spearhead our penetration across Europe.

An estimated 40,000 people are affected by CF in Europe, and Bronchitol has orphan drug designation, which provides for 11 years market protection.

Potent new asthma therapy

Pharmaxis' evolution to a specialist respiratory pharmaceutical company was enhanced this year with the purchase, of an exciting new asthma drug, ASM8. In March ASM8 reported outstanding results in a Phase 2 trial, reducing the response by asthmatics to their allergic trigger by an impressive 32-49 per cent.

ASM8 shows enormous promise

About 22 million people in the US have asthma, and medications offer good control for many patients. However, asthma is responsible for 4,000 deaths a year and half a million will be hospitalised. As many as 2.5 million patients have severe disease, experiencing frequent attacks despite daily medication.

It is this group of people that ASM8 is designed to benefit.

And lastly, our 10-year journey to becoming a fully integrated pharmaceutical company is now completed, after our move to custom-built new premises and a state of the art factory in Frenchs Forest, Sydney. The Australian Therapeutic Goods Administration licensed the factory to produce clinical trial medicines earlier this year.

While much has changed since our inception in 1999, our drive remains the same – to help people with respiratory diseases breath more easily.

We are excited by the future, and greatly appreciate your support in building an innovative and sustainable pharmaceutical company that is making a real difference to people's lives.

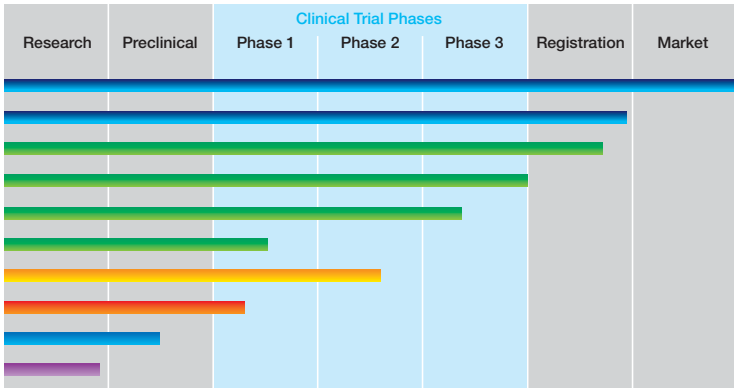
I am pleased to present our 2010 Annual Review.

Alan Robertson
Chief Executive Officer

25 August 2010

Product Review

Growing products and pipeline



Pharmaxis is committed to bringing innovative new products to patients living with undertreated diseases.

Our growing pipeline and portfolio of products available worldwide are testament to the company's drive to become one of the world's leading respiratory pharmaceutical firms. Pharmaxis strives to retain as much of the value chain as possible in the development of its new products.

Making treatments for…
Cystic Fibrosis

Bronchitol

Much of our efforts this year were focused on bringing Bronchitol to cystic fibrosis patients worldwide. Three key milestones were achieved:

→ **The completion of the second large-scale global Phase 3 clinical trial.**
The CF302 trial results were consistent with previous trials, with Bronchitol producing an improvement in lung function as measured by Forced Expiratory Volume in 1 second of 107 mL or 8.2%. This compares favourably to an improvement of 6.3% demonstrated in the first Phase 3 trial that is the subject of the European marketing application.

After delivering consistent and positive results in two major trials in over 600 patients, Pharmaxis will now be seeking US marketing approval for the drug. Intensive work is underway preparing for a pre-New Drug Application meeting with the US FDA. This will likely occur during the fourth quarter of 2010 and is the first step before submitting the formal New Drug Application to the US regulatory authorities. Bronchitol has received Orphan Drug Designation and fast track status from the FDA and has been the subject of numerous discussions with the FDA.

→ **European and Australian marketing applications filed.**
In October 2009 Pharmaxis submitted an application with the European Medicines Agency to market Bronchitol for cystic fibrosis in all European Union countries. Pharmaxis remains on track to receive a decision from the EMA later this year. Working to gain approvals on individual countries' public health formularies will be the focus of the year ahead.

A marketing application was also lodged with the Australian regulatory agency, the Therapeutic Goods Administration, in December 2009, to gain Australian approval. A final decision on the application is expected in the first quarter of 2011.

→ **Bronchitol found to be effective long-term.** The final stage of the first CF301 trial reported in May, showing that Bronchitol provides sustained benefit for people with CF, improving their lung function by 7.9% after 18 months. These results emphasises that Bronchitol has the potential to slow the progression of the disease. The results of the first Phase 3 trial were presented to capacity audiences of respiratory specialists at two international conferences this financial year – the North American Cystic Fibrosis Conference and the European Respiratory Society Annual Congress.

Asthma

ASM8

Pharmaxis' portfolio of potential new therapies has been boosted with the purchase of ASM8, an inhaled asthma molecule that delivered outstanding results in a Phase 2 trial announced in March.

ASM8 represents a new class of disease modifying anti-inflammatory drugs targeting the biochemical processes that cause asthma. ASM8 switches off the production of the proteins that cause so much damage in the asthmatic lung. This multi-factorial approach is something new and, we believe, is just what is needed to control the complex inflammatory process that typifies asthma. Today, in spite of the medications that are routinely used for asthma, about half a million people struggle for breath and are hospitalized in America each year and up to 15% of asthmatics experience frequent attacks— all too often requiring emergency-room care to end the gasping.

As a once-a-day inhaled medicine with a strong safety profile, ASM8 is already showing clear advantages over many of its in-market competitors, which require injections, intravenous transfusion, are expensive or have significant side-effects.

A second Phase 2 trial of longer duration will begin recruiting later this year.

Aridol

Sales of Aridol continued to grow steadily, rising 39% to total sales of $0.83 million this financial year. Aridol is available throughout Europe, South Korea and Australia, and has been the subject of more than 70 peer reviewed articles in major scientific journals.

Negotiations continue with the FDA to have Aridol approved for marketing in the US. We were pleased to receive a positive recommendation for Aridol by the US FDA advisory committee. While we were not granted the final approval on the legislated date, a resubmitted New Drug Application is now progressing, with a decision expected before the end of the year.

PXS4206

In an early research project, our drug discovery team has now designed a large library of small molecules that inhibit a critical protein responsible for inflammation in many diseases – including asthma.

PXS4206 represents the most exciting candidate from this work. PXS4206 has been shown to be a genuine anti-inflammatory agent and we have begun scale-up manufacture and pre-clinical safety studies before evaluating the compound in human trials.

Other lung diseases

Bronchiectasis

A pivotal 12-month Phase 3 trial of Bronchitol for bronchiectasis is underway, recruiting patients in nine countries including the United States, the United Kingdom and Australia. This study, B305, is based on our discussions with the FDA and EMA and will support a robust label claim in bronchiectatic patients where there remains a high unmet medical need.

Lung fibrosis

Pharmaxis' agent for pulmonary fibrosis, PXS25, has successfully completed its first clinical hurdle, delivering encouraging results in a Phase 1 trial. The study found the drug to be safe, well tolerated and with an excellent pharmacokinetic profile in healthy volunteers.

Pulmonary fibrosis affects over 500,000 people in the major pharmaceutical markets. Additional Phase 1 trials will be completed before PXS25 is evaluated in patients with lung disease.

COPD

PXS TPI1100 is a unique, inhaled, drug candidate in development to treat chronic obstructive pulmonary disease. It has been evaluated in preclinical models, and found to be very effective in reducing the inflammation associated with COPD. PXS TPI1100 represents a new and exciting addition to the drugs under development for COPD and in the forthcoming year will be moving into preclinical development.

Operations

TGA licenses new factory

Our new state of the art manufacturing plant in Rodborough Road, Frenchs Forest is now fully operational and the qualification work on the new equipment almost complete.

During the year, the Australian Therapeutic Goods Administration granted Pharmaxis a license for the manufacture of inhalation product for clinical trial and compassionate use purposes. A license for the manufacture of product for commercial sale will be sought after process validation is completed later this year.

The spray dryer successfully produces both Bronchitol and Aridol within our specifications. As one of the largest of its kind in the world, it has capacity to produce enough Bronchitol to treat 40,000 patients a year, and can be expanded to manufacture more if required. The automatic capsule filler, or encapsulator, is also now in place, with the capacity of filling 50,000 capsules an hour for world markets.

Governance

- In August last year Pharmaxis voluntarily de-listed from the Nasdaq Global Market. This follows a review of market requirements which found the benefits of the Nasdaq listing could no longer justify the related ongoing costs. The Company's primary listing on the Australian Securities Exchange continues without change.
- Detailed Director biographies can be found on our website www.pharmaxis.com.au and in the 2010 Statutory Annual Report.
- Pharmaxis has a Corporate Governance Framework which is reviewed and updated as necessary each year. A summary can also be found on our website and in our Statutory Annual Report.

Our Board of Directors is:

Denis M Hanley
Chairman

Alan D Robertson
Chief Executive Officer

William L Delaat
Independent Director

Malcolm J McComas
Independent Director

Richard van den Broek
Independent Director

John W Villiger
Independent Director

David McGarvey
Company Secretary and Chief Financial Officer

Financial History

Pharmaxis completed 2010 with a cash position of $86 million.

Research & development continues to be our major area of expenditure, increasing from $29 million in 2009 to $35 million in 2010. Research and development includes drug discovery (9%), preclinical development (3%), clinical development (62%) and manufacturing (26%). The largest expenditure increases were: in clinical development where we had three international Phase 3 trials dosing subjects during the year and had an active dialogue with regulators in the EU, US, and Australia; in manufacturing where we supplied product for clinical trials and progressed validation of the new manufacturing facility; and, in drug discovery where we added the Montreal laboratory following the acquisition of Topigen Pharmaceuticals Inc.

Commercial expenses of $5.7 million include sales and marketing costs and preparation for the commercial launch of Bronchitol for CF in Europe and the US and for Aridol in the US.

Administration expenses of $9.7 compares to $5.8 million in 2009. The increase relates to restructuring costs associated with the Topigen acquisition. Finance costs represent the finance charge associated with the capitalised finance lease of our new facility which commenced in May 2009, and the increase in 2010 reflects a full year's expense.

Aridol sales for 2010 of $0.8 million increased 40% from 2009. Australian, European and Korean sales grew 16%, 49% and 406% respectively.

In 2010 we invested $2.9 million in property, plant and equipment as we completed the manufacturing expansion. We also received $4.1 net cash from the acquisition of subsidiaries.

Year ended 30 June (in thousands, except per share data)	2010 A$	2009 A$	2008 A$	2007 A$	2006 A$
Income Statements					
Revenue from sale of goods	828	595	527	205	8
Gross profit	521	442	398	156	6
Interest	3,935	5,347	7,402	5,278	4,282
Other income	616	523	1,576	2,152	1,299
Expenses					
Research & development	(35,140)	(29,308)	(19,996)	(23,840)	(16,978)
Commercial	(5,657)	(6,202)	(4,557)	(3,240)	(1,946)
Administration	(9,715)	(5,800)	(5,231)	(4,666)	(4,391)
Finance expenses	(854)	(122)	–	–	–
Loss before income tax	(46,294)	(35,120)	(20,408)	(24,160)	(17,728)
Income tax expense	(51)	(51)	(32)	(19)	(5)
Loss for the year	(46,345)	(35,171)	(20,440)	(24,179)	(17,733)
	Cents	Cents	Cents	Cents	Cents
Earnings per share	(21.0)	(18.0)	(10.8)	(13.6)	(11.1)

As at 30 June	2010 A$	2009 A$	2008 A$	2007 A$	2006 A$
Balance Sheet Data					
Cash and cash equivalents	85,787	124,993	111,842	76,182	97,840
Plant & equipment	32,537	32,698	3,668	3,521	3,205
Total Assets	140,767	163,997	125,049	82,648	104,267
Total liabilities	25,751	26,306	5,928	6,089	5,379
Total shareholders' equity	115,016	137,691	119,121	76,559	98,888
Share Data					
Ordinary shares on issue	225,410	217,659	194,515	177,949	176,904
Options over ordinary shares on issue	13,155	15,075	11,536	9,836	9,692

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Pharmaxis Ltd

20 Rodborough Rd
Frenchs Forest NSW 2086
AUSTRALIA
Phone: +61 2 9454 7200
Fax: +61 2 9451 3622
Email: info@pharmaxis.com.au
Web: www.pharmaxis.com.au