Pharmaxis is developing human healthcare products for the treatment and management of respiratory and autoimmune diseases.

Company Overview

- We have a diversified portfolio of products at various stages along the path to international commercialisation.
- We are building a fully integrated pharmaceutical company with activities spanning research & development through to manufacture, marketing and distribution.
- Products include a new management tool for both asthma and chronic obstructive pulmonary disease (Aridol) and a new treatment for cystic fibrosis and chronic obstructive pulmonary disease (Bronchitol).
- Aridol is at the pre-market approval registration phase of its development.
- Bronchitol is at the Phase III stage of its clinical development in bronchiectasis and Phase II in cystic fibrosis.
- Projects include new treatments for multiple sclerosis (PXS25 and PXS2030) and for rheumatoid arthritis (PXS2076).

"Two clinical trials completed, one in progress"

Quarter Highlights

- Completion of patient enrolment of Aridol Phase III asthma clinical trial.
- Completion of patient enrolment for Bronchitol Phase II bronchiectasis trial.
- Announcement of results from Bronchitol Phase II clinical trial.
- Commencement of investigator sponsored UK trial with Aridol.
- Progress on the development of PXS25 for multiple sclerosis.
- Aridol for asthma pre-IND meeting held with the US Food and Drug Administration (FDA).
- Presentation of Bronchitol interim results from the Phase II bronchiectasis study at the European Respiratory Society in Glasgow, Scotland.

"Enrolment completed for Aridol and Bronchitol clinical studies"

Current Activities

Bronchitol

- Having completed a successful clinical trial in patients suffering with bronchiectasis, we are now in a position to implement the next steps in its development to bring this important new therapy to the marketplace. It is important that the right clinical trial is planned for the longer term clinical studies. To that end, we have been working with key centres treating the disease in Australia, Europe and the USA. In addition, we are part way through an extensive safety study to ensure that Bronchitol is safe to administer to patients over extended periods of time.

"Positive bronchiectasis results announced"

Aridol

- For Aridol, we recently completed the pre-registration clinical study and additional analysis of the results are in progress. We have commenced planning for the international launch of Aridol. The manufacturing facility is being expanded and, when finished, our capacity to produce Aridol and Bronchitol will be increased threefold. We are undertaking market research in the major territories of the world to ensure a successful launch following approval to market. In the forthcoming quarter our focus will be on the market development for Aridol to ensure demand is created for the product and that we meet that demand.

"Aridol and Bronchitol further development"

Facilities update

"Expansion of manufacturing facility on track"

Throughout the quarter, both Aridol and Bronchitol continue to be manufactured to satisfy demand from the various clinical trial sites and to complete the necessary stability and pre-clinical studies required for the registration of both Aridol and Bronchitol.

Research

Our research laboratories are located in Canberra where we are actively researching the mechanisms of autoimmune diseases such as multiple sclerosis and rheumatoid arthritis. We have identified a new approach to combating these diseases and our research group have made good progress towards identifying new drug candidates for development.

Preclinical Development

"PXS25 under development"

PXS25 is under development as an oral product for the treatment of multiple sclerosis.

PXS25 inhibits the function of an important protein that is required for the progression of multiple sclerosis. It is based on many years of research conducted by our scientists and has a unique approach to combating this diseases. Prior to evaluation in patients, PXS25 has to pass a number of safety hurdles and it is currently in that phase of its development.

Clinical Development

Aridol™

"Aridol Phase III study successful"

Aridol is a patented, inhalable, dry powder that can be administered using a convenient, hand-held device. It is designed to identify patients with active asthma and provide information on the severity of their disease and the effectiveness of their current treatment. We have just completed the largest clinical trial undertaken by an Australian company. In the trial, Aridol correlated well with patients diagnosed as asthmatic by an expert physician. Importantly, preliminary analysis of the Aridol test results also suggests that 25% of the asthmatic patients studied should have their medication increased or changed to improve control of their disease, and up to 17% could have their medication decreased without adverse effects.

The Phase III, open label, blinded, randomised, crossover trial commenced in January 2004, and studied 646 asthmatic and non-asthmatic subjects aged from 6 to 83 years, at 12 hospitals across Australia.

This successful completion of the study allows a marketing application to be submitted in Australia and Europe.

Bronchitol™ for Chronic Obstructive Pulmonary Disease (COPD)

"World first for Bronchitol in bronchiectasis"

Bronchitol is being evaluated as a therapeutic for people suffering from diseases such as bronchiectasis and chronic bronchitis. Bronchitol has been designed to restore a more normal quality of life for people with long term lung infections and congestion.

A 60 patient Phase II clinical trial has been completed in Australia and New Zealand in volunteers with bronchiectasis.

The results from the study were released in September. The trial was very successful and demonstrated that Bronchitol had a major impact on improving the quality of life for people suffering with bronchiectasis. This is the first time anywhere in the world that a new drug has shown to be of benefit for people with this disease. Most encouraging was the unsolicited feedback from people who had participated in the trial. Many of whom have asked us to accelerate the development programme and ensure this important product is brought to market as quickly as possible. We are responding to this request and expect to start the final pre-registration trials in the first half of next year.

"Bronchitol effective in treating bronchiectasis"

The results from this study are being prepared for publication and positions Bronchitol in a unique class. We are now working with key international respiratory physicians and eagerly await the commencement of the new study.

Bronchitol™ for cystic fibrosis

This multicentre Phase II study across Australia and New Zealand in patients with cystic fibrosis is recruiting steadily. The primary objective of the study is to improve quality of life and the lung function of patients following two weeks of treatment.

"Patient recruitment into the cystic fibrosis clinical study remains steady"

Recruitment into this study has accelerated during the last quarter particularly amongst children affected by the disease.

The study is expected to close during the fourth quarter.

Publications/Presentations

Aridol and Bronchitol have been the subject of more than 25 publications in peer reviewed journals by a variety of research laboratories throughout the world.

"Bronchitol at the European Respiratory Society meeting"

At the European Respiratory Society Annual congress held in Glasgow, Scotland on September 4-8, two presentations were made on the role of Bronchitol in treating bronchiectasis. In addition, one presentation was made on Aridol.

"New PCT application filed"

Intellectual Property

Our patent portfolio continues its journey without incident through the approval stages in the various territories.

During this quarter, Patent Family 6 has been filed as a single Patent Cooperation Treaty (PCT) international application for which we have designated the 120 member countries. Under the PCT, an international prior art search is conducted and this is in progress through the European Patent Office.

	USA	Europe	Australia	ROW
Patent Family 1 – Aridol and Bronchitol	G	P	G	P/G
Patent Family 2 – Phosphosugar based anti-inflammatory and/or immunosuppressive drugs	G	G	G	G
Patent Family 3 – Novel phosphosugars and phosphosugar-containing compounds having anti-inflammatory activity	G	n/a	G	n/a
Patent Family 4 – Novel compounds and methods	P	P	P	G/P
Patent Family 5 – Novel pyrans and methods (PXS25)	PCT	PCT	PCT	PCT
Patent Family 6 – Novel cannabinoid agonists (PXS2030)	PCT	PCT	PCT	PCT

*G = granted; P = pending; prov = provisional; PCT = Patent Cooperation Treaty; ROW denotes rest of the world including Japan
*Details of the patent portfolio can be found in the annual report

Financial Highlights

	Quarter ended 30 Sept 2004 $	Quarter ended 30 Sept 2003 $
Financial Performance		
Revenue		
Interest received	320,841	80,250
Research grants	323,179	433,549
Other		17,065
	644,020	530,864
Expenses		
Research & development	(2,376,830)	(978,042)
Commercial	(200,023)	–
Administration	(903,149)	(426,860)
Net loss before and after tax	(2,835,982)	(874,038)
Depreciation & amortisation	137,499	116,819

	Quarter ended 30 Sept 2004	Quarter ended 30 Sept 2003
Cash Flows		
Cash flows from operating activities	(2,043,583)	(1,088,156)
Cash flows from investing activities	(275,448)	(50,063)
Cash flows from financing activities	34,000	–
Net increase (decrease) in cash held	(2,285,031)	(1,138,219)

"Cash reserves of approximately $23 million"

	30 Sept 2004	30 June 2004
Financial Position		
Cash and bank accepted commercial bills	22,931,992	25,217,014
Plant & equipment	1,609,882	1,473,888
Intangible assets	1,163,865	1,161,909
Total assets	26,554,992	28,261,020
Total liabilities	2,576,742	1,480,789
Total shareholders' equity	23,978,249	26,780,231
Shares on Issue	108,240,000	108,016,000

- Cash and bank accepted commercial bills totalled $22.9 million at 30 September 2004.
- Research & development expenses, while 140% over the prior comparative quarter remained at a similar level to that of the June 2004 quarter. Clinical trials are the largest component of R&D expenses representing approximately 50 percent of the total. During the current quarter Pharmaxis had one clinical trial in its ongoing dosing phase and two trials completing the dosing phase and entering data analysis. Preclinical development expenses represent approximately 20 percent of total R&D expenses and during the current quarter were predominantly directed at mannitol toxicology studies required for the registration of Aridol and ongoing clinical trials of Bronchitol.

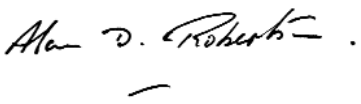
"Preparing for Aridol launch"

Manufacturing expenses represent approximately 20 percent of total R&D expenses, and during the current quarter were directed at both supplying clinical trial material and upgrading manufacturing processes and performance. The ANU based research group makes up the balance of the R&D expenses. It is focussed on autoimmune research and its expenditure does not vary significantly from quarter to quarter.

- Preparation for the market launch of Aridol has commenced. Therefore, we have separated our commercial expenses starting this quarter.
- Administration expenses have increased significantly over the prior comparative quarter and the June 2004 quarter, mainly as a result of costs associated with being a listed public company.
- Interest revenue as compared to the prior comparative quarter reflects the cash raised at the company's IPO in November 2003 and is comparable with the June 2004 quarter. Revenue from research grants varies directly with the level of underlying project research expenditure, which varies as the projects move through various stages.

Media

Financial & Corporate Relations Pty Ltd have been appointed to assist with investor communication.



Alan D Robertson
Chief Executive Officer

Contact Details

Further information on Pharmaxis can be obtained from www.pharmaxis.com.au or by contacting the Company Secretary.

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