

Pharmaxis is committed to the research, development and commercialization of human therapeutic products that improve the clinical management of chronic respiratory and autoimmune diseases.

“Three clinical trials in progress”

Company Overview

- Pharmaxis has 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.
- There are three clinical trials in progress, two in Phase II and one in Phase III.
- 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).
- Projects include new treatments for multiple sclerosis (PXS25 and PXS2030) and for rheumatoid arthritis (PXS2076).
- The company is supported by an experienced board of directors and led by a management team with extensive experience in successfully developing and bringing to market innovative products.

Quarter Highlights

- Pharmaxis was successful in its application for a \$6 million grant under the AusIndustry Pharmaceuticals Partnerships Program (P3).
- Over 450 people enrolled in the Phase III asthma clinical trial with Aridol.
- Over 50 people enrolled in the Phase II bronchiectasis trial with Bronchitol.
- Three new hospitals join the Phase II cystic fibrosis trial.
- Presentation of the results of Aridol in the management of chronic obstructive pulmonary disease (COPD) at the American Thoracic Society meeting in Orlando on Tuesday, 25 May 2004.
- PXS2076 discovered to be effective in controlling rheumatoid arthritis in a rodent model of human disease.

“\$6 million Federal Government grant awarded”

Expected Key Milestones/Activities

July

- Signing of P3 agreement with AusIndustry.
- Phase II Bronchitol study in bronchiectasis patients to close recruitment.
- Phase III Aridol study in asthma patients to close recruitment.
- Quarterly ASX report (Appendix 4C) lodged with the ASX.
- Meeting with US regulatory authority (FDA) on Aridol plans.

August

- Quarterly report issued to shareholders.
- June 2004 Preliminary Final Report to be filed with ASX.
- Commencement of investigator sponsored UK trial with Aridol.

September

- Results of Aridol Phase III study in asthma due.
- Results of Bronchitol Phase II study in patients with bronchiectasis due.
- Presentation of bronchiectasis study at European respiratory meeting.

“Two clinical trials scheduled to report in September”

“Expansion of manufacturing facility on track”

Facilities update

Preparation for the expansion of the clean rooms and warehousing to cater for the forecast demand for both Aridol and Bronchitol is well underway. Work is scheduled to commence during October 2004. Currently, the manufacturing facility is producing product for clinical trials and for long term stability trials.

A consultant group with experience in GMP manufacture have been appointed to assist with the project.

Personnel

28 full time staff are now employed by the company, an increase of three during the quarter. Appointments have been made in the areas of clinical trial management and manufacture.

Business Development

- A meeting is to be held with the Food and Drugs Administration (FDA) in the USA at the end of July to discuss the entry of Aridol to the USA. The outcome from this meeting will be known in August and will shape the strategy for Aridol in the USA.
- The US Asthma Clinical Trial Network and the US COPD Clinical Research Network have expressed their interest in working with Pharmaxis in relation to Aridol and its role in asthma and COPD.

“Strong US clinician support for Aridol”

Research

PXS2030

PXS2030 represents a new class of anti-inflammatory agent that inhibits immune cell trafficking. PXS2030 is believed to exert its pharmacological action through stimulation of specific receptors on the immune cell. Current studies are focused on its suitability as a clinical development candidate.

PXS2076

PXS2076 has been identified as a new compound that inhibits the release of inflammatory proteins from immune cells. One of the major inflammatory proteins released by immune cells is called TNF and a number of companies have achieved commercial and clinical success by blocking the effects of TNF. These approaches have involved inactivating TNF once it has been released, however, the drugs are large proteins given by injection. PXS2030 prevents the immune cell from releasing TNF and is active in models of rheumatoid arthritis. Studies are in progress to determine the suitability of PXS2076 as a clinical development candidate.

“PXS2076 inhibits TNF release and reduces RA severity in a rodent model”

Preclinical Development

PXS25 is being developed as an oral product for the treatment of multiple sclerosis. An independent study into the effects of PXS25 following oral administration in a rodent model of multiple sclerosis has been completed by a research institute in London, UK. This study showed that PXS25 was effective in reducing the severity of the disease and provides further support for the clinical development of PXS25.

The development of PXS25 has reached the stage of formal long term toxicity studies, which are required before the drug can be evaluated on patients. The formal development is now waiting for additional data from a new form of PXS25 that delivers PXS25 much more efficiently. This new form of PXS25 has significant advantages over the original form of the drug.

“New form of PXS25 under investigation”

Clinical Development

Aridol™

Aridol is a specific test for revealing the existence and extent of lung inflammation and has utility in the management of asthma and chronic obstructive lung disease (COPD). Currently, there is no convenient, specific test for asthma or for measuring its severity. Aridol offers an asthma sufferer the ability to use the minimum amount of preventative medication to ensure lung inflammation is controlled and the lungs are not subjected to excess anti-inflammatory drugs.

Aridol is currently being studied in a 600 patient Phase III clinical trial across 12 hospitals in Australia.

At the end of June 2004, over 450 subjects had been enrolled into the study. The study is scheduled to be completed in July 2004. The outcome of the study is expected to be proof that Aridol is an effective and safe bronchial challenge test with utility in the management of asthma. Positive trial results will be sufficient to allow a marketing authorization application to be submitted in Europe and Australia towards the end of the year.

Submission plans for the USA will be finalized following the meeting with the FDA at the end of July 2004.

Bronchitol™ for Chronic Obstructive Pulmonary Disease (COPD)

Bronchitol is being evaluated as a therapeutic option for people suffering from diseases such as bronchiectasis and chronic bronchitis. Bronchitol has been designed to enhance lung clearance, improve lung function and improve quality of life.

A Phase II clinical trial is being completed in Australia and New Zealand in volunteers with bronchiectasis. This study is scheduled to close enrolment of patients in July of this year. Once the final patients have completed their treatment, the data collected from the study will be analysed by an independent statistician. The results from the analysis will be made known to the company in September 2004. A positive outcome from this study will position Bronchitol for the final pre-registration Phase III study, which is scheduled to commence during the first quarter of 2005.

Bronchitol™ for cystic fibrosis

Bronchitol is being investigated in a multicentre Phase II study across Australia in patients with cystic fibrosis. The primary objective of the study is to improve quality of life and lung function. Recruitment into this study has been somewhat slower than the bronchiectasis study (above), reflecting amongst other things the smaller patient population. The consequence is that the study will not now close during the third quarter of this year but is expected to close during the fourth quarter. The study protocol has been well received by those trial participants that have completed the study so far. In recognition of the particular issues surrounding this patient group, we have added two hospitals in Perth and one in Auckland to the trial.

“Aridol clinical trial recruitment on schedule for mid-year completion”

“Patient recruitment into the Bronchitol clinical study on track”

“Additional hospitals join the cystic fibrosis clinical study to help with patient recruitment” Bronchitol clinical study on track”

“Aridol presented to American Thoracic Society”

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.

There have been no additional publications this quarter.

Two studies using Aridol as a lung function test were presented at the American Thoracic Society meeting in Florida, on 25th May 2004, by Jorge Leuppi from Basel, Switzerland.

1. A study on the value of using Aridol to determine those patients with chronic obstructive pulmonary disease that respond to steroid treatment.
2. A study on the effects of smoking cessation on the response to Aridol .

Governance

The Board has completed the implementation of the Pharmaxis Corporate Governance Framework. Details have been posted on the Pharmaxis web site.

Intellectual Property

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

	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)	prov			

*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 prospectus

During this quarter, Patent Family 5 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.

Media

An awareness campaign to assist with recruitment of volunteers for the final stage of the Aridol clinical trial was launched on 29 June 2004. This campaign resulted in Aridol and the clinical trial appearing on all the major television networks, and being reported in all the major National and Regional newspapers. In addition, a number of segments on the clinical trial appeared on the major radio stations.

An article on the company was published in the Perth newspaper, The West Australian on 22 June 2004 commenting on the Aridol and Bronchitol clinical trials.

Late News

- The Phase IIb clinical trial investigating the role of Bronchitol in the treatment of bronchiectasis completed its enrolment on 15 July 2004.
- The Phase III clinical trial investigating the role of Aridol in the management of asthma completed its enrolment on 30 July 2004.

“Aridol in the news”

“Two clinical trials close recruitment”

Financial Highlights

Pharmaxis Ltd
Quarterly Report to Shareholders
Financial Summary

	Quarter ended 30 June 2004 \$	Year ended 30 June 2004 \$	Year ended 30 June 2004 \$
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Financial Performance

Revenue

Interest received	355,370	1,075,380	284,417
Research grants	308,091	1,104,616	975,974
Other	–	48,002	43,058
	663,461	2,227,998	1,303,449

Expenses

Research & development	(2,541,361)	(6,047,014)	(1,789,762)
Administration	(678,776)	(2,181,653)	(981,220)
Net loss before and after tax	(2,556,676)	(6,000,669)	(1,467,533)
Depreciation & amortisation	130,295	489,808	255,734

Cash Flows

Cash flows from operating activities	(1,594,093)	(4,652,150)	(1,167,903)
Cash flows from investing activities	(33,271)	(405,589)	(1,652,353)
Cash flows from financing activities	–	22,890,839	9,453,320
Net increase (decrease) in cash held	(1,627,364)	17,833,100	6,633,064

	30 June 2004 \$	30 June 2004 \$
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Financial Position

Cash and bank accepted commercial bills	25,217,014	7,383,923
Plant & equipment	1,473,888	1,515,016
Intangible assets	1,161,909	1,205,000
Total assets	28,261,020	10,494,556
Total liabilities	1,480,789	604,495
Total shareholders' equity	26,780,231	9,890,061

- Cash and bank accepted commercial bills totalled \$25.2 million at 30 June 2004. Pharmaxis therefore remains well positioned to fund its clinical trial and preclinical development programs and the lead up to the commercial launch of Aridol.
- Research & development expenses have increased approximately 115% over the average of the first three quarters. The clinical trial component of this expenditure for the quarter increased by more than 200% over the average of the first three quarters reflecting the ongoing dosing stage in three trials and increased staffing in the clinical trial group. Expenditure by the preclinical development group increased by approximately 150% for the quarter compared to the average of the first three quarters reflecting increased work in both autoimmune and respiratory projects. Expenditure by the ANU based research group was marginally above prior quarter expenditure levels. Expenditure by the Frenchs Forest based manufacturing group was approximately 40% over the average for the first three quarters reflecting the increase in material produced for clinical trials and further work improving manufacturing performance.

“Cash reserves of
\$25.2 million”

- Administration expenses for the quarter increased approximately 35% over the average of the first three quarters reflecting public company costs only incurred since listing, the recruitment of additional staff, and annual incentive
- Interest revenue for the quarter was marginally below the March quarter while revenue from research grants increased in line with increases in the expenditure to which the grant relates.



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. Thank you for your support.

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