Quarterly Report to Shareholders No 8

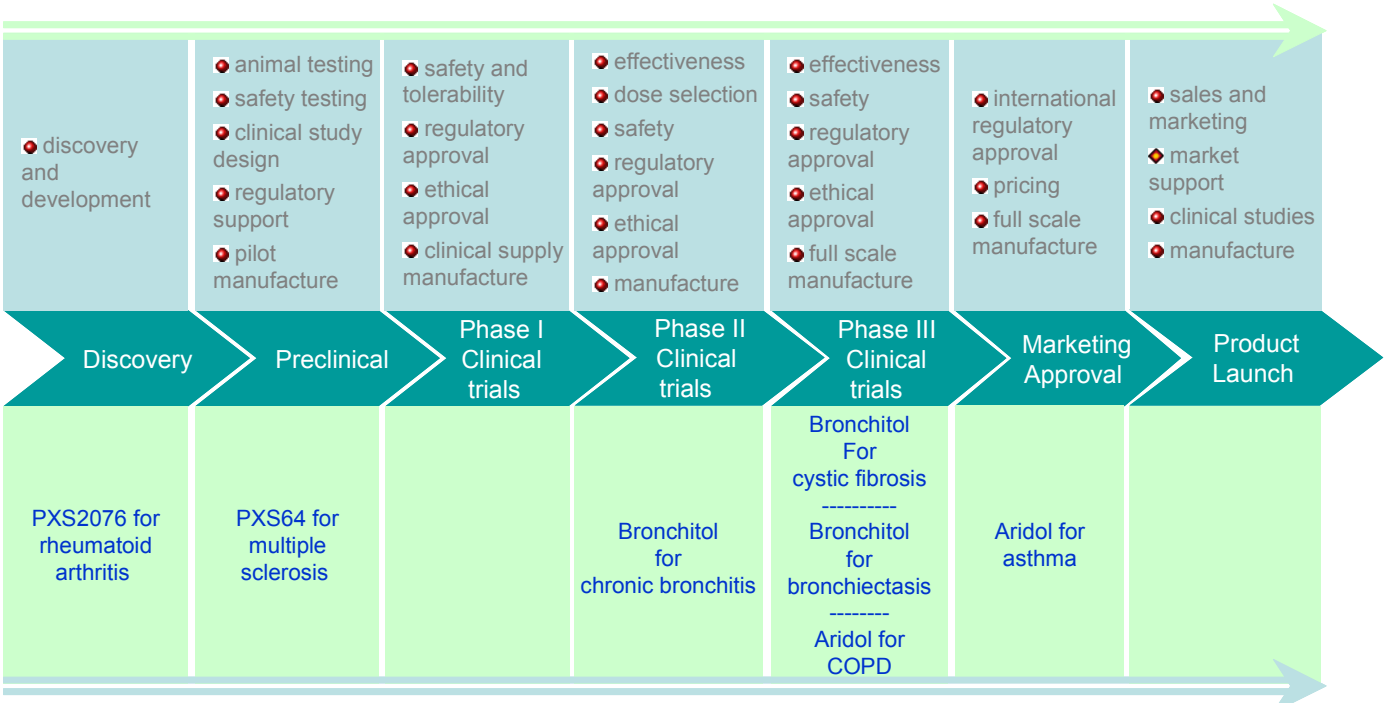
Alan D Robertson
Chief Executive Officer

July - September 2005

pharmaxis

Pharmaxis Ltd
ABN 75 082 811 630

The development of human healthcare products for the treatment and management of respiratory and autoimmune diseases.



Front cover: Bronchitol capsules

Overview

"New treatments for respiratory and autoimmune disease"

Our company is located in Sydney, Australia and is a specialty pharmaceutical business with activities spanning research & development through to manufacture, marketing and distribution.

Our interests include diseases of the lung - such as cystic fibrosis, asthma, bronchiectasis and chronic obstructive pulmonary disease and diseases of the immune system such as multiple sclerosis and rheumatoid arthritis.

Our 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).

Quarter Highlights

"Pharmaxis lists on NASDAQ"

⇒ Successful completion of the Phase II clinical trial with Bronchitol in patients suffering from cystic fibrosis.

⇒ The Canadian regulatory authorities approved the use of Bronchitol for a dose finding study in patients with cystic fibrosis.

⇒ First patient enrolment in the clinical trial to determine the role of Aridol in management of patients with chronic obstructive pulmonary disease (COPD).

⇒ A new Cooperative Research Centre for Asthma and Airways was established, with Pharmaxis as one of the three core industry participants.

⇒ Pharmaxis listed on the NASDAQ National Market.

Post Quarter Capital Raising Update

"$87 raised through global capital raising"

The shareholder letter this quarter has been delayed due to regulatory constraints that were in place as part of the global capital raising announced in October. The capital raising involved close co-ordination between banks in the USA and in Australia and resulted in the raising of $87 million. Shares were placed both here and on Nasdaq. On 26 September we announced the global capital raising and the transaction was completed successfully on 11 November. The US public offering was led by CIBC World Markets Corp and JMP Securities LLC served as co-manager. The Australian placement was managed by Wilson HTM Corporate Finance Ltd.

A total of 39.4 million shares (including 1.3 million American Depositary Shares) were issued bringing total shares on issue after the raising to 174.4 million.

In the US, 19.5 million shares (as 1.3 million American Depositary Shares—ADS) were issued to US institutional investors at a price of US$24.16 per ADS. Each ADS represents 15 ordinary shares in Pharmaxis.

In Australia, 19.9 million ordinary shares were issued to Australian and other non US institutional, sophisticated and professional investors at a price of A$2.20 per ordinary share, equivalent to the ADS price.

The issue price of A$2.20 represented a 10% discount to the five day value weighted average price at pricing and a 0.5% discount to the 30 day value weighted average price at announcement of the capital raising.

The net proceeds of the offering will be used to fund:

⇒ The clinical development of Bronchitol for cystic fibrosis

⇒ Additional clinical trials in asthma and chronic obstructive pulmonary disease to broaden the commercial opportunity for Bronchitol and Aridol

⇒ The international commercial launch of Aridol

⇒ Clinical development for Bronchitol in patients with bronchiectasis and chronic bronchitis and the investigation of additional clinical opportunities for Bronchitol

"Strong financial position to bring products to market"

⇒ Further expansion of Pharmaxis' manufacturing facilities

⇒ Further development of the preclinical pipeline

We are now in a position to bring to the international market place our two lead products (Bronchitol for cystic fibrosis and bronchiectasis and Aridol for asthma and chronic obstructive pulmonary disease). Both products offer significant commercial potential. Asthma now affects over 50 million people worldwide and chronic obstructive pulmonary disease is a global problem with over 100 million people affected. Sales of drugs to treat cystic fibrosis were over $500 million last year.

Forthcoming Events

"Anticipating Aridol approval "

❒	Anticipated 1st Aridol approval for asthma management	1H 2006
❒	Market launch of Aridol	1H 2006
❒	Completion of Aridol COPD management study	2H 2006
❒	Initiation of bronchiectasis Phase III study	1H 2006
❒	Initiation of cystic fibrosis Phase III study	2H 2006
❒	Initiation of chronic bronchitis Phase II study	2H 2006

Current Activities — Clinical

Bronchitol for cystic fibrosis

Bronchitol is under development to assist patients clear mucus from their lungs and is delivered as a dry powder in a convenient hand-held device for inhalation into the lungs.

"Cystic fibrosis study a success "

⇒ The results of CF201, the Phase II trial conducted in Australia were released in August. The aim of the trial was to show that Bronchitol improved mucus clearance as demonstrated by an improvement in lung function. This primary end-point was achieved, with patients gaining an average of 7% increase in FEV1 (the amount of air that can be forcibly expelled in a second) compared to placebo. Secondary end-points were also met: there was a 15.5% increase in maximum midexpiratory flow (MMEF), the most important parameter to measure small airway function, and an improvement in respiratory symptoms score, all relative to placebo. These very important results underscore the value of Bronchitol as a new treatment for people with serious lung congestion. The build up of mucus is a daily problem for people with diseases such as cystic fibrosis and bronchiectasis and we are moving this important new treatment rapidly through the development process.

⇒ In July, a Phase II cystic fibrosis study designed to determine the optimal dose of Bronchitol, received approval from Health Canada, Canada's regulatory authority. This study has now begun recruitment.

"Bronchiectasis study to begin"

Bronchitol for bronchiectasis

We are now well into the planning for B301, a Phase III trial with Bronchitol in bronchiectatic patients. The trial, to be run in Australia and in Europe, will be used to provide the necessary data required for marketing authorisation in these jurisdictions. We expect the first patient to enroll during the fourth quarter of

2005 or the first quarter of 2006. The trial will record symptom details over an eight month period. We aim to show an improvement in quality of life as measured by cough-free periods, ability to exercise, quality and ability to sleep and lung function capacity.

Aridol for asthma

"US Aridol study ready to commence"

Aridol is an inhalable dry powder that can be administered using a convenient, hand-held device. It is designed to identify patients with active airway inflammation such as occurs in asthma, provide information on the severity of their disease and the effectiveness of their current treatment.

⇒ An additional trial requested by the Food and Drug Administration (FDA), the responsible regulatory agency in the U.S., is at the commencement stage. The protocol for the trial has been agreed with the FDA, and we expect the first patient to be enrolled in Q4 2005.

Aridol for chronic obstructive pulmonary disease

"COPD study underway"

In addition to its utility in detecting airway inflammation in patients suspected of having asthma, Aridol can also be used in patients with COPD suspected of having airway inflammation. This subset comprises approximately 20-25% of patients and are the group most likely to have a positive treatment response to inhaled anti-inflammatory drugs. Currently there is no effective method to determine this subgroup of patients.

⇒ A new trial in chronic obstructive pulmonary disease (COPD) will look at the ability of Aridol to predict a positive response to steroids when used to treat COPD. This trial (COPD201) is being run in Australia in general practice surgeries and specialist clinics. The first patient was entered into the study during September, results are expected in the middle of 2006 and the outcome of the study will allow us to expand the market for Aridol beyond asthma management.

Current Activities — Research

PXS64 is under development as a new treatment for multiple sclerosis. It is currently in the safety testing phase of development prior to seeking approval for a clinical study.

PXS2076 is being investigated as a possible treatment for rheumatoid arthritis. It is in the research phase as we study the effects of the molecule in various biological systems.

Current Activities — Marketing

"Pharmaxis joins new Cooperative Research Centre"

During this past quarter, Pharmaxis also joined the newly formed Cooperative Research Centre for Asthma and Airways (CRCAA). Its formation was marked by a public celebration opened by the Minister for Health, Tony Abbott. The CRC which previously researched asthma-related diseases had its charter expanded to include all airways diseases in recognition of the common importance of inflammation in asthma and other lung diseases. The CRC has three core areas of airways research: diagnosis and monitoring, new treatments and assessing the consequences of air quality.

Pharmaxis was represented at the annual European Respiratory Society meeting held in Copenhagen during September. Four posters describing the use of Aridol in diagnosing and managing asthma were presented and meetings held with several European investigators.

In preparation for the launch of Aridol in 2006, the marketing department has hired a Head of Sales and Marketing to begin work on 01 November. Joanne Prior has considerable experience in the launch of new products. Most recently Jo was marketing manager, OTC (over the counter) Pharmacy at Sanofi-Aventis, and earlier held a number of management positions in marketing and sales with Sanofi-Synthelabo.

Publications/Presentations

Over 38 scientific articles have been published on the technology. Articles that have been published this quarter include:

"Four new publications on Aridol"

1. **Dissociation in the effect of necrodomil on mannitol-induced cough or bronchoconstriction in asthmatic subjects** by H O Koskela, R. Martens, J D Brannan, SD Anderson, J Leuppi, H-K Chan. Respirology (2005) 10; 42-448
2. **Airway hyperresponsiveness in asymptomatic subjects: is bronchial provocation with mannitol a more specific test?** By CM Porsbjerg, ML Rasmussen, FS Thomsen, JD Brannan, SD Anderson, V Backer. ERS 2005 abstract 1463.
3. **Effect of treatment on recovery to mannitol challenge: a phase 3 study** by JD Brannan, R Freed-Martens, SD Anderson, The Aridol Study Group. ERS 2005 Abstract 2394
4. **Montelukast sodium (MS) in addition to sodium cromoglycate (SCG) on the airway response to the same cumulative dose of inhaled mannitol** by JD Brannan, C Caillaud, SD Anderson ERS 2005 Abstract 2393

Intellectual Property

There have been no changes to the patent portfolio during this quarter.

"IP position unchanged"

	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	G	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

Financial Highlights

Australian Generally Accepted Accounting Principles

(Unaudited)
('000 except per share data)

Financial Performance

	Three months ended	
	30-Sep-05	30-Sep-04
Revenue		
Interest received	439	321
Research grants	358	335
Other	-	-
	797	656
Expenses		
Research & development	(2,443)	(2,376)
Commercial	(176)	(200)
Administration	(930)	(903)
Expense arising from employee option plan	(156)	(47)
Total expenses	(3,705)	(3,526)
Net loss before and after tax	(2,908)	(2,870)
Basic and diluted earnings (loss) per share	(0.02)	(0.03)
Depreciation & amortisation	225	137

Financial Position

	As at	
	30-Sep-05	30-Jun-05
Cash and bank accepted commercial bills	30,040	33,389
Plant & equipment	2,681	2,477
Intangible assets	1,092	1,106
Total assets	35,292	37,937
Total liabilities	2,528	2,369
Total shareholders' equity	32,764	35,569

Share Data	30-Sep-05	30-Jun-05
Ordinary shares on issue	134,982	134,770
Equivalent ADSs on issue	8,999	8,985
Options over ordinary shares on issue	11,302	10,914

Pharmaxis finished the quarter with $30.0 million in cash and bank accepted commercial bills. Together with approximately $80 million net proceeds from the recent global capital raising, we are well funded to progress our business plan.

Research & development expenditure for the quarter was in line with the prior comparable quarter, but lower than expenditure in the previous quarter, primarily due to a lower level of active clinical trial work. Our clinical trial programs continue to account for the highest proportion of our R&D activities, followed by manufacturing and pre-clinical research. During the current quarter, the clinical group completed the cystic fibrosis Phase II study, while also preparing studies for Bronchitol in cystic fibrosis (US, UK and Australia) and bronchiectasis (US, UK, Australia and New Zealand), and Aridol in asthma (US) and chronic obstructive pulmonary disease (Australia); the manufacturing group has focused on stability studies necessary to support regulatory applications; and pre-clinical expenditure has been predominantly directed towards extended toxicology studies on Aridol and Bronchitol.

Commercial expenditure includes costs associated with preparations for the commercial launch of Aridol and these activities will increase in the next two quarters. Administration expenditure for the quarter included the final costs associated with our listing on the NASDAQ National Markets in August.

Financial Highlights (II)

US Generally Accepted Accounting Principles

(Unaudited)
('000 except per share data)

Statement of Operations

	Three months ended	
	30-Sep-05	30-Sep-04
Revenue	-	-
Operating expenses		
Research & development	2,061	2,019
Commercial	176	200
General and administrative	930	903
Fair value of stock options issued to employees related to:		
Research & development	92	17
Commercial	29	-
General and administrative	35	30
Total operating expenses	3,323	3,169
Loss from operations	(3,323)	(3,169)
Interest and other income	439	321
Amortization of preference share issue expenses	-	-
Net loss	(2,884)	(2,848)
Basic and diluted net loss per ADS	(0.32)	(0.40)
Depreciation & amortisation	213	126

Balance Sheet Data

	As of	
	30-Sep-05	30-Jun-05
Cash and bank accepted commercial bills	30,040	33,268
Plant & equipment	2,592	2,376
Intangible assets	1,092	1,106
Total assets	35,203	37,836
Total liabilities	2,439	2,369
Total shareholders' equity	32,764	35,467

Due to our listing on the NASDAQ National Market in August 2005 we are now also providing financial information prepared under US Generally Accepted Accounting Principles (US GAAP). The major difference between US and Australian GAAP apart from presentation format is that under US GAAP we offset research grants against research expenditure.

Chief Executive Officer

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