Quarterly Report to Shareholders No 9

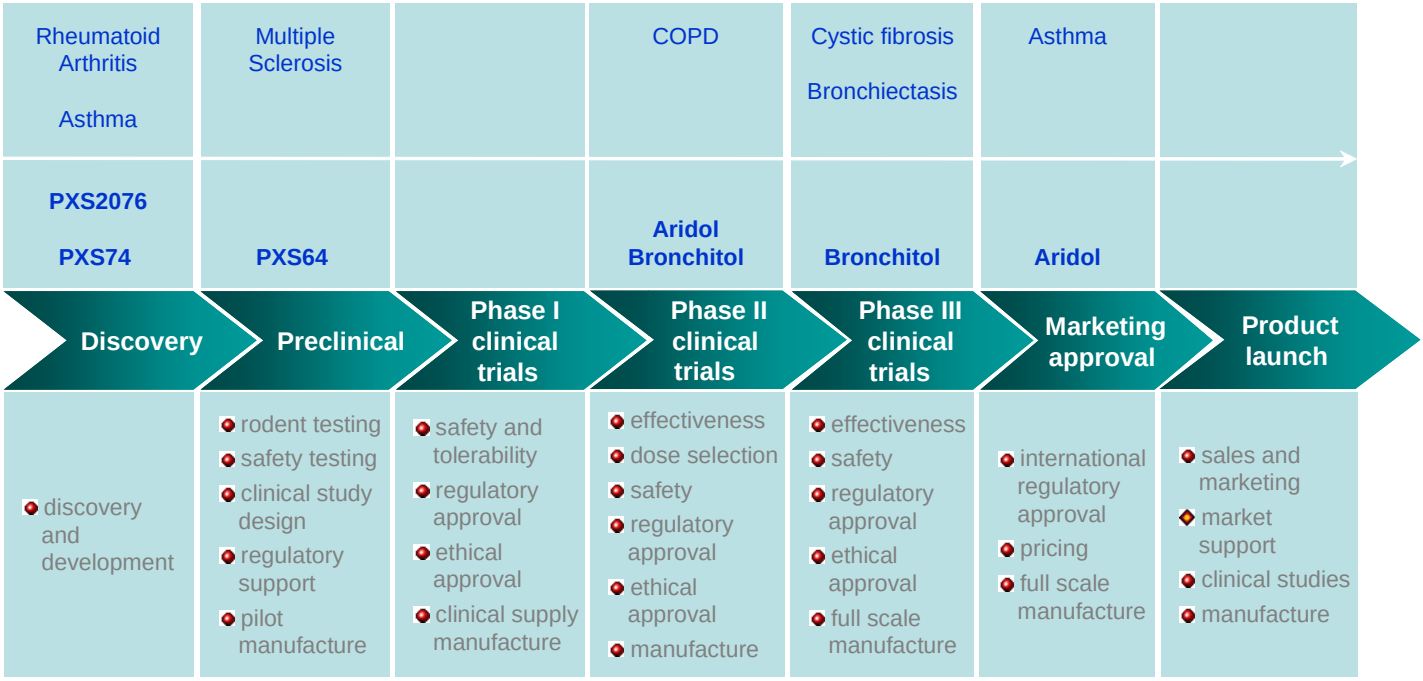
pharmaxis

October—December 2005

Pharmaxis Ltd
ABN 75 082 811 630

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

Product Development at Pharmaxis



COPD = Chronic Obstructive Pulmonary Disease - a fatal disease related to smoking

Front cover: *John Brannan, Aridol Research Fellow at McMaster University, Canada and first listed author of 'The safety and efficacy of inhaled dry powder mannitol….' see p6, Publications.*

Overview

"New treatments for respiratory and autoimmune disease"

We are a specialty pharmaceutical business with activities spanning product research & development through to manufacture, sales and marketing.

Our therapeutic 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.

Aridol is the furthest advanced product for the management of both asthma and chronic obstructive pulmonary disease and behind Aridol, Bronchitol is being developed as a new treatment for cystic fibrosis and chronic obstructive pulmonary diseases.

Quarter Highlights

"Three new trials commence enrolment"

- ❒ Bronchitol European cystic fibrosis trial enrolled first patients
- ❒ Bronchitol cystic fibrosis dosing study enrolled first patients
- ❒ US Phase III Aridol trial enrolled first patients
- ❒ European Orphan Drug designation granted to Bronchitol for cystic fibrosis
- ❒ Completion of a global capital raising totaling $87 million
- ❒ Annual General Meeting in November 2005

Anticipated Forthcoming Events

"Anticipating first product launch"

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

Current Activities — Clinical and Regulatory

Bronchitol for cystic fibrosis

"Two CF trials begin enrolling patients"

Bronchitol is delivered as a dry powder in a convenient, hand-held device for inhalation into the lungs. Patients with cystic fibrosis have a depleted layer of fluid that surrounds the lung surface and this causes a weakening of lung defence and a breakdown in normal lung clearance. Bronchitol is designed to rehydrate the fluid layer surrounding the lungs, to improve mucus clearance and thus restore lung function. This quarter, two Bronchitol CF trials enrolled their first patients.

⇒ In November, CF-202, our Canadian dose-ranging study enrolled its first patient. This study is designed to compare the clinical effects of different doses of Bronchitol in the same patient, with the aim of determining the most effective dose for future use.

⇒ In December, CF-203, a trial comparing Bronchitol with existing treatments began in the UK. Pulmozyme is the most commonly prescribed drug to improve mucus clearance in cystic fibrosis. We aim to

determine how Bronchitol works with, and in comparison to, Pulmozyme. The trial is being conducted in children who might benefit most from improved lung function.

"European Orphan Drug for Bronchitol"

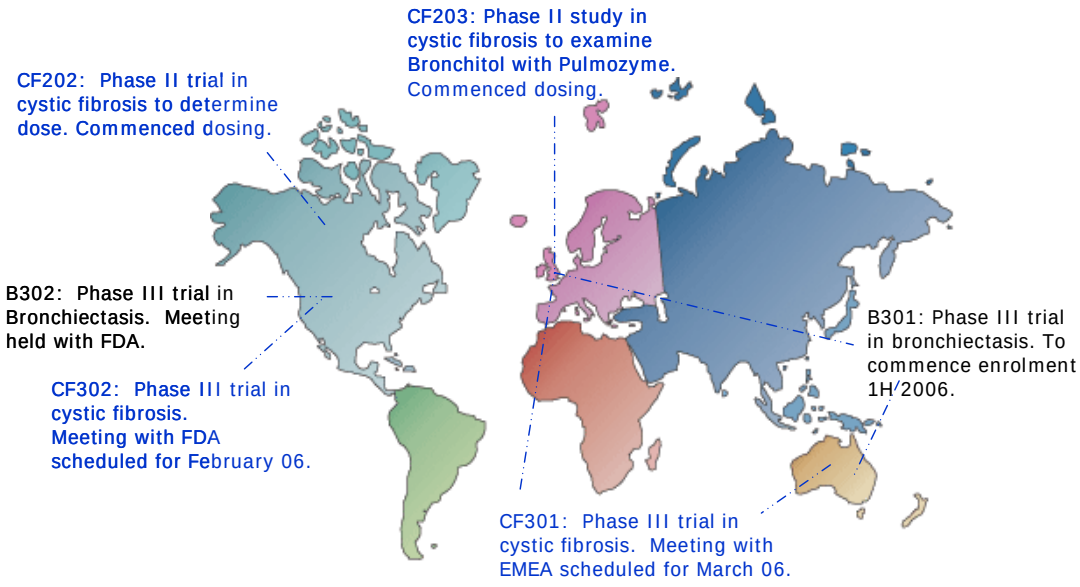
⇒ During the quarter, Bronchitol also received Orphan Drug status from the European Medicines Agency (EMEA). Orphan designation is granted to products intended for the diagnosis, prevention and treatment of diseases affecting not more than 5 in 10,000 people in the European Community. It entitles Pharmaxis to a range of incentives including a 10-year period of market exclusivity, protocol assistance to optimise drug development in the designated indication, reduction in registration fees and eligibility for grants and incentives supporting research and development.

Bronchitol for bronchiectasis

"Bronchiectasis trial awaits first patient"

The planning and set up for the multinational Phase III study is now complete and most ethics and regulatory approvals have been granted. The study, being run in Australia, New Zealand and the UK, will record symptom details over a three month treatment period. We aim to show an improvement in quality of life, the ability to exercise and sleep, and the lung function of patients receiving Bronchitol.

Bronchitol development worldwide



Aridol for asthma

Aridol is an inhalable dry powder that 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. Marketing applications have been submitted in Europe and in Australia.

"US asthma trial enrols first patient"

⇒ A US-based trial, A-305, is required for Aridol registration in the US. This trial enrolled its first patient in December and we anticipate trial recruitment to be completed by mid 2006. Following completion of the trial we intend to lodge the US marketing application with the FDA.

Aridol for chronic obstructive pulmonary disease

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 the approximately 30 million patients with COPD in the western world, 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.

"Expanding the utility of Aridol"

⇒ The first patient in our Australian-based trial, COPD-201, was enrolled in September. The trial is required to document and confirm a formal link between lung inflammation as detected by an Aridol test, and a positive response to inhaled corticosteroids in patients with COPD. A much smaller investigator-led trial indicated that this was the case, and we anticipate the larger numbers of patients in the COPD-201 trial will confirm those earlier findings. Trial closure is expected mid 2006.

Current Activities – 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.

PXS64 is under development as a new treatment for multiple sclerosis.

PXS2076 is being investigated as a possible treatment for rheumatoid arthritis.

Current Activities — Marketing

We expect the first markets to register Aridol for commercial sale to be Australia and Sweden. Launch preparations for Aridol in both markets are now underway and are likely to follow a similar path. We will:

"Marketing preparations for Aridol"

Build a marketing and sales force. In Australia, Pharmaxis will market Aridol directly. We have recruited a National Sales and Marketing manager and a sales team will be recruited and trained shortly before product launch. In Sweden we have recently announced the signing of Nigaard Pharma as our marketing partner. They too have hired a sales and marketing manager for Aridol and will build a dedicated Sales team in the months ahead. Market research to complete our understanding of market needs in diagnosis and management of Asthma is currently being completed in both Australia and Europe. We can then:

Prepare promotional materials / pricing for the Sales teams to use in meetings with clinicians. Our European partners will use similar materials to ensure Aridol becomes a global brand with consistent promotional claims and brand image.

Introduce Aridol to the market in several distinct steps:

The main group of people performing bronchial challenge tests are respiratory lab staff. They must understand Aridol's unique features before the clinicians can refer their first patients. Thus in the first 3 months after registration, **Respiratory Laboratories** will be our target for training in both performance and interpretation of the test.
Respiratory specialists refer the patients to laboratories for testing and in some markets undertake the tests themselves. We will approach **Respiratory specialists** and present the clinical data supporting Aridol and outline the kind of patients who will benefit from Aridol.
For Aridol to be used within a hospital it must be included in the hospital's formulary. **Hospital listing** is a rigorously controlled process for products used within their facilities. Usually, a 'Formulary Committee' reviews requests from clinicians and health economic data before approving the purchase of new products. The Hospital Formulary submission document is in preparation.

"Expanding the marketing effort"

A **Primary Care Physicians** education program will begin about 9 months after registration. In some markets primary care (PC) physicians are a major source of patient referrals to respiratory laboratories. At present, very few PC physicians undertake the testing themselves so an additional program to promote Aridol to those interested will be necessary to realize Aridol's full potential.

This first wave of promotion will focus on how Aridol can benefit physicians wishing to accurately diagnose and assess asthma in their patients. We will utilize promotional media such as sales representatives, advertising and congresses to communicate Aridol's main features and its benefits to our customers. As new data from our clinical trials becomes available, we will repeat the cycle and expand the market to include Aridol's use in managing asthma and identifying COPD patients who respond to steroids.

Publications / Presentations

"Aridol Phase III study results published"

Over 40 scientific articles have been published on the technology. Articles that have been published this quarter include:

1. The safety and efficacy of inhaled dry powder mannitol as a bronchial provocation test for airway hyperresponsiveness: a phase 3 comparison study with hypertonic (4.5%) saline. JD Brannan, SD Anderson, CP Perry, R Freed-Martens, AR Lassig, B Charlton and The Aridol Study Group. Respiratory Research, 2005,**6:**144 doi:10.1186/1465-9921-6-144

Intellectual Property

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

"No changes to patent portfolio"

	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 Summary

As a result of Pharmaxis listing on Nasdaq in August 2005 our financial statements are presented in both Australian and US Generally Accepted Accounting Principles (GAAP). The major differences between the two GAAPs, apart from presentation format and line item descriptions are:

- In the US GAAP Statement of Operations we offset research grants against research expenditure,
- In the US GAAP Statement of Operations we separately report the amortization of intangibles from research expenditure. This is included in research expenditure as reported under Australian GAAP.

In the US GAAP Balance Sheet, research grants received in relation to plant & equipment is netted against the cost of the plant and equipment. Under Australian GAAP the grant is deferred as a liability and amortized over the life of the plant and equipment.

Australian GAAP financial statements are prepared in accordance with Australian Equivalents to International Financial Reporting Standards (AIFRS). Details of our adoption of AIFRS are outlined in the Half Year Report lodged with the ASX and also available on the Pharmaxis website.

The US public offering and Australian placement in November 2005 raised $79.5 million and consequently Pharmaxis finished the quarter with $106 million in cash and cash equivalents.

Research and development expenses for the three months ended 31 December 2005 were over 65% above the level of expenditure in the prior comparable quarter and over 25% above the level of expenditure in the three months ended 30 September 2005. Our clinical trial programs are consistently the largest component of our research, and this quarter also accounted for approximately half of the increase in expenditure. We commenced the dosing phase of three clinical trials during the quarter - Aridol Phase III for asthma (USA), Bronchitol for cystic fibrosis Phase II dosing study (Canada) and Bronchitol for cystic fibrosis Phase II comparator study (UK). The Aridol for COPD Phase III trial in Australia continues recruiting. Preparation for Bronchitol Phase III clinical trials in cystic fibrosis and bronchiectasis also continues. Manufacturing work associated with stability studies for product registration and pre-clinical toxicology studies on Aridol and Bronchitol accounted for the remainder of the increased expenditure.

Commercial expenses for the quarter have increased as the Company continues its preparation for the commercial launch of Aridol in Australia and Europe. Administration expenses for the quarter have increased as a result of costs associated with hiring new employees, an increased level of investor relation activity, and the increase in the size of the Company - we now employ fifty staff.

Investing activities for the quarter included the installation of a new encapsulator and laboratory equipment to increase QC capacity.

Alan D Robertson
Chief Executive Officer

Further information on Pharmaxis can be obtained from www.pharmaxis.com.au or by contacting Jane Sugden, Investor Relations.

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Australian Generally Accepted Accounting Principles
(Unaudited)
('000 except per share data)

Income Statement

	Three months ended		Half year ended	
	31-Dec-05	31-Dec-04	31-Dec-05	31-Dec-04
Revenue				
Interest	997	390	1,436	711
Other income				
Grant income	72	155	430	490
Other	-	-	-	-
	1,069	545	1,866	1,201
Expenses				
Research & development	(3,113)	(1,886)	(5,646)	(4,279)
Commercial	(397)	(120)	(603)	(320)
Administration	(1,217)	(663)	(2,182)	(1,596)
Total expenses	(4,727)	(2,669)	(8,431)	(6,195)
Net loss before and after tax	(3,658)	(2,124)	(6,565)	(4,994)
Basic and diluted earnings (loss) per share	(0.023)	(0.018)	(0.045)	(0.044)
Depreciation & amortisation	307	137	532	274
Expense arising from employee option plan	247	47	403	94

Balance Sheet Data

	As at	
	31-Dec-05	30-Jun-05
Cash and cash equivalents	106,434	33,389
Plant & equipment	2,950	2,477
Intangible assets	1,077	1,106
Total assets	111,875	37,937
Total liabilities	2,969	2,470
Total shareholders' equity	108,906	35,467

Cash Flow Data

	Three months ended		Half year ended	
	31-Dec-05	31-Dec-04	31-Dec-05	31-Dec-04
Net cash flows from operating activities	(2,596)	(2,740)	(5,579)	(4,784)
Net cash flows from investing activities	(562)	(313)	(976)	(588)
Net cash flows from financing activities	79,552	18,981	79,600	19,015
Net increase (decrease) in cash held	76,394	15,928	73,045	13,643

Share Data

	As at	
	31-Dec-05	30-Jun-05
Ordinary shares on issue	174,454	134,770
Equivalent ADSs on issue	11,630	8,985
Options over ordinary shares outstanding	11,720	10,914

US Generally Accepted Accounting Principles
(Unaudited)
('000 except per share data)

Statement of Operations

	Three months ended		Six months ended	
	Dec-31-05	Dec-31-04	Dec-31-05	Dec-31-04
Revenue	-	-	-	-
Operating expenses				
Research & development	2,904	1,692	4,965	3,711
Commercial	362	120	538	320
General and administrative	1,119	633	2,049	1,535
Amortization of intangible assets	23	22	46	45
Fair value of stock options issued to employees				
Research & development (Options)	120	17	212	34
Commercial (Options)	29	-	58	-
General and administrative (Options)	98	30	133	60
Total operating expenses	4,655	2,514	8,001	5,705
Loss from operations	(4,655)	(2,514)	(8,001)	(5,705)
Interest and other income	997	390	1,436	711
Net loss	(3,658)	(2,124)	(6,565)	(4,994)
Basic and diluted net loss per ADS	(0.023)	(0.018)	(0.045)	(0.044)
Depreciation & amortisation	295	125	508	251

Balance Sheet Data

	As of	
	Dec-31-05	Jun-30-05
Cash and cash equivalents	106,434	33,268
Plant & equipment	2,873	2,376
Intangible assets	1,077	1,106
Total assets	111,797	37,836
Total liabilities	2,891	2,369
Total shareholders' equity	108,906	35,467

Cash Flow Data

	Three months ended		Six months ended	
	Dec-31-05	Dec-31-04	Dec-31-05	Dec-31-04
Net cash used in operating activities	(2,596)	(2,772)	(5,458)	(4,780)
Net cash used in investing activities	(562)	(313)	(976)	(588)
Net cash provided by financing activities	79,552	18,981	79,600	19,015
Net increase in cash and cash equivalents	76,394	15,896	73,166	13,647