Quarterly Report to Shareholders No 11

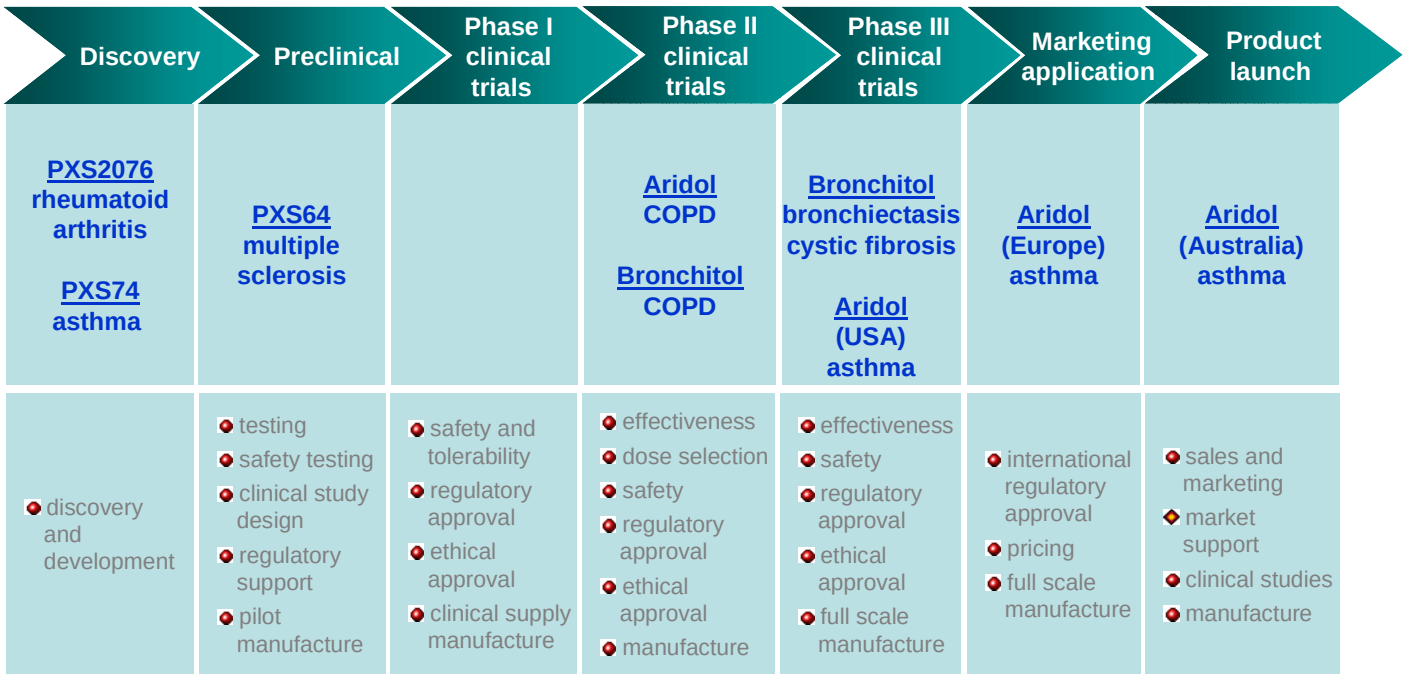
April—June 2006

pharmaxis

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 of the lungs, related to smoking

Front cover: Gary Phillips, Jo Prior and Philip Gregory from the marketing department

Overview

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

"New treatments for respiratory and autoimmune disease"

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.

Our first product, Aridol, is now registered for sale in Australia to identify hyperresponsive airways associated with asthma. Aridol is designed to assist in the management of both asthma and chronic obstructive pulmonary disease. Our second product, Bronchitol, is in final clinical trials as a new treatment for cystic fibrosis and chronic obstructive pulmonary diseases such as bronchiectasis and chronic bronchitis.

Quarter Highlights

"First sales in Australia and in the USA

⇒ US FDA meeting to agree final cystic fibrosis clinical trials

⇒ EMEA protocol assistance meeting for cystic fibrosis trial

⇒ Aridol in COPD trial completes enrolment

⇒ Bronchitol in bronchiectasis Phase III trial enrolls first patient

⇒ First Aridol sales in Australia

⇒ First Aridol sales to a US biopharmaceutical company

⇒ Successful TGA audit enabling commercial manufacture

Anticipated Forthcoming Events

⇒ Aridol marketing authorisation in Sweden	2H 2006
⇒ Appointment of additional European distributors	2H 2006
⇒ Completion of US Aridol asthma trial	2H 2006
⇒ Aridol marketing authorisation in other EU countries	2H 2006
⇒ Completion of Aridol COPD management study	2H 2006
⇒ Completion of Bronchitol cystic fibrosis dosing study	2H 2006
⇒ Initiation of Bronchitol cystic fibrosis Phase III study	2H 2006

Current Activities— Regulatory

Aridol marketing authorisation in Sweden

"Anticipating European registration"

The dossier seeking approval to market Aridol in Sweden was filed with the Swedish Medical Products Agency in May 2005. Approval in Sweden provides entry to rest of the European Union through what is known as "the mutual recognition procedure". The Swedish review has taken longer than the average review period advertised by the Swedish agency and longer than the directive issued by the European Commission. This reflects an increased workload for the agency rather than any difficulties with the application or with Aridol. Fortunately, the formal review process has finally begun and we expect a decision in the third quarter of the year.

A successful TGA audit of our manufacturing facility in April resulted in a licence being issued to manufacture Aridol for commercial sale.

Current Activities—Marketing

Aridol commercial launch

"Australian sales force appointed"

Aridol was launched to the Australian pulmonary specialist community at the Thoracic Society of Australia and New Zealand annual conference in late March. A sales force of six was recruited and trained during the quarter. We organized a series of state-based Aridol educational seminars that were attended by over half of the key respiratory physicians and senior scientists in the country, and a series of state-based training seminars where over 65% of respiratory laboratories were represented. The sales force is now focusing on visiting individual respiratory laboratories to continue training in administering the Aridol test. Approximately 70% of respiratory laboratories have registered as customers. Product was available from mid June enabling initial orders to be shipped and first revenue from product sales to be booked. We also received a large order to supply Aridol to a US pharmaceutical company for a series of Phase II trials involving their potential new treatment for asthma.

Current Activities — Clinical

In May, we attended an end of Phase II meeting with the FDA, the US regulatory agency, and a protocol assistance meeting with the European regulatory agency, the EMEA in relation to our Phase III cystic fibrosis clinical trials for Bronchitol. Planning for both Phase III trials is now well advanced.

We have currently five major clinical trials in progress, as detailed below. Three other trials are being planned—two Phase III trials of Bronchitol in cystic fibrosis and an acute study in chronic bronchitis.

Aridol for asthma

"US Aridol trial near to closing recruitment"

The pivotal trial for registration in the US, A-305, has enrolled more than 300 patients against an initial target at the outset of the trial of 280. On the advice of our statistician, and because we found a different to expected ratio of asthma negative to asthma positive, we are over-enrolling the study to ensure we achieve the forecast outcome. We expect to be able to close the trial in August. Following reporting of the trial, we will lodge the US marketing application with the FDA.

Aridol for chronic obstructive pulmonary disease

"COPD trial enrollment closes"

COPD is one of the four principal causes of death and affects an estimated 30 million patients in the western world. A proportion of COPD patients respond clinically to inhaled corticosteroids (ICS), however, there is no effective way of determining those patients who will benefit from treatment. Based on earlier work by a Swiss physician, and in addition to its utility in detecting airway inflammation in patients suspected of having asthma, Aridol may be of use in identifying this subset of patients.

Our Phase II trial reached full enrollment in April 2006, and we are expecting the results to be available in Q4 2006.

Bronchitol for cystic fibrosis

The lung of a person with cystic fibrosis has a depleted layer of the fluid that normally surrounds and protects the delicate surface of the lung. This results from an inability to maintain proper hydration of the lung and this, in turn, causes a weakening of lung defence and a breakdown in normal lung clearance. Bronchitol is a new class of agent designed to restore normal lung hydration and return normal lung defence and normal lung clearance processes.

"CF trials enrolling steadily"

Following the successful Phase II clinical trial in Australia and New Zealand, we initiated a dose-ranging study through clinical centres in Canada. This study has now reached 50% enrollment. The study compares the clinical effects of different doses of Bronchitol in the same patient, with the objective of providing advice to the patient on the most suitable dose. Although the study has been challenging to recruit, data from the study is expected during the second half of the year.

A UK-based, investigator-led, clinical trial is being conducted in cystic fibrosis children between the ages of 8 and 18. The trial compares Bronchitol with existing treatments. Each enrolled patient will assess three different treatments regimens over a 9 month period (Bronchitol alone, Bronchitol plus Pulmozyme and Pulmozyme alone). Pulmozyme is the most commonly prescribed drug to improve mucus clearance in patients with cystic fibrosis and the aim is to determine how Bronchitol works with Pulmozyme. This study is expected to close towards the end of the year and, while the trial is not on the path to approval, it will provide valuable insights into the best treatment options for the patient.

Bronchitol for bronchiectasis

"Phase III study enrolling strongly"

The bronchiectasis Phase III trial is the final trial before seeking approval to market Bronchitol. It follows patients for an 18 week dosing period and promises to be the first, and only, therapeutic agent to improve lung clearance in this patient group. This trial follows our successful Phase II program and is being run in Australia, New Zealand, and the United Kingdom. We aim to recruit 350 patients into this study and so far over a third of the required patients have been enrolled. The recruitment phase of the trial is due to be completed by the end of the year and the objective is to show an improvement in quality of life, exercise, sleep, and lung function in patients receiving Bronchitol.

Current Activities – Manufacturing and Distribution

"Clean audit from Australian regulator"

Subsequent to the successful auditing of our GMP manufacturing facility in Sydney, and the upgrading of our licence in March, we commenced manufacture of Aridol for commercial supply. The blister-packaged, approved, final product became available in June and we have established an efficient packing and distribution capability within the company. Orders are now being dispatched from our warehouse.

Publications / Presentations

Over 40 scientific articles have been published in numerous peer reviewed journals on both Aridol and Bronchitol. Articles that have been published, or presentations made this quarter include:

"CF trial presented to international community"

1. Brannan JD, Gulliksson M, Anderson SD, Chew N, Seale JP, Kumlin M. Inhibition of mast cell PGD2 release protects against mannitol-induced airway narrowing. Eur Respir J. 2006 May;27(5):944-50
2. Anderson SD, Sue-Chu M, Perry CP, Gratziou C, Kippelen P, McKenzie DC, Beck KC, Fitch KD. Bronchial challenges in athletes applying to inhale a beta2-agonist at the 2004 Summer Olympics. J Allergy Clin Immunol. 2006 Apr;117(4):767-73. Epub 2006 Mar 3.
3. Results of the Phase II cystic fibrosis trial were presented at the annual meeting of the American Thoracic Society (ATS) in May (San Diego) and at the 29th European Cystic Fibrosis Conference in June (Copenhagen)

Intellectual Property 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)	A	A	A	A
Patent Family 7 – Novel inhibitors of TNF (PXS2076 and PXS2098)	Prov			

*G = granted; P = pending; prov = provisional; PCT = Patent Cooperation Treaty; ROW denotes rest of the world including Japan; A = abandoned

"Australian patent granted"

During the quarter, we received notification that the patent covering new treatments for autoimmune diseases (Patent Family 4) was granted in Australia. This follows approval in the US and New Zealand recently.

A final response to the European examiners comments were filed with the European patent office for Patent Family 1, which covers both Aridol and Bronchitol. In addition, the first comments were received from the Japanese examination of this patent.

Financial Overview for the Quarter

Pharmaxis recorded the initial sale of product in June when Aridol was supplied to its first commercial customer. By the end of the month, Pharmaxis had shipped and invoiced product to the value of $8,383. By 30 June 2006, the group had received sales orders totalling $121,611, including an order from a US Biopharmaceutical company that will use Aridol in a series of Phase II asthma clinical trials. The backlog of outstanding sales orders at 30 June 2006 stood at $113,228. Gross margin for the period was 75% of sales.

Pharmaxis finished the quarter with $98 million in cash and cash equivalents.
The increase in interest income over the prior comparable quarter to $1.4 million reflects the increased cash balance following an $87 million capital raising in November 2005.

Research and development expenses for the quarter were over 130% above the level of expenditure in the prior comparable quarter and over 50% above the level of expenditure in the quarter ended 31 March 2006. The clinical trial programs are consistently the largest component of research, and accounted for approximately 75% of the increase in research expenditure. We experienced strong recruitment for both the US Phase III clinical trial of Aridol for asthma, and the Phase III clinical trial of Bronchitol for bronchiectasis. Steady recruitment continued in the Canadian Bronchitol for cystic fibrosis Phase II dosing trial and the UK investigator-led Bronchitol for cystic fibrosis Phase II trial in children. Preparation continues for international Bronchitol Phase III clinical trials in cystic fibrosis. Long term pre-clinical safety studies of Bronchitol were the other major expenditure increase during the quarter.
Commercial expenses have increased significantly over both the prior comparable quarter and the quarter ended 31 March 2006; the increase being principally related to recruiting a sales and marketing force, the market launch of Aridol in Australia and preparations for its European launch.

Administration expenses have increased approximately 25% over the prior comparable quarter, mainly as a result of an increase in the expense associated with options issued to employees. Compared to the quarter ended 31 March 2006, expenses also increased by approximately 25%, as a result of a number of accruals related to the financial year end such as annual bonuses, annual US filings, etc.

Income tax expense relates to income generated by the UK subsidiary which was incorporated during the year and is currently reimbursed for its expenditures on a cost plus basis.

Australian and US Generally Accepted Accounting Principles

Our financial statements are presented in both Australian and US Generally Accepted Accounting Principles (GAAP). Australian GAAP financial statements are prepared in accordance with Australian Equivalents to International Financial Reporting Standards (AIFRS). The major differences between the two sets of financial statements, apart from presentation format and line item descriptions are:

- US GAAP Statement of Operations offset research grants against research expenditure,
- US GAAP Statement of Operations 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 are netted against the cost of the plant and equipment. Under Australian GAAP the grants are deferred as a liability and amortized over the life of the plant and equipment.

Jane Sugden
Investor Relations and Communications
jane.sugden@pharmaxis.com.au
Telephone: 02 9454 7230

Pharmaxis Ltd
ABN 75 082 811 630
2/10 Rodborough Road
Frenchs Forest, NSW

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

Income Statement

	Three months ended		Year-to-date	
	30-Jun-06	30-Jun-05	30-Jun-06	30-Jun-05
	A$	A$	A$	A$
Revenue from sale of goods	8	-	8	-
Cost of sales	(2)	-	(2)	-
Gross profit	6	-	6	-
Other income				
Interest	1,428	493	4,282	1,702
Grant income	401	372	1,299	1,219
Other	-	-	-	
Expenses				
Research & development	(6,928)	(2,906)	(16,978)	(9,269)
Commercial	(851)	(298)	(1,951)	(963)
Administration	(1,223)	(1,006)	(4,386)	(3,134)
Total expenses	(9,002)	(4,210)	(23,315)	(13,366)
Net loss before tax	(7,167)	(3,345)	(17,728)	(10,445)
Income tax expense	(5)	-	(5)	-
Net loss after tax	(7,172)	(3,345)	(17,733)	(10,445)
Basic and diluted earnings (loss) per share	(0.041)	(0.025)	(0.111)	(0.084)
Depreciation & amortisation	240	205	946	626
Fair value of options issued under employee plan	312	97	1,124	260

Balance Sheet

	As at	
	30-Jun-06	30-Jun-05
	A$	A$
Cash and cash equivalents	97,840	33,390
Plant & equipment	3,205	2,477
Intangible assets	1,195	1,106
Total assets	104,267	37,937
Total liabilities	5,379	2,470
Total shareholders' equity	98,888	35,467

Cash Flow

	Three months ended		Year-to-date	
	30-Jun-06	30-Jun-05	30-Jun-06	30-Jun-05
	A$	A$	A$	A$
Cash flows from operating activities	(4,698)	(3,049)	(13,775)	(9,275)
Cash flows from investing activities	(439)	(473)	(1,804)	(1,573)
Cash flows from financing activities	368	-	80,029	19,021
Net increase (decrease) in cash held	(4,769)	(3,522)	64,450	8,173

Share Data

	As at	
	30-Jun-06	30-Jun-05
Ordinary shares on issue	176,904	134,770
Options over ordinary shares outstanding	9,692	10,914

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

Statement of Operations

	Three months ended			Twelve months ended		
	Jun-30-05	Jun-30-06	Jun-30-06	Jun-30-05	Jun-30-06	Jun-30-06
	A$	A$	US$(1)	A$	A$	US$(1)
Revenue from sale of goods	-	8	6	-	8	6
Cost of sales	-	(2)	(1)	-	(2)	(1)
Gross profit	-	6	5	-	6	5
Operating expenses						
Research & development	2,486	6,333	4,701	7,885	14,975	11,116
Commercial	197	806	598	807	1,769	1,313
General and administrative	1,035	1,121	832	3,105	4,051	3,007
Amortisation of intangible assets	23	29	22	90	97	72
Fair value of stock options issued to employees			-			-
Research & development	67	165	122	115	614	456
Commercial	60	45	33	116	175	130
General and administrative	(30)	102	76	29	335	249
Total operating expenses	3,838	8,601	6,384	12,147	22,016	16,343
Loss from operations	(3,838)	(8,595)	(6,379)	(12,147)	(22,010)	(16,338)
Interest and other income	493	1,428	1,060	1,702	4,282	3,179
Net loss before tax	(3,345)	(7,167)	(5,319)	(10,445)	(17,728)	(13,159)
Income tax expense		(5)			(5)	
Net loss	(3,345)	(7,172)	(5,319)	(10,445)	(17,733)	(13,159)
Basic and diluted net loss per ADS	(0.372)	(0.612)	(0.454)	(1.260)	(1.659)	(1.231)
Depreciation & amortisation	194	184	137	579	854	634

Balance Sheet Data

	As at		
	Jun-30-05	Jun-30-06	Jun-30-06
	A$	A$	US$(1)
Cash and cash equivalents	33,268	97,840	72,627
Plant & equipment	2,376	3,151	2,339
Intangible assets	1,106	1,195	887
Total assets	37,836	104,213	77,357
Total liabilities	2,369	5,325	3,953
Total shareholders' equity	35,467	98,888	73,405

Cash Flow Data

	Three months ended			Year-to-date		
	Jun-30-05	Jun-30-06	Jun-30-06	Jun-30-05	Jun-30-06	Jun-30-06
	A$	A$	US$(1)	A$	A$	US$(1)
Net cash used in operating activities	(3,006)	(4,698)	(3,487)	(9,280)	(13,653)	(10,135)
Net cash used in investing activities	(474)	(439)	(326)	(1,574)	(1,804)	(1,339)
Net cash provided by financing activities	-	368	273	19,021	80,029	59,406
Net increase in cash and cash equivalents	(3,480)	(4,769)	(3,540)	8,167	64,572	47,932

American Depositary Share Data

	As at	
	30-Jun-05	30-Jun-06
Equivalent ADSs on issue	8,985	11,794
Equivalent Options over ADSs outstanding	728	646

(1) Convenience translation into U.S. dollars from Australian dollars based upon rate on June 30, 2006