

Pharmaxis Ltd ABN 75 082 811 630

Quarterly Report to Shareholders

Issue 15 April – June 2007



pharmaxis



Developing human healthcare products to treat and manage respiratory and autoimmune diseases.

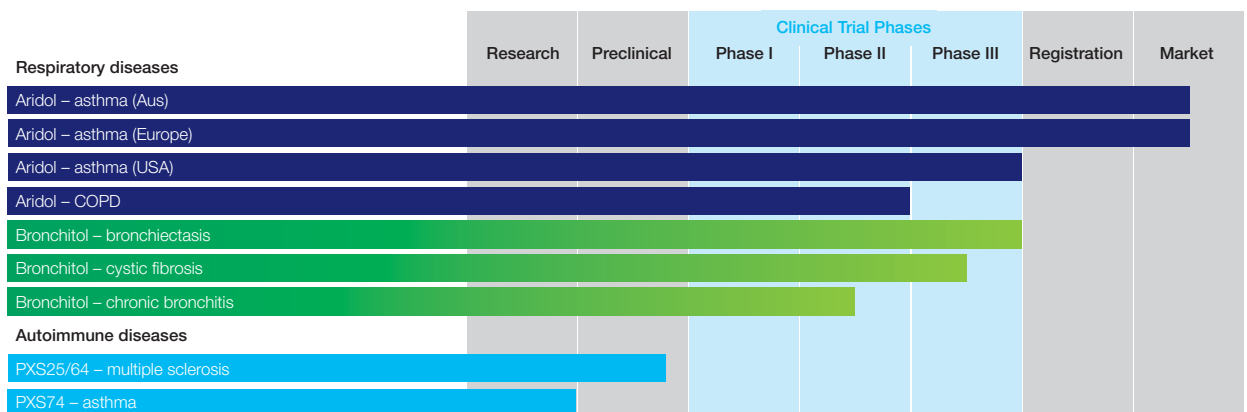
Overview

Pharmaxis is a specialty pharmaceutical company with activities spanning product research & development through to manufacture, sales and marketing.

Our therapeutic interests include lung diseases 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 and Europe to diagnose asthma through an airways function test. 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.

Pharmaxis Product Development at June 2007



COPD = Chronic Obstructive Pulmonary Disease – a fatal disease of the lungs, related to smoking.

Front cover: Dry powder mannitol is manufactured under strictly controlled conditions to ensure the final product meets GMP standards: Paul Wood checks a fresh batch of mannitol.



CEO Report

It was very pleasing to successfully complete the European Mutual Recognition for our lung function test Aridol. We now look forward to the commercial launch of Aridol in each of the 13 nominated countries. During this past quarter we also attained two important milestones in the clinical development of Bronchitol: we commenced an international Phase III clinical trial in cystic fibrosis and we completed an international Phase III clinical trial in bronchiectasis. Recruitment for the cystic fibrosis trial is on schedule, and the landmark bronchiectasis trial will report very soon.

Alan D Robertson, Chief Executive Officer

**Aridol wins
European
approval**

Second Quarter Highlights

- Aridol approved for marketing as a lung challenge test in 13 European countries
- Korean marketing application for Aridol filed
- Phase III Bronchitol clinical trial in bronchiectasis closed to recruitment
- Phase III Bronchitol clinical trial in cystic fibrosis began recruitment
- An independent trial of Bronchitol in COPD enrolls the first patient

**Bronchitol Phase III
study to
report**

Coming Events

- Reporting of Bronchitol bronchiectasis Phase III trial 3Q 2007
- Appointment of further European Aridol distributors 2H 2007
- Complete inpatient COPD Bronchitol trial 2H 2007
- Completion of Phase II Bronchitol CF dosing study 2H 2007
- Commencement of US Phase III bronchiectasis trial 2H 2007
- Registration of Aridol in Korea 1Q 2008
- File U.S. Aridol marketing application 2H 2007

**European approval
now granted in
14 countries**

Current Regulatory Activities

Aridol gains EU approval in 13 additional countries

In June, the European Mutual Recognition Process formally closed when Pharmaxis received approval to market Aridol in an additional 13 European countries.

This augments our preliminary registration in Sweden (the reference state) and demonstrates Pharmaxis' capability to bring an innovative product from concept to global markets. The decision represents the culmination of a significant drug registration process and allows Aridol, the first lung challenge test to be approved Europe-wide, to be used to identify airway reactivity in patients with asthma and other respiratory diseases.

**Korean
application
submitted**

Korean Application submitted

The regulatory dossier for Aridol has been submitted to the South Korean authorities. In addition to allowing access to Korea's estimated 2.5 million asthma sufferers, the filing represents a beachhead for Pharmaxis in Asia. We expect that the Korean regulatory process will complete during the first quarter of 2008.

**Aridol endorsed
by World Anti-
Doping Agency**

Current Marketing Activities

Global agency and Swedish army endorse Aridol

WADA, the World Anti-Doping Agency, has announced its inclusion of Aridol on its schedule of approved tests for athletes requesting to use asthma medication. WADA guidelines are utilized by sports organizations worldwide to monitor compliance of athletes competing at an elite level. The **Swedish army** has also endorsed Aridol and will start to use it to assess asthmatic symptoms in army SCUBA divers.

Respiratory experts show strong interest in products

Pharmaxis attended the annual European Cystic Fibrosis meeting in June. The conference attracted a significant proportion of European respiratory specialists and interest in both Aridol and Bronchitol was high. The gathering also provided an opportunity for the investigators in our international CF trial to meet.

Aridol and Bronchitol were also presented to a global audience of respiratory physicians at the American Thoracic Society meeting held in San Francisco during May. It was a good opportunity for Pharmaxis to hold meetings for physicians interested in participating in the US-based Phase III bronchiectasis trial, and introduce our products to important investigators and opinion leaders.

**Solid uptake
of Aridol**

Eighty percent of respiratory labs sign on

Looking back on our first year of selling Aridol in Australia we have seen the number of Aridol kits and the average selling price increase each quarter. Approximately 80 percent of our target respiratory laboratories have signed on as customers and we are witnessing ongoing repeat orders.

Planning for European launches underway

The commercial launch of Aridol in the recently approved additional European countries will occur later in the year as local marketing authorizations are issued and local packaging requirements completed.

**New spray
dryers to increase
capacity**

Current Manufacturing Activities

Planning for new facility nears completion

Our operations and corporate teams have been busy completing the specifications and documentation for a new facility which should commence construction next quarter. The facility of approximately 7,000 square meters will accommodate all of the company's operations, and importantly will house a new, significantly increased manufacturing capacity needed for commercial scale production of Bronchitol. Work on the design of the key manufacturing component, the spray dryer, began nearly two years ago.

Phase III trial for bronchiectasis closes

Current Clinical Activities

Bronchitol for bronchiectasis

Despite more than half a million patients seeking treatment for bronchiectasis, Pharmaxis is the only company conducting a Phase III clinical trial in the condition. Ours is also the largest study ever run in this debilitating lung disease. We recruited 362 patients from 22 hospitals in Australia, New Zealand and the United Kingdom, the last of whom completed the trial in the first week of July. We are now awaiting analysis of the tests conducted during the trial. A positive outcome from the study will enable us to seek approval to market Bronchitol.

An extension of the trial allows participants access to Bronchitol for a total of twelve months to determine the safety of long term Bronchitol treatment. This second component of the trial is fully recruited and will complete in 2008.

Until recently, bronchiectasis has been a little known and poorly researched respiratory condition associated with continuous coughing and regular lung infections. Currently, there are no effective pharmaceutical treatments available, and physical treatments such as physiotherapy have limited usefulness.

Bronchitol for cystic fibrosis

Our three separate trials for cystic fibrosis have shown steady progress over the last three months.

The Phase III international trial being conducted in 30 hospitals across Australia, the UK and Ireland, is recruiting well. The trial will enroll up to 250 cystic fibrosis sufferers aged six years and over and follow their changes in lung function, frequency of infections and quality of life for six months. An additional six month optional treatment period will assess the safety of long term Bronchitol use in this patient group.

The Phase II dosing study begun in Canada is now continuing in Argentina. All study sites are established, the staff trained, and the first patients have been recruited.

The third trial, a Phase II study in children, is in its final stages. This trial involves three different treatment regimens, each of three months, and is not expected to close until the end of the year.

Phase III CF trial recruiting steadily

Current Research Activities

Following the consolidation of all of our research facilities in Sydney earlier in the year, Pharmaxis has initiated some new research projects. An agreement with **CSIRO Molecular and Health Technologies** will facilitate the development of an existing capacity to identify the three dimensional structure of proteins involved in inflammatory diseases such as asthma and rheumatoid arthritis. We will use the knowledge to refine our drug discovery capabilities and streamline the process of selecting potential new drugs.

Pharmaxis has also expanded links with the University of Sydney, which has been involved with the company's spray drying technology for a number of years. An **Australian Research Council Linkage Grant** awarded in May, will be used to develop new and improved dry powder formulations to enhance lung delivery of different pharmaceutical agents.

Research partnership with CSIRO

University-industry linkage grant awarded

Publications and Presentations

More than 50 papers about Aridol, Bronchitol or mannitol for inhalation have now been published in peer-reviewed journals. Three mannitol papers have been cited more than 50 times, indicating the widespread interest by respiratory research in this developing field.

New papers published this past quarter include:

Publications and Presentations

- 1 Response to mannitol in asymptomatic subjects with airway hyper-responsiveness to methacholine C. Porsbjerg, L. Rasmussen, S. F. Thomsen et al. *Clinical and Experimental Allergy*, 2007; 37 (1): 22–28
- 2 Diagnostic Test for Asthma in Firefighters. Chhajed P, Tamm M, Stolz D et al. *Chest* 2007; 131 (6): 1760-1767
- 3 Airway reactivity to inhaled mannitol in cigarette smokers: A longitudinal study. Stolz D, Anderson S, Gysin C et al. *Respiratory Medicine* 2007 in press (accepted 11Jan2007)
- 4 Inhaled mannitol in cystic fibrosis. Wills P. *Expert Opin Investig Drugs*, 2007; 16 (7): 1121-1126
- 5 Other mucoactive agents for cystic fibrosis. Bye P and Elkins M. *Paed Resp Rev* 2007; 8:30-39

Over 50
publications
about mannitol

Intellectual Property Portfolio

The Japanese patent office has granted the patent application that includes Aridol. The Japanese patent covering Bronchitol remains under review.

	USA	Europe	Australia	ROW
Patent Family 1—Aridol and Bronchitol	G	P	G	G/P 1
Patent Family 2—Phosphosugar based anti-inflammatory and/or immunosuppressive drugs	G	G	G	G
Patent Family 3—Novel phosphosugars 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)	NP	NP	NP	NP
Patent Family 6—Novel cannabinoid agonists (PXS2030)	A	A	A	A
Patent Family 7—Novel inhibitors of TNF (PXS2076)	Prov			

G= granted; P = pending; Prov = provisional; PCT = patent cooperation treaty; NP—national phase; ROW = rest of world including Japan; A = abandoned; (1) Aridol granted in Japan

Japan grants
Aridol patent

Financial Overview for the Fourth Quarter

We finished the quarter with A\$76.2 million in cash and cash equivalents, and therefore remain well funded to build the Pharmaxis business.

Aridol sales for the quarter were A\$46,000, with an overall gross margin of 78 percent. During the quarter we sold Aridol in Australia and also made our third shipment to a US biopharmaceutical company for use in its clinical trial program. Australian sales for the current quarter increased 52 percent over the average sales for the prior three quarters. At quarter end we had outstanding customer orders of approximately \$33,000.

The small decrease in interest income over the prior comparable quarter to A\$1.2 million reflects the decrease in invested cash funds, marginally offset by higher prevailing short term interest rates.

Grant income increased slightly over the prior comparable quarter due to an increase in the proportion of research activities in areas not eligible for grant support.

Research and development expenses of \$4.9 million for the quarter compare to \$6.9 million in the prior comparable quarter, and \$5.2 million in the March 2007 quarter. Clinical studies continue to represent the largest component of research, accounting for approximately 50 percent of research expenditure in the current quarter. The major clinical study ongoing during the quarter was the international Phase III clinical trial of Bronchitol in bronchiectasis. In the prior comparable period (June 2006) the major clinical expenditure related to the Phase III US clinical trial of Aridol. Other clinical expenditure included the costs for the international Phase III clinical trial of Bronchitol in cystic fibrosis which began during the quarter, and ongoing costs of the Phase II cystic fibrosis dosing study. The manufacture of Aridol and Bronchitol accounted for approximately 35 percent of research expenditure in the current quarter. The product is used for clinical trials, preclinical development and product stability studies required to support registration applications.

Commercial expenses include the Australian sales and marketing teams, the European sales and marketing team based in the UK, and corporate marketing and development based at Frenchs Forest.

Administration expense increases over the prior comparative quarter reflect costs associated with developing specifications for a new facility and manufacturing capacity, and costs associated with validating the company's financial control systems.

Income tax expense relates to income generated by our UK subsidiary which is reimbursed for its expenditure on a cost plus basis.

Contact Details

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			Year-to-date		
	30-Jun-07	30-Jun-06	30-Jun-06	30-Jun-07	30-Jun-06	30-Jun-06
Revenue from sale of goods	A\$ 46	A\$ 8	A\$ 205	A\$ 8	A\$ 8	A\$ 8
Cost of sales	(10)	(2)	(49)	(2)	(2)	(2)
Gross profit	36	6	156	6	6	6
	78%					
Other income						
Interest	1,219	1,428	5,278	4,282	4,282	4,282
Grant income	569	401	2,152	1,299	1,299	1,299
Expenses						
Research & development	4,856	6,928	23,840	16,978	16,978	16,978
Commercial	779	846	3,240	1,946	1,946	1,946
Administration	1,409	1,223	4,619	4,386	4,386	4,386
Foreign exchange (gains) losses	(2)	5	47	5	5	5
Total expenses	7,042	9,002	31,746	23,315	23,315	23,315
Net loss before tax	(5,218)	(7,167)	(24,160)	(17,728)	(17,728)	(17,728)
Income tax expense	7	5	19	5	5	5
Net loss after tax	(5,225)	(7,172)	(24,179)	(17,733)	(17,733)	(17,733)
Basic and diluted earnings (loss) per share - \$	(0.029)	(0.041)	(0.136)	(0.111)	(0.111)	(0.111)
Depreciation & amortisation	246	241	939	947	947	947
Fair value of options issued under employee plan	397	312	1,488	1,124	1,124	1,124

Balance Sheet Data

	As at	
	30-Jun-07	30-Jun-06
Cash and cash equivalents	A\$ 76,182	A\$ 97,840
Plant & equipment	3,521	3,205
Intangible assets	1,239	1,195
Total assets	82,648	104,267
Total liabilities	(6,089)	(5,379)
Total shareholders' equity	76,559	98,888

Cash Flow Data

	Three months ended			Year-to-date		
	30-Jun-07	30-Jun-06	30-Jun-06	30-Jun-07	30-Jun-06	30-Jun-06
Cash flows from operating activities	A\$ (3,609)	A\$ (4,699)	A\$ (20,697)	A\$ (13,775)	A\$ (13,775)	A\$ (13,775)
Cash flows from investing activities	(296)	(439)	(1,322)	(1,804)	(1,804)	(1,804)
Cash flows from financing activities	171	368	363	80,029	80,029	80,029
Net increase (decrease) in cash held	(3,734)	(4,770)	(21,656)	64,450	64,450	64,450

Ordinary Share Data

	As at	
	30-Jun-07	30-Jun-06
Ordinary shares on issue	177,949	176,904
Options over ordinary shares outstanding	9,836	9,692

US Generally Accepted Accounting Principles

(Unaudited)
('000 except per share data)

Statement of Operations

	Three months ended			Twelve months ended		
	Jun-30-06	Jun-30-07	Jun-30-07	Jun-30-06	Jun-30-07	Jun-30-07
Revenue from sale of goods	A\$ 8	A\$ 46	US\$ ⁽¹⁾ 39	A\$ 8	A\$ 205	US\$ ⁽¹⁾ 174
Cost of sales	(2)	(10)	(8)	(2)	(49)	(42)
Gross profit	6	36	31	6	156	132
Operating expenses						
Research & development	6,341	4,295	3,647	14,982	21,177	17,981
Commercial	801	557	473	1,764	2,814	2,389
General and administrative	1,075	1,203	1,021	4,005	3,973	3,373
Amortization of intangible assets	68	25	21	136	95	81
Fair value of stock options issued to employees						
Research & development	164	119	101	613	569	483
Commercial	45	71	60	175	276	234
General and administrative	102	205	175	336	643	546
Total operating expenses	8,596	6,475	5,498	22,011	29,547	25,087
Loss from operations	(8,590)	(6,439)	(5,467)	(22,005)	(29,391)	(24,955)
Interest and other income	1,428	1,219	1,035	4,282	5,278	4,482
Foreign exchange gains (losses)	(5)	2	2	(5)	(47)	(40)
Net loss before tax	(7,167)	(5,218)	(4,430)	(17,728)	(24,160)	(20,513)
Income tax expense	(5)	(7)	(6)	(5)	(19)	(16)
Net loss	(7,172)	(5,225)	(4,436)	(17,733)	(24,179)	(20,529)
Basic and diluted net loss per ADS	(0.612)	(0.441)	(0.375)	(1.659)	(2.046)	(1.737)
Depreciation & amortisation	230	234	199	900	892	757

Balance Sheet Data

	As at	
	30-Jun-06	30-Jun-07
Cash and cash equivalents	A\$ 97,840	A\$ 76,182
Plant & equipment	3,289	3,730
Intangible assets	1,057	1,002
Total assets	104,213	82,642
Total liabilities	(5,325)	(6,083)
Total shareholders' equity	98,888	76,559

Cash Flow Data

	Three months ended			Twelve months ended		
	Jun-30-06	Jun-30-07	Jun-30-07	Jun-30-06	Jun-30-07	Jun-30-07
Net cash used in operating activities	A\$ (4,699)	A\$ (3,609)	US\$ ⁽¹⁾ (3,064)	A\$ (13,653)	A\$ (20,698)	US\$ ⁽¹⁾ (17,574)
Net cash used in investing activities	(439)	(296)	(251)	(1,804)	(1,323)	(1,123)
Net cash provided by financing activities	368	171	145	80,029	363	308
Net increase in cash and cash equivalents	(4,770)	(3,734)	(3,170)	64,572	(21,658)	(18,389)

American Depository Share Data

	As at	
	30-Jun-06	30-Jun-07
Equivalent ADSs on issue	11,794	11,863
Equivalent Options over ADSs outstanding	646	656

(1) Convenience translation into U.S. dollars from Australian dollars based upon rate on June 30, 2007

US Generally Accepted Accounting Principles

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