

Pharmaxis Ltd ABN 75 082 811 630

# Quarterly Report to Shareholders

Issue 13 September—December 2006



pharmaxis



## Producing human healthcare products to treat and manage respiratory and autoimmune diseases

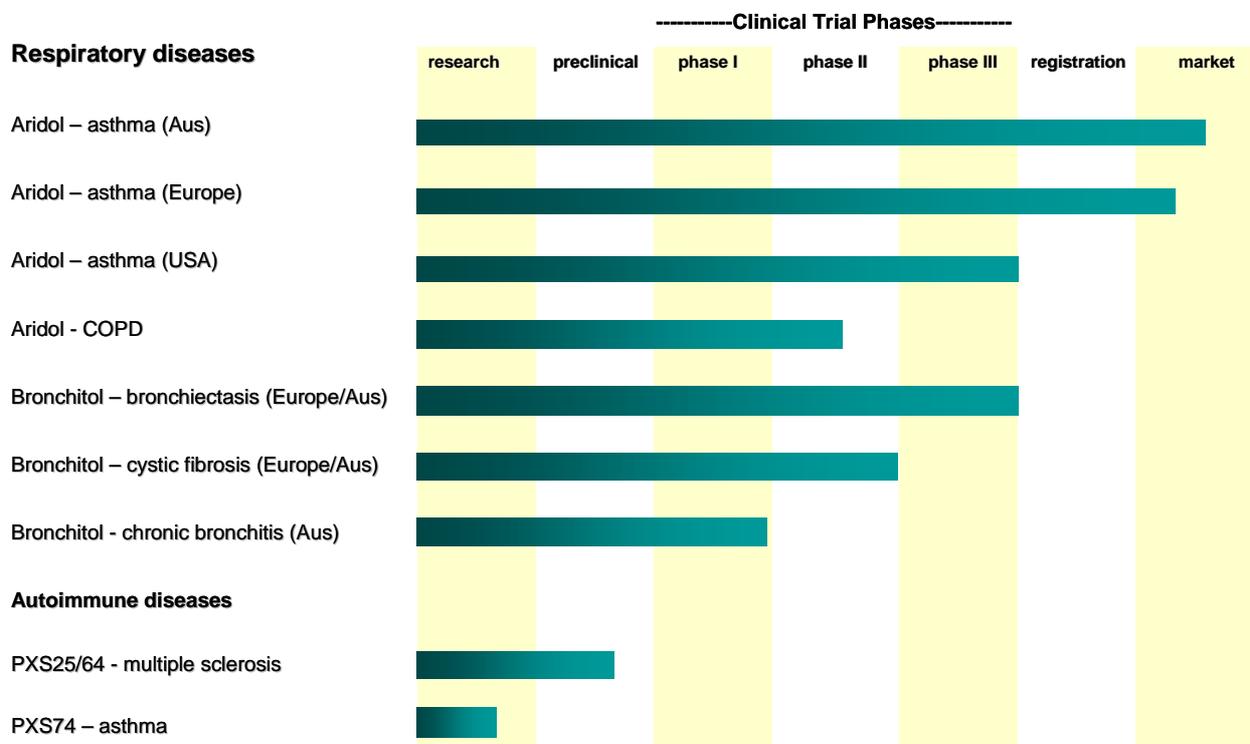
### Overview

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 Sweden to identify airway hyper-responsiveness and to assist in the diagnosis and management of asthma. 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 December 2006



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

Front cover: Regulatory Affairs Manager, Laurence Garceau, celebrating good news from Europe



## CEO Report

During the December quarter, the European marketing application for Aridol required a sterling effort from the regulatory department as we filed our Mutual Recognition Procedure documents following the Swedish marketing approval.

National approval in Sweden was granted on 20 October 2006 and our team was able to assemble documents for 13 European countries in 30 days — a third of the time normally required. The documents were filed with the various agencies on 22 November and officially accepted by all countries on 5 December. The end of the MRP process should occur during the first quarter of 2007.

Approval in Sweden meant we were finally in a position to manufacture launch stock for our Scandinavian partner. We dispatched our first order to Sweden during the quarter – a milestone signifying Pharmaxis becoming an international exporter.

I hope you find this brief quarterly update of our activities helpful in understanding our business.

Alan D Robertson, Chief Executive Officer

**Aridol wins  
Swedish  
approval**

## Fourth Quarter Highlights

- Aridol approved for marketing in Sweden (its first European country)
- Headline Aridol Phase III U.S. clinical trial results reported
- Bronchitol received fast track status from the U.S. FDA
- Dutch, Italian and Greek distributors for Aridol appointed
- First export order to Europe dispatched

**Bronchitol fast  
tracked in US**

## Coming Events

- Completion of bronchiectasis Phase III trial recruitment Q1 2007
- Reporting results of bronchiectasis Phase III trial Q3 2007
- Outcome of Aridol European Union marketing application 1H 2007
- Reporting of Aridol COPD study 1H 2007
- Reporting of Bronchitol COPD hospital trial 1H 2007
- Initiation of international Phase III Bronchitol CF study 1H 2007
- Complete enrolment of cystic fibrosis dosing study 1H 2007

## Corporate News

Following Brigitte Smith's retirement at the annual general meeting, all non executive directors are now independent. In November, Dr John Villiger joined the board of Pharmaxis. John brings strong international pharmaceutical business building experience to Pharmaxis, having helped to create a successful NASDAQ-listed pharmaceutical company and held senior global roles at Roche. In particular, John's commercial and regulatory skills will complement and extend those of the existing Board members.

**New Board  
director**

## Current Regulatory Activities

### Aridol gains Swedish approval

Swedish approval granted

As reported in last quarter's edition, we received Swedish marketing approval for Aridol in October. The registration has allowed us to progress the marketing application for Aridol in the 27 other European Union member states via the Mutual Recognition Procedure. Our first choice countries are Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Holland, Norway, Portugal, Spain and the United Kingdom. Marketing approval will be sought in the remaining European Union countries later in the year.

Formal meetings have been held with the Canadian regulatory authorities and we plan to file a marketing application for Aridol in Canada during the first half of 2007.

### Bronchitol fast tracked

The US Food and Drug Administration (FDA) also designated Bronchitol for cystic fibrosis as a fast track product.

Designation as a fast track product provides for expedited regulatory review of the Bronchitol New Drug Application (NDA) on a rolling basis and follows the FDA and European Medicines Agency previous granting of Bronchitol orphan drug status.

## Current Marketing Activities

### Aridol endorsed in global asthma guidelines

Aridol included in international guidelines

In asthma, as in many other multifaceted diseases, guidelines drawn up by leading specialists from around the world form the basis of how medical practitioners approach the diagnosis, treatment and management of the disease. The latest edition of the GINA (Global Initiative for Asthma) report which outlines a global strategy for managing and preventing asthma, was released in November. Aridol is now included in this influential publication.

Aridol has also been included in the National Asthma Council of Australia's latest version of the Asthma Management Handbook. The publication is practical guide by Australian experts to assist healthcare professionals in the diagnosis and management of asthma. The NAC handbook is distributed to respiratory specialists and general practitioners nationally. Together, the two inclusions will substantially increase awareness and encourage further use of Aridol in the future.

### Additional distributors for Aridol appointed

More European distributors appointed

We have added to our network of European distributors. In October, Allertec (for Greece) and Italchimici (for Italy), and in December Romedic (for the Netherlands) were appointed to market Aridol in their respective countries. We believe they are excellent marketing partners that will make the most of the Aridol opportunity in their countries.

### Australian sales and marketing

Aridol gaining momentum

The sales and marketing team continue to enjoy support from the respiratory physicians and the testing laboratories. New hospitals have signed up as customers and, having completed the first stage of training, awareness and education, our current focus is on increasing the number of tests that are conducted. We are doing this through a variety of initiatives.

## Current Clinical Activities

### Aridol completes clinical development

The results from our Phase III U.S. based pre-registration trial were released in November. We enrolled a total of 501 patients, and the study showed that Aridol performed as well or better than the only currently approved test, methacholine. Additional data analysis is ongoing and we intend to discuss the clinical, non clinical and manufacturing aspects of Aridol with the FDA during the first half of 2007, with a view to submitting the marketing application shortly thereafter.

### Aridol for chronic obstructive pulmonary disease

We are expecting the results from our Phase II trial of Aridol in COPD during Q1 2007.

### Phase III bronchiectasis trial underway

### Bronchitol for bronchiectasis

Bronchiectasis is a chronic respiratory condition and affected patients suffer with continuous coughing and excessive mucus production which disrupts both their social and private lives. Currently, there are no effective therapeutic options available to help relieve the symptoms associated with this condition. Our final Phase III trial before registration is being run in Australia, New Zealand, England and Ireland. This international study closed recruitment at the end of January 2007. Participants in the study are offered an option of continuing on treatment after the formal part of the study has concluded and the uptake rate has been very strong. The first headline data from this comprehensive study are expected mid 2007.

### Phase III CF trial to begin recruiting

### Bronchitol for cystic fibrosis

Bronchitol is a new class of therapeutic designed to restore normal lung defence and normal lung clearance mechanisms in patients with cystic fibrosis.

Very positive and satisfactory meetings have been held with the European regulatory authorities and we have reached agreement on the number of sites and subjects to be recruited for the Phase III pre-registration trial. The trial will examine subjects over a six month period, followed by an optional six month extension period. A great deal of effort has gone into selecting the right hospitals to participate in the trial and recruitment is expected to begin during the first quarter of 2007 and continue through to the second half of 2008.

The Phase II dose-finding study in subjects with cystic fibrosis taking place in Canada exhausted its available subjects at the participating hospitals. Consequently, new centres have been opened in Argentina to ensure the trial completes with the correct number of subjects. This trial is important for setting the right dose for the U.S. Phase III trial and recruitment is now expected to close during the first half of 2007.

### New indication for Bronchitol

### Bronchitol in acute care

Patients with severe infections associated with COPD are currently treated with anti-inflammatory agents, antibiotics and bronchodilators. The missing therapy to help the patient deal with their congested lungs is an effective mucus clearing agent. This trial aims to examine the feasibility of using Bronchitol in these circumstances. We expect the study to have completed recruitment and report during the first half of 2007.

## Current Activities—Research

During the quarter, our research laboratories at the Australian National University in Canberra closed and all research activity centralised in Sydney. Active research programs are underway to identify new treatments for respiratory diseases such as asthma and autoimmune diseases such as multiple sclerosis.

### New research initiative

In 2006, Pharmaxis and the University of Sydney were awarded a linkage grant from the Australian Research Council, to commence in early 2007. The grant will allow the Molecular and Microbial Biosciences Department of the University of Sydney to determine the three-dimensional structure of an inflammatory mediator and its known inhibitors.

We will use the information to identify additional compounds that have the potential to become potent and selective pharmaceuticals suitable for pre-clinical development. Diseases such as rheumatoid arthritis, multiple sclerosis, Crohn's disease and various respiratory diseases all have an inflammatory component, so this research dovetails extremely well with our current disease focus.

## Publications and Presentations

Lung Deposition of Mannitol Powder Aerosol in Healthy Subjects. Glover W, Chan HK, Ebrel S, Daviskas E, Anderson S. J Aerosol Med. 2006 Winter; 19 (4):522-532.

### New publications

Recovery from bronchoconstriction and bronchodilator tolerance. Haney S, Hancox RJ. Clin Rev Allergy Immunol. 2006 Oct-Dec; 31(2-3):181-96.

Over 45 scientific articles have now been published in peer reviewed journals on both Aridol and Bronchitol.

## Intellectual Property Portfolio

There has been no material change to the patent portfolio this quarter. Comments have been received on Patent Family 1 from the Japanese examiner and a response has been filed.

### No material changes to patents

	USA	Europe	Australia	ROW
Patent Family 1—Aridol and Bronchitol	G	P	G	G/P
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 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;

## Financial Overview for the December Quarter

We finished the quarter with A\$86 million in cash and cash equivalents, and therefore remain well funded to progress our business plan.

Aridol sales for the quarter were A\$68,000, with an overall gross margin of 75%. During the period we shipped our first sale of Aridol to Europe following the receipt of Swedish marketing approval. At quarter end we had outstanding customer orders totalling \$60,000.

The \$1.4 million increase in interest income over the prior comparable quarter reflects a larger balance of invested cash funds held in the current quarter.

Research and development expenses for the quarter increased significantly over the level of expenditure in the prior comparable quarter. Approximately 75 percent of the additional expenditure is the result of an increase in the level of clinical studies during the period, in particular the international Phase III clinical trial of Bronchitol in bronchiectasis. The remainder of the increased expenditure is mainly attributable to the manufacture of product for clinical trials and preclinical development and product stability studies required to support registration applications.

Commercial expenses for the current quarter include both the Australian sales and marketing team and the UK marketing office, neither of which existed in the prior comparable period.

Administration expenses for the current quarter decreased from the prior comparative quarter, mainly because of one-off costs in the comparable quarter in relation to listing the Company on Nasdaq and staff relocation expenses.

Foreign exchange gains and losses relate to the movement in foreign exchange rates between the point in time when invoices from overseas suppliers are booked as liabilities and the date on which the invoices are paid.

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

During the current quarter we used net cash of \$4.5 million for operating activities. This consisted of a net loss for the quarter of \$7.0 million, which included non-cash depreciation and amortisation of approximately \$200,000 and non-cash stock option expense of approximately \$307,000, and working capital movements of approximately \$2.0 million. Net cash used in investing activities during the quarter was approximately \$450,000, predominantly relating to the purchase of plant and equipment for quality control expansion. Net cash flows from investing activities of approximately \$156,000 relate to the exercise of employee options.

*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)					US Generally Accepted Accounting Principles (Unaudited) ('000 except per share data)					
Income Statement					Statement of Operations					
Three months ended		Year-to-date			Three months ended			Six months ended		
	31-Dec-06	31-Dec-05	31-Dec-06	31-Dec-05	Dec-31-05	Dec-31-06	Dec-31-06	Dec-31-05	Dec-31-06	Dec-31-06
	A\$	A\$	A\$	A\$	A\$	A\$	US\$(1)	A\$	A\$	US\$(1)
Revenue from sale of goods	68	-	117	-	-	68	53	-	117	93
Cost of sales	(20)	-	(29)	-	-	(20)	(16)	-	(29)	(23)
Gross profit	48	-	88	-	-	48	37	-	88	70
Other income										
Interest	1,366	997	2,776	1,436	2,904	6,397	5,043	4,965	12,250	9,658
Grant income	688	72	1,187	431	362	856	675	538	1,486	1,172
Expenses					1,119	865	682	2,049	1,649	1,300
Research & development	7,251	3,113	13,772	5,646	23	38	30	45	68	54
Commercial	919	397	1,616	603						
Administration	981	1,217	1,881	2,182						
Foreign exchange gains(losses)	(8)	-	52	-						
Total expenses	9,143	4,727	17,321	8,431						
Net loss before tax	(7,041)	(3,658)	(13,270)	(6,564)						
Income tax expense	6	-	8	-						
Net loss after tax	(7,047)	(3,658)	(13,278)	(6,564)						
Basic and diluted earnings (loss) per share - \$	(0.040)	(0.023)	(0.075)	(0.045)						
Depreciation & amortisation	238	307	455	532						
Fair value of options issued under employee plan	307	247	629	404						
<b>Balance Sheet Data</b>					<b>Balance Sheet Data</b>					
		As at						As at		
	31-Dec-06	30-Jun-06			30-Jun-06	31-Dec-06	31-Dec-06			
	A\$	A\$			A\$	A\$	US\$(1)			
Cash and cash equivalents	86,073	97,840			97,840	86,073	67,860			
Plant & equipment	3,637	3,205			3,289	3,779	2,979			
Intangible assets	1,181	1,195			1,057	1,010	796			
Total assets	93,168	104,267			104,213	93,139	73,431			
Total liabilities	(6,750)	(5,378)			(5,325)	(6,720)	(5,298)			
Total shareholders' equity	(86,419)	(98,888)			(98,888)	(86,419)	(68,133)			
<b>Cash Flow Data</b>					<b>Cash Flow Data</b>					
Three months ended		Year-to-date			Three months ended			Year-to-date		
	31-Dec-06	31-Dec-05	31-Dec-06	31-Dec-05	Dec-31-05	Dec-31-06	Dec-31-06	Dec-31-05	Dec-31-06	Dec-31-06
	A\$	A\$	A\$	A\$	A\$	A\$	US\$(1)	A\$	A\$	US\$(1)
Cash flows from operating activities	(4,554)	(2,596)	(11,071)	(5,579)	(2,596)	(4,554)	(3,591)	(5,458)	(11,071)	(8,728)
Cash flows from investing activities	(449)	(562)	(876)	(976)	(562)	(449)	(354)	(976)	(876)	(691)
Cash flows from financing activities	156	79,552	179	79,600	79,552	156	123	79,600	179	141
Net increase (decrease) in cash held	(4,847)	76,394	(11,768)	73,045	76,394	(4,847)	(3,822)	73,166	(11,768)	(9,278)
<b>Ordinary Share Data</b>					<b>American Depository Share Data</b>					
		As at						As at		
	31-Dec-06	30-Jun-06			30-Jun-06	31-Dec-06				
Ordinary shares on issue	177,356	176,904			11,794	11,824				
Options over ordinary shares outstanding	10,330	9,692			646	689				

(1) Convenience translation into U.S. dollars from Australian dollars based upon rate on December 31, 2006