# Quarterly Report to Shareholders

## Issue 14

January—March 2007

pharmaxis

**Pharmaxis Ltd** ABN 75 082 811 630

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

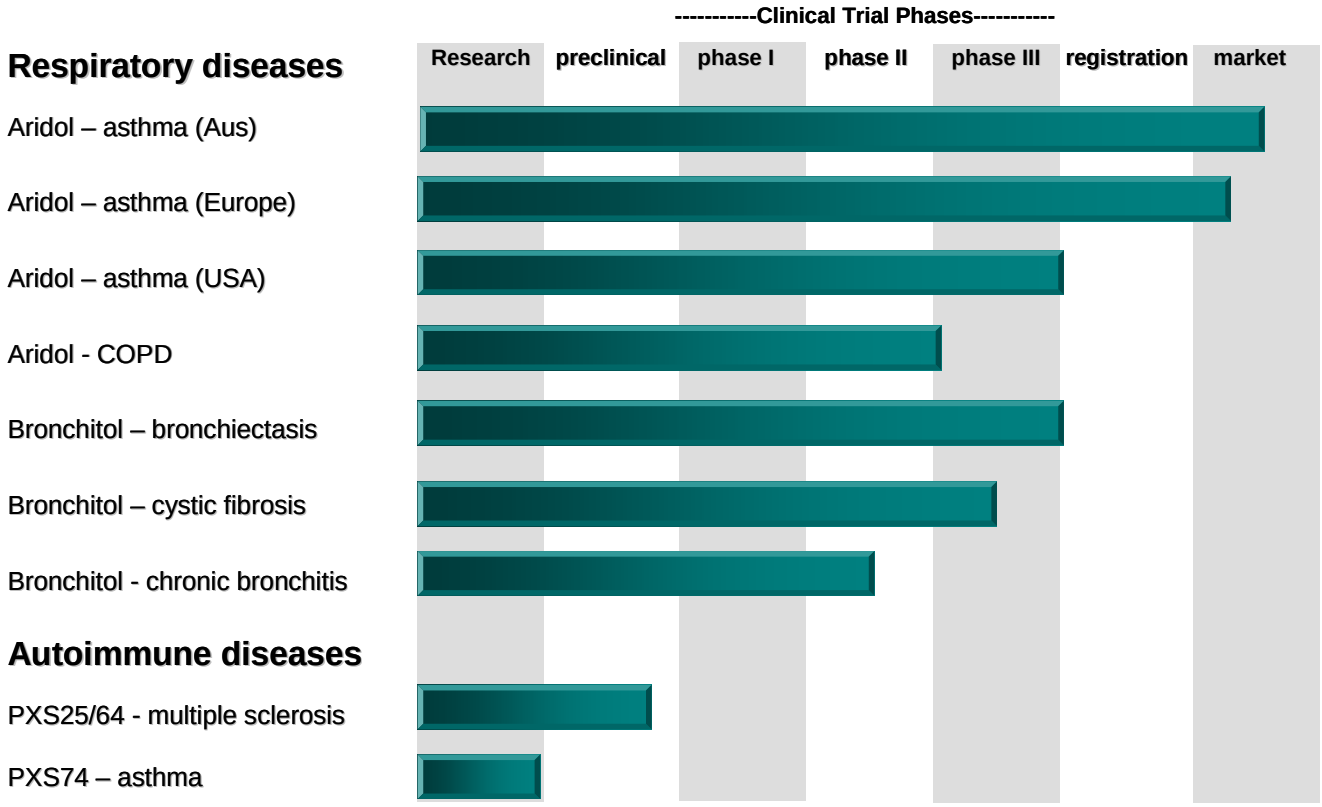
## Overview

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 March 2007




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

*Front cover: Braedan Delaney, a young cystic fibrosis patient from the U.S., benefits from recent medical advances and provides us with inspiration as we develop Bronchitol to help treat his condition.*

## CEO Report

This has been a busy quarter behind the scenes for Pharmaxis. The clinical department has seen two Bronchitol studies close enrolment and an Aridol trial report; the marketing department has appointed another European distributor; and a shelf registration statement has been filed with the Securities and Exchange Commission in the United States. All activities have taken many months of work, but it is not until completion that they can be publicly acknowledged.

The coming quarter promises to be just as demanding, as registration in the EU proceeds, and new trials begin to confirm our products' safety and effectiveness. I hope you continue to find these updates useful in understanding the activities that we undertake on your behalf.

Alan D Robertson, Chief Executive Officer

## First Quarter Highlights

**Bronchitol studies close enrolment**

- Phase III Bronchitol study in bronchiectasis closes enrolment
- Phase II Bronchitol study in cystic fibrosis children closes enrolment
- Phase II Aridol study in COPD reports
- Additional European distributor for Aridol appointed
- US shelf registration statement filed

## Coming Events

**Completion of Phase III bronchiectasis study**

| | |
|---|---|
| • Reporting of Bronchitol bronchiectasis Phase III trial | 2Q/3Q 2007 |
| • Appointment of U.S. Aridol distributor | 2Q/3Q 2007 |
| • Completion of Aridol EU marketing application process | 2Q/3Q 2007 |
| • Complete inpatient COPD Bronchitol trial | 2Q/3Q 2007 |
| • File U.S. Aridol marketing application (NDA) | 2Q/3Q 2007 |
| • Complete enrolment of Bronchitol CF dosing trial | 2Q/3Q 2007 |

## Corporate News

**SEC shelf registration statement filed**

In February Pharmaxis filed a shelf registration statement with the U.S. Securities and Exchange Commission (SEC). The registration statement gives Pharmaxis the flexibility to issue up to US$250 million of its ordinary shares or other securities over the next three years in the United States. Pharmaxis has been listed on the U.S. Nasdaq Global Market since 2005.

A shelf registration is an effective, prudent and frequently-used planning measure for U.S. listed companies. It enables them to act quickly as needed and to complete the sometimes extensive SEC review process prior to issuing any securities.

## Current Regulatory Activities

### European marketing approvals

The European registration process for gaining marketing approval of Aridol continues to progress steadily. We expect the process to conclude before the end of the June quarter.

## Current Marketing Activities

### Additional distributor for Aridol

**Leading Spanish company appointed partner**

In January, Aldo-Union was appointed to distribute and market Aridol in Spain. Spain is a key market, and Aldo-Union is a specialist respiratory pharmaceutical company with more than 40 years' experience in selling inhaled medicines for asthma.

Its strong reputation in respiratory medicine and broad coverage of the domestic territory with its own sales force make it an ideal partner for Pharmaxis.

The total Spanish population affected by asthma is estimated to be 2.7 million people. Spain is an important European market where challenge testing to assess effectiveness of treatment is currently performed.

### World experts discuss Aridol

**Respiratory specialists share Aridol experiences**

In February, the American Academy for Asthma Allergy and Immunology (AAAAI) held its annual meeting for more than 6,000 respiratory specialist physicians. There were four well-attended plenary sessions about the uses of Aridol during the five-day meeting.

The Thoracic Society of Australia and New Zealand (TSANZ) also held its annual meeting in March. Following the launch of Aridol last year, laboratory and physician experience with the product has grown significantly with many scientists and specialists visiting the Pharmaxis stand to share their experiences.

Both meetings are attended by a large number of experts in the respiratory field, and several meetings with opinion leaders were held during the course of the program. A list of the posters and papers published is included in the publications section of this report *(see page 6).*

## Current Clinical Activities

### Bronchitol for bronchiectasis

The most significant clinical activity for Pharmaxis this year, the Phase III trial of Bronchitol in bronchiectasis, successfully reached its patient recruitment target in February.

**Phase III bronchiectasis trial closes enrolment**

The double-blinded, placebo-controlled trial of 363 subjects is being conducted at 22 hospitals across Australia, New Zealand and the United Kingdom. It is expected to report in the middle of this year.

Pharmaxis has the only product in Phase III clinical trials for bronchiectasis worldwide, and we continue to supply the drug on a compassionate use basis to patients throughout Australia. A positive outcome from this study will enable us to seek approval to market Bronchitol.

Bronchiectasis is an incurable, degenerative and chronic lung condition affecting more than half a million people worldwide and costing US$630 million to treat in the U.S. alone. Currently, there are no effective therapeutic options available to help relieve the symptoms associated with continued mucus production.

## Bronchitol for cystic fibrosis

Three separate trials of Bronchitol in cystic fibrosis made headway in the past quarter:

**International Phase III trial begins**

Just days after the close of the January-March quarter, the first patient was enrolled in our international Phase III clinical trial evaluating Bronchitol in cystic fibrosis patients.

The trial is being conducted initially in 40 hospitals across Australia, the UK and Ireland, and is the final clinical step before Pharmaxis seeks approval to market Bronchitol for cystic fibrosis in Europe and Australia.

This trial represents significant progress for our cystic fibrosis program, and follows the successful Phase II trial where Bronchitol led to a demonstrable improvement in patients' lung function.

The one-year trial is enrolling up to 250 cystic fibrosis sufferers aged six years and above, with participants assessed for improvements in lung function, infectious episodes and quality of life.

**...while Phase II trial starts in children**

Meantime, a Phase II clinical trial of Bronchitol in children with cystic fibrosis closed its enrolment phase during the quarter. The UK-based, investigator-led trial involves children undertaking three months' treatment with three different therapies—Bronchitol alone, both Bronchitol and Pulmozyme together and Pulmozyme alone.

While not on the regulatory approval path, this is an important study for children with cystic fibrosis. It will help clinicians understand how emerging therapies such as Bronchitol should be positioned in a patient's daily treatment regime.

**...and dosing study approved in Argentina**

Regulatory approval has also been received to undertake a Phase II Bronchitol dose ranging study in Argentina. The study is designed to determine the optimal dose of Bronchitol to generate clinical improvement in patients with cystic fibrosis. It is the second stage of a dosing trial begun in Canada, and we are now actively recruiting patients. The study results are expected later this year.

## Aridol for chronic obstructive pulmonary disease

Pharmaxis will move to position Aridol as a key tool for managing treatment of COPD sufferers, following the outcomes of a Phase II trial.

**Trial confirms Aridol as tool for COPD management**

The trial found that COPD patients with a positive Aridol challenge test experienced a highly significant improvement in hyper-responsive airways following treatment with inhaled corticosteroids. Hyper-responsive airways are increasingly recognised as the most accurate indicator of COPD severity.

The study results validates Aridol's ability over the current diagnostic tool, spirometry, to determine the severity of COPD. Spirometry measures lung function only, compromising its use for assessing the need for drug treatment. Following this clinically important result, Pharmaxis will now support a larger Swiss-based Phase III study using Aridol as the main measure of COPD control. There are more than 30 million COPD sufferers in the developed world.

## Current Research Activities

Active research programs are underway to identify new treatments for inflammatory and respiratory diseases such as asthma, rheumatoid arthritis, Crohn's Diseases, and multiple sclerosis. Pharmaxis' strategy is to design new medicines to prevent the migration of inflammatory cells to sites of inflammation, thus reducing or eliminating the symptoms of these chronic diseases.

## Recent Publications and Presentations

**45 articles now published**

1. Response to mannitol in asymptomatic subjects with airway hyper-responsiveness to methacholine C. Porsbjerg, L. Rasmussen, S. F. Thomsen, J. D. Brannan, S. D. Anderson and V. Backer. Clinical and Experimental Allergy, 2007. 37, 22–28 (accepted for publication)
2. AAAAI session 3301: Methacholine, adenosine monophosphate and mannitol challenges: Dr S. Anderson
3. AAAAI session 3701: Mannitol: Will it replace conventional challenges? Dr Ken Rundell
4. AAAAI session 4101: Pulmonary physiology and measurement: Influence of gender, age and obesity. Dr S. Anderson
5. AAAAI session 4803: Workshop: Inhalation Challenge Tests: Mannitol. Dr S. Anderson

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

## Intellectual Property Portfolio

**No material changes to patents**

There has been no material change to the patent portfolio this quarter.

| | 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; A = abandoned*

## Financial Overview for Quarter ended 31 March 2007

We finished the quarter with A$79.9 million in cash and cash equivalents, and therefore remain well funded to progress our business plan.

**Australian Aridol sales increasing**

Aridol sales for the quarter were A$41,000, with an overall gross margin of 75%. During the quarter we sold Aridol in Australia and also to a US biopharmaceutical company for use in its clinical trial program. Australian sales for the current quarter increased 53% over the average sales for the prior two quarters. At quarter end we had outstanding customer orders of approximately $60,000.

The small decrease in interest income over the prior comparable quarter to A$1.3 million reflects the decrease in invested cash funds, marginally offset by higher prevailing short term interest rates.

Grant income is less than the prior comparable quarter due to an increase in the proportion of research activities in areas not eligible for grant support.

**Clinical trials responsible for most research expenditure**

Research and development expenses increased approximately 20 percent over the prior comparable quarter, but decreased approximately 30 percent compared to the December 2006 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. Other clinical expenditure included the remaining costs for the US Phase III trial of Aridol, initial costs for the international Phase III clinical trial of Bronchitol in cystic fibrosis and ongoing costs of the Phase II cystic fibrosis dosing study. The manufacture of Aridol and Bronchitol accounted for approximately 30 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 for the current quarter 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 additional public company costs particularly in relation to the US capital markets and the filing of a shelf registration statement with the US SEC.

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

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

### Income Statement

| | Three months ended | | Year-to-date | |
|---|---|---|---|---|
| | 31-Mar-07 | 31-Mar-06 | 31-Mar-07 | 31-Mar-06 |
| | A$ | A$ | A$ | A$ |
| Revenue from sale of goods | 41 | - | 159 | - |
| Cost of sales | (10) | - | (39) | - |
| Gross profit | 31 | - | 120 | - |
| Other income | | | | |
| Interest | 1,283 | 1,418 | 4,059 | 2,854 |
| Grant income | 396 | 468 | 1,583 | 898 |
| Expenses | | | | |
| Research & development | 5,212 | 4,404 | 18,984 | 10,051 |
| Commercial | 845 | 497 | 2,461 | 1,100 |
| Administration | 1,329 | 981 | 3,210 | 3,163 |
| Foreign exchange (gains) losses | (3) | - | 49 | - |
| Total expenses | 7,383 | 5,882 | 24,704 | 14,314 |
| Net loss before tax | (5,673) | (3,996) | (18,942) | (10,562) |
| Income tax expense | 4 | - | 12 | - |
| Net loss after tax | (5,677) | (3,996) | (18,954) | (10,562) |
| Basic and diluted earnings (loss) per share - $ | (0.032) | (0.023) | (0.107) | (0.068) |
| Depreciation & amortisation | 239 | 174 | 693 | 706 |
| Fair value of options issued under employee plan | 462 | 409 | 1,091 | 812 |

### Balance Sheet Data

| | As at | |
|---|---|---|
| | 31-Mar-07 | 30-Jun-06 |
| | A$ | A$ |
| Cash and cash equivalents | 79,915 | 97,840 |
| Plant & equipment | 3,559 | 3,205 |
| Intangible assets | 1,167 | 1,195 |
| Total assets | 86,359 | 104,267 |
| Total liabilities | (5,143) | (5,378) |
| Total shareholders' equity | 81,216 | 98,888 |

### Cash Flow Data

| | Three months ended | | Year-to-date | |
|---|---|---|---|---|
| | 31-Mar-07 | 31-Mar-06 | 31-Mar-07 | 31-Mar-06 |
| | A$ | A$ | A$ | A$ |
| Cash flows from operating activities | (6,017) | (3,497) | (17,089) | (9,076) |
| Cash flows from investing activities | (151) | (389) | (1,027) | (1,365) |
| Cash flows from financing activities | 12 | 61 | 192 | 79,661 |
| Net increase (decrease) in cash held | (6,156) | (3,825) | (17,924) | 69,220 |

### Ordinary Share Data

| | As at | |
|---|---|---|
| | 31-Mar-07 | 30-Jun-06 |
| Ordinary shares on issue | 177,365 | 176,904 |
| Options over ordinary shares outstanding | 10,188 | 9,692 |

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

### Statement of Operations

| | Three months ended | | | Six months ended | | |
|---|---|---|---|---|---|---|
| | Mar-31-06 | Mar-31-07 | Mar-31-07 | Mar-31-06 | Mar-31-07 | Mar-31-07 |
| | A$ | A$ | US$(1) | A$ | A$ | US$(1) |
| Revenue from sale of goods | - | 41 | 34 | - | 159 | 129 |
| Cost of sales | - | (10) | (8) | - | (39) | (32) |
| Gross profit | - | 31 | 26 | - | 120 | 97 |
| Operating expenses | | | | | | |
| Research & development | 3,676 | 4,632 | 3,754 | 8,641 | 16,882 | 13,681 |
| Commercial | 426 | 771 | 625 | 963 | 2,257 | 1,829 |
| General and administrative | 881 | 1,100 | 892 | 2,930 | 2,770 | 2,245 |
| Amortization of intangible assets | 23 | 24 | 19 | 68 | 70 | 58 |
| Fair value of stock options issued to employees | | | | | | |
| Research & development | 237 | 161 | 130 | 449 | 450 | 364 |
| Commercial | 71 | 75 | 60 | 130 | 205 | 166 |
| General and administrative | 100 | 227 | 184 | 232 | 437 | 354 |
| Total operating expenses | 5,414 | 6,990 | 5,664 | 13,413 | 23,071 | 18,697 |
| Loss from operations | (5,414) | (6,959) | (5,638) | (13,413) | (22,951) | (18,600) |
| Interest and other income | 1,418 | 1,283 | 1,040 | 2,854 | 4,059 | 3,290 |
| Foreign exchange gains (losses) | - | 3 | 3 | - | (49) | (39) |
| Net loss before tax | (3,996) | (5,673) | (4,595) | (10,559) | (18,941) | (15,349) |
| Income tax expense | - | (4) | (3) | - | (12) | (10) |
| Net loss | (3,996) | (5,677) | (4,598) | (10,559) | (18,953) | (15,359) |
| Basic and diluted net loss per ADS | (0.023) | (0.032) | (0.026) | (0.068) | (0.107) | (0.087) |
| Depreciation & amortisation | 162 | 227 | 184 | 670 | 658 | 533 |

### Balance Sheet Data

| | As at | | |
|---|---|---|---|
| | 30-Jun-06 | 31-Mar-07 | 31-Mar-07 |
| | A$ | A$ | US$(1) |
| Cash and cash equivalents | 97,840 | 79,915 | 64,763 |
| Plant & equipment | 3,289 | 3,723 | 3,017 |
| Intangible assets | 1,057 | 986 | 799 |
| Total assets | 104,213 | 86,341 | 69,971 |
| Total liabilities | (5,325) | (5,125) | (4,154) |
| Total shareholders' equity | 98,888 | 81,216 | 65,817 |

### Cash Flow Data

| | Three months ended | | | Year-to-date | | |
|---|---|---|---|---|---|---|
| | Mar-31-06 | Mar-31-07 | Mar-31-07 | Mar-31-06 | Mar-31-07 | Mar-31-07 |
| | A$ | A$ | US$(1) | A$ | A$ | US$(1) |
| Net cash used in operating activities | (3,497) | (6,017) | (4,876) | (8,955) | (17,089) | (13,849) |
| Net cash used in investing activities | (389) | (151) | (122) | (1,365) | (1,027) | (832) |
| Net cash provided by financing activities | 61 | 12 | 10 | 79,661 | 192 | 155 |
| Net increase in cash and cash equivalents | (3,825) | (6,156) | (4,988) | 69,341 | (17,924) | (14,526) |

### American Depositary Share Data

| | As at | |
|---|---|---|
| | 30-Jun-06 | 31-Mar-07 |
| Equivalent ADSs on issue | 11,794 | 11,824 |
| Equivalent Options over ADSs outsdtanding | 646 | 679 |

(1) Convenience translation into U.S. dollars from Australian dollars based upon rate on March 31, 2007