# Quarterly Report to Shareholders No 10

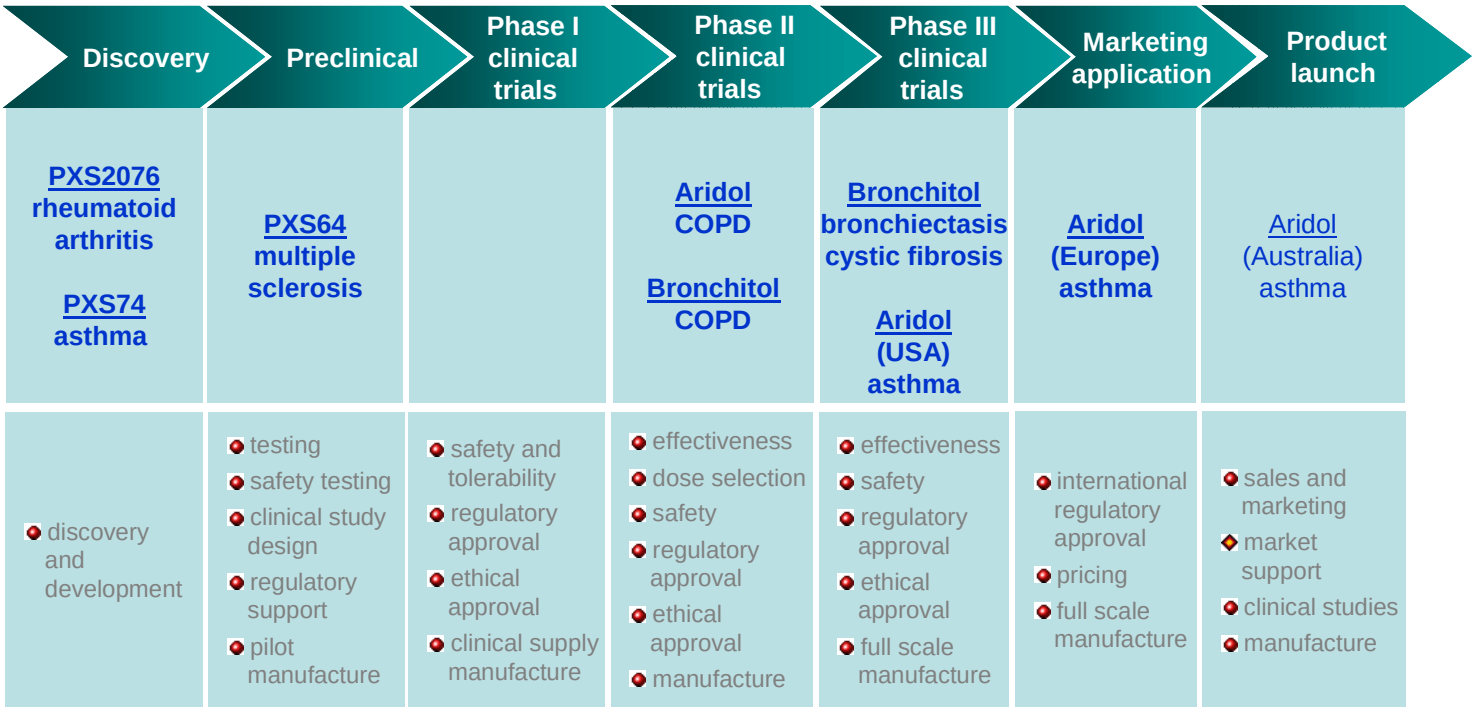
January – March 2006


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 related to smoking*

Front cover: Aridol lung function testing kit

## 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.

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

*"Aridol registered by the TGA"*

⇒ Aridol approved by the Australian TGA

⇒ Aridol introduced at TSANZ in Canberra, Australia

⇒ Manufacturing facility passes TGA audit

⇒ Marketing partners for Scandinavia and Switzerland appointed

⇒ European operations commence

⇒ Pharmaxis Board—majority now independent

⇒ Pharmaxis admitted to S&P/ASX Top 300

## Anticipated Forthcoming Events

*"Anticipating European registration"*

| | |
|---|---|
| ⇒ Initiation of Bronchitol bronchiectasis Phase III study | 1H 2006 |
| ⇒ Aridol marketing authorisation in Sweden | 1H 2006 |
| ⇒ Aridol marketing authorisation in European Union | 2H 2006 |
| ⇒ Appointment of additional European distributors | 1H 2006 |
| ⇒ Completion of Aridol COPD management study | 2H 2006 |
| ⇒ Completion of US Aridol asthma trial | 1H 2006 |
| ⇒ Completion of Bronchitol cystic fibrosis dosing study | 2H 2006 |
| ⇒ Initiation of Bronchitol cystic fibrosis Phase III study | 2H 2006 |

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## Current Activities— Regulatory

### ***Aridol Registered by the TGA***

On March 23, the Australian regulatory body, the Therapeutic Goods Authority (TGA) registered Aridol to identify bronchial hyperresponsiveness to assist in the diagnosis of asthma. This represents the culmination of over 10 years work by a large number of people—from the scientists at the Royal Prince Alfred Hospital, Sydney, to the preclinical, clinical and regulatory teams – the registration of Aridol is a significant outcome for all involved.

The TGA has re-issued our existing GMP (Good Manufacturing Practice) licence to manufacture. We are now manufacturing Aridol for commercial sale in Australia and other parts of the world.

## Current Activities—Marketing

*"Australian launch for Aridol"*

***Aridol launched at TSANZ***

Aridol's professional launch was at the Thoracic Society of Australia and New Zealand (TSANZ) annual meeting in Canberra, Australia. The 5-day meeting was attended by about 450 respiratory specialists and over 200 of those attending the meeting made enquiries at the Aridol stand, giving some indication of the high level of interest within the asthma and allergy fraternity.

***Marketing Partners for Scandinavia and Switzerland announced***

*"Marketing partners announced"*

In anticipation of Aridol's registration in Sweden this coming quarter, we appointed two regional marketing and distribution specialists. Nigaard Pharma AS is based in Oslo, Norway and will service the Scandinavian countries, and Trimedal AG based in Zurich, will service Switzerland and Liechtenstein. Both companies have well-established networks within the respiratory field, plus excellent local knowledge. At approximately 24 million, Scandinavia has a slightly larger population than that of Australia.

***Pharmaxis European Office established***

This quarter we have appointed a European Regional Director. Mark Sanders is based in the UK and is a seasoned marketing and business development professional with many years international experience within the respiratory therapeutics and devices fields. He has also consulted to the FDA on respiratory devices.

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## Current Activities — Clinical

***Aridol for asthma***

*"US Aridol trial enrolling well"*

The pivotal trial for registration in the US, A-305, has enrolled more than half the required patients. We are expecting full recruitment 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 is 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.

*"COPD trial enrollment closes"*

Our Australian-based trial, COPD-201 commenced enrollment in September 2005 and closed this quarter. Enrolled patients take an Aridol test followed by 12 weeks treatment with an inhaled corticosteroid. The objective is to test if Aridol can predict those patients who will respond to inhaled steroids and have an improved clinical outcome. A full report should be ready for release in the September quarter.

### ***Bronchitol for cystic fibrosis***

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.

The Canadian dose-ranging study, CF-202 is approaching 50% enrollment. 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. We expect the last patient to enrol in Q2 2006, and to finish dosing 3 months later.

*"CF trials steadily enrolling"*

The UK-based CF-203 trial is an investigator-led study and is being conducted in children aged 8—18. The earlier in life that normal lung function is restored, the greater the likely benefit for patients taking Bronchitol. This trial compares Bronchitol with existing treatments and is recruiting patients steadily. Each enrolled patient will assess three different treatment 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.

### ***Bronchitol for bronchiectasis***

The Phase III bronchiectasis trial, B301 is being run in Australia, New Zealand, and the United Kingdom. All the preparation work has been completed and we now await the first patient. Recruitment is expected to take 9 months and when patients are enrolled they will follow an 18 week treatment regimen. The objective is to show an improvement in quality of life, exercise, sleep, and lung function in patients receiving Bronchitol.

*"Phase III study ready to start"*

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## Current Activities – Research

This quarter we have established a research laboratory in the Sydney area to extend our drug discovery research capacity. The scientists in the Sydney laboratory will support research currently underway in our main laboratories in Canberra where we are actively pursuing new medicines to treat autoimmune diseases, such as multiple sclerosis and rheumatoid arthritis.

*"New research labs in Sydney"*

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

PXS2076 is being investigated for the treatment of rheumatoid arthritis.

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## Board Changes

Recent changes to the Board of Directors mark the transition of Pharmaxis from a start-up biotech to a maturing specialist pharmaceutical company. The appointment of Dr Peter Farrell, the founding chairman and CEO of ResMed Inc., will bring additional skills and experience related to developing a global company with listings in both Australia and in the USA.

## Publications / Presentations

*"This month's publications"*

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

1. Hyperosmolar Agents and Clearance of Mucus in the diseased airway. Journal of Aerosol Medicine, 2006, 19: 100-109

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## Intellectual Property

| | 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

*"New Patent family filed as a provisional application"*

There have been two changes to the patent portfolio this quarter. Patent Family 6 has been allowed to lapse because the family of molecules contained within the patent were replaced by the PXS2076 series. The PXS2076 family of molecules have improved properties over the PXS2030 family in terms of their solubility, stability, activity and ability to be developed as pharmaceutical agents.

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## S&P / ASX Top 300

*"PXS becomes an index stock"*

On 17 March 2006, the company was admitted to the S&P/ASX 300. The S&P/ASX 300 index provides extra depth and coverage to the S&P/ASX 200 whilst maintaining strict liquidity guidelines. It provides up to an additional 100 small-cap stocks to the S&P/ASX 200. The S&P/ASX 200 index addresses the needs of investment managers to benchmark against a portfolio characterized by sufficient size and liquidity.

## Financial Summary

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:

- In the US GAAP Statement of Operations we offset research grant income against research expenditure. Under Australian GAAP research grant income is a separate component of revenue.
- 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 Statement of Operations we separately report the fair value of options. Under Australian GAAP this expenditure is included within the relevant expense line.
- 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.

Pharmaxis finished the quarter with $A102.6 million ($US73.5) in cash and cash equivalents. The increase in interest income for the quarter to $A1.4 ($US1.0) million reflects a full quarter of interest on invested funds which more than tripled in November 2005 subsequent to the completion of an $A87 million($US62) capital raising.

Research and development expenses for the three months ended 31 March 2006 were more than 130% above the level of expenditure in the prior comparable quarter and more than 29% above the level of expenditure in the three months ended 31 December 2005. Our clinical trial programs are consistently the largest component of our research, and this quarter accounted for approximately 85 percent of the increase in research expenditure. We experienced accelerated recruitment in our Phase III study of Aridol for asthma (USA), our Phase II dosing study of Bronchitol for cystic fibrosis (Canada) and our Australian study of Aridol for COPD, while the investigator-led Phase II comparator study of Bronchitol for cystic fibrosis (UK) continued steady recruitment. Preparation for Phase III clinical trials of Bronchitol in both cystic fibrosis and bronchiectasis continues. Manufacturing work associated with stability studies for product registration accounted for the remainder of the increased expenditure.

Commercial expenses for the three months have increased over both the prior comparable quarter (approximately 45%) and the three months ended 31 December 2005 (approximately 20%) as the Company continues to prepare for the commercial launch of Aridol in Australia and Europe.

Administration expenses for the three months have increased over the prior comparable quarter (more than 65%) as a result of an increased level of investor relation activity, particularly in the United States, and the increase in the size of the Company over the last twelve months. When compared to the three months ended 31 December 2005 however, expenses have decreased by approximately 20% as the December quarter included larger than usual staff recruitment and relocation costs as well as the costs of annual report filings in both Australia and the US.

Capital expenditures for the quarter included the final installment on the new encapsulator, additional manufacturing and QC equipment and the initial payment for a fully integrated business software system to be implemented over the next two quarters.

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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-06 | 31-Mar-05 | 31-Mar-06 | 31-Mar-05 |
| | A$ | A$ | A$ | A$ |
| Revenue | | | | |
| Interest | 1,418 | 498 | 2,854 | 1,209 |
| Other income | | | | |
| Grant income | 468 | 357 | 898 | 847 |
| Other | - | 1 | - | 1 |
| | 1,886 | 856 | 3,752 | 2,057 |
| Expenses | | | | |
| Research & development | (4,404) | (2,083) | (10,050) | (6,363) |
| Commercial | (497) | (345) | (1,100) | (665) |
| Administration | (981) | (533) | (3,163) | (2,128) |
| Total expenses | (5,882) | (2,961) | (14,313) | (9,156) |
| Net loss before and after tax | (3,996) | (2,105) | (10,561) | (7,099) |
| Basic and diluted earnings (loss) per share | (0.023) | (0.016) | (0.068) | (0.059) |
| Depreciation & amortisation | 174 | 146 | 706 | 421 |
| Fair value of options issued under employee plan | 408 | 69 | 812 | 163 |

**Balance Sheet**

| | As at | |
|---|---|---|
| | 31-Mar-06 | 30-Jun-05 |
| | A$ | A$ |
| Cash and cash equivalents | 102,609 | 33,389 |
| Plant & equipment | 3,069 | 2,477 |
| Intangible assets | 1,174 | 1,106 |
| Total assets | 108,379 | 37,937 |
| Total liabilities | 2,999 | 2,470 |
| Total shareholders' equity | 105,380 | 35,467 |

**Cash Flow**

| | Three months ended | | Year-to-date | |
|---|---|---|---|---|
| | 31-Mar-06 | 31-Mar-05 | 31-Mar-06 | 31-Mar-05 |
| | A$ | A$ | A$ | A$ |
| Cash flows from operating activities | (3,497) | (1,442) | (9,076) | (6,226) |
| Cash flows from investing activities | (389) | (512) | (1,365) | (1,100) |
| Cash flows from financing activities | 61 | 6 | 79,661 | 19,021 |
| Net increase (decrease) in cash held | (3,825) | (1,948) | 69,220 | 11,695 |

**Share Data**

| | As at | |
|---|---|---|
| | 31-Mar-06 | 30-Jun-05 |
| Ordinary shares on issue | 175,124 | 134,770 |
| Options over ordinary shares outstanding | 11,370 | 10,914 |

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

**Statement of Operations**

| | Three months ended | | | Year-to-date | | |
|---|---|---|---|---|---|---|
| | Mar-31-05 | Mar-31-06 | Mar-31-06 | Mar-31-05 | Mar-31-06 | Mar-31-06 |
| | A$ | A$ | US$ (1) | A$ | A$ | US$(1) |
| Revenue | - | - | - | - | - | - |
| Operating expenses | | | | | | |
| Research & development | 1,687 | 3,676 | 2,634 | 5,398 | 8,642 | 6,192 |
| Commercial | 290 | 426 | 305 | 610 | 963 | 690 |
| General and administrative | 534 | 881 | 631 | 2,070 | 2,930 | 2,099 |
| Amortization of intangible assets | 23 | 23 | 16 | 67 | 68 | 49 |
| Fair value of stock options issued to employees | | | - | | | - |
| Research & development (Options) | 14 | 237 | 170 | 48 | 449 | 322 |
| Commercial (Options) | 56 | 71 | 51 | 56 | 130 | 93 |
| General and administrative (Options) | (1) | 100 | 72 | 59 | 233 | 167 |
| Total operating expenses | 2,603 | 5,414 | 3,879 | 8,308 | 13,415 | 9,612 |
| Loss from operations | (2,603) | (5,414) | (3,879) | (8,308) | (13,415) | (9,612) |
| Interest and other income | 498 | 1,418 | 1,016 | 1,209 | 2,854 | 2,045 |
| Net loss | (2,105) | (3,996) | (2,863) | (7,099) | (10,561) | (7,567) |
| Basic and diluted net loss per ADS | (0.234) | (0.343) | (0.246) | (0.884) | (1.020) | (0.731) |
| Depreciation & amortisation | 135 | 162 | 116 | 385 | 670 | 480 |

**Balance Sheet Data**

| | As at | | |
|---|---|---|---|
| | Jun-30-05 | Mar-31-06 | Mar-31-06 |
| | A$ | A$ | US$ (1) |
| Cash and cash equivalents | 33,268 | 102,609 | 73,519 |
| Plant & equipment | 2,376 | 3,003 | 2,152 |
| Intangible assets | 1,106 | 1,174 | 841 |
| Total assets | 37,836 | 108,314 | 77,607 |
| Total liabilities | 2,369 | 2,934 | 2,102 |
| Total shareholders' equity | 35,467 | 105,380 | 75,505 |

**Cash Flow Data**

| | Three months ended | | | Year-to-date | | |
|---|---|---|---|---|---|---|
| | Mar-31-05 | Mar-31-06 | Mar-31-06 | Mar-31-05 | Mar-31-06 | Mar-31-06 |
| | A$ | A$ | US$ (1) | A$ | A$ | US$(1) |
| Net cash used in operating activities | (1,494) | (3,497) | (2,506) | (6,274) | (8,955) | (6,416) |
| Net cash used in investing activities | (512) | (389) | (279) | (1,100) | (1,365) | (978) |
| Net cash provided by financing activities | 6 | 61 | 44 | 19,021 | 79,661 | 57,077 |
| Net increase in cash and cash equivalents | (2,000) | (3,825) | (2,741) | 11,647 | 69,341 | 49,683 |

**American Depositary Share Data**

| | As at | |
|---|---|---|
| | 30-Jun-05 | 31-Mar-06 |
| Equivalent ADSs on issue | 8,985 | 11,675 |
| Equivalent Options over ADSs outstanding | 758 | 728 |

(1) Convenience translation into US dollars from Australian dollars based upon rate on March 31, 2006