

Quarterly Report to Shareholders No 6

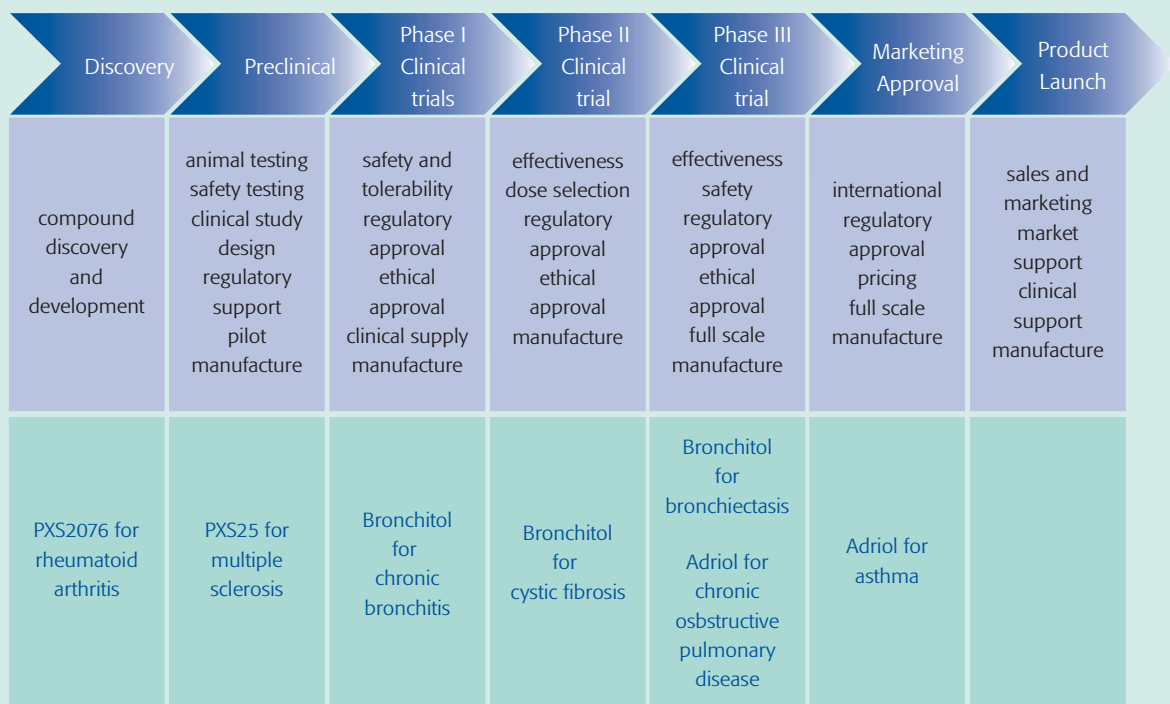
pharmaxis

Alan D Robertson
Chief Executive Officer

January – March 2005



Pharmaxis is developing human healthcare products for the treatment and management of respiratory and autoimmune diseases.



Overview

Pharmaxis is located in Sydney, Australia and is a specialty pharmaceutical company with activities spanning research & development through to manufacture, marketing and distribution.

Our interests are in 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 products include a new management tool for both asthma and chronic obstructive pulmonary disease (Aridol) and a new treatment for cystic fibrosis and chronic obstructive pulmonary disease (Bronchitol).

“New treatments for respiratory and autoimmune disease”

“Orphan drug status received for Bronchitol”

“Manufacturing expansion completed”

Quarter Highlights

- Orphan drug status was granted by the US Food and Drug Administration (FDA) for Bronchitol in the treatment of bronchiectasis.
- The manufacturing expansion was completed on time and on budget.
- The Therapeutic Goods Administration (TGA) audited our upgraded manufacturing facility without incident.
- Regulatory and ethical approval to conduct a clinical trial in London, UK was received. This trial will examine the effects of Bronchitol *versus* the market leading drug (Pulmozyme) in patients with cystic fibrosis.
- Aridol clinical study results were presented at two international scientific meetings – the American Academy of Allergy Asthma and Immunology in San Antonio, Texas and at the Thoracic Society of Australia and New Zealand in Perth. The presentation in Perth was recognized by a prestigious award.
- A clinical study demonstrating the role of Aridol in the management of COPD was published in a leading international journal.

Current Activities — Clinical

Bronchitol for cystic fibrosis

Bronchitol is under development to assist patients with mucus clearance from their lungs and is delivered to the patient as a dry powder in a convenient hand-held device.

- Patient enrolment has accelerated in two of the centres participating in the Phase IIa cystic fibrosis study. The other centres are still recruiting at a steady rate. The study is designed to determine to what extent Bronchitol improves the symptoms of the disease and we hope to complete the study mid-2005.
- We are testing the hypothesis that Bronchitol is superior to Pulmozyme, the market leading drug for the management of cystic fibrosis. This Phase II study is being conducted in the United Kingdom, the clinical trial materials have been shipped to the hospitals and personnel have been recruited. Patient enrolment will commence shortly and results are expected in 2006.
- A study to determine the lowest effective dose of Bronchitol required for its therapeutic effect is being planned with an international group of CF clinicians.

“Cystic fibrosis study recruitment accelerates”

“UK study to test Bronchitol against the market leader”

“Bronchiectasis protocol being developed”

Bronchitol for bronchiectasis

- Discussions have been held with European regulatory authorities to determine the extent and scope of the clinical studies required to gain approval to market Bronchitol for bronchiectasis. A protocol is being finalized with the key investigators and we expect to be in a position to commence the dosing phase of the Phase III study in the middle of the year.
- A number of patients who participated in the previous clinical studies have requested a continuing supply of Bronchitol. We are working with the respiratory clinicians and the TGA to meet this request.

“Marketing application accepted for review”

Aridol for asthma

Aridol is an inhalable dry powder that can be administered using a convenient, hand-held device. It is designed to identify patients with active airway inflammation such as occurs in asthma, provide information on the severity of their disease and the effectiveness of their current treatment.

- The marketing application for asthma was lodged with the Australian TGA in early January and we were informed in March that the dossier has been accepted for review.
- The protocols for the US Phase III asthma clinical studies have been finalized and they are scheduled to start mid 2005. The outcome from the studies will be the submission of a New Drug Application with the FDA, seeking approval to market Aridol in the USA.
- Additional stability data has been collected for the European marketing approval and we expect to be in a position to submit the application during the forthcoming quarter.
- A clinical study sponsored by a clinical investigator in Copenhagen has completed and the data is to be presented at the European Respiratory Society meeting in September, 2005.

“European marketing application to be submitted”

Aridol for chronic obstructive pulmonary disease

In addition to its utility in asthma management, other uses for Aridol include the identification of patients with COPD that are likely to respond to treatment of their condition with inhaled steroids.

- Following the success of the pilot COPD study, in which Aridol was able to predict those patients that responded to anti-inflammatory medication, a larger study has been planned to expand Aridol’s utility. We expect to commence this study during the forthcoming quarter.

“Additional indication for Aridol”

Current Activities — preclinical

Research

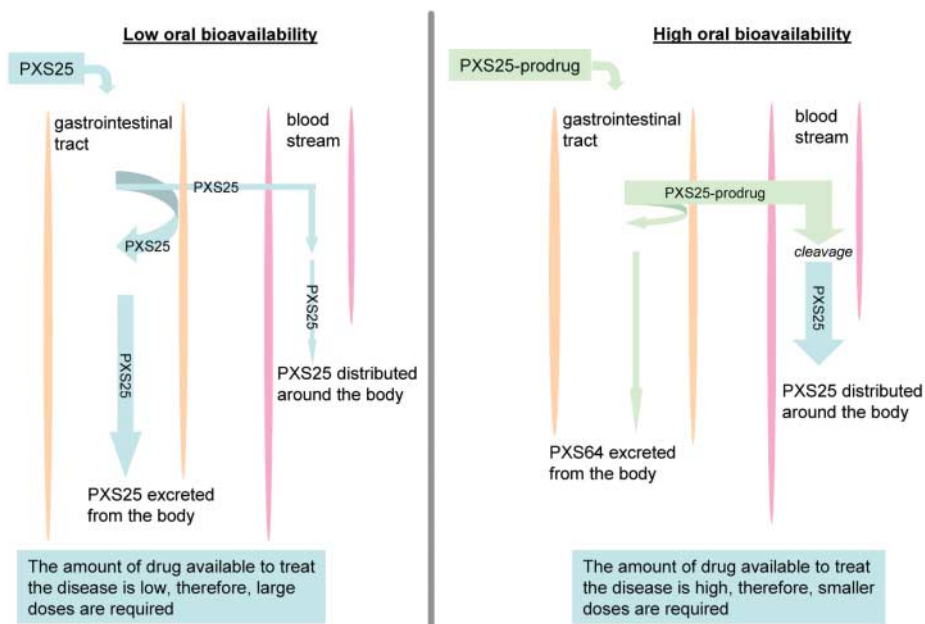
Our research laboratories are located in Canberra where we are actively researching the mechanisms of autoimmune diseases such as multiple sclerosis and rheumatoid arthritis. The research group is targeting a particular protein that is implicated in the progression of autoimmune disease. New molecules have been identified that inhibit the function of this protein and are effective in animal models of rheumatoid arthritis. We have selected a lead candidate and are in the process of determining its suitability for development.

“Research into rheumatoid arthritis”

Development

The prodrug of PXS25 efficiently delivers PXS25 following oral administration.

“New oral version of PXS 25 improves drug availability by 700%”



“Improved oral version of PXS25 in development”

PXS25 is under development as an oral product for the treatment of multiple sclerosis. An improved version of PXS25 that is particularly suitable for delivery by mouth has now been developed. This compound, PXS64, is termed a prodrug of PXS25 and delivers high concentrations of PXS25 to the blood stream providing significant advantages in the development of PXS25. During the quarter, we received additional supplies of PXS64 from the contract manufacturer for preclinical safety evaluation.

PXS25 inhibits the function of an enzyme that contributes to the inappropriate migration of immune cells that can lead to multiple sclerosis. Our plan is to move PXS64 through an extensive safety testing programme to allow clinical studies to commence during 2005.

Publications/Presentations

Over 35 scientific articles have been published on our technology. Articles that have been published this quarter include:

- 1 **Indirect bronchial hyper-responsiveness: the coming of age of a specific group of bronchial challenges** by J. Van Schoor, R. Pauwels and G. Joos in *Clinical and Experimental Allergy*, 2005, 35:250-261.
- 2 **Provoking dose of mannitol to assess airway hyperresponsiveness in asthma: a retrospective analysis.** Presented at the 61st Annual Meeting of the American Academy of Allergy, Asthma & Immunology, March 18-22, San Antonio, Texas, USA by S. D. Anderson *et al.*
- 3 **Bronchial provocation using inhaled mannitol—a Phase III trial of adult & pediatric asthmatics & non-asthmatics.** Presented at the Thoracic Society of Australia and New Zealand Annual Conference, March 18-23, Perth, Australia by J. Brannan *et al.*
- 4 **Effect of treatment recovery of FEV1 to baseline after a mannitol challenge: a Phase III study.** Presented at the Thoracic Society of Australia and New Zealand Annual Conference, March 18-23, Perth, Australia by R. Freed-Martens *et al.*

“Aridol presented at international meetings”

Intellectual Property

There has been no change to the patent portfolio during the quarter.

“No change to patent 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)	PCT	PCT	PCT	PCT

*G = granted; P = pending; prov = provisional; PCT = Patent Cooperation Treaty; ROW denotes rest of the world including Japan
*Details of the patent portfolio can be found in the annual report

Financial Highlights

Pharmaxis finished the quarter with \$36.9 million in cash and bank accepted commercial bills. We are well funded to progress our business plan.

Research & development expenditure for the quarter of \$2.1 million was 57% higher than the prior comparable quarter, but only 11% higher than expenditure in the previous quarter. While our clinical trial program remains the largest component of our research & development effort, over half of the current quarter increase in expenditure is attributable to extended toxicology studies on Aridol and Bronchitol. These are necessary to support marketing applications with international regulatory agencies and the longer term Bronchitol clinical studies.

“Well funded to execute business plan”

Manufacturing research for the quarter was focused on stability studies required for regulatory filings, and process improvements integral to a three fold increase in manufacturing capacity. Clinical research for the quarter included the ongoing Australian study of Bronchitol in cystic fibrosis, as well as the planning and design of new studies for Bronchitol in cystic fibrosis and bronchiectasis and Aridol in asthma (US) and COPD.

Commercial expenditure for the quarter of \$290,000 represents a 140% increase over expenditure for the December quarter, and is associated with preparations for the international commercial launch of Aridol later in 2005.

Administration expenditure for the quarter of \$534,000 was 18% lower than the prior comparable quarter, in part reflecting certain relocation expenses incurred in the 2004 period. The current quarter also includes certain costs incurred in preparing the US SEC filings necessary for the company to apply for a NASDAQ listing.

Cash flows from investing activities include approximately \$0.5 million for the quarter and \$1.0 million year to date related to the tripling of manufacturing capacity. While the key processes were installed and commissioned during the quarter, the installation of ancillary equipment will continue for the remainder of the calendar year.

Financial Summary

	Three months ended		Nine months ended	
	31 March 2005	31 March 2004	31 March 2005	31 March 2004
	\$'000	\$'000	\$'000	\$'000
Financial Performance				
Revenue				
Interest received	498	366	1,209	720
Research grants	345	210	811	797
Other	1	14	1	48
	844	590	2,021	1,565
Expenses				
Research & development	(2,068)	(1,320)	(6,314)	(3,506)
Commercial	(290)	–	(610)	–
Administration	(534)	(651)	(2,070)	(1,503)
Total expenses	(2,892)	(1,971)	(8,994)	(5,009)
Net loss before and after tax	(2,048)	(1,381)	(6,973)	(3,444)
Depreciation & amortisation	146	124	421	360
EBITDA	(2,399)	(1,624)	(7,760)	(3,804)
Cash Flows				
Cash flows from operating activities	(1,442)	(693)	(6,226)	(3,058)
Cash flows from investing activities	(512)	(185)	(1,100)	(372)
Cash flows from financing activities	6	(3)	19,021	22,891
Net increase (decrease) in cash held	(1,948)	(881)	11,695	19,461

	31 March 2005	30 June 2004
Financial Position		
Cash and bank accepted commercial bills	36,912	25,217
Plant & equipment	2,186	1,474
Intangible assets	1,129	1,162
Total assets	41,210	28,261
Total liabilities	2,382	1,481
Total shareholders' equity	38,828	26,780
Shares on Issue	134,770	108,016



Alan D Robertson
Chief Executive Officer

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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