

Quarterly Report to Shareholders No 5

Alan D Robertson
Chief Executive Officer

October – December 2004

pharmaxis



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

“Focus on
respiratory and
autoimmune disease”

“Aridol registration
documents submitted
to the TGA”

“FDA accepts IND
submission”

“Cystic fibrosis
study recruitment
continues steadily”

“Bronchiectasis final
clinical study planning
well advanced”

Company Overview

- Our objective is to bring new, effective and safe medicines to people
- We are building an integrated pharmaceutical company, with activities spanning research & development through to manufacture, marketing and distribution
- Our interests are in respiratory diseases, such as asthma, and diseases of the immune system, such as multiple sclerosis
- 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)
- Aridol is at the registration for sale phase of its development
- Bronchitol is at the Phase III clinical stage of its development in the lung disease bronchiectasis and at Phase II clinical stage of its development in cystic fibrosis
- Research and development projects include new treatments for multiple sclerosis (PXS25) and for rheumatoid arthritis (PXS2076)

Quarter Highlights

- Successful capital raising of \$19.8 million
- Successful completion of the pivotal Phase III Ardiol clinical study
- Successful completion of the Phase II Bronchitol clinical study
- US patent issued for multiple sclerosis treatment
- Acceptance of Investigational New Drug Application (IND) to allow a US Phase III clinical trial with Ardiol
- Regulatory approval documents submitted to the Therapeutic Goods Administration (TGA) for the sale and marketing of Ardiol in Australia
- Level One American Depositary Receipt (ADR) program established
- Preclinical, long term, safety study completed for Bronchitol

Current Activities

Bronchitol

- A three month safety study in rodents has been completed successfully by a contract laboratory in Europe. The data from this study will support the various international clinical trial applications.
- Recruitment continues steadily in the Australian Phase IIa study investigating the performance of Bronchitol in patients suffering from cystic fibrosis. The study is designed to measure the effects on disease symptoms of twice daily administration of Bronchitol versus an inactive control.
- The planning is well advanced for the late stage, pre-registration clinical trials in patients with bronchiectasis and meetings have been held with the key investigators. The significant clinical investigator interest underscores the importance of new treatment options for this patient group and we expect to be in a position to commence the dosing phase of the study during the first half of 2005.

Aridol

- We recently completed the pre-registration clinical study and analysis of the results are complete. The marketing authorization application for Australia has been submitted and the European application is in final stages of preparation.
- We have received feedback from the FDA on the US Phase III Ardiol study and are adjusting the protocol accordingly. We expect to be in a position to commence the study during the first half of 2005.

“Expansion of manufacturing facility on track”

Facilities update

The \$2.5 million expansion of the manufacturing facility is in progress and on completion will allow us to manufacture approximately one million Aridol kits per year at full capacity. Additional equipment to improve the efficiency of Aridol and Bronchitol production has arrived from Europe and is being installed.

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 are 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 have shown to be effective in animal models of rheumatoid arthritis and to be active when administered orally.

Preclinical Development

PXS25 is under development as an oral product for the treatment of multiple sclerosis. During the quarter, we received additional supplies of PXS25 from the contract manufacturer for additional preclinical safety evaluation.

PXS25 inhibits the function of an important enzyme that is required for the progression of multiple sclerosis. Prior to evaluation in patients, PXS25 has to pass a number of safety hurdles and it is currently in that phase of its development. A number of collaborations have been initiated with internationally recognized research groups to better understand the full potential of PXS25.

Clinical Development

Aridol™

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

Other uses for Aridol include the identification of patients with COPD that are likely to respond to treatment of their condition with inhaled steroids

The successful market launch of Aridol depends, in part, on educating respiratory physicians of the merits of the product. Fortunately, there has been extensive worldwide interest in Aridol and we regularly receive requests from respiratory specialists wishing to undertake clinical studies with the product. Currently there are 18 studies throughout the world either in progress or at the planning stage involving over 3,500 people. Successful completion of these studies will add to our knowledge base, demonstrate more clearly the exact role Aridol has to play in asthma and COPD management and assist with the successful commercialization of the product.

“PXS25 in development for multiple sclerosis”

“Aridol marketing authorization application submitted”

“Aridol in clinical study throughout the world”

Summary of international clinical studies either in progress or being planned

“Over 18 international studies involving Aridol”



Bronchitol™

Bronchitol is being evaluated as a therapeutic agent for people suffering from diseases such as cystic fibrosis, bronchiectasis and chronic bronchitis. Bronchitol has been designed to enhance normal lung clearance mechanisms and assist with the clearance of mucus from patients lungs.

Following the successful completion of the Australian and New Zealand study in patients with bronchiectasis, additional clinical studies are being assembled.

These studies will involve centres in Australia, Europe and the USA and are scheduled to commence during the first half of 2005. The study design has been agreed, the protocol developed and the principal investigators have been selected.

Bronchitol is also being investigated in patients with cystic fibrosis. This multicentre Phase II study across Australia and New Zealand is recruiting steadily.

The primary objective of the study is to improve the quality of life and lung function of patients following two weeks of treatment.

Recruitment into this study remains steady particularly amongst children affected by the disease.

The study is expected to report during the first half of 2005.

Additional studies with Bronchitol in cystic fibrosis patients are being planned.

Publications/Presentations

Aridol and Bronchitol have been the subject of more than 25 publications in peer reviewed journals by a variety of research laboratories throughout the world.

A scientific paper describing the potential of Aridol in the management of COPD has been published in a leading international journal. This study, from a group of researchers in Switzerland, demonstrated that Aridol can accurately predict those patients with COPD that will respond to treatment with inhaled steroids.

Prediction of treatment response to inhaled corticosteroids by mannitol challenge test in COPD. A proof of concept. Leuppi JD et al., Pulmonary Pharmacology & Therapeutics 2005;18(2):83-88 (www.sciencedirect.com)

“Cystic fibrosis study likely to report during the first half of 2005”

“Aridol study in COPD published”

Intellectual Property

“US patent granted on new compounds for the treatment of multiple sclerosis”

	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

“Successful capital raising strengthens cash position”

During the quarter Pharmaxis raised a total of \$19.8 million - \$16.5 million from a share placement to qualified institutional buyers and sophisticated investors, and a further \$3.3 million from a share purchase plan that allowed existing shareholders to purchase up to five thousand dollars worth of shares at the same price as the placement (\$0.75). Approximately half of our shareholders participated in the plan. The funds were raised to replenish the cash expended in 2004 on our successful clinical trials and to provide funds for a Phase III clinical trial of Bronchitol for bronchiectasis. At 31 December 2004 Pharmaxis had cash and bank accepted commercial bills totalling \$38.9 million and 134,750,092 shares on issue.

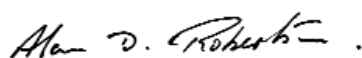
In November, Pharmaxis established a Level One American Depositary Receipt (ADR) Program to facilitate the purchase of Pharmaxis shares by US investors. Pharmaxis Level One ADR's are freely tradeable in the US over-the-counter (OTC) market under the symbol PHMXY (CUSIP number 71715J105) and trading activity is available on the Bloomberg website: www.bloomberg.com.

Our half-year financial statements will be lodged with the ASX on 11th February and will include commentary on the half year's expenditures. The level of activity in clinical trials has been the major factor in our research and development expenditure increasing to approximately \$1.9 million for the quarter and \$4.2 million for the half-year. Our expenditure on commercial activities for the quarter was approximately \$120,000 bringing the half year total to approximately \$320,000. Our commercial group is preparing for the launch of Aridol in Australia and Europe. Administration expenses for the quarter were approximately \$630,000 bringing the half year total to approximately \$1.5 million. Administrative expenses included one-off costs associated with the company's ADR program.

Financial Summary

	Quarter ended 31 Dec 2004	Quarter ended 31 Dec 2003	Half-year ended 31 Dec 2004	Half-year ended 31 Dec 2003
Financial Performance				
Revenue				
Interest received	390,202	273,783	711,043	354,033
Research grants	143,006	153,207	466,185	586,756
Other	–	17,365		34,430
	533,208	444,355	1,177,228	975,219
Expenses				
Research & development	(1,869,068)	(1,208,020)	(4,245,898)	(2,186,062)
Commercial	(119,968)	–	(319,991)	–
Administration	(633,021)	(424,883)	(1,536,170)	(851,743)
Net loss before and after tax	(2,088,849)	(1,188,548)	(4,924,831)	(2,062,586)
Depreciation & amortisation	137,329	119,135	274,828	235,954
Cash Flows				
Cash flows from operating activities	(2,740,165)	(1,276,528)	(4,783,748)	(2,364,684)
Cash flows from investing activities	(312,660)	(137,065)	(588,108)	(187,128)
Cash flows from financing activities	18,980,602	22,894,283	19,014,602	22,894,283
Net increase (decrease) in cash held	15,927,777	21,480,690	13,642,746	20,342,471

	31 Dec 2004	30 June 2004
Financial Position		
Cash and bank accepted commercial bills	38,859,769	25,217,023
Plant & equipment	1,804,633	1,473,888
Intangible assets	1,144,443	1,161,909
Total assets	42,502,695	28,261,020
Total liabilities	1,632,693	1,480,789
Total shareholders' equity	40,870,002	26,780,231
Shares on Issue	134,750,092	108,016,000



Alan D Robertson
Chief Executive Officer

Contact Details

Further information on Pharmaxis can be obtained from www.pharmaxis.com.au or by contacting the Company Secretary.

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