

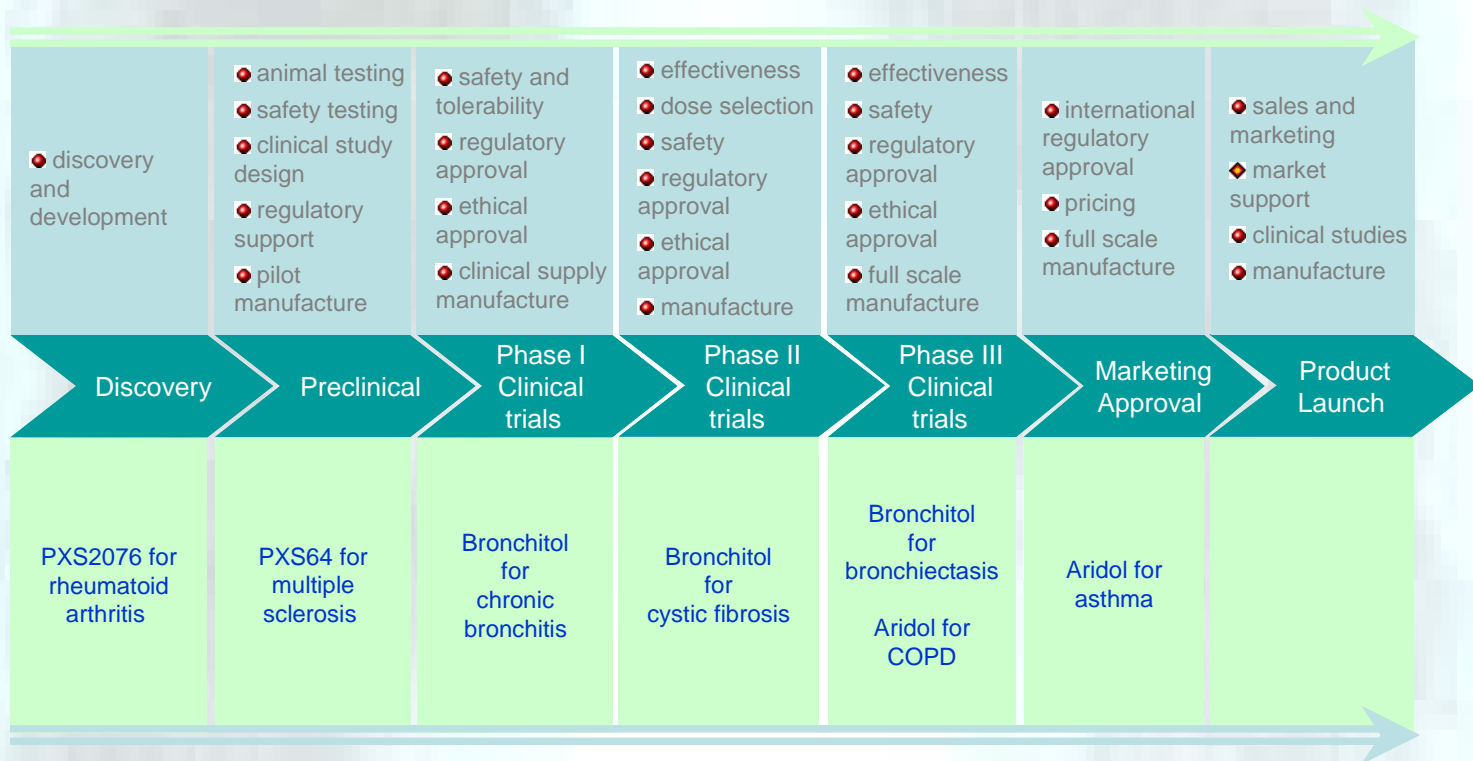
Quarterly Report to Shareholders No 7

Alan D Robertson
Chief Executive Officer
April - June 2005



pharmaxis

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



Overview

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

“New treatments for respiratory and autoimmune disease”

Our 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.

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).

Quarter Highlights

“Second orphan drug indication received for Bronchitol”

- ⇒ Orphan drug status was granted by the US Food and Drug Administration (FDA) for the use of Bronchitol to facilitate mucus clearance in patients with cystic fibrosis.
- ⇒ The Phase II Australian cystic fibrosis clinical trial reached its target patient recruitment.
- ⇒ An application was submitted to the European regulatory authorities seeking approval to market Aridol.
- ⇒ The Australian Therapeutic Goods Administration approved the use of Bronchitol for patients with bronchiectasis on an individual, compassionate use basis.
- ⇒ Aridol clinical study results were presented at the American Thoracic Society meeting in San Diego.
- ⇒ Regulatory approval was received from the Canadian health authorities to begin a clinical trial in patients with cystic fibrosis aimed at determining the ideal dose for Bronchitol.
- ⇒ An investigator meeting was held with participating clinicians in the USA to initiate the final pre-registration Aridol US clinical trial.

“Aridol submitted for European marketing”

Current Activities — Clinical

Bronchitol for cystic fibrosis

Bronchitol is under development to assist patients with lung mucus clearance and is delivered as a dry powder for inhalation in a convenient hand-held device.

“Cystic fibrosis study recruitment closes”

- ⇒ Patient enrolment for the Australian clinical trial in patients with cystic fibrosis accelerated towards the end of the study and reached the revised target more quickly than was anticipated. In addition, the data from the trial had less variation than expected. Rather than unblind the interim data, we decided to let the trial run its full course before interpreting the results. By following this course of action, we were able to truncate the trial and save some time on completing the study. This will enable us to proceed more quickly to the final studies that will be run to seek approval to market Bronchitol in this serious disease. The trial will determine to what

*“UK study to test
Bronchitol
against the
market leader”*

extent Bronchitol improves the symptoms of the disease and we expect data to be available during the third quarter of 2005.

⇒ A Phase II study is being conducted in the United Kingdom to determine how Bronchitol compares to the market leading drug, Pulmozyme, in children with cystic fibrosis. The clinical trial is sponsored by the chief investigator and involves studying patients for three months on each drug. Results from this study are not expected until 2006 and, although the study is important for the future of Bronchitol, it does not affect our time to lodge the marketing application. A meeting was held in London recently with the clinical trial team to discuss the study and its progress.

*“Cystic fibrosis
study to start in
Canada”*

⇒ After a worldwide search to find suitable centres to conduct a Bronchitol dosing study in patients with cystic fibrosis, we settled on Canada as the most suitable venue. While we would have much preferred to have run the study in Australia, we felt that patient enrolment would occur much faster in Canada due to the requirement of the study to involve patients not on existing mucus clearing agents. The aim of the study is to find the lowest effective dose of Bronchitol required for its therapeutic effect and should be completed during the first quarter of 2006.

Bronchitol for bronchiectasis

*“Meetings held
with regulatory
agencies
worldwide ”*

⇒ We have now held meetings with the Swedish (MPA), United Kingdom (MHRA) and US (FDA) regulatory agencies to discuss the forthcoming Phase III study in patients with bronchiectasis. Patients with bronchiectasis have had no new therapeutic intervention to assist with mucus clearance for over forty years, however, designing clinical trials that provide the necessary proof of effectiveness to secure a marketing application is complicated in this patient group. Nevertheless, we have received strong encouragement from the various regulatory agencies and the Phase III clinical trial will commence in Europe and Australia during the second half of this year and in the USA sometime during the first half of 2006.

*“Patients receive
Bronchitol on
compassionate
grounds”*

⇒ While the regulatory agencies rightly look for objective measures to assist with assessing marketing applications, there seems to be little doubt that some patients benefit from the drug. A number of patients who participated in the previous Phase II clinical studies have requested a continuing supply of Bronchitol. In certain circumstances, patients are able to obtain access to unapproved drugs such as Bronchitol through the Special Access Scheme that provides approval on an individual compassionate use basis. Special Access Scheme approval was received from the TGA recently and we are now supplying Bronchitol to certain patients.

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.

“Marketing application submitted”

⇒ The Aridol marketing application for the detection of airway inflammation in patients with asthma was lodged with the Swedish regulatory agency during the quarter. We have chosen a process known as the Mutual Recognition Procedure, which allows for approval in the other European Union countries following approval by Sweden.

“US Phase III study to commence shortly”

⇒ The protocols for the US Phase III asthma clinical studies have been finalized, an investigator meeting was held in Las Vegas and the protocols have been submitted to the FDA. The outcome from the study will be the submission of a New Drug Application with the FDA, seeking approval to market Aridol in the USA. The dosing phase of the study is due to start this quarter.

“Aridol presented at the ATS”

⇒ An important study investigating the ability of Aridol to manage treatment of patients with asthma is being conducted in the UK. In this study, patients are tested with Aridol prior to receiving inhaled steroids and then monitored over a three month period. This investigator sponsored study is being conducted in the primary care setting and is being run by one of the UK’s leading asthma specialists.

⇒ The American Thoracic Society held its annual meeting in San Diego, where Aridol featured in two presentations concerning the recent Australian Phase III clinical trial.

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 is likely to have a positive treatment response to inhaled steroids.

“New study to start in COPD”

⇒ We are conducting a formal regulatory study amongst General Practitioners and Respiratory Specialists to determine the ability of Aridol to predict treatment outcomes for patients with COPD. This study will commence recruitment during the quarter.

Current Activities—Manufacturing

Our manufacturing facility is located in Frenchs Forest. During the first quarter of 2005 its size and capacity has been expanded considerably. This quarter, following the re-certification by the TGA, manufacturing of Aridol and Bronchitol supplies for our clinical trials resumed and we are now able to manufacture over a million Aridol kits yearly.

“Production of Bronchitol and Aridol resumes”

The first batches of Bronchitol have been used to supply those patients who received permission from the TGA to be supplied under the Special Access Scheme. Further batches will supply the trials we are running in Australia, the USA and in Europe.

We will be seeking to upgrade our existing GMP manufacturing licence to allow for the production of Aridol for commercial sale during the second half of the year.

Current Activities — Non clinical

Research

“Research into multiple sclerosis and rheumatoid arthritis”

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.

Development

“PXS64 being studied in rodent models”

PXS64 is a prodrug of the active molecular species PXS25 and is under development for the treatment of multiple sclerosis. A prodrug is a more effective method of delivering the active molecular species following oral administration. PXS64 is being evaluated in rodent models of multiple sclerosis. A key study is being conducted in London and the results are due this forthcoming quarter.

Intellectual Property

“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

Publications/Presentations

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

“Early results from Phase III study published”

- Bronchial Provocation Using Inhaled Mannitol – A Phase 3 Trial of Pediatric Asthmatics and Non-Asthmatics** by S.D. Anderson, J.D. Brannan, R.H. Freed-Martens, The Aridol Study Group, Camperdown, NSW, Australia.
- Bronchial Provocation Using Inhaled Mannitol – A Phase 3 Trial of Adult Asthmatics and Non-Asthmatics** by J.D. Brannan, S.D. Anderson, R.H. Freed-Martens, The Aridol Study Group, Camperdown, NSW, Australia

3. **Airway Hyperresponsiveness and current Asthma in Swiss Professional Firefighters and Policemen** by D. Miedinger, D. Stolz, C. Gysin, M. Tamm, P. Chhaged, H. Bucher, J. Leuppi, Basel Switzerland

The above papers were presented at the American Thoracic Society meeting in May 2005.

Financial Highlights

Pharmaxis finished the quarter with \$33.4 million in cash and bank accepted commercial bills. We remain well funded to progress our business plan.

Our clinical trial programs continue to account for more than half of our research and development expenditure, followed by manufacturing research. The clinical group is focused on completing the Australian Phase II study in cystic fibrosis and preparing for the commencement of a series of Australian and international studies for Bronchitol in both bronchiectasis and cystic fibrosis, and Aridol in both asthma and chronic obstructive pulmonary disease. The manufacturing group is prioritising stability studies necessary to support regulatory applications and manufacturing scale up and development.

Commercial expenditure for the quarter was directed at the international commercial launch of Aridol in Australia and Europe scheduled for early next year, and identifying possible commercial distribution partners in Europe and the US.

Administration expenditure included costs incurred in preparing the US filings necessary for listing Pharmaxis on the NASDAQ National Market.

Investing activities for the quarter related primarily to ancillary equipment related to the manufacturing capacity increase.

The financial report for the year ended 30 June 2005 and additional commentary will be contained in the Pharmaxis Preliminary Final Report to the Australian Stock Exchange. This will be released to shareholders once the audited financial statements are complete and will be posted on the Pharmaxis website.

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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