

The logo for Pharmaxis, featuring the word "pharmaxis" in a lowercase, sans-serif font. The "ph" is in a dark blue color, and the "armaxis" is in a lighter blue color. The background of the entire page is a close-up photograph of green grass blades against a bright blue sky with light clouds. A large, white, curved graphic element is positioned in the upper left and center of the page.

**Annual Report 2006**

Quality of life through innovative medicine

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## Our mission

'To build an internationally successful speciality pharmaceutical business by bringing innovative medicines to patients with respiratory and autoimmune diseases.'

## Notice of meeting

The Annual General Meeting of Pharmaxis Ltd will be held at the Sheraton on the Park, 161 Elizabeth Street, Sydney on Thursday 26th October at 2.30pm.

# Overview

Pharmaxis is building an international specialty pharmaceutical business focused on patients with respiratory and autoimmune diseases.



Aridol has been designed to assist the management of asthma. Aridol is registered and sold in Australia and we are awaiting its market approval in Europe. A final Phase III clinical trial is nearing completion in the U.S. which will allow us to file for marketing approval with the FDA.

## bronchitol

Bronchitol is under development as a new treatment for cystic fibrosis, bronchiectasis and chronic bronchitis. The product is likely to reach the market first for use in bronchiectasis as we are well into the final Phase III clinical trial. Planning is well advanced for our Phase III clinical trials for the use of Bronchitol in cystic fibrosis. In addition, Bronchitol has applications in acute exacerbations of chronic obstructive pulmonary disease (COPD) and clinical work in this area is being planned.

Both Aridol and Bronchitol are manufactured at our licensed GMP manufacturing facility in Sydney, Australia.

We are researching diseases of the immune system such as multiple sclerosis, rheumatoid arthritis and asthma at our laboratories within the Australian National University in Canberra, Australia, and at our recently established research facilities in Sydney.

Pharmaxis listed on the Australian Stock Exchange in 2003 and the US NASDAQ Global Market in 2005. We are well funded to advance our clinical and commercial programs.



## Aridol for asthma

Aridol is a point-of-care test for airway inflammation that facilitates the diagnosis of asthma

Patient population: 52 million



### Current status

Aridol is approved for commercial sale in Australia  
Sydney factory is GMP approved by Australian Therapeutic Goods Administration (TGA)  
Commercial manufacture and sale of Aridol kits in Australia underway  
Marketing applications filed in Sweden and Switzerland  
Final registration clinical trial in US well advanced

### Upcoming milestones

Sales expansion in Australia  
Approval in EU countries under mutual recognition procedure  
Appointment of additional international marketing/distribution partners  
Commencement of sales in Sweden and other EU countries  
Filing of New Drug Application in US

### Label extension for Aridol in COPD

During 2006, we commenced and closed recruitment on a clinical study investigating the ability of Aridol to identify patients with chronic obstructive pulmonary disease, (COPD), who will respond to inhaled steroid treatment

Patient population: 30 million

## Product Pipeline

### Respiratory diseases

Aridol – asthma

Aridol – COPD

Bronchitol – bronchiectasis

Bronchitol – cystic fibrosis

Bronchitol – chronic bronchitis (hospital)

### Autoimmune diseases

PXS25/64 – multiple sclerosis

PXS74 – asthma

## bronchitol

### Bronchitol for cystic fibrosis

Bronchitol is designed to clear lungs of excessive mucus and arrest the decline in lung function of patients with cystic fibrosis

Patient population: 75,000



### Current status

Bronchitol has orphan drug designation in US and EU  
Phase II clinical trial successfully completed  
Phase III clinical trial protocols agreed with US FDA and European Medicines Agency  
Planning is well advanced for two Phase III clinical trials

### Upcoming milestones

Commencement of Phase III trial in EU and Australia – 2006  
Commencement of Phase III trial in US – 2007

## Bronchitol for COPD/ bronchiectasis

Bronchitol is a therapeutic dry powder delivered to the lungs twice a day to facilitate mucus clearance in patients with bronchiectasis, a progressive lung disease

**Patient population: 580,000**

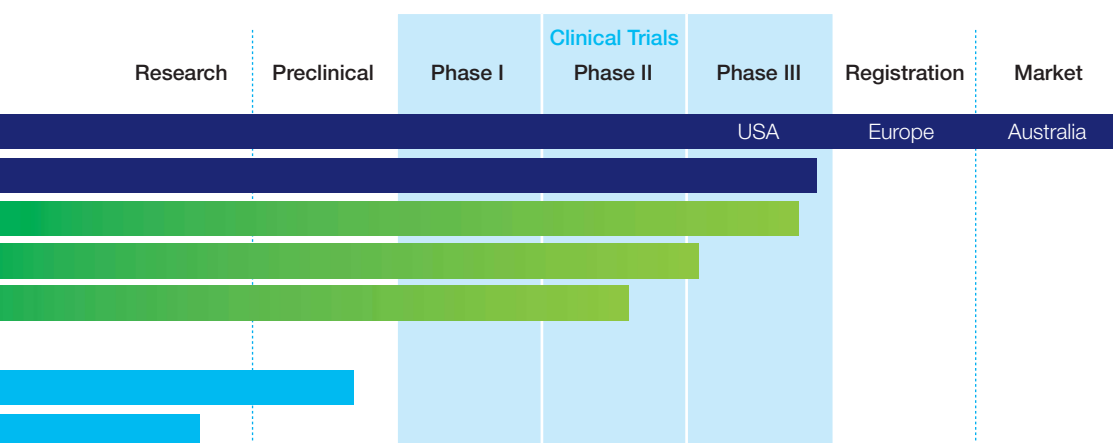


### Current status

Bronchitol has orphan drug designation for bronchiectasis in the US  
Phase III clinical trial in progress in Europe & Australia  
Bronchitol is supplied to select patients under the TGA Special Access Scheme

### Upcoming milestones

Completion of European & Australian Phase III clinical trial  
Filing of marketing authorisation application in EU and Australia  
Commencement of US Phase III trial



## Bronchitol for COPD/ chronic bronchitis

Acute exacerbations of COPD are the most common cause of admissions to hospital for respiratory illness. Bronchitol is designed to help patients clear congested chests during an exacerbation and improve their disease management

**Patient population: 30 million**



### Current status

Bronchitol has been supplied to patients in a hospital setting on an individual basis to help mucus removal, as a last treatment option. A clinical trial to establish the proof of concept is underway

### Upcoming milestones

Data from the proof of concept study  
Commencement of Phase III pivotal clinical trial

# 5 Year History

## 2006

Aridol approved for sale and marketing in Australia; first orders taken and first sales shipped to customers

Manufacturing process for Aridol and Bronchitol licensed by Therapeutic Goods Administration (TGA); commercial production of Aridol commences

Bronchitol Phase II clinical trial in cystic fibrosis successfully completed

European operations commenced and first European distributors appointed

Commenced:

Final US pre-registration trial of Aridol

Phase III trial of Bronchitol in bronchiectasis

Label extension study of Aridol in COPD

Phase II dose ranging trial of Bronchitol in cystic fibrosis

Phase II comparator trial of Bronchitol in cystic fibrosis

Orphan Drug status granted by the European Medicines Agency for Bronchitol in cystic fibrosis

Established Sydney-based research laboratories

Completed global capital raising of \$87 million on ASX and NASDAQ



## 05

Tripled manufacturing capacity

Applied to market Aridol in Australia and Europe

Orphan Drug status for Bronchitol granted by US FDA for bronchiectasis and cystic fibrosis

NASDAQ Global Market listing of Pharmaxis American Depository Receipts (ADRs)

## 04

Awarded \$6.1 million AusIndustry P3 Grant

Aridol Phase III and Bronchitol Phase II in bronchiectasis clinical trials completed

Capital raising of \$19.8 million

Level One ADR program established

## 03

Australian Stock Exchange Initial Public Offering raised \$25 million

Manufacturing facility licensed by TGA; production commences

Awarded \$6 million AusIndustry R&D Start Grant for the development of new treatments for cystic fibrosis

## 02

Completed Series B private funding of \$9.6 million

Frenchs Forest facility established

# Chairman's Review

## Dear Shareholder

There are defining moments in the evolution of any business and it's important to recognize those moments and to celebrate in their achievement. The company first started working on the lung function test we now know as Aridol back in 2002. Aridol was brought into the company through a licensing agreement with the Sydney South West Area Health Service in October 2001. Since that time, we have set up a manufacturing facility with the necessary regulatory approvals and manufactured product for clinical use, undertaken extensive safety studies including a 650 patient clinical trial involving 13 hospitals, reported and published the trial findings, filed the marketing application and received approval to sell Aridol in Australia. Pharmaxis became a public company listed on the Australian Stock Exchange in November 2003 and since that time we have gone through a very productive period of growth.

In the 2006 fiscal year, Pharmaxis commenced commercial operations with the booking of the first Aridol sale. Commercial operations are expected to expand internationally; first in Europe, and then to the U.S. Pharmaxis UK Limited was established in February 2006, creating a European Pharmaxis presence to manage the commercial operations in Europe and the increasing number of international clinical trials.

The development of Aridol is a clear demonstration of the capability of the management team to negotiate the very complex path to the approval of a new therapeutic agent.

Coming up fast behind Aridol is Bronchitol, a product with an even brighter future accessing different patient populations totalling over 31 million people and operating in a very favourable competitive climate. For Bronchitol we have set up a pilot manufacturing facility, completed extensive safety trials, received approvals to produce clinical trial product, successfully completed Phase II clinical trials for the product and commenced Phase III clinical trials.

There is work to be done but our prospects are indeed exciting.

To complement our Australian listing, in August 2005, the company listed on the U.S. NASDAQ exchange and followed on immediately with an A\$87 million capital raising, simultaneously completed in both Australia and the US. Access to, and recognition by, the large US

capital markets are important components of building an international pharmaceutical business. As a result of this transaction the company has sufficient funds to complete the clinical programs and international commercial launch of both Aridol and Bronchitol for cystic fibrosis and for bronchiectasis.


We are, therefore, well positioned to achieve our exciting prospects.

The Board of Directors commenced the initial steps of transformation during the year and now comprises a majority of independent directors. Following the appointment of Dr Peter Farrell, Dr Carrie Hillyard and Dr Brett Charlton stepped down from the Board. Dr Charlton was a founding director and continues as a full time executive of the company, overseeing our extensive clinical program. Dr Hillyard originally joined the board in 2002 as representative of a venture capital fund shareholder of which she is a partner. I thank both Dr Charlton and Dr Hillyard for their contribution to the board over the crucial formative years of the company.

I trust you will enjoy reading this, our third, annual report and share with me the excitement that comes with our achievements and the prospects in front of us.

On behalf of you, our shareholders, I thank the board, our management and our staff for their efforts over the past year.

Yours respectfully



**Denis Hanley AM**



# CEO's

It is a great pleasure to present the 2006 annual report of your company. The year we are leaving behind has been one of great challenge and great reward.

We have put a number of very important milestones behind us, of which the most significant were; a capital raising sufficient for our medium term needs, generating income from the sale of Aridol and commencing a pivotal Bronchitol Phase III clinical study. If ever there was a time to pause and look behind at what has been achieved and look ahead at what is to come, it would be now.

## Review

This year marks another important turning point in the relatively short life of Pharmaxis Ltd. It has been a year of quality achievements on the roadway to realising our ambition of becoming a successful international healthcare company. We are now supplying important new medicines to patients dealing with the daily challenges of long term intractable diseases. The focus for everyone within the company is, as always, the patient and as we bring our products to the international market place, we believe our products will enjoy a bright future as they make a positive impact on people's lives. The demand we are experiencing for both Aridol and Bronchitol is very welcome and gratifying and offers some reward as we work our way through the long and oftentimes arduous process of satisfying the regulatory demands of the various healthcare administrations worldwide.

This year, we announced the results from an important clinical trial involving patients with cystic fibrosis and, in March 2006, we received the first marketing approval for Aridol from the Australian regulatory authorities. These are two very significant operational milestones behind us and positions us well for the next phase of growth. For the year going forward, our chief tasks are disarmingly simple in concept but peppered with potential pitfalls in execution. We must move Bronchitol through the final phase of its clinical testing as rapidly and as efficiently as possible and we must ensure that Aridol enjoys a market success.





# Report

## Aridol

For Aridol, the Australian marketing approval pertains to the use of Aridol in detecting hyperresponsive airways in patients suspected of having asthma. A marketing authorisation application was filed with the Swedish Medical Products Agency in May 2005 as entry to the mutual recognition procedure in the European Union. The Swedish review has taken longer than we were advised when the documentation was submitted and longer than the average review period advertised by the Swedish agency. This reflects an increased workload for the agency rather than difficulties with the application or difficulties with the data supporting the use of Aridol. The various regulatory bodies within the European Union have subscribed to a process known as the mutual recognition procedure. This formalised procedure is designed to give pharmaceutical companies access to all markets within the European Union following review and approval by a member country. While there is still a significant review process to go through for each individual country within the European Union, we are planning the European launch of Aridol and are looking forward to the conclusion of the mutual recognition procedure.

During the year, a pivotal Aridol Phase III trial was initiated in the U.S. with a target patient recruitment of 280 involving 30 participating clinical centres. This is certainly the largest clinical trial ever undertaken in the U.S. by an Australian pharmaceutical company. The study commenced enrolment in December 2005 and data from the trial is expected to be available during the September 2006 quarter. We expect that the outcome of the study will lead to a filing for marketing approval of Aridol in the U.S.

A high degree of skill is involved in navigating the clinical trial and regulatory review process and an additional compounding complexity is our desire to control the manufacturing processes for both Aridol and Bronchitol. We hold a strong belief that full control and understanding of the manufacturing process is essential for a full return to our shareholders, and to ensure a full return on our investment in product development. Of course, maintaining compliance with manufacturing regulatory requirements is part of our business and, during the year, we were very pleased to receive a positive opinion from the Australian regulators on the

expansion of our manufacturing facility. We now have a licence to manufacture Aridol and Bronchitol for commercial sale and for clinical trials. Further expansion of our manufacturing facility will be required as Bronchitol enters the market. Subject to the clinical trial process and regulatory review process, we are planning for a 2008 launch for Bronchitol in its first market. With a two year lead time to install and qualify our manufacturing equipment, we have already started the planning process to ensure we are well prepared when 2008 comes around. This year, we have manufactured and shipped over 2,600 Aridol kits, 198,000 capsules of Bronchitol for clinical trial and supplied 20,000 capsules of Bronchitol, on a compassionate use basis to people with no other alternative to help with clearing their lungs.

An important United Kingdom investigator sponsored study is evaluating the power of Aridol to manage patients with asthma, over a 12 month period, in the setting of the general practice. We expect patient enrolment will close by the end of 2006 and data from the study to be available in 2007. This is one of many studies that we have with the world leading asthma researchers to ensure that Aridol is embraced as the principal technology for assessing airway inflammation. The ultimate success of Aridol is dependent upon uptake by the major research and teaching laboratories around the world and currently we have over 65 such studies at various stages in their gestation. This enthusiasm for Aridol amongst the international key opinion leading scientists bodes well for its future and underscores the importance of improving asthma management.

The misdiagnosis of asthma is common, particularly in the primary care setting and, as with any inaccurate diagnosis, this brings treatment difficulties for both the patient and the physician. While there are a number of effective therapies for treating asthma, there still exists a need for new drugs as many sufferers still have an inadequate response to existing treatments. New therapies are under development to address this clinical need and within our own research laboratories we have an active programme looking for new asthma therapies. We were very pleased, therefore, to receive an order for Aridol from a U.S. biopharmaceutical company investigating a new treatment for people with asthma. Aridol was selected by the company to help identify those patients most likely to respond to the

investigational treatment and to monitor the patients health throughout the clinical trial. We expect this side of the Aridol business to grow over the coming years.

## Bronchitol

Bronchitol has also had a very important year and we have enjoyed the support of many people with chronic lung complaints willing to participate in our clinical studies. Running clinical trials is fraught with difficulties and there are an inordinate number of activities that require orchestration. However, the greatest unknown, the biggest challenge, and the single most common reason for clinical trials to overrun budget and timeline, is patient recruitment. We never take patient participation for granted and when we can return the commitment, we do. During the year we have supplied Bronchitol to people with no alternative treatment options under the Australian government sponsored Special Access Scheme. Many of these patients have been taking Bronchitol for well over a year. In addition, we have supplied Bronchitol to a number of Category A patients with severe life threatening lung congestion - again on compassionate grounds. A Category A patient is defined in the legislation as one who is seriously ill with a condition from which death is reasonably likely to occur. These patients have responded well to Bronchitol treatment and it is a great reward to know that the endeavour we have put into product development is directly, and dramatically, affecting peoples lives.

Now Bronchitol has entered the last lap of its development. We have commenced our Phase III programme designed to lead to the approval to use Bronchitol for patients with cystic fibrosis and bronchiectasis. The first study to commence recruitment is being conducted in patients with bronchiectasis and is taking place in Australia and Europe. There are no treatments approved to enhance mucus clearance in patients with bronchiectasis. While this provides us with an excellent opportunity to ensure Bronchitol is the treatment of choice, it also means that no precedents have been set to navigate through the regulatory hurdles. For all of us involved, it's very exciting to have the potential to be the first company to bring a new medicine for bronchiectasis to the market. The clinical trial has started and we look forward with a great deal of anticipation to the first set of results which are due in 2007.

During the year we reported a very successful clinical trial in patients with cystic fibrosis. This study showed that Bronchitol improved lung function and quality of life in people with cystic fibrosis. The results from the study were presented at the U.S. Cystic Fibrosis Foundation

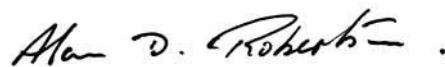
annual meeting in Baltimore and generated considerable interest amongst the research community. Since then, the study results have been presented at the American Thoracic Society Meeting in San Diego and at the European Cystic Fibrosis Conference in Copenhagen. In addition, meetings to discuss the path to market approval have been held with the U.S. Food and Drug Administration and the European Medicines Agency. We are now getting organised to commence the first Phase III clinical trial which will take place in Europe and Australia. In addition to this study, we have clinical studies running in London and in Canada to help us better understand the positioning of the drug and the most appropriate dose for use in children and adults.

## The Year Ahead

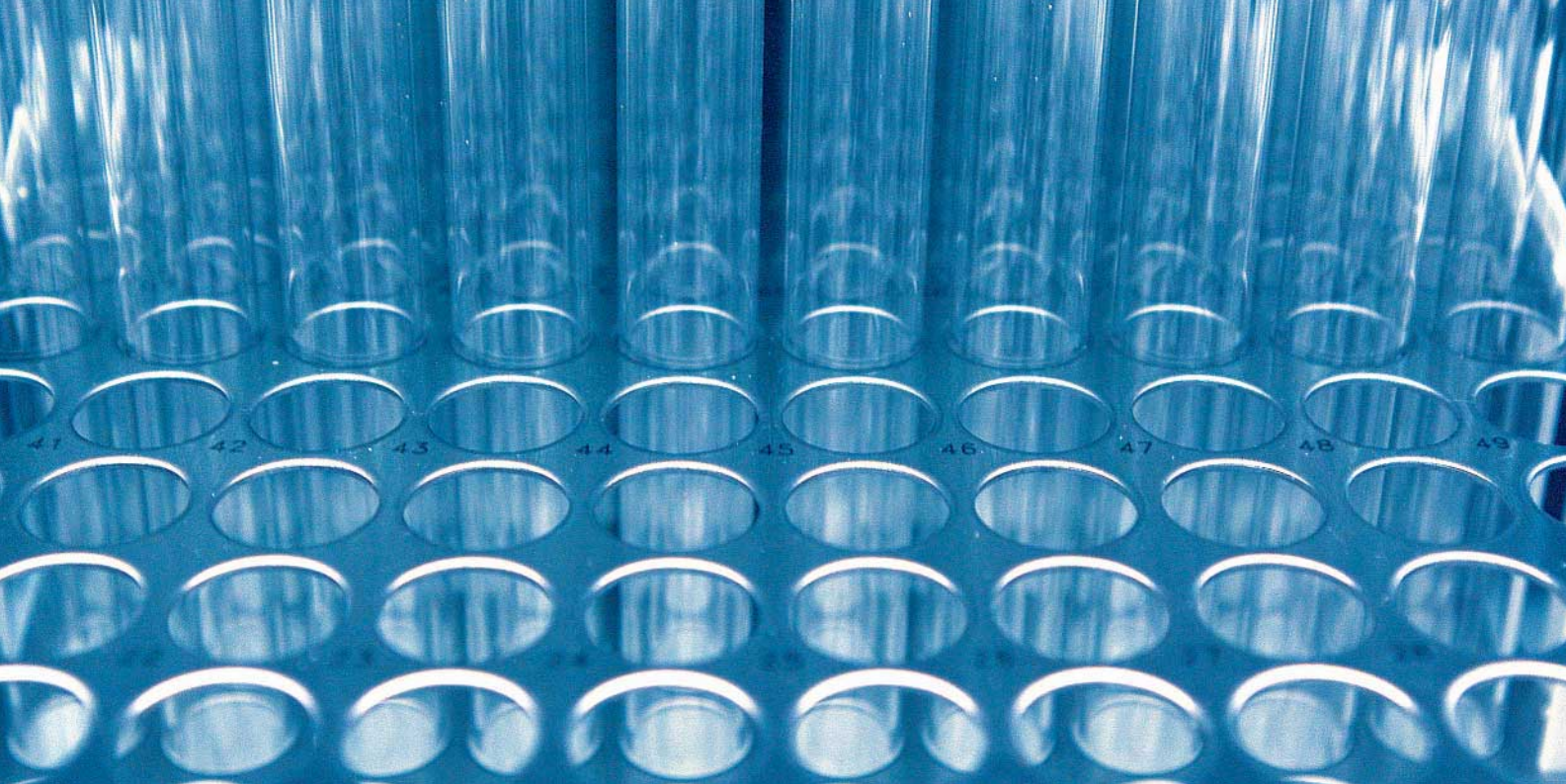
We have now joined the ranks of those companies generating revenue from the sale of our products. Although Australia is a small percentage of the world market, it represents a sophisticated market and many of the market dynamics are replayed in other territories. Lessons learned here can be quickly adopted in other territories. For Europe, we have chosen to work with small local sales and distribution partners and the first of those to be established was Nigaard for Scandinavia. Europe is a diverse market, with different approaches to managing asthma and different pricing pressures across the continent. Following the decisions from the relevant authorities, we will work closely with our distributors over the coming year to achieve a successful uptake of Aridol into this important market. For the U.S. we look forward to the results from our current clinical program and expect to be in a position to file our New Drug Application to apply for the marketing of Aridol. As always, we will work to ensure a smooth regulatory review process.

For Bronchitol we hope to be able to report a successful Phase III clinical study in patients with bronchiectasis and that we have filed for our first marketing application for this condition. In cystic fibrosis, we hope to be well into the final pivotal Phase III studies.

With the successful November 2005 capital raising behind us, we have the financial reserves to complete the full product development of both Aridol and Bronchitol. I thank you for your support and look forward to another important year for your company.



**Alan Robertson**  
Chief Executive Officer



# Products

Pharmaxis is committed to the development of human healthcare products for the treatment and management of chronic respiratory and autoimmune disorders.

As 2006 marks the year in which our first product was registered and launched, this year's annual report includes a new section – Product Delivery (an update on bringing Aridol to market) – as well as Product Development (our progress in clinical trials of Bronchitol), and Discovery

(our research activities). For descriptions of the diseases we target, a glossary of terms, and a guide to the clinical trials, regulatory and approval process, see pages 93-104.



# Product Delivery

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## Introducing Aridol for Asthma

Aridol is the company's first product to reach the market. On 22 March 2006, the Australian Therapeutic Goods Administration (TGA) approved Aridol for identifying bronchial hyper-responsiveness to assist in the diagnosis of asthma. The registration 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, regulatory and manufacturing teams at Pharmaxis. The registration of Aridol is a significant outcome for all involved, and we are now focused on also obtaining registration in Europe and the US. Along the way, Pharmaxis has grown from a small group of scientists to an integrated company comprising more than 60 professionals.

Aridol is unique for a number of reasons. It is the only lung function test registered for sale in Australia and will be the first indirect bronchial provocation test registered in the US and Europe. It has the advantage of being highly specific in identifying people with active asthma who have the potential to respond to treatment with anti-inflammatory drugs. Of particular interest to busy healthcare professionals is the availability of Aridol in a small, complete kit form that requires no preparation time, specialist equipment, sterilisation or even clean-up. Additionally, one trained operator can administer the test within a relatively short time.

Aridol was first patented as an osmotic inhalant in 1995, and licensed from the Central Sydney Area Health Service (now the Sydney South West Area Health Service) by Pharmaxis in 2001. During the five years since licensing Aridol, Pharmaxis has completed the clinical trials necessary for registration in Australia and Europe and developed and refined the Aridol manufacturing process, which is now licensed to GMP standards by the TGA. We also raised the capital required to fund these activities.



## Commercial launch of Aridol

The final phase of development – building commercial infrastructure – has so far seen an Australian sales and marketing force established, the first international marketing and distribution partners appointed in Switzerland and Sweden, and the establishment of a European Pharmaxis operation. Additional marketing and distribution partners will be appointed over the coming months. We have also continued to build relationships with leading respiratory physicians that, along with associated investigator sponsored clinical trials, will facilitate wider usage and acceptance of Aridol within the global respiratory community.

A distinctive Aridol logo and colour scheme has been designed, and is now used in all packaging and promotional materials to ensure consistent branding across all markets.

An essential component of the commercial launch of Aridol has been direct targeting of the respiratory healthcare professionals and related organisations. It is important to ensure healthcare professionals understand Aridol's unique features and how to incorporate Aridol into their patient care regimen.

- **Respiratory laboratories** currently perform most bronchial challenge tests in Australia. We have identified the several hundred laboratories in Australia and our sales force has been progressively introducing them to Aridol and training them in how to administer an Aridol test.



## 2006 Aridol Highlights

- Registered for marketing in Australia by the TGA
- Commenced commercial product manufacture
- Commenced sales and marketing activities in Australia
- Commenced preparations for marketing in Europe
- Launched to healthcare professionals at Thoracic Society of Australia & NZ meeting
- First orders received for Aridol
- Established European operation and appointed initial marketing partners
- Commenced US trial for FDA registration



- **Respiratory specialists** refer patients to laboratories for testing or may administer a test themselves. Specialists are particularly interested in the underlying scientific and clinical data.
- **Hospitals.** A number of the laboratories and specialist clinicians are attached to hospitals. Approval of a Hospital Formulary submission is required before its centralised pharmacy may purchase products such as Aridol. Our sales force assists in the preparation of submissions to hospital formulary committees.

The diagnosis and management of asthma is guideline-driven, and we have deliberately concentrated marketing efforts initially on the specialists who dictate the approach to disease management, before approaching primary care physicians.

The Australian launch of Aridol took place at the annual meeting of the Australian Thoracic Society in Canberra from 24-29 March 2006, and product became available to health professionals from mid-June 2006. In the few weeks prior to the end of the financial year, we received the first orders for Aridol including the first commercial sale to the US, where a biopharmaceutical company will use Aridol in a series of Phase II clinical trials of a new asthma therapeutic under development.

### Progressing US FDA registration

To obtain marketing approval for Aridol from the FDA, Pharmaxis is completing an additional clinical trial in the US. This Phase III Aridol study is one of the largest clinical trials ever conducted by an Australian company

in the US. The trial is designed to assess the predictive power of Aridol to identify patients with asthma. Following release of the results of the trial a New Drug Application will be lodged with the FDA.

### Progressing EU marketing authorisation

Our marketing authorisation application was lodged with the Swedish Medical Products Agency in May 2005, as the first step to the mutual recognition procedure that will enable Pharmaxis to sell Aridol throughout the European Union.

### Scientific community activities

Specialist respiratory physicians around the world have shown significant interest in Aridol, as evidenced by the large number of investigator-sponsored studies currently in planning or in process – more than 65 in total. One study of particular interest is in the United Kingdom. It is evaluating the ability of Aridol to accurately determine the optimal dose of inhaled corticosteroid (ICS) in newly and already diagnosed asthmatic patients. The trial is being conducted over a 12-month period, in the general practice setting. Full enrolment is expected by the end of 2006 and we anticipate data from the study will be available in 2007.

Publications in respected journals and presentations have continued. During the year, the results of our trials and further research associated with Aridol have been published in peer-reviewed professional journals such as: Respiratory Research (Brannan, Anderson, Perry et al); Respirology (Koskela, Martens, Brannan et al); European Respiratory Society proceedings (Pjorsberg et al, and

Brannan et al). In addition, posters and presentations have been made at the European Respiratory Society (ERS); Thoracic Society of Australia and New Zealand (TSANZ), American Academy of Allergy, Asthma and Immunology (AAAAI), and European Cystic Fibrosis Society (ECFS).

During the year, Pharmaxis joined the newly formed Australian Cooperative Research Centre for Asthma and Airways (CRCAA), which focuses on three core areas of airways research: diagnosis and monitoring; new treatments; and assessing the consequences of air quality.

## Aridol for COPD

In addition to its utility in detecting airway hyperresponsiveness in patients suspected of having asthma, Aridol can also be used in patients with COPD who also have airway hyperresponsiveness. This subset comprises approximately 20-25 per cent 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.

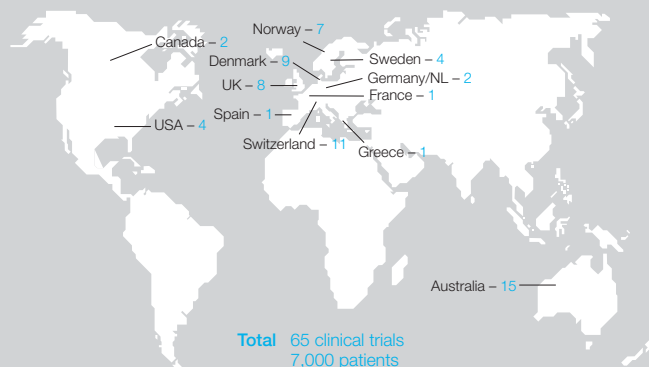
The first patient in our Australian-based trial, COPD-201, enrolled in September 2005. The trial seeks to confirm a formal link between airway hyperresponsiveness as detected by an Aridol test, and a positive response to inhaled corticosteroids in patients with COPD. An investigator-led trial previously indicated that this was the case. The trial closed enrolment at the end of March and results are expected in the third quarter of 2006.



## Outlook for Aridol in 2007

- Expansion of commercial sales in Australia
- Marketing approval in European Union
- Report on US Phase III trial and lodgement of New Drug Application with US FDA
- Appointment of additional distributors
- Completion of trials of Aridol in COPD

## Clinical Trials of Aridol led by Investigators



# Product Development

## Progress with Bronchitol

Bronchitol is the second product under development. It is now in the final stages of evaluation for two clinical conditions. We have commenced a Phase III clinical trial for bronchiectasis and expect to commence a Phase III clinical trial in cystic fibrosis during the second half of 2006.

Bronchitol is proving to be a powerful agent to mobilise and clear mucus from a range of lung conditions. We have initially targeted two diseases where consistent long term mucus build up significantly encroaches upon a patient's daily quality of life: cystic fibrosis and bronchiectasis. The completed Phase II clinical studies in these two conditions demonstrated that Bronchitol will have a significant role to play once it has completed the clinical and regulatory process. Bronchitol is also being developed for chronic bronchitis where the mucus build up is not always the consistent daily challenge it is in cystic fibrosis and bronchiectasis.

Over the past twelve months, as we have reviewed the results of our own clinical studies and reviewed the work of others, we have expanded our expectations for the use of Bronchitol in cystic fibrosis. Bronchitol facilitates mucus clearance by restoring normal lung defence mechanisms and improving the flow of mucus. Restoring normal lung defence before the patient's lung deteriorates offers the possibility of reduced lung infections and

improved lung performance. A long-term goal of the project is to deliver Bronchitol to very young children with cystic fibrosis. To date, our youngest patients have been aged six, but we are working on new ways to deliver Bronchitol to patients as young as 24 months of age.

Over the last year, we also carried out research into the application of Bronchitol in conditions where short-term mucus build-up requires clinical intervention within a hospital. Hospitals treat a large number of patients each week for retained mucus in the lungs. While the underlying cause can be quite varied, the current treatment typically involves physiotherapists assisting with postural drainage and cough clearance. Our early pilot studies in bronchiectasis, cystic fibrosis and chronic bronchitis indicate that Bronchitol has a potential role to play, and we are planning clinical studies to investigate this further.

## Bronchitol for Cystic Fibrosis

### Phase II trial successfully completed

Results of our Phase II trial using Bronchitol for cystic fibrosis were released in August 2005. The aim of the trial was to show that Bronchitol improved mucus clearance as demonstrated by an improvement in lung function. This primary objective of the trial was achieved, with patients' overall lung function improving significantly

## 2006 Bronchitol Highlights

### Cystic Fibrosis

- Successfully completed Phase II clinical trial
- Commenced recruitment of Phase II dose finding trial
- Commenced investigator-led European trial comparing Bronchitol with existing treatments
- Concluded an End of Phase II meeting with the US FDA
- Concluded a Protocol Assistance meeting with the European Medicines Agency
- Planning for Phase III trial well advanced
- European Orphan Drug designation granted

### Bronchiectasis

- Commenced international Phase III trial



during the study period. A person with cystic fibrosis will generally experience a drop in lung function every year, so to improve lung function is of great benefit to the patient. Additional study objectives were also achieved, the most important of which was a significant improvement in the air flowing in the small airways. This is an important measure to improve, as it is in the small airways that lung function deterioration usually starts in patients with cystic fibrosis.

The outcome from this study has been discussed with the regulatory agencies in Europe and in the USA and agreement has been reached on the design of a Phase III clinical trial. The planning for these trials is now well advanced and we expect to commence the European trial in the second half of 2006 and the US trial in the beginning of 2007.

#### **Canadian dose finding trial underway**

In July 2005, a Phase II trial designed to determine the most suitable dose of Bronchitol for patients with cystic fibrosis received approval from Health Canada, Canada's regulatory authority. The first patient enrolled in November 2005; all participants follow a three-month study period, during which time four different strengths of Bronchitol are tested. There have been no difficulties with the patients once they have been enrolled into the study, but enrolment has been slower than anticipated. Nevertheless, the outcome of the trial is important for our marketing application dossier and we now expect that results from the study will be due in the second half of 2006.

#### **European comparator trial underway**

A UK-based investigator-led trial is being conducted in children aged 8 to 18 years and is recruiting patients steadily. This trial compares Bronchitol with the most commonly prescribed drug to improve mucus clearance in patients with cystic fibrosis. The market leading therapy, recombinant human DNAse, is designed to cleave the mucus and help patients with its removal. Bronchitol, on the other hand, is designed to restore the protective fluid layer surrounding the lungs and improve normal lung clearance mechanisms. Our expectation is that patients being treated with DNAse will also receive additional benefit from receiving Bronchitol, as the two drugs work in a quite different fashion. Each patient is

being treated for three months and each patient receives Bronchitol and DNAse either alone or together. The outcome of the study is important for the patients with cystic fibrosis and will allow us to give appropriate guidance on the use of Bronchitol following its marketing approval.

#### **European Orphan Drug designation**

In 2005, the US FDA and the European Medicines Agency (EMA) granted orphan drug status for Bronchitol in cystic fibrosis. The Orphan Drug Act is designed to encourage the development of drugs for relatively rare diseases; incentives associated with orphan designation include the availability of assistance in planning and preparation of the Phase III trials in both jurisdictions, reduced registration fees, and a period of market exclusivity from marketing approval of seven years in the USA and ten years in the European Union.

### **Bronchitol for Bronchiectasis**

Bronchiectasis is a lung disease in which the small airways become irreversibly damaged, resulting in dilation of the small airways, inflammation and excessive mucus production. For the patient, this means difficulty in breathing, constant lung clearance and a high impact on the quality of life. As lung function deteriorates later in life, the difficulties associated with living with the disease are exacerbated and a high burden is placed on the patient and their family. There are no drugs used currently that effectively help the patient with mucus clearance and Bronchitol is the leading agent under development for this patient group. This has meant a series of detailed discussions with the regulatory agencies and key opinion-leading scientists on the best way to demonstrate that Bronchitol is improving the welfare of the patients. There is no road map to follow and no precedent from which to draw in a patient group that has waited a long time for something that will improve life.

#### **Recruitment for Phase III trial**

Agreement was reached with the European authorities on a suitable design for a Phase III trial and the first patient was enrolled in the study in Australia in April 2006. The trial is being run in Australia, New Zealand and the United Kingdom. The trial is progressing well,



with patients showing a high level of enthusiasm to be involved. The outcome of the study is anticipated to be a marketing application that will be filed in Europe and Australia, and we aim to be the first company ever to bring an innovative medicine for mucus clearance to this patient population. The double-blind, placebo-controlled trial aims to show an improvement in quality of life, exercise, sleep, and lung function. Full recruitment is expected to take about nine months and results are not expected before mid-2007.

### **Bronchitol for Chronic Bronchitis**

A major opportunity has been identified to help people in hospital that have difficulty with clearing mucus. We have supplied Bronchitol on a number of occasions to patients in life threatening situations due to mucus build-up in their lungs. The supply of Bronchitol is through the Special Access Scheme, which allows the supply of Bronchitol where no other suitable therapy exists. While people can be admitted to hospital with congested chests for many different reasons, the initial focus of the clinical work in this area will be patients with chronic bronchitis. The problem is extensive. For example, in the United Kingdom, chronic bronchitis was responsible for 90,000 admissions to hospital last year and the mean duration of hospital stay was 11 days. To assist with this problem, a clinical trial is being conducted in hospitals in patients with chronic bronchitis. The first study is expected to report its findings during the second half of 2006.



### **Outlook for Bronchitol in 2007**

#### **Cystic Fibrosis**

- Canadian Phase II dose-ranging results available
- European Phase II study with DNase to close recruitment
- US and international Phase III studies commence

#### **Bronchiectasis**

- Results of international Phase III trial available
- File for regulatory approval

#### **Chronic Bronchitis**

- Pilot Study
- Phase III trial undertaken and preliminary results available

Pharmaxis was founded on research into autoimmune disease that was being conducted at the John Curtin School of Medical Research in Canberra, which has been the home of the research scientists within the company since 1999. The research led to PXS64, which is in pre-clinical development for the treatment of multiple sclerosis. To provide more critical mass to the research effort, a small research group has been established in Sydney to complement the activities of the group in Canberra. The research focus is in the area of respiratory medicine, and new approaches to the management of diseases such as asthma and COPD are under active investigation. During the year, talented scientists have been recruited, the laboratories have been equipped, and research has commenced. PXS74 is the first lead compound to emerge from the enlarged research group, and has shown promising activity in models of asthma.

### **PXS25/64 for Multiple Sclerosis**

PXS64 is in pre-clinical development to establish its credentials as a potential therapeutic agent for the treatment of multiple sclerosis. PXS64 has shown promising activity in models of multiple sclerosis and works by preventing the movement or migration of immune cells from the blood stream to surrounding tissues.

Inhibiting immune cell migration has been a topic of great debate with the regulatory agencies around the world over the past twelve months, particularly when treating multiple sclerosis. The safety of the patients who

take an experimental therapy is paramount, and we have spent significant effort establishing the safety profile of PXS64. The safety studies are designed to ensure, among other things, that PXS64 does not interfere with normal immune function. The pharmaceutical properties of PXS64 are excellent and it is expected to be taken as a once-a-day pill. This represents an advance for patients who are currently being treated by injection to help control their multiple sclerosis.

### **PXS2076 for Rheumatoid Arthritis**

PXS2076 was a lead compound identified from a research program established to identify new treatments for rheumatoid arthritis. A key property of PXS2076 was its ability to inhibit the release of inflammatory proteins from immune cells. While PXS2076 was found to lack suitable pharmaceutical properties for development, it is now being used both as a research tool to help understand the mechanism of action of the class of molecule and as a benchmark from which improved versions can be measured. Although PXS2076 is no longer considered to be a candidate for clinical development, it continues to show promise; during the year, it was shown to be effective in models of neuropathic pain.

Improved versions of PXS2076 suitable for clinical development are being sought.

### **PXS74 for Asthma**

A research program to identify new therapeutic approaches to asthma and COPD has made steady progress through the year. Asthma and COPD have distinct causes, and different inflammatory mediators are responsible for the development of the two diseases. However, it is thought that intervening at the initial stages of the inflammatory process may provide better treatments for sufferers of both diseases. PXS74 is believed to interfere with the inflammatory cell adhesion cascade and prevent inflammatory cells migrating to inflamed tissue. By this process, PXS74 has been able to reduce lung damage caused by excessive cellular infiltration in models of asthma. PXS74 represents the first of a new series of molecules from which it is hoped to choose one for clinical development in asthma.







# Management

Pharmaxis is led by experienced senior pharmaceutical and technology industry professionals with an international track record of developing and commercialising breakthrough products. We have an experienced Board of Directors and a Scientific Advisory Board.

Board changes over the year mark the beginnings of the transition of Pharmaxis from a start-up biotech to a maturing specialist pharmaceutical company. Dr Peter Farrell, founding chairman and CEO of ResMed Inc., was appointed to the board in April 2006 as an additional independent non-executive director. Dr Brett Charlton resigned from the board in March 2006; he had been a director since 1998. Dr Carrie Hillyard resigned as a director in April 2006, having been a director since August 2002.

The company currently employs 65 people. At our Frenchs Forest headquarters in Sydney's north, which includes our TGA-accredited manufacturing facilities, pre-clinical development, and clinical, commercial and administration activities, there are 53 people. In the coming year, the company will be focused on building a sales and marketing capability to deliver Aridol to the market.

Our main laboratories are located at the John Curtin School of Medical Research at the Australian National University in Canberra, where we have seven people actively researching autoimmune diseases. In March 2006, we established a research laboratory in North Ryde, Sydney, to extend our capacity in drug discovery and support the work of our Canberra laboratories. At the end of June 2006, there were three people at North Ryde.

On the international front, in February 2006 Pharmaxis established a European office, based in the United Kingdom, and appointed a European Regional Director. Mark Sanders is a seasoned marketing and business development professional with many years of international experience in the field of respiratory therapeutics and devices. We have since hired a European Product Manager.



## Board of Directors

**Denis M Hanley** AM MBA FCPA  
Independent Chairman

Denis Hanley is a qualified accountant and company director with more than 35 years experience in the management of technology-based growth businesses. He joined the Pharmaxis Board in 2001.

Denis spent 14 years with Baxter International Inc., a global medical products and services company. His career at Baxter included a number of international assignments including its Chicago headquarters, and his last position was managing director of Baxter's Australian operations. In 1983, Denis was founding chief executive officer and, in 1986, executive chairman of the Australian-based separations technology company Memtec Ltd. Under his leadership, Memtec grew into a NYSE-listed global operating filtration and separations business with 1700 employees. Since the sale of Memtec to US Filter in 1997, Denis has been a successful angel investor, assisting the commercialisation of several Australian technologies. He is non-executive chairman of CathRx Ltd and Lochard Ltd and a non-executive director of Universal Biosensors Inc. Denis holds an MBA with High Distinction from Harvard Graduate School of Business, where he was named a Baker Scholar.

**Alan D Robertson** BSc PhD  
Chief Executive Officer

Dr Alan Robertson has more than 20 years experience in drug discovery and product development with leading pharmaceutical companies, including 8 years with

Wellcome plc in London and with Australian companies Faulding Ltd and Amrad Ltd. He also assisted early-stage pharmaceutical companies in their start-up and development and was the founding Managing Director of Pharmaxis. Alan has been CEO of Pharmaxis since December 1999 and has been instrumental in building the company to its present position. Alan joined the board of Pharmaxis in July 2000.

The co-inventor of 18 patents and author of more than 35 scientific papers, Alan has a PhD in synthetic organic chemistry from the University of Glasgow and has extensive practical understanding of both the clinical and management aspects of the pharmaceutical industry. He has been actively involved in the discovery, development and marketing of various compounds, including new treatments for migraine and cardiovascular disease. Alan is the inventor of the migraine therapeutic Zomig, which is marketed worldwide by AstraZeneca.

**Peter Farrell** AM PhD DSc  
Non-Executive Director

Dr Peter Farrell has spent more than 20 years developing and commercialising medical products in the USA, Europe, Japan and Australia. He is widely recognised as a leader in engineering, biomedicine and entrepreneurship, and was appointed a Member of the Order of Australia in 2004 for his services to biomedical research and engineering. In 2005, Peter was named the US Entrepreneur of the Year for Health Sciences.

Peter began his commercial career with Baxter Healthcare Inc. in Japan as Director and Vice President of Research and Development, then as Managing Director of the Baxter Center for Medical Research. He left Baxter in 1989 to establish ResMed Inc., a company that develops treatments for sleep-disordered breathing and respiratory failure. Peter is currently founding Chairman and Chief Executive Officer of ResMed Inc. Since its initial public offering in 1995, ResMed has achieved 40 consecutive quarters of record year-on-year growth in revenue and profits. Peter also serves on the Executive Councils of Harvard Medical School and the University of California at San Diego, and is visiting Professor at the University of Sydney. He has written more than 150 papers covering topics from engineering applications in medicine to focusing technology to meet business objectives.

**Charles PH Kiefel** BCom FCA  
Non-Executive Director

Charles Kiefel is a Fellow of the Institute of Chartered Accountants in Australia and a Fellow of the Australian Institute of Company Directors. He joined the board in May 2003, and is Chairman of the Audit Committee. Charles has more than 20 years experience in finance, investment banking and the investment sector in London with Lazard Bros, New York with Lazard Freres, Sydney with Ord Minnett, and Melbourne with ANZ Investment Bank. He has significant exposure on the buy-side of money management in a range of asset classes.





Charles is Chairman of the Military Superannuation Board, an Australian Pension fund with assets in excess of A\$9 billion, and serves on the Advisory Boards of two of Australia's largest private equity funds, Pacific Equity Fund and CHAMP II Fund. He is a Director of Business Development for two major US money managers: Turner Investment Partners and LSV Asset Management. Charles is also a Director of Universal Biosensors Inc, a small technology start-up in which he has a personal investment.

**Malcolm J McComas** BEc LLB  
Non-Executive Director

Malcolm McComas is a company director and former lawyer with more than 20 years investment banking experience. He joined the Pharmaxis board in July 2003. He is currently a consultant to Grant Samuel, the investment banking, property services and funds management group, and was a director of Grant Samuel from 1999 to 2004. He previously served for 10 years as Managing Director of Investment Banking at County NatWest and its successor organisation Salomon Smith Barney (now Citigroup), and in various executive roles with Morgan Grenfell (now Deutsche Bank) in Melbourne, Sydney and London.

Malcolm has worked with many high growth companies across various industry sectors and has experience in equity and debt finance, acquisitions and divestments and privatisations. He has led more than 50 initial public offerings and significant secondary offerings for companies, institutions, and governments. He is non-executive

Chairman of Sunshine Heart, Inc and a national councillor of the Financial Services Institute of Australia.

**Brigitte Smith** BChemEng  
MBA MALD  
Non-Executive Director

Brigitte is a venture capital investor with more than 15 years experience in strategic management consulting and working with early-stage technology-based businesses in the USA and in Australia. She has served on the Pharmaxis board since October 1999. Brigitte is managing director of GBS Venture Partners, the specialist life science venture capital business she co-founded in 2002 after completing a management buy-out from Rothschild. Brigitte sits on the board of seven of GBS Venture Partners' portfolio companies, including Dynamic Hearing Pty Ltd, Kalobios Inc. and Proacta Inc.

A former Fulbright scholar, Brigitte is also an Adjunct Senior Lecturer at Melbourne Business School where she teaches Entrepreneurial Finance. Brigitte has an MBA with Honours from Harvard Business School, a Master of Arts from Fletcher School of Law and Diplomacy, and a Bachelor of Chemical Engineering from the University of Melbourne.

**David M McGarvey** BA CA  
Company Secretary and Chief  
Financial Officer

David has 18 years experience as Chief Financial Officer of successful Australian-based international technology businesses, and he joined Pharmaxis in December 2002 in his current role.

After 10 years with PricewaterhouseCoopers, David joined high technology start-up Memtec Limited as Chief Financial Officer in 1985. David was instrumental in the US listing of Memtec Ltd on NASDAQ and subsequently on the NYSE, involving SEC filings, full US GAAP financial statements, and dual-jurisdiction debt and equity raisings. During his time at Memtec and its acquirer US Filter, David managed the financial and legal aspects of more than 30 acquisitions, mergers and divestitures in a number of European and American countries.

Pictured left to right:  
Denis Hanley, Alan Robertson,  
Charles Kiefel, Peter Farrell,  
David McGarvey, Malcolm McComas  
and Brigitte Smith.

## Scientific Advisory Board

**Sandra Anderson** BSc PhD  
DSc FANZSRS

Dr Sandra Anderson is an expert in the diagnosis and treatment of asthma. She is a world authority in the measurement, management and mechanisms of exercise-induced asthma, and has developed a variety of tests for identifying asthma, including Aridol.

A prolific author and the recipient of numerous awards for her work, Sandra is Principal Hospital Scientist in the Department of Respiratory Medicine of the Royal Prince Alfred Hospital, Sydney. She is a Vice President of Asthma NSW and Co-Chairman of their Research Advisory Committee. Sandra has served on various international taskforces and committees and is currently part of an independent panel of the International Olympic Committee Medical Commission.

Sandra is actively engaged in the company's development, participating in technical presentations to various opinion leaders and regulatory authorities around the world.

**Norbert Berend** AM MBBS  
MD FRACP

Dr Norbert Berend is Director of the Woolcock Institute of Medical Research at Royal Prince Alfred Hospital, Sydney and is internationally recognised for his work in chronic obstructive pulmonary disease (COPD).

Norbert is active in national and international peer groups, is a member of the COPD Guidelines Working Party, and serves on the Respiratory Clinical Expert Reference Committee of the NSW Department of Health. In addition, Norbert is a Senior Investigator for the Cooperative Research Centre (CRC) for Asthma and a Director of the CRC for Chronic Inflammatory Diseases. He is the author of more than 95 publications on airways disease, emphysema, and infection in COPD.

Norbert was a principal investigator at one site participating in the Australian Aridol trial, as well as serving on trial related safety committees.

**Malcolm Fisher** AO MBChB MD

Professor Malcolm Fisher is renowned for his work in critical care medicine, having received numerous awards and being named an officer in the Order of Australia.

Based in Sydney, Malcolm is a Staff Specialist in the Intensive Care Unit of Royal North Shore Hospital, and Area Director of Intensive Care and Clinical Professor in Intensive Care Medicine in the Departments of Medicine and Anaesthesia at the University of Sydney. He is a past President of the World Federation of Intensive and Critical Care Medicine Societies, and its Australasian chapter, ANZICS. He is the author of two books and more than 130 scientific articles.

**Richard JI Morgan** CBiol MIBiol  
DRCPATH

Richard Morgan has more than 25 years experience in pharmaceutical research and development, and has been involved in the development of a large number of successful, marketed pharmaceutical products.

He has held senior management positions within preclinical safety (a vital precursor to human clinical trials), including Head of Toxicology at pharmaceutical giant Wellcome and International Head of Toxicology and Preclinical Outsourcing for GlaxoWellcome (later GlaxoSmithKline). He has been responsible for evaluating the preclinical safety of more than 100 new chemical entities, ranging from anti-infectives and anti-parasitics to cancer compounds and vaccines. Richard currently advises UK and Australian companies on toxicology and preclinical discovery and development. He consults to Pharmaxis on the preclinical safety aspects of developing products.

## Senior Management

Pharmaxis' senior management has decades of combined experience in drug discovery and development, clinical trial design and management, intellectual property protection and management, commercialisation, manufacturing, and international business.

**Alan Robertson** BSc PhD  
Chief Executive Officer

(refer to preceding Board section for details)

**David McGarvey** BA CA  
Chief Financial Officer

(refer to preceding Board section for details)

David oversees finance and administration at Pharmaxis. Financial highlights during the year have included the company's successful global capital raising, its listing on NASDAQ National Market, and its admission to the S&P/ASX Top 300.

**Brett Charlton** MBBS PhD  
Medical Director

Dr Brett Charlton is a medical researcher and specialist in autoimmune disease and diabetes, and has over 15 years experience in clinical trial design and management. Brett co-founded Pharmaxis with Bill Cowden in 1998 and was instrumental in negotiating licence and research arrangements and attracting funding. He has been medical director since 1998.

Brett has written more than 60 scientific papers, attracted significant research grants and served on professional society committees. He has been a consultant to the pharmaceutical, medical and biotech industry since 1985. Brett was founding Medical Director of the National Health Sciences Centre and established its Clinical Trial Unit. Prior to joining Pharmaxis, he held positions with the Australian National University, Stanford University, the Baxter Centre for Medical Research, Royal Melbourne Hospital and the Walter and Eliza Hall Institute. Brett has an MBBS with Honours from the University of New South Wales and completed his PhD at the Centre for Biomedical Engineering in 1985.

Brett is responsible for the company's clinical trials program. Pharmaxis manages its own clinical trials for Aridol and Bronchitol and supports selected specialists wishing to undertake clinical trials using our products. With major international and Australian clinical trials in asthma, cystic fibrosis, bronchiectasis and COPD in various stages of progress (see details in Products section), the division has increased over the year to 16 people.

**William B Cowden** PhD  
Chief Scientific Officer

Dr Bill Cowden co-founded Pharmaxis with Dr Brett Charlton in 1998 to commercialise new molecules with the potential to treat inflammatory diseases, and has been Chief Scientific Officer since June 1998.

Bill has 20 years experience researching and developing therapeutic compounds to treat cancer, infectious disease and inflammatory diseases, including multiple sclerosis. He is the co-inventor of 12 patents and author of more than 130 scientific papers. Bill has a long association with the John Curtin School of Medical Research at the Australian National University, including senior research positions with the Departments of Medical Chemistry, Experimental Pathology, and Cell Biology and Virology. He is Head of the Immunopathology Research Group and directs Pharmaxis' research into autoimmune compounds for multiple sclerosis and rheumatoid arthritis. Bill received a PhD in Medical Chemistry from the University of Queensland in 1979.

Bill heads the company's research and development at the John Curtin School of Medical Research within the Australian National University campus in Canberra. Work is currently focused on research into new treatments for multiple sclerosis and rheumatoid arthritis, particularly the development of oral medications.

**Ian A McDonald** BSc PhD  
Chief Technical Officer

Dr Ian McDonald has 25 years international experience in managing drug discovery and design teams in Europe and USA. He was most recently Vice President of Drug Discovery at Structural GenomiX, USA. Prior experience includes a similar position at Structural Bioinformatics, Vice President of Chemistry with responsibilities for medicinal and bio-chemistry at SIBIA Neuroscience (now part of Merck Research Laboratories) and Merrell Dow (now part of Sanofi-Aventis). Under his leadership, six compounds have been developed and evaluated in clinical trials.

Ian was awarded his BSc and PhD degrees in chemistry from the University of Western Australia, has co-authored more than 74 peer-reviewed manuscripts and book chapters, and is an inventor on 38 issued US patents.

Based in Sydney, Ian oversees research and development at the company's new North Ryde laboratories, which were established in March 2006. It now employs 5 people focused on respiratory medicine research and complements the work of our Canberra laboratories.

**John F Crapper** BSc MBA  
Chief Operations Officer

John Crapper has 32 years of manufacturing and operations experience, 17 years of which have been in the pharmaceutical industry. He is formerly Senior Vice-President and General Manager of Memcor International and Managing Director of Memcor Australia Pty Ltd. Formerly a subsidiary of Memtec Ltd, Memcor is a world leader in the design and manufacture of microfiltration membranes and systems.

During his 15 years at Memcor, John managed the scale-up of manufacturing equipment and processes from the company's research and development group, created full scale production operations and managed the

establishment of the Quality Assurance and Enterprise Planning Resource systems. Prior to this, John was Technical Director at Syntex Pharmaceutical's Animal Health division and start-up veterinary pharmaceutical company VR Laboratories.

John heads manufacturing at Pharmaxis. With the Australian Therapeutic Goods Administration registering Aridol in March and reissuing and upgrading the company's licence to manufacture, Pharmaxis is now manufacturing Aridol for commercial sale in Australia and other parts of the world. This has required the installation of additional manufacturing and quality control equipment, including a new encapsulator.

**Gary Phillips** BPharm MBA  
Commercial Director

Gary Phillips has broad operational experience across the pharmaceutical industry value chain after spending the last 22 years in the healthcare industry in Europe, Asia and Australia. He joined Pharmaxis in December 2003. Gary has an extensive track record in marketing and sales, including new product launches, brand repositioning, process improvement and customer targeting programs. He was previously CEO of Novartis Australia where he successfully launched breakthrough oncology and ophthalmology products and relaunched newly acquired primary care products. His previous roles include Area Director, Asia, for Novartis, and CEO of Ciba Geigy in Hungary. Gary has an honours degree in Pharmacy from Nottingham University, UK, and an MBA from Henley Management College.

At Pharmaxis, Gary heads the company's commercial activities, which are currently focussed on the launch of Aridol in Australia, Europe and the US.





## Administration

Financial highlights for the year included the company's successful global capital raising, its listing on NASDAQ National Market and its admission to the S&P/ASX Top 300.



## Commercial

Commercial activities are focussed on the launch of Aridol in Australia, Europe and the US.





# Clinical



Pharmaxis manages its own clinical trials for Aridol and Bronchitol and supports selected specialists wishing to undertake clinical trials using our products. With major international and Australian clinical trials in asthma, cystic fibrosis, bronchiectasis and COPD in various stages of progress, the clinical team has increased to 16.

# Research



The Canberra labs currently focus on research into new treatments for multiple sclerosis and rheumatoid arthritis, particularly the development of oral medications, while Ryde focuses on respiratory medicine research.

# Manufacturing

With the Australian Therapeutic Goods Administration registering Aridol in March and reissuing the company's licence to manufacture, Pharmaxis is now manufacturing Aridol for commercial sale in Australia and other parts of the world.



# Financial History

(prepared in accordance with Australian equivalents to International Financial Reporting Standards)

	Year ended 30 June				
	2006	2005	2004	2003	2002
	A\$	A\$	A\$	A\$	A\$
	(in thousands, except per share data)				
<b>Income Statements</b>					
Revenue from sale of goods	8	–	–	–	–
Cost of sales	(2)	–	–	–	–
Gross profit	6	–	–	–	–
Interest	4,282	1,702	1,075	284	43
Grant income	1,299	1,219	1,152	779	646
Other income	–	–	48	43	–
Expenses					
Research & development	(16,978)	(9,269)	(6,301)	(2,051)	(1,151)
Administration	(4,386)	(3,134)	(2,461)	(1,103)	(140)
Commercial	(1,951)	(963)	–	–	–
Loss before income tax	(17,728)	(10,445)	(6,486)	(2,048)	(602)
Income tax expense	(5)	–	–	–	–
Loss for the year	(17,733)	(10,445)	(6,486)	(2,048)	(602)
	Cents	Cents	Cents	Cents	Cents
Earnings per share:					
Basic and diluted earnings / (loss) per share	(11.1)	(8.4)	(7.1)	(3.9)	(2.2)

	As at 30 June				
	2006	2005	2004	2003	2002
	A\$	A\$	A\$	A\$	A\$
<b>Balance Sheets</b>					
Cash and cash equivalents	97,840	33,390	25,217	7,384	750
Plant & equipment	3,205	2,477	1,474	1,515	116
Total Assets	104,267	37,937	28,261	10,495	2,144
Total liabilities	5,379	2,470	1,630	802	190
Total shareholders' equity	98,888	35,467	26,631	9,693	1,953
<b>Share Data</b>					
Ordinary shares on issue	176,904	134,770	108,016	11,200	11,200
Converting preference shares	–	–	–	46,816	16,000
Options over ordinary shares on issue	9,692	10,914	10,751	9,024	3,680

# Corporate Governance

Pharmaxis is a dual-listed Australian company. Our primary listing is on the Australian Stock Exchange (ASX) and our secondary listing is on the US NASDAQ Global Market (NASDAQ). The Pharmaxis Corporate Governance Framework and supporting policies and practices have been designed to comply with the 'Principles of Good Corporate Governance and Best Practice Recommendations' issued by the Australian Stock Exchange Corporate Governance Council, relevant US requirements arising from our NASDAQ listing, and other current best practice guidance. The Board is conscious of the need for Pharmaxis policies to be appropriate for the company, and has identified several areas where Pharmaxis is best served by policies that differ from the Australian Stock Exchange Recommendations. However, the Board expects that our Corporate Governance Framework will continue to change as Pharmaxis progresses its business, as the company grows in operational complexity, and as the shareholder base of the company grows.

Pharmaxis completed the initial implementation of its Corporate Governance Framework in June 2004 and completed a review and update in June 2005 and again in June 2006.

An overview of the principal corporate governance policies and procedures adopted by the Board are described and discussed in this section. Additional information is available on the Pharmaxis website. For ease of reference, this section is structured consistently with the ASX Best Practice Recommendations.

## 1. Lay Solid Foundations for Management and Oversight

*Recognise and publish the respective roles and responsibilities of board and management*

### 1.1. Formalise and disclose the functions reserved to the board and those delegated to management

#### Role of the Board:

The Board is responsible to shareholders for the overall governance of Pharmaxis including:

- Contributing to and approval of the corporate strategy and performance objectives of the company
- Approving business plans, the annual budget, significant corporate projects, and major capital expenditure initiatives
- Monitoring senior management's performance and implementation of strategy and plans including major capital expenditures, significant corporate projects, and any acquisitions or divestments
- Monitoring financial performance and reporting including approval of the annual and half-year financial reports and liaison with the company's auditors
- Approving major changes to organisational structures
- Approving and overseeing policies and procedures for the effective management and control of the company, including overseeing and monitoring the integrity of the company's internal control and management information systems, codes of conduct, and legal compliance
- Defining and monitoring the respective roles of the Board and management
- Succession planning, including board and key executive succession planning
- Remuneration policy covering directors and senior management
- Appointing and removing the chief executive officer, the chief financial officer, and the company secretary
- Monitoring investor relations and shareholder communications, including the company's Continuous Disclosure and Shareholder Communications Policy
- Ensuring the various Board committees are appropriately constituted and performing their functions
- Ensuring, through responsibility delegated to the Audit Committee, that the company auditor is properly appointed and is performing its duties adequately and independently.

## Role of Management:

The Chief Executive Officer (CEO) and senior management are responsible for:

- Developing corporate strategy, performance objectives, business plans, budgets etc for review and approval by the Board
- Developing appropriate policies and procedures for the management of the business
- Managing the company's day-to-day affairs and the implementation of corporate strategy and policy initiatives.

The Board will regularly review the respective roles and the allocation of responsibilities between the Board and management as the company grows, and will annually update and/or affirm the allocation of roles and responsibilities described above.

## 2. Structure the Board to Add Value

*Have a board of an effective composition, size and commitment to adequately discharge its responsibilities and duties*

### 2.1. A majority of the board should be independent directors

As a result of the appointment of an additional independent director in March 2006, Pharmaxis now complies with this recommendation. The Pharmaxis Corporate Governance Framework has been amended to make it an ongoing requirement for a majority of the Board to be independent. Pharmaxis has four independent directors and two directors that are not independent as defined by ASX Guidelines: one is an executive of the company (CEO); and the other is associated with a major shareholder. The Board believes that its membership is appropriate for the current stage of the company's development.

Board membership is managed by the Board itself, with guidance from the Remuneration and Nomination Committee.

The Board assesses director independence using the criteria outlined in the ASX Recommendations. The threshold for materiality is set at \$250,000 in any one year in relation to financial/contractual dealings with the company, and ten years in relation to years of service. In relation to directors serving on the Audit Committee, the director and/or their associates may not receive any fees from the company other than those related to director fees or committee fees.

Name	Status	Relevant Skills & Experience	Initially Appointed
Denis Hanley	Independent Chairman	Leading expert in management of technology-based growth businesses; extensive experience in building Australian corporations to become successful global entities	24 October 2001
Malcolm McComas	Independent director	Extensive investment banking experience, particularly equity and debt finance, acquisitions, divestments and privatisations	4 July 2003
Charles Kiefel	Independent director	More than 20 years experience in banking and the investment sector with significant exposure on the buy-side of money management in a range of asset classes	1 May 2003
Alan Robertson	Chief Executive Officer	More than 20 years experience in drug discovery and product development; experience in assisting early-stage pharmaceutical companies in start-up and development	25 July 2000
Brigitte Smith	Non-executive director	Venture capital investor with over 15 years experience in strategic management consulting and working with early stage technology-based businesses in the US and Australia	22 October 1999
Peter Farrell	Independent director	Extensive experience in building Australian medical product businesses into successful international corporations	16 March 2006
Brett Charlton	Medical Director	Co-founder of company. Medical researcher and specialist in autoimmune disease and diabetes; has over 15 years experience in clinical trial design and management	1 June 1998 Resigned 20 March 2006
Carrie Hillyard	Non-executive director	More than 30 years experience of the complete healthcare product lifecycle	28 August 2002 Resigned 10 April 2006



## 2.2. The chairman should be an independent director

The Pharmaxis Corporate Governance Framework requires the chairman to be independent.

## 2.3. The roles of chairman and chief executive officer should not be exercised by the same individual

The Pharmaxis Corporate Governance Framework requires the chairman to be a different individual to the chief executive officer.

## 2.4. The board should establish a nomination committee

Pharmaxis has a Remuneration and Nomination Committee. The combined role is considered appropriate for a company of this size. A copy of the Remuneration and Nomination Committee Charter is available on the Pharmaxis website.

Responsibilities of the Remuneration and Nomination Committee include assessing the appropriate size, composition, and skill mix of the Board. The appointment of new directors will be based on the committee's recommendations.

The Remuneration & Nomination Committee consists of:

Name	Meetings Held	Meetings Attended
Denis Hanley – Chairman	4	4
Carrie Hillyard – resigned 10 April 2006	3	3
Brigitte Smith	4	4
Alan Robertson – appointed 4 May 2006	1	1

The commentary and guidance to the ASX Principles of Good Corporate Governance recommends nomination committees comprise a majority of independent directors. Only the chairman of the Remuneration and Nomination Committee is independent. Brigitte Smith and Carrie Hillyard are considered not to be independent because of their association with venture capital firms that are significant shareholders in Pharmaxis. Their specific industry knowledge and experience is considered particularly relevant and valuable to the work of this committee. Carrie Hillyard resigned in April 2006 and was replaced by the chief executive officer on a temporary basis.

## 2.5. Independent professional advice

The Board has an agreed procedure for directors and board committees to obtain independent professional advice at the company's expense.

## 3. Promote Ethical and Responsible Decision Making

*Actively promote ethical and responsible decision making*

### 3.1. Establish a code of conduct to guide the directors, the chief executive officer (or equivalent), the chief financial officer (or equivalent) and any other key executives as to:

- the practices necessary to maintain confidence in the company's integrity
- the responsibility and accountability of individuals for reporting and investigating reports of unethical practices.

Due to the size of Pharmaxis, oversight of decision-making by the Board and senior management is not overly complex at this time. However, the Board recognises the importance of clearly articulating the values on which they are building the company and the manner in which they wish to see those values maintained. The company has therefore developed a Code of Conduct applicable to directors, senior management and employees generally. The Code of Conduct is available on the Pharmaxis website. During the current year, the company has developed a Whistleblower's policy and upgraded its Occupational Health & Safety policy.

### 3.2. Disclose the policy concerning trading in company securities by directors, officers and employees

A copy of the Pharmaxis Share Trading Policy is available on the Pharmaxis website. This policy was reviewed and updated during the year.

## 4. Safeguard Integrity in Financial Reporting

*Have a structure to independently verify and safeguard the integrity of the company's financial reporting*

### 4.1. Require the chief executive officer and the chief financial officer to state in writing to the board that the company's financial reports present a true and fair view, in all material respects, of the company's financial condition and operational results and are in accordance with relevant accounting standards

This is a requirement of the Pharmaxis Corporate Governance Framework, as well as Australian and US securities regulations.

### 4.2. The board should establish an audit committee

Pharmaxis has an Audit Committee.

#### 4.3. Structure the audit committee so that it consists of:

- only non-executive directors
- majority of independent directors
- an independent chairman, not chairman of the board
- at least three members

The structure of the Pharmaxis Audit Committee complies with the above recommendation. The Audit Committee consists of:

Name	Qualifications	Meetings Held	Meetings Attended
Charles Kiefel – Chairman	BCom. FCA FAICD	4	3
Denis Hanley	MBA FCPA FAICD	4	4
Malcolm McComas	BEC. LLB FSIA AICD	4	4

#### 4.4. The audit committee should have a formal charter

The Pharmaxis Audit Committee Charter is available on the Pharmaxis website. The Audit Committee is responsible for the integrity of the company's financial reporting, and overseeing the work and independence of the external auditors.

The Audit Committee is responsible for the appointment of the external auditor. The charter discusses the rotation of the external audit engagement partner.

#### 5. Make Timely and Balanced Disclosure

*Make timely and balanced disclosure of all material matters concerning the company*

##### 5.1. Establish written policies and procedures designed to ensure compliance with ASX Listing Rule disclosure requirements and to ensure accountability at a senior management level for that compliance

Pharmaxis has established a Disclosure Committee to oversee the establishment of appropriate policies and procedures in relation to communications with the market, and to review all announcements to the market. The Disclosure Committee consists of:

- chief executive officer
- chief financial officer/company secretary
- chairman of the Board

Pharmaxis has a Continuous Disclosure and Shareholder Communications Policy, which is available on the Pharmaxis website. The policy requires the company to comply with the voluntary Code of Best Practice for Reporting by Life Science Companies issued by AusBiotech and the ASX.

#### 6. Respect the Rights of Shareholders

*Respect the rights of shareholders and facilitate the effective exercise of those rights.*

##### 6.1. Design and disclose a communications strategy to promote effective communication with shareholders and encourage effective participation at general meetings

The Board believes that regular and relevant communication to shareholders and the market generally is key to investor support of the company. Shareholders are then better able to assess the opportunities and the risks inherent in investing in the company. Pharmaxis has therefore developed a Continuous Disclosure and Shareholder Communication Policy, referred to in 5.1 above.

The Board has also resolved to provide shareholders with quarterly updates of the company's progress across all areas of the business (in addition to continuous disclosure requirements), to comply with the voluntary Code of Best Practice for Reporting by Life Science Companies issued by AusBiotech and the ASX, and to utilise its website to disclose useful and relevant information about the company.

**6.2. Request the external auditor to attend the annual general meeting and be available to answer shareholder questions about the conduct of the audit and the preparation and content of the auditor's report**

The Pharmaxis Corporate Governance Framework requires that the external auditor be requested to attend annual general meetings so as to be able to answer shareholder questions.

**7. Recognise and Manage Risk**

*Establish a sound system of risk oversight and management and internal control.*

**7.1. The board or appropriate board committee should establish policies on risk oversight and management**

The Audit Committee is responsible for oversight in this area. The Pharmaxis Risk Management Statement is available on the Pharmaxis website and provides an overview of the company's risk profile and management strategies.

**7.2. The chief executive officer (or equivalent) and the chief financial officer (or equivalent) should state to the board in writing that:**

- **The statement given in 4.1 above is based on a sound system of risk management and internal compliance and control that implements policies adopted by the board.**
- **The company's risk management and internal compliance and control system is operating effectively in all material respects.**

This recommendation is a requirement of the Pharmaxis Corporate Governance Framework as well as Australian and US Securities regulation.

**8. Encourage Enhanced Performance**

*Fairly review and actively encourage enhanced board and management effectiveness.*

**8.1. Disclose the process for performance evaluation of the board, its committees and individual directors, and key executives.**

The Pharmaxis Remuneration and Nomination Committee is responsible for assessing the performance of the Board and senior management. The process adopted by the Committee to fulfil this responsibility is described below.

**Pharmaxis Board**

The Board recognises the value of an annual review of Board performance and processes. However, the Board is mindful that any concerns a director may have in this area are dealt with on a timely basis. Therefore, the agenda at each formal meeting of the Board includes consideration on the Board's processes and performance.

In addition, the Committee conducts an annual survey of directors consisting of two separate components – Board Performance and Individual Performance.

The Board Performance survey is designed to:

- Review the current corporate governance practices of the company, identify any requirements for change
- Review the respective roles of the Board and management
- Review the mix of experience and skills required by the Board
- Assess the performance of the Board as a whole over the previous 12 months
- Assess the effectiveness of board processes
- Examine ways of assisting the board in performing its duties more effectively and efficiently.

The Board Performance surveys are collated by the Company Secretary and discussed at a board meeting to agree on the implementation of any recommendations.

During the current year, the company engaged an external consultant to assist in the review of the mix of experience and skills required by the Board.

The Individual Performance survey is designed to assess the performance of individual directors. Each director completes a survey in relation to every member of the Board including themselves and the company secretary. The results of the surveys are collated by the company secretary and provided to the director concerned and the Chairman as a basis for one-on-one meetings (see below).

## Board Committees

Board Committee performance is assessed using the Board performance survey, separately completed by committee members in relation to their respective committee. Individual committees are then asked to:

- Review recommendations and comments arising from the survey, and implement changes considered appropriate
- Review their committee charter annually, and recommend changes to the Board.

## Individual Directors

- The chairman meets with each non-executive director separately to discuss individual performance and contribution, based on Individual Performance surveys.

## Key Executives

The Remuneration and Nomination Committee is specifically responsible for reviewing the ongoing performance of the chief executive officer, the chief financial officer and the company secretary. In June of each year, the Committee:

- Approves individual milestones/objectives for all senior executives business plan approved by the Board for the forthcoming year
- Evaluates individual performance compared to milestones/objectives set at the beginning of the year
- Approves the payment of any bonuses based on performance against milestones/objectives for the current financial year
- Approves the vesting of employee options based on attainment of milestones/objectives for the current financial year.

## 9. Remunerate Fairly and Responsibly

*Ensure that the level and composition of remuneration is sufficient and reasonable and that its relationship to corporate and individual performance is defined*

### 9.1. Provide disclosure in relation to the company's remuneration policies to enable investors to understand (i) the costs and benefits of those policies and (ii) the link between remuneration paid to directors and key executives and corporate performance.

The Directors' Report includes a remuneration report that discloses the principles used to determine the nature and amount of remuneration, details of remuneration including incentive payments, service agreements, share-based compensation and loans to directors and executives.

Form 20-F, filed by the Company with the US Securities and Exchange Commission and available on the Pharmaxis website, also discusses remuneration of directors and senior management.

### 9.2. The board should establish a remuneration committee

Pharmaxis has a Remuneration and Nomination Committee. A copy of the Remuneration and Nomination Committee Charter is available on the Pharmaxis website. Names of committee members are detailed at 2.4 above.

### 9.3. Clearly distinguish the structure of non-executive directors' remuneration from that of executives

As non-executive directors assess individual and company performance, their remuneration does not have any variable incentive component. Only executive director and senior management remuneration includes a variable component such as the vesting of options or bonus payments linked to the achievement of performance targets.

During the current year, the company engaged an external consultant to assist in the determination of non-executive directors' fees appropriate to the company's stage of development.

As a result of this review, non-executive directors are able to receive any portion of their remuneration in the form of options in Pharmaxis as an alternative to cash.

### 9.4. Ensure that payment of equity-based executive remuneration is made in accordance with thresholds set in plans approved by shareholders

The Pharmaxis Employee Option Plan (EOP) was initially approved by the company's shareholders in 1999. The shareholders also approved amendments to the EOP in May 2003. Future amendments to the EOP, the introduction of any other equity-based remuneration schemes, or the issue of further options to directors will be approved by shareholders before being implemented.

## 10. Recognise the Legitimate Interests of Stakeholders

*Recognise legal and other obligations to all legitimate stakeholders*

*10.1. Establish and disclose a code of conduct to guide compliance with legal and other obligations to legitimate stakeholders*

Refer to 3.1 above



# Directors' Report and Financial Report

30 June 2006

The financial report covers both Pharmaxis Ltd as an individual entity and the consolidated entity consisting of Pharmaxis Ltd and its subsidiary. The financial report is presented in the Australian currency.

Pharmaxis Ltd is a company limited by shares, incorporated and domiciled in Australia. Its registered office and principal place of business is:

Pharmaxis Ltd  
Unit 2, 10 Rodborough Road  
Frenchs Forest, Australia 2086.

A description of the nature of the consolidated entity's operations and its principal activities is included in the review of operations and activities in the directors' report which is not part of the financial report.

The financial report was authorised for issue by the directors on 8th August 2006. The company has the power to amend and reissue the financial report.

Through the use of the internet, we have ensured that our corporate reporting is timely, complete, and available globally at minimum cost to the company. Press releases, financial reports and other information are available at our website: [www.pharmaxis.com.au](http://www.pharmaxis.com.au)

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# Directors' Report

30 June 2006

Your directors present their report on the consolidated entity (referred to hereafter as the Group) consisting of Pharmaxis Ltd and the entities it controlled at the end of, or during, the year ended 30 June 2006.

## Directors

The following persons were directors of Pharmaxis Ltd during the whole of the financial year and up to the date of this report:

Denis Hanley

Charles Kiefel

Malcolm McComas

Alan Robertson

Brigitte Smith

Peter Farrell was appointed a director on 15 March 2006 and continues in office at the date of this report.

Carmel Hillyard was a director from the beginning of the financial year until her resignation on 6 April 2006.

Brett Charlton was a director from the beginning of the financial year until his resignation on 20 March 2006.

## Principal activities

During the year the principal continuing activities of the Group consisted of the research, development and commercialisation of human healthcare products for the treatment and management of chronic respiratory and autoimmune diseases.

## Dividends

No dividends were paid during the year and the directors have not recommended the payment of a dividend.

## Review of operations

### Overview

Major milestones achieved during the year include:

- The Group's first product Aridol was approved for sale by the Australian Therapeutic Goods Administration (TGA) and was subsequently launched in March to the Australian pulmonary specialist community at the Thoracic Society of Australia and New Zealand annual conference.
- Subsequent to the successful auditing of the Group's GMP manufacturing facility at Frenchs Forest by the TGA, the licence to manufacture for both Aridol and Bronchitol was upgraded and manufacture of Aridol for commercial supply commenced. The first commercial batches of Aridol were available in mid June.
- An Australian sales force was recruited, trained and commenced promoting Aridol to the respiratory community. The Group's first orders were taken, first product shipped and the first product sales were recorded.
- Successful completion of a Phase II clinical trial of Bronchitol in cystic fibrosis.
- Commencement of European operations and appointment of the Group's first two European distributors.
- Commencement of a final US pre-registration trial of Aridol.
- Commencement of a Phase III trial of Bronchitol in bronchiectasis.
- Commencement and closing recruitment in a label extension study of Aridol in COPD.
- Commencement of a Phase II dose ranging trial of Bronchitol in cystic fibrosis.
- Commencement of a Phase II comparator trial of Bronchitol in cystic fibrosis.
- The European Medicines Agency granted the Group Orphan Drug status for Bronchitol for cystic fibrosis.
- Establishment of Sydney-based research laboratories.
- Successfully listing on the US NASDAQ Global Market, and subsequently successfully concluding a global capital raising of \$87 million on both the ASX and NASDAQ.

## Financial Highlights

	Consolidated	
	2006 \$'000	2005 \$'000
<b>Revenue from sale of goods</b>	<b>8</b>	–
Cost of sales	(2)	–
<b>Gross profit</b>	<b>6</b>	–
Government research grants	1,299	1,219
Interest income	4,282	1,702
Other expenses from ordinary activities		
Research & development expenses	(16,364)	(9,154)
Administration expenses	(4,051)	(3,105)
Commercial expenses	(1,776)	(847)
Fair value of stock options issued to employees related to:		
Research & development	(614)	(115)
Administration	(335)	(29)
Commercial	(175)	(116)
<b>Loss before income tax</b>	<b>(17,728)</b>	(10,445)
Income tax expense	(5)	–
<b>Loss for the year</b>	<b>(17,733)</b>	(10,445)
<b>Sales orders received</b>	<b>122</b>	–
<b>Backlog of outstanding sales orders</b>	<b>113</b>	–
<b>Cash and bank accepted commercial bills</b>	<b>97,840</b>	33,390
<b>Net assets</b>	<b>98,888</b>	35,467

### *Revenue from continuing operations:*

Following approval of Aridol for sale and marketing and the issue of the Group's commercial manufacturing licence by the Australian Therapeutics Goods Administration, the first product was shipped to customers in mid June. By 30 June 2006 the Group had booked sales orders totalling \$121,611 and had shipped product to customers totalling \$8,383. The backlog of outstanding sales orders at 30 June 2006 was \$113,228, including a large order from a US Biopharmaceutical who will be using Aridol in a series of Phase II clinical trials of a new asthma treatment they are developing. Gross margin was 75% of sales.

### *Grant income:*

Approximately 65% of grant income in 2006 derives from the Pharmaceuticals Partnerships Program (P3) grant awarded to the Group in April 2004. This grant payable to Pharmaxis is 30% of the increase of eligible R&D expenditure over a base amount derived from average prior year expenditures. The increase in the P3 grant in 2006 correlates with the increased level of research expenditure in 2006. The remainder of the grant income relates to the R&D Start Grant for the development of new treatments for cystic fibrosis which was awarded to the Group in June 2003, and which concluded in December 2005. The R&D Start Grant payable to Pharmaxis is 50% of eligible expenditure on the research project, and the decrease in the income for this grant compared to 2005 when most of the grant income related to the R&D Start Grant, correlates to the project concluding half way through the financial year.

### *Interest:*

The increase in interest income is attributable to the greater level of funds invested during fiscal 2006. The Group started the current fiscal year with \$33 million of cash and bank accepted bills of exchange, to which was added approximately \$80 million in November 2005 from the capital raising undertaken in Australia and the United States. By contrast, the Group started the 2005 fiscal year with \$25.2 million of cash and bank accepted bills of exchange, to which was added approximately \$19 million in November and December 2004 from a share placement and share purchase plan.



# Directors' Report

30 June 2006

## *Research & development expenses:*

Research & development expenses increased by approximately \$7.2 million in 2006 compared to 2005. There are five components to the research & development expenses:

The research unit based at the John Curtin School of Medical Research within the Australian National University accounted for approximately five percent of our total research and development expenditure in the current year. The research unit is focused on autoimmune diseases. The level of expenditure in fiscal 2006 for this research unit has increased by approximately two percent compared to the 2005 financial year.

During the last half of the financial year we established a drug discovery unit based in leased laboratories at North Ryde. This unit accounted for approximately two percent of our total research and development expenditure in the current year. It is focused on autoimmune and respiratory drug discovery and is complementary to the work carried out at the Australian National University. This area of expenditure accounted for approximately four percent of the increase in overall research & development expenditure during the current year.

The preclinical development unit located at our Frenchs Forest facility accounted for approximately twelve percent of our total research and development expenditure in the current year and increased by approximately 38 percent compared to the 2005 financial year. This unit is managing the outsourced safety/toxicology studies of the Aridol and Bronchitol products and the preclinical development of lead compounds in the autoimmune area. Over 90 percent of expenditure in the current year related to Bronchitol long term safety studies. This area of research accounted for approximately seven percent of the increase in overall research & development expenditure during the current year.

The clinical unit located at our Frenchs Forest facility accounted for approximately 61 percent of our total research and development expenditure in the current year and increased by approximately 118 percent compared to the 2005 financial year. The clinical unit designs and manages the clinical trials run by Pharmaxis. The majority of the expenditures of this unit are directed at hospitals and other services related to the conduct and analysis of clinical trials. This increase in expenditure reflects the number of clinical trials ongoing during fiscal 2006. This area of research accounted for approximately 75 percent of the increase in overall research & development expenditure during the current year.

Before the change of its TGA licence in April 2006, the manufacturing facility at Frenchs Forest was totally focused on producing material for clinical trials and developing enhanced manufacturing processes. Manufacturing expenses for the financial year have therefore mainly been classified as a research & development expenditure, with the small amount of expenses relating to the Aridol product sold classified as cost of sales. Manufacturing accounted for approximately 20 percent of our total research and development expenditure in the current year and increased by approximately 40 percent compared to the 2005 financial year, reflecting additional manufacturing capacity/productivity research and product stability studies required to support registration applications. This area of expenditure accounted for approximately 13 percent of the increase in overall research & development expenditure during the current year.

## *Commercial expenses:*

The commercial department is responsible for sales and marketing. Commercial expenses for the 2006 financial year were \$1.8 million, an increase of approximately 109% over the 2005 financial year. The commercial launch of Aridol was the predominant cause of the increased level of expenses involving the hiring of a sales and marketing manager and a sales team of five, and the state by state presentations of Aridol to the respiratory communities. The creation of a European Pharmaxis operation also added to commercial expenses in the year. The operation, based in the UK and employing two people, is required to coordinate and manage the marketing/distribution partners we are appointing to market, sell and distribute Aridol throughout Europe.

## *Administration expenses:*

Administration expenses include accounting, administration, office, recruitment, legal and public company costs. Administration expenses for the current year were \$4.1 million, an increase of 30 percent over the prior comparable period. This increase in expenses reflects growth in the size and complexity of the Group's operations, as well as the incremental costs of being listed on both the ASX and NASDAQ.

## *Fair value of stock options issued to employees:*

The employee option related expense increased from \$260,000 in 2005 to \$1.1 million in the 2006 financial year. The valuation and amortization methodology is discussed elsewhere in this report and the financial statements. The increase in the recorded expense is the result of three factors: the increase in the number of employees working for the Group all of whom are issued options upon commencement; the issue in August 2005 of an annual grant of options to all employees, the first Group wide issue of options since May 2003; and the increase in the Pharmaxis share price which is a major determinate of the valuation.

*Income tax expense:*

Income tax expense relates to income generated by the Group's UK subsidiary which was incorporated during the year and is currently reimbursed for its expenditures on a cost plus basis upon which tax is payable.

**Significant changes in the state of affairs**

The capital raising in November 2005 increased cash funds of the Group by approximately \$80 million after deducting associated expenses. The issue of shares subsequent to the exercise of employee options contributed \$597,000. Together with pre-existing funds the Group ended the year with \$98 million in cash and bank accepted commercial bills.

Capital expenditure for the 2006 financial year was consistent with 2005. The major item of expenditure was a new encapsulator which provides greater capacity, yield and in-process quality control features. Other major items of expenditure included QC laboratory equipment, and computer equipment, the latter including a new integrated financial and manufacturing management system being progressively installed from 1 July 2006.

**Matters subsequent to the end of the financial year**

No matter or circumstance has arisen since 30 June 2006 that has significantly affected, or may significantly affect:

- (a) the Group's operations in future financial years, or
- (b) the results of those operations in future financial years, or
- (c) the Group's state of affairs in future financial years.

**Likely developments and expected results of operations**

Likely developments in the operations of the Group that were not finalised at the date of this report include approval of Aridol in Sweden which is expected in the September quarter and the completion of enrolment of the US Phase III clinical trial of Aridol which is also expected in the September quarter.

Additional comments on expected results of certain of the operations of the Group are included in this report under the review of operations.

Further information on likely developments in the operations of the Group and the expected results of operations have not been included in this report because the directors believe it would be likely to result in unreasonable prejudice to the Group.

**Environmental regulation**

The Group is subject to environmental regulation in respect of its manufacturing activities including the Clean Air Act 1961, Clean Waters Act 1970, Pollution Control Act 1970, Noise Control Act 1975 and Waste Minimisation & Management Act 1995. However, the Group is not presently required to hold any licences for its current scale of manufacturing operations. The Group expects to apply for water discharge licences as it expands its manufacturing capacity.

The Group holds a licence to manufacture goods for commercial sale.

# Directors' Report

30 June 2006

## Information on directors

Director	Experience and other public company directorships	Special responsibilities	Particulars of directors' interests in shares and options of Pharmaxis Ltd	
			Ordinary shares	Options
<i>Chairman – non-executive</i>				
Denis M Hanley MBA, FCPA, FAICD	Independent non-executive Chairman for five years. Age 59. Extensive experience in developing and commercialising new Australian technology including 14 years as CEO of Memtec Ltd which grew from a small enterprise to a successful NYSE-listed global business with 1,700 employees, multiple technology platforms and a market capitalisation of \$600 million. Prior to his Memtec experience, Denis worked for the international medical company Baxter Inc. in the US and also as their Australian managing director.  Denis is non-executive chairman of CathRx Ltd, an Australian listed company.	Chairman  Chairman of Remuneration and Nomination Committee  Member of Audit Committee	717,997	1,080,000
<i>Executive</i>				
Alan D Robertson BSc, PhD	Managing Director and CEO for six years. Age 50. More than 20 years experience in drug discovery and development with leading pharmaceutical companies, during which time his team developed a new migraine therapeutic now known as Zomig, marketed worldwide by Astra Zeneca. Subsequent experience was with the Faulding Group as New Product Development Manager, Amrad Ltd as Head of Drug Development and more recently assisting early-stage pharmaceutical companies in their start-up and development, including Promics Pty Ltd and Kinacia Pty Ltd.	Managing Director and Chief Executive Officer  Member of Remuneration and Nomination Committee	–	2,230,000
<i>Non-executive directors</i>				
Brigitte H Smith B.Chem Eng, MBA, MALD	Non-executive director for six years. Age 39. A venture capital investor and managing director of GBS Venture Partners; sits on the board of seven GBS Venture Partners portfolio companies. Previous strategic management experience with Bain & Company, Motorola and Molten Metal Technology.	Member of Remuneration and Nomination Committee	(a)	–
Charles PH Kiefel BCom, FCA, FAICD	Non-executive director for three years. Age 51. More than 20 years experience in the financial, investment banking and investment (buy side) sector including managing director of corporate finance at ANZ Investment Bank, director of corporate finance at Ord Minnett and also with Lazard Brothers & Co. Ltd (London) and Lazard Frere (New York).	Chairman of Audit Committee	200,000	220,000
Malcolm J McComas BEc, LLB, FSIA, AICD	Non-executive director for three years. Age 51. More than 20 years investment banking experience and five years legal experience. From 1999 until 2004 was a director of Grant Samuel, and is now a consultant to Grant Samuel, the corporate advisory, property services and funds management company. Prior to that a managing director of Salomon Smith Barney. Mr McComas is currently non-executive chairman of Sunshine Heart Inc.	Member of Audit Committee	126,666	220,000



## Information on directors

Director	Experience and other public company directorships	Special responsibilities	Particulars of directors' interests in shares and options of Pharmaxis Ltd	
			Ordinary shares	Options
Peter C Farrell DSc, PhD	Non-executive director appointed 16 March 2006. Age 64. More than 20 years developing and commercialising medical products in the USA, Europe, Japan and Australia. Peter began his commercial career with Baxter Healthcare Inc. in Japan as director and vice president of research and development, then as managing director of the Baxter Center for Medical Research. He left Baxter in 1989 to establish ResMed Inc., a company that develops treatments for sleep-disordered breathing and respiratory failure. Peter is currently founding Chairman and Chief Executive Officer of ResMed Inc.		101,645	–

- (a) BH Smith is associated with GBS Venture Partners Ltd, The Australian Bioscience Trust and Bioscience Ventures II. Perpetual Trustees Nominees as trustee of The Australian Bioscience Trust, holds 13,583,010 shares at 30 June 2006. GBS Venture Partners Ltd as trustee and manager of Bioscience Venture II, holds 7,481,890 shares at 30 June 2006.

## Company secretary

The company secretary is Mr David M McGarvey, CA, who was appointed to the position of company secretary in 2002. Before joining Pharmaxis Ltd he held similar positions with both listed and unlisted companies, including Memtec Limited, which was listed on the Australian Stock Exchange, NASDAQ and subsequently the New York Stock Exchange.

## Meeting of directors

The number of meetings of the company's board of directors and of each board committee held during the year ended 30 June 2006, and the number of meetings attended by each director were:

	Board		Meetings of Committees			
	Meetings		Audit		Remuneration & Nomination	
	A	B	A	B	A	B
DM Hanley	16	16	4	4	4	4
AD Robertson	16	16	–	–	1	1
B Charlton	13	13	–	–	–	–
CJ Hillyard	14	14	–	–	3	3
CPH Kiefel	15	12	4	3	–	–
MJ McComas	16	16	4	4	–	–
BH Smith	16	15	–	–	4	4
PC Farrell	3	1	–	–	–	–

A = Number of meetings held during the time the director held office or was a member of the committee during the year

B = Number of meetings attended

30 June 2006

## Remuneration Report

The remuneration report is set out under the following main headings:

- A. Principles used to determine the nature and amount of remuneration
- B. Details of remuneration
- C. Service agreements
- D. Share-based compensation
- E. Additional information.

The information provided under headings A-D includes remuneration disclosures that are required under Accounting Standard AASB 124 *Related Party Disclosures*. These disclosures have been transferred from the financial report and have been audited. The disclosures in Section E are additional disclosures required by the *Corporations Act 2001* and the *Corporations Regulations 2001* which have not been audited.

### **A. Principles used to determine the nature and amount of remuneration (audited)**

As a company building an international pharmaceutical business, Pharmaxis requires a board and senior management team that have both the technical capability and relevant experience to execute the Group's business plan. The directors consider options a key tool in attracting the required talented individuals to the Board and management team while staying within the fiscal constraints of a growing group.

Director and executive remuneration includes a mix of short and long-term components. Remuneration of executive directors and other executives include a meaningful proportion that varies with individual performance. Variable cash incentives and the vesting of options are subject to performance assessment by the Remuneration and Nomination Committee. Performance targets in the main relate to objectives and milestones assigned to individual executives from the Group's annual business plan. At this stage of the Group's development, shareholder wealth is enhanced by the achievement of milestones in the development of the Group's products, within a framework of prudent financial management. The Group's earnings have therefore not been a significant component of enhancing shareholder wealth during 2006 and therefore do not form a measure of executive performance. Individual performance targets are agreed by the Remuneration and Nomination Committee and the full Board each year. Annual performance of each executive is reviewed by the Remuneration and Nomination Committee each year.

As non-executive directors assess individual and Group performance, their remuneration does not have a variable performance related component.

#### *Non-executive directors*

Fees and payments to non-executive directors reflect the demands that are made on, and the responsibilities of, the directors. Non-executive directors' fees and payments are reviewed annually by the Remuneration and Nomination Committee of the Board. During the year the Group engaged an external consultant to assist in the determination of independent non-executive directors' fees appropriate to the Group's stage of development. There are two components to the fees of independent non-executive directors:

- a base fee, currently \$110,000 for the chairman and \$60,000 for other non-executive directors
- an flat annual fee for non-executive directors serving on committees, currently \$5,000 as a committee member and \$10,000 as a committee chair
- independent non-executive directors are allowed to package their remuneration to include superannuation and options in the Group, the latter being determined as the number of options granted during the year valued at the option value used to determine the amounts expensed in the financial statements. Options are granted under the Pharmaxis Ltd Employee Option Plan and vest over a period of approximately four years from grant date.

Other non-executive directors during the year were BH Smith and CJ Hillyard. They are principals of their respective venture capital firms that manage funds which are significant shareholders of the company. These directors are each paid a cash fee of \$40,696 per annum and are not granted any options in the company.

Non-executive directors' fees (including statutory superannuation) are determined within an aggregate directors' fee pool limit, which is periodically recommended for approval by shareholders. The pool currently stands at a maximum of \$300,000 per annum in total.

#### *Retirement allowances for directors*

Termination payments apply only to executive directors, as discussed below.

#### *Executive directors and other senior executives:*

There are four components to executive remuneration:

- a base salary paid in cash or packaged at the executive's discretion within FBT guidelines as a total cost package
- superannuation of 9%
- a variable cash incentive component payable annually dependent upon achievement of performance targets set and approved by the Remuneration and Nomination Committee. Individual performance targets are set by reference to the components of the Group's annual business plan for which the individual executive is responsible
- options under the Pharmaxis Employee Option Plan. Options typically vest over a four-year time frame. For options granted after 1 January 2003, the number of an individual executive's options vesting is subject to achievement of the performance targets set and approved by the Remuneration and Nomination Committee. The committee may approve the vesting of all or only a portion of the relevant options. Founder options were granted in 2003 to the founding scientists – WB Cowden and B Charlton. These options vested at 30 June 2003. Sign-on options were granted to DM McGarvey in 2003, JF Crapper and GJ Phillips in 2004 and IA McDonald in 2005. Sign-on options vest completely on the first anniversary of the executive commencing employment with the Group.

Base pay for senior executives is reviewed annually to ensure the executive's pay is competitive with the market. An executive's pay is also reviewed on promotion.

#### *Termination payments*

Termination payments apply only to executive directors and senior management. The employment contracts for each of the executive directors and key management personnel can be terminated immediately by the company for serious misconduct, with one months notice if the employee becomes mentally or physically unfit to perform or carry out their employment, with two months notice on the grounds of redundancy and with three months notice without cause. No additional payments apply on termination.

#### *Pharmaxis Ltd Employee Option Plan*

Information on the Pharmaxis Ltd Employee Option Plan is set out in note 30 to the financial statements.

### **B. Details of remuneration (audited)**

Details of the remuneration of the directors and the key management personnel (as defined in AASB 124 Related Party Disclosures) of Pharmaxis Ltd and the Pharmaxis Group are set out in the following tables.

The key management personnel of Pharmaxis Ltd includes the directors of Pharmaxis Ltd and the following executive officers, who are also the 6 highest paid executives of the entity:

<i>Name</i>	<i>Position</i>	<i>Employer</i>
William Butler Cowden	Chief Scientific Officer	Pharmaxis Ltd
John Francis Crapper	Chief Operations Officer	Pharmaxis Ltd
Ian Alexander McDonald	Chief Technical Officer	Pharmaxis Ltd
Brett Charlton	Medical Director	Pharmaxis Ltd
David Morris McGarvey	Chief Financial Officer	Pharmaxis Ltd
Gary Jonathan Phillips	Commercial Director	Pharmaxis Ltd

The cash bonuses are dependent on the satisfaction of performance conditions as discussed in Section A above, and the options are not granted unless approved by the Remuneration and Nomination Committee. All other elements of remuneration are not directly related to performance.

# Directors' Report

30 June 2006

## Key management personnel of Pharmaxis Ltd and the Group

2006	Short-term benefits			Post-employment benefits		Share-based payment	Total
	Cash salary and fees	Cash bonus	Non-monetary benefits	Superannuation	Retirement benefits	Options	
Name	\$	\$	\$	\$	\$	\$	\$
<i>Non-executive directors</i>							
DM Hanley <i>Chairman</i>	66,668	–	–	6,000	–	39,186	111,854
CPH Kiefel	37,805	–	–	3,402	–	21,622	62,829
MJ McComas	38,708	–	–	–	–	21,832	60,540
PC Farrell	17,500	–	–	–	–	–	17,500
BH Smith	37,192	–	–	–	–	–	37,192
CJ Hillyard	27,017	–	–	–	–	–	27,017
<b>Sub-total non-executive directors</b>	<b>224,890</b>	<b>–</b>	<b>–</b>	<b>9,402</b>	<b>–</b>	<b>82,640</b>	<b>316,932</b>
<i>Executive directors</i>							
AD Robertson	270,500	92,400	–	24,345	–	139,722	526,967
<i>Other key management personnel</i>							
WB Cowden	147,087	20,000	–	13,238	–	67,678	248,003
JF Crapper	208,750	40,000	–	18,788	–	73,023	340,561
IA McDonald	177,625	18,750	–	15,986	–	83,841	296,202
B Charlton <sup>(1)</sup>	215,000	40,000	–	19,350	–	95,236	369,586
DM McGarvey	226,750	42,500	–	20,408	–	67,678	357,336
GJ Phillips	222,250	40,000	–	20,003	–	73,488	355,741
<b>Totals</b>	<b>1,692,852</b>	<b>293,650</b>	<b>–</b>	<b>141,520</b>	<b>–</b>	<b>683,306</b>	<b>2,811,328</b>

<sup>1</sup> Dr B Charlton resigned as a director on 20 March 2006. Amounts shown above include all Dr Charlton's remuneration during the reporting period, whether as a director or in his management capacity as Medical Director.



## Key management personnel of Pharmaxis Ltd and the Group

2005	Short-term benefits			Post-employment benefits		Share-based payment	Total
	Cash salary and fees	Cash bonus	Non-monetary benefits	Superannuation	Retirement benefits	Options	
Name	\$	\$	\$	\$	\$	\$	\$
<i>Non-executive directors</i>							
DM Hanley <i>Chairman</i>	57,500	–	–	5,175	–	13,209	75,884
CPH Kiefel	30,625	–	–	2,756	–	8,634	42,015
MJ McComas	30,625	–	–	2,756	–	9,135	42,516
BH Smith	30,625	–	–	–	–	–	30,625
CJ Hillyard	30,625	–	–	–	–	–	30,625
<b>Sub-total non-executive directors</b>	<b>180,000</b>	<b>–</b>	<b>–</b>	<b>10,687</b>	<b>–</b>	<b>30,978</b>	<b>221,665</b>
<i>Executive directors</i>							
AD Robertson	194,750	68,000	–	15,750	–	31,702	310,202
B Charlton	160,750	36,000	–	11,700	–	15,851	224,301
<i>Other key management personnel</i>							
WB Cowden	139,913	20,000	–	11,700	–	15,851	187,464
JF Crapper	182,963	22,500	–	15,300	–	21,853	242,616
IA McDonald	42,628	–	–	3,837	–	10,187	56,652
DM McGarvey	193,722	40,000	–	16,200	–	15,851	265,773
GJ Phillips	189,625	36,000	–	16,650	–	41,413	283,688
<b>Totals</b>	<b>1,284,351</b>	<b>222,500</b>	<b>–</b>	<b>101,824</b>	<b>–</b>	<b>183,686</b>	<b>1,792,361</b>

### C. Service agreements (audited)

Remuneration and other terms of employment for the Chief Executive Officer and the other key management personnel are formalised in service agreements. Each of these agreements provide for the provision of performance-related cash incentives and participation, when eligible, in the Pharmaxis Ltd Employee Option Plan. Other major provisions of the agreements relating to remuneration are set out below.

Alan Duncan Robertson, *Managing Director & Chief Executive Officer*

- Term of agreement – 30 June 2008.
- Effective 1 January 2006, a base salary of \$321,000, superannuation of \$28,890 and a bonus potential of \$110,000. The base salary and bonus potential are reviewed annually by the Remuneration and Nomination Committee.
- The employment can be terminated immediately by the company for serious misconduct, with one months notice if the employee becomes mentally or physically unfit to carry out or perform his employment, with two months notice on the grounds of redundancy, and with three months notice without cause. No additional payments apply on termination other than accrued annual leave.

## Directors' Report

30 June 2006

Brett Charlton, *Medical Director*

- Term of agreement – 30 June 2008.
- Effective 1 January 2006, a base salary of \$245,000, superannuation of \$22,050 and a bonus potential of \$50,000. The base salary and bonus potential are reviewed annually by the Remuneration and Nomination Committee.
- The employment can be terminated immediately by the company for serious misconduct, with one months notice if the employee becomes mentally or physically unfit to carry out or perform his employment, with two months notice on the grounds of redundancy, and with three months notice without cause. No additional payments apply on termination other than accrued annual leave.

William Butler Cowden, *Chief Scientific Officer*

- Term of agreement – 30 June 2008.
- Effective 1 January 2006, a base salary of \$150,675, superannuation of \$13,561 and a bonus potential of \$40,000. The base salary and bonus potential are reviewed annually by the Remuneration and Nomination Committee.
- The employment can be terminated immediately by the company for serious misconduct, with one months notice if the employee becomes mentally or physically unfit to carry out or perform his employment, with two months notice on the grounds of redundancy, and with three months notice without cause. No additional payments apply on termination other than accrued annual leave.

John Francis Crapper, *Chief Operations Officer*

- Term of agreement – 30 June 2008.
- Effective 1 January 2006, a base salary of \$230,000, superannuation of \$20,700 and a bonus potential of \$50,000. The base salary and bonus potential are reviewed annually by the Remuneration and Nomination Committee.
- The employment can be terminated immediately by the company for serious misconduct, with one months notice if the employee becomes mentally or physically unfit to carry out or perform his employment, with two months notice on the grounds of redundancy, and with three months notice without cause. No additional payments apply on termination other than accrued annual leave.

Ian Alexander McDonald, *Chief Technical Officer*

- Term of agreement – 30 June 2008.
- Effective 1 January 2006, a base salary of \$180,250, superannuation of \$16,223 and a bonus potential of \$25,000. The base salary and bonus potential are reviewed annually by the Remuneration and Nomination Committee.
- The employment can be terminated immediately by the company for serious misconduct, with one months notice if the employee becomes mentally or physically unfit to carry out or perform his employment, with two months notice on the grounds of redundancy, and with three months notice without cause. No additional payments apply on termination other than accrued annual leave.

David Morris McGarvey, *Chief Financial Officer and Company Secretary*

- Term of agreement – 30 June 2008.
- Effective 1 January 2006, a base salary of \$255,000, superannuation of \$22,950 and a bonus potential of \$50,000. The base salary and bonus potential are reviewed annually by the Remuneration and Nomination Committee.
- The employment can be terminated immediately by the company for serious misconduct, with one months notice if the employee becomes mentally or physically unfit to carry out or perform his employment, with two months notice on the grounds of redundancy, and with three months notice without cause. No additional payments apply on termination other than accrued annual leave.

Gary Jonathan Phillips, *Commercial Director*

- Term of agreement – 30 June 2008.
- Effective 1 January 2006, a base salary of \$250,000, superannuation of \$22,500 and a bonus potential of \$50,000. The base salary and bonus potential are reviewed annually by the Remuneration and Nomination Committee.

- The employment can be terminated immediately by the company for serious misconduct, with one months notice if the employee becomes mentally or physically unfit to carry out or perform his employment, with two months notice on the grounds of redundancy, and with three months notice without cause. No additional payments apply on termination other than accrued annual leave.

#### **D Share-based compensation (audited)**

##### *Options*

The Pharmaxis Employee Option Plan ('EOP') was approved by shareholders in 1999 and amended by shareholders in June 2003. The maximum number of options available to be issued under the EOP is 15% of total issued shares including the EOP. All employees and directors are eligible to participate in the EOP, but do so at the invitation of the Board. The terms of option issues are determined by the Board. Options are generally granted for no consideration and vest equally over a four year period. For options granted after 1 January 2003 the annual vesting is subject to approval by the Remuneration and Nomination Committee of the Board. The Committee gives its approval for vesting based on the achievement of individual employee's personal annual objectives.

Options granted under the EOP carry no dividend or voting rights. When exercisable, each option is convertible into one ordinary share.

The exercise price is set by the Board. Before the company listed on the Australian Stock Exchange in November 2003, the Board set the exercise price based on its assessment of the market value of the underlying shares at the time of grant. Since listing the exercise price is set as the average closing price of Pharmaxis Ltd shares on the Australian Stock Exchange on the five business days prior to the grant of the options.

The terms and conditions of each grant of options affecting remuneration in the previous, this or future reporting periods are as follows:

<b>Grant date</b>	<b>Expiry date</b>	<b>Exercise price</b>	<b>Value per option at grant date</b>	<b>Number of options granted</b>	<b>Number of option grantees</b>	<b>Date exercisable</b>
12 May 2003	30 June 2012	\$0.3125	\$0.1679	2,400,000	4	25% at each of 30 June 2003, 2004, 2005 and 2006, subject to Remuneration and Nomination Committee annual approval. Directors' options subject to ASX escrow until 10 November 2005.
12 May 2003	30 June 2012	\$0.3125	\$0.1679	400,000	1	25% at each of 30 June 2003, 2004, 2005 and 2006. Subject to ASX escrow until 10 November 2005.
12 May 2003	30 June 2012	\$0.3125	\$0.1679	480,000	1	1 December 2003 (sign-on options)
12 May 2003	30 June 2012	\$0.3125	\$0.1679	960,000	2	30 June 2003. Subject to ASX escrow until 10 November 2005.
1 July 2003	30 June 2013	\$0.3125	\$0.1681	480,000	1	25% at each of 30 June 2004, 2005, 2006 and 2007, subject to Remuneration and Nomination Committee annual approval.

# Directors' Report

30 June 2006

## D Share-based compensation (audited) (continued)

Options (continued)

Grant date	Expiry date	Exercise price	Value per option at grant date	Number of options granted	Number of option grantees	Date exercisable
1 July 2003	30 June 2013	\$0.3125	\$0.1681	480,000	1	1 July 2004 (sign-on options)
4 July 2003	3 July 2013	\$0.3125	\$0.1681	200,000	1	25% at each of 30 June 2004, 2005, 2006 and 2007. Options issued to directors are also subject to ASX escrow until 10 November 2005.
9 December 2003	30 November 2013	\$0.3760	\$0.2184	250,000	1	25% at each of 30 June 2004, 2005, 2006 and 2007, subject to Remuneration and Nomination Committee annual approval.
9 December 2003	30 November 2013	\$0.3760	\$0.2184	250,000	1	30 November 2004 (sign-on options)
12 May 2005	11 May 2015	\$1.147	\$0.6228	50,000	1	3 April 2006 (sign-on options)
12 May 2005	11 May 2015	\$1.147	\$0.6228	150,000	1	25% at each of 30 June 2006, 2007, 2008 and 2009, subject to Remuneration and Nomination Committee annual approval.
5 August 2005	4 August 2015	\$1.7900	\$1.2152	425,000	5	25% at each of 30 June 2006, 2007, 2008 and 2009, subject to Remuneration and Nomination Committee annual approval.
5 August 2005	4 August 2015	\$1.7900	\$1.6780	335,000	5	25% at each of 30 June 2006, 2007, 2008 and 2009, 255,000 of which are subject to Remuneration and Nomination Committee annual approval.

No option holder has any right under the options to participate in any other share issue of the company or of any other entity.

Details of options over ordinary shares in the company provided as remuneration to each director of Pharmaxis Ltd and each of the key management personnel of the Group are set out below. When exercisable, each option is convertible into one ordinary share of Pharmaxis Ltd. Further information on the options is set out in note 30 to the financial statements.



Name	Number of options granted during the year		Number of options vested during the year	
	2006	2005	2006	2005
<b>Directors of Pharmaxis Ltd</b>				
DM Hanley <i>Chairman</i>	40,000	–	110,000	100,000
AD Robertson	150,000	–	277,500	240,000
CPH Kiefel	20,000	–	55,000	50,000
MJ McComas	20,000	–	55,000	50,000
PC Farrell <sup>1</sup>	–	–	–	–
BH Smith	–	–	–	–
CJ Hillyard	–	–	–	–
<b>Other key management personnel of the Company</b>				
WB Cowden	100,000	–	145,000	120,000
JF Crapper	100,000	–	145,000	120,000
IA McDonald	20,000	200,000	42,500	–
B Charlton	105,000	–	146,250	120,000
DM McGarvey	100,000	–	145,000	120,000
GJ Phillips	105,000	–	88,750	62,500

<sup>1</sup> On 27 March 2006 the Board announced that it had resolved to grant 200,000 options to Dr Peter Farrell under the Pharmaxis Employee Option Plan subsequent to his appointment to the Board. The option grant is subject to shareholder approval which will be sought at the 2006 Annual General Meeting.

The assessed fair value at grant date of options granted to the individuals is allocated equally over the period from grant date to vesting date, and the amount is included in the remuneration tables above. Fair values at grant date are determined using a Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the share price at grant date and expected price volatility of the underlying share, and the risk-free interest rate for the term of the option.

*The model inputs for options granted during the year ended 30 June 2006 included:*

- (a) options are granted for no consideration, 25% vesting at each of 30 June 2006, 2007, 2008 and 2009, subject to Remuneration and Nomination Committee annual approval
- (b) exercise price: \$1.79
- (c) grant date: 5 August 2005
- (d) expiry date: 4 August 2015
- (e) share price at grant date: \$1.79
- (f) expected price volatility of the company's shares: 50%
- (g) risk-free interest rate: 5.31%.

*Shares provided on exercise of remuneration options*

Details of ordinary shares in the company provided as a result of the exercise of remuneration options to each director of Pharmaxis Ltd and other key management personnel of the Group are set out below.

Name	Date of exercise of options	Number of ordinary shares issued on exercise of options during the year	
		2006	2005
<b>Other key management personnel of the Group</b>			
WB Cowden	6 June 2006	1,480,000	–
JF Crapper	4 May 2006	300,000	–
B Charlton	31 January 2006	640,000	–

# Directors' Report

30 June 2006

The amounts paid per ordinary share by each director and other key management personnel on the exercise of options at the date of exercise were as follows:

Exercise date	Amount paid per share
31 January 2006	\$0.1250
4 May 2006	\$0.3125
6 June 2006	\$0.1250
6 June 2006	\$0.3125

No amounts are unpaid on any shares issued on the exercise of options.

## E Additional information (unaudited)

### Details of remuneration: cash bonuses and options

For each cash bonus and grant of options included in the tables above, the percentage of the available bonus or grant that was paid, or that vested, in the financial year, and the percentage that was forfeited because the person did not meet the service and performance criteria is set out below. No part of the bonuses is payable in future years. The options vest over four years, provided the vesting conditions are met (see above). No options will vest if the conditions are not satisfied, hence the minimum value of the option yet to vest is nil. The maximum value of the options yet to vest has been determined as the portion of the grant date fair value that has not been expensed as at 30 June 2006.

Name	Cash bonus		Options					
	Paid %	Forfeited %	Year granted	Vested %	Forfeited %	Financial years in which options may vest	Minimum total value of grant yet to vest \$	Maximum total value of grant yet to vest \$
DM Hanley	-	-	2006 2003	100 100	- -	2007 to 2009 -	- -	36,456 -
AD Robertson	84	16	2006 2003	100 100	- -	2007 to 2009 -	- -	- -
CPH Kiefel	-	-	2006 2003	100 100	- -	2007 to 2009 2007	- -	18,228 8,395
MJ McComas	-	-	2006 2004	100 100	- -	2007 to 2009 2007	- -	18,228 8,405
WB Cowden	50	50	2006 2003	100 100	- -	2007 - 2009 -	- -	- -
JF Crapper	80	20	2006 2004	100 100	- -	2007 - 2009 2007	- -	90,140 20,172
IA McDonald	75	25	2006 2005	100 100	- -	2007 - 2009 2007 - 2009	- -	18,228 70,065
B Charlton	80	20	2006 2003	100 100	- -	2007 - 2009 -	- -	95,697 -
DM McGarvey	85	15	2006 2003	100 100	- -	2007 - 2009 -	- -	91,140 -
GJ Phillips	80	20	2006 2004	100 100	- -	2007 - 2009 2007	- -	95,697 13,650

As detailed above, options typically vest over a four-year time frame and for options granted after 1 January 2003, the number of an individual executive's options vesting is subject to achievement of the performance targets set and approved by the Remuneration and Nomination Committee. The Committee has determined that performance targets set by the Committee in relation to options vesting at 30 June 2006, have been achieved by all executives.

*Share-based compensation: Options*

Further details relating to options are set out below.

Name	A Remuneration consisting of options	B Value at grant date \$	C Value at exercise date \$	D Value at lapse date \$	E Total of columns B-D \$
DM Hanley	35%	48,608	–	–	48,608
AD Robertson	27%	182,280	–	–	182,280
CPH Kiefel	34%	24,304	–	–	24,304
MJ McComas	36%	24,304	–	–	24,304
PC Farrell	–	–	–	–	–
BH Smith	–	–	–	–	–
CJ Hillyard	–	–	–	–	–
WB Cowden	27%	121,520	186,028	–	307,548
JF Crapper	21%	121,520	50,430	–	171,950
IA McDonald	28%	24,304	–	–	24,304
B Charlton	26%	127,596	44,992	–	172,588
DM McGarvey	19%	121,520	–	–	121,520
GJ Phillips	21%	127,596	–	–	127,596

A = The percentage of the value of remuneration consisting of options, based on the value at grant date set out in column B.

B = The value at grant date calculated in accordance with AASB 2 *Share-based Payment* of options granted during the year as part of remuneration.

C = The value at exercise date of options that were granted as part of remuneration and were exercised during the year.

D = The value at lapse date of options that were granted as part of remuneration and that lapsed during the year.

**Loans to directors and executives**

Nil.

**Share options granted to directors and the most highly remunerated officers**

Options over unissued ordinary shares of Pharmaxis Ltd granted during or since the end of the financial year to the 6 most highly remunerated officers of the company as part of their remuneration are set out in Section D above.

# Directors' Report

30 June 2006

## Shares under option

Total unissued ordinary shares of Pharmaxis Ltd under option at the date of this report are as follows:

Date options granted	Expiry date	Issue price of shares	Number under option
1 December 1999	30 November 2009	\$0.1250	1,120,000
1 July 2000	30 June 2010	\$0.1250	60,000
1 September 2001	30 August 2011	\$0.3125	640,000
2 December 2001	30 November 2011	\$0.1250	160,000
12 May 2003	30 June 2012	\$0.3125	3,446,000
12 May 2003	30 November 2012	\$0.3125	480,000
12 May 2003	30 April 2013	\$0.3125	216,000
1 July 2003	30 June 2013	\$0.3125	660,000
4 July 2003	3 July 2013	\$0.3125	200,000
9 December 2003	30 November 2013	\$0.3760	500,000
25 April 2004	24 April 2014	\$0.5080	22,500
4 June 2004	3 June 2014	\$0.4260	15,000
2 February 2005	1 February 2015	\$0.8340	255,000
12 May 2005	11 May 2015	\$1.1470	330,000
5 August 2005	4 August 2015	\$1.7900	953,000
17 October 2005	16 October 2015	\$2.7720	155,000
13 February 2006	12 February 2016	\$2.1940	310,000
1 June 2006	31 May 2016	\$2.0340	111,500
			9,634,000

No option holder has any right under the options to participate in any other share issue of the company or any other entity.

## Shares issued on the exercise of options

The following ordinary shares of Pharmaxis Ltd were issued during the year ended 30 June 2006 on the exercise of options granted under the Pharmaxis Employee Option Plan. On 19 July 2006, the company issued 56,000 shares at \$0.3125 each and 1,500 shares at \$1.79 each upon the exercise of options granted under the Pharmaxis Employee Option Plan on 12 May 2003 and 5 August 2005 respectively. No amounts are unpaid on any of the shares.

Date options granted	Issue price of shares	Number of shares issued
12 May 2003	\$0.3125	40,000
12 May 2003	\$0.3125	72,000
1 July 2000	\$0.1250	100,000
12 May 2003	\$0.3125	16,000
12 May 2003	\$0.3125	48,000
25 April 2004	\$0.5080	7,500
1 December 1999	\$0.1250	640,000
12 May 2003	\$0.3125	30,000
1 July 2003	\$0.3125	300,000
1 December 1999	\$0.1250	640,000
12 May 2003	\$0.3125	840,000
		2,733,500



### **Insurance of officers**

During the financial year, Pharmaxis Ltd paid a premium of \$124,070 to insure the directors and officers of the Group for the policy year ended 26 September 2006 and \$402,078 to insure the directors and officers of the Group in relation to the US initial public offering, the latter being a six year policy expiring 23 September 2011.

The liabilities insured are legal costs that may be incurred in defending civil or criminal proceedings that may be brought against the officers in their capacity as officers of the Group, and any other payments arising from liabilities incurred by the officers in connection with such proceedings. Policy exclusions include: liabilities that arise out of conduct involving a willful breach of duty by the officers or the improper use by the officers of their position or of information to gain advantage for themselves or someone else or to cause detriment to the Group; pollution that could reasonably be known to management; and, bodily injury and property damage. It is not possible to apportion the premium between amounts relating to the insurance against legal costs and those relating to other liabilities.

### **Agreement to indemnify officers**

Pharmaxis Ltd has entered into Deeds of Access, Indemnity and Insurance with each of the officers of the directors and the company secretary. Each deed provides each respective officer with the following:

- a right to access certain board papers of the company during the period of their tenure and for a period of seven years after that tenure ends;
- subject to the Corporations Act, an indemnity in respect of liability to persons other than the company and its related bodies corporate that they may incur while acting in their capacity as an officer of the Group or a related body corporate, except where that liability involves a lack of good faith and for defending certain legal proceedings; and
- the requirement that the company maintain appropriate directors' and officers' insurance for the officer.

No liability has arisen under these indemnities as at the date of this report.

### **Non-audit services**

The company may decide to employ the auditor on assignments additional to their statutory audit duties where the auditors' expertise and experience with the company are important.

Details of the amounts paid to the auditor (PricewaterhouseCoopers) for audit and non-audit services provided during the year are set out in note 20 to the financial statements.

The Board of directors has considered the position and, in accordance with the advice received from the audit committee, is satisfied that the provision of the non-audit services is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001. The directors are satisfied that the provision of non-audit services by the auditor did not compromise the auditor independence requirements of the Corporations Act 2001 for the following reasons:

- all non-audit services have been reviewed by the audit committee to ensure they do not impact the integrity and objectivity of the auditor
- none of the services undermine the general principles relating to auditor independence as set out in Professional Statement F1, including reviewing or auditing the auditor's own work, acting in a management or a decision-making capacity for the company, acting as advocate for the company or jointly sharing economic risk and rewards.

### **Auditors' independence declaration**

A copy of the auditors' independence declaration as required under section 307C of the *Corporations Act 2001* is set out on page 51.

### **Rounding of amounts**

The company is of a kind referred to in Class Order 98/100, issued by the Australian Securities and Investments Commission, relating to the 'rounding off' of amounts in the directors' report. Amounts in the directors' report have been rounded off in accordance with that Class Order to the nearest thousand dollars, or in certain cases, to the nearest dollar.

## Directors' Report

30 June 2006

### Auditor

PricewaterhouseCoopers continues in office in accordance with section 327 of the *Corporations Act 2001*.

This report is made in accordance with a resolution of directors.



Alan D Robertson  
Director

Sydney  
8 August 2006



**PricewaterhouseCoopers**  
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## Auditors' Independence Declaration

As lead auditor for the audit of Pharmaxis Ltd for the year ended 30 June 2006, I declare that to the best of my knowledge and belief, there have been:

- a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the audit; and
- b) no contraventions of any applicable code of professional conduct in relation to the audit.

This declaration is in respect of Pharmaxis Ltd and the entities it controlled during the period.

A handwritten signature in black ink, appearing to read 'WHB Seaton'.

WHB Seaton  
Partner  
PricewaterhouseCoopers

Sydney  
8 August 2006

# Income Statements

For the year ended 30 June 2006

	Notes	Consolidated	Parent Entity	
		2006 \$'000	2006 \$'000	2005 \$'000
<b>Revenue from continuing operations</b>				
Revenue from sale of goods	2	8	8	–
Cost of sales		(2)	(2)	–
<b>Gross profit</b>		<b>6</b>	<b>6</b>	–
Other revenue	2	4,282	4,282	1,702
Other income	3	1,299	1,299	1,219
Other expenses from ordinary activities	4			
Research & development expenses		(16,978)	(16,978)	(9,269)
Administration expenses		(4,386)	(4,386)	(3,134)
Commercial expenses		(1,951)	(1,975)	(963)
<b>Loss before income tax</b>		<b>(17,728)</b>	<b>(17,752)</b>	(10,445)
Income tax expense	5	(5)	–	–
<b>Loss for the year</b>		<b>(17,733)</b>	<b>(17,752)</b>	(10,445)
<b>Earnings per share:</b>				
		<b>Cents</b>	<b>Cents</b>	Cents
Basic earnings / (loss) per share	28	(11.1)	(11.1)	(8.4)
Diluted earnings / (loss) per share	28	(11.1)	(11.1)	(8.4)

The above income statements should be read in conjunction with the accompanying notes.



# Balance Sheets

As at 30 June 2006

		Consolidated		Parent Entity	
	Notes	2006	2006	2005	
		\$'000	\$'000	\$'000	
<b>ASSETS</b>					
<b>Current assets</b>					
Cash and cash equivalents	6	97,840	97,822	33,390	
Trade and other receivables	7	1,371	1,371	702	
Inventories	8	100	100	–	
Total current assets		99,311	99,293	34,092	
<b>Non-current assets</b>					
Receivables	9	284	284	–	
Other financial assets	10	272	267	262	
Plant and equipment	11	3,205	3,205	2,477	
Intangible assets	12	1,195	1,195	1,106	
Total non-current assets		4,956	4,951	3,845	
<b>Total assets</b>		<b>104,267</b>	<b>104,244</b>	<b>37,937</b>	
<b>LIABILITIES</b>					
<b>Current liabilities</b>					
Trade and other payables	13	5,257	5,259	2,287	
Other liabilities	14	48	48	103	
Current tax liabilities		5	–	–	
Total current liabilities		5,310	5,307	2,390	
<b>Non-current liabilities</b>					
Provisions	15	63	63	26	
Other liabilities	16	6	6	54	
Total non-current liabilities		69	69	80	
<b>Total liabilities</b>		<b>5,379</b>	<b>5,376</b>	<b>2,470</b>	
<b>Net assets</b>		<b>98,888</b>	<b>98,868</b>	<b>35,467</b>	
<b>EQUITY</b>					
Contributed equity	17	134,745	134,745	54,716	
Reserves	18(a)	2,522	2,521	1,397	
Accumulated losses	18(b)	(38,379)	(38,398)	(20,646)	
<b>Total equity</b>		<b>98,888</b>	<b>98,868</b>	<b>35,467</b>	

The above balance sheets should be read in conjunction with the accompanying notes.

## Statements of Changes in Equity

For the year ended 30 June 2006

	Notes	Consolidated	Parent Entity	
		2006 \$'000	2006 \$'000	2005 \$'000
<b>Total equity at the beginning of the financial year</b>		<b>35,467</b>	<b>35,467</b>	26,631
Exchange differences on translation of foreign operations	18(a)	1	-	-
<b>Net income recognised directly in equity</b>		<b>1</b>	-	-
<b>Loss for the year</b>		<b>(17,733)</b>	<b>(17,752)</b>	(10,445)
<b>Total recognised income and expense for the year</b>		<b>(17,732)</b>	<b>(17,752)</b>	(10,445)
Contributions of equity, net of transaction costs	17(a)	80,029	80,029	19,021
Employee share options	18(a)	1,124	1,124	260
<b>Total equity at the end of the financial year</b>		<b>98,888</b>	<b>98,868</b>	35,467

*The above statements of changes in equity should be read in conjunction with the accompanying notes.*

# Cash Flow Statements

For the year ended 30 June 2006

		Consolidated	Parent Entity	
	Notes	2006 \$'000	2006 \$'000	2005 \$'000
<b>Cash flows from operating activities</b>				
Receipts from customers (inclusive of goods and services tax)		1	1	-
Payments to suppliers and employees (inclusive of goods and services tax)		(18,960)	(18,978)	(12,074)
		(18,959)	(18,977)	(12,074)
Research grant receipts from government		902	902	1,097
Interest received		4,282	4,282	1,702
Income taxes paid		-	-	-
<b>Net cash outflow from operating activities</b>	27	(13,775)	(13,793)	(9,275)
<b>Cash flows from investing activities</b>				
Payments for plant and equipment		(1,572)	(1,572)	(1,539)
Payments for intangible assets		(232)	(232)	(34)
<b>Net cash outflow from investing activities</b>		(1,804)	(1,804)	(1,573)
<b>Cash flows from financing activities</b>				
Proceeds from issues of shares		87,080	87,080	19,834
Share issue transaction costs		(7,051)	(7,051)	(813)
<b>Net cash inflow from financing activities</b>		80,029	80,029	19,021
<b>Net increase in cash and cash equivalents</b>		64,450	64,432	8,173
Cash and cash equivalents at the beginning of the financial year		33,390	33,390	25,217
<b>Cash and cash equivalents at the end of the financial year</b>	6	97,840	97,822	33,390

The above cash flow statements should be read in conjunction with the accompanying notes.

# Notes to the Financial Statements

30 June 2006

## 1. Summary of significant accounting policies

The principal accounting policies adopted in the preparation of the financial report are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial report includes separate financial statements for Pharmaxis Ltd as an individual entity and the consolidated entity consisting of Pharmaxis Ltd and its subsidiary.

### (a) Basis of preparation

This general purpose financial report has been prepared in accordance with Australian equivalents to International Financial Reporting Standards (AIFRSs), other authoritative pronouncements of the Australian Accounting Standards Board, Urgent Issues Group Interpretations and the *Corporations Act 2001*.

#### *Compliance with IFRSs*

Australian Accounting Standards include AIFRSs. Compliance with AIFRSs ensures that the consolidated financial statements and notes of Pharmaxis Ltd comply with International Financial Reporting Standards (IFRSs). The parent entity financial statements and notes also comply with IFRSs except that it has elected to apply the relief provided to parent entities in respect of certain disclosure requirements contained in AASB 132 Financial Instruments: Presentation and Disclosure.

#### *Application of AASB 1 First-time Adoption of Australian Equivalents to International Financial Reporting Standards*

These financial statements are the first Pharmaxis Ltd financial statements to be prepared in accordance with AIFRSs. AASB 1 First-time Adoption of Australian Equivalents to International Financial Reporting Standards has been applied in preparing these financial statements.

Financial statements of Pharmaxis Ltd until 30 June 2005 had been prepared in accordance with previous Australian Generally Accepted Accounting Principles (AGAAP). AGAAP differs in certain respects from AIFRS. When preparing Pharmaxis Ltd 2006 financial statements, management has amended certain accounting, valuation and consolidation methods applied in the AGAAP financial statements to comply with AIFRS.

Reconciliations and descriptions of the effect of transition from previous AGAAP to AIFRSs on the Group's equity and its net income are given in note 31.

#### *Historical cost convention*

These financial statements have been prepared under the historical cost convention.

#### *Critical accounting estimates*

The preparation of financial statements in conformity with AIFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. Management believe that any estimation uncertainty would not have a significant risk of causing a material adjustment to the carrying values of assets and liabilities and no judgements were made that could have significant effects on the amounts recognised in the financial report.

### (b) Principles of consolidation

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Pharmaxis Ltd ('company' or 'parent entity') as at 30 June 2006 and the results of all subsidiaries for the year then ended. Pharmaxis Ltd and its subsidiaries together are referred to in this financial report as the Group or the consolidated entity. For the year ended 30 June 2005 there were no subsidiaries and therefore no consolidated accounts were prepared for the year.

Subsidiaries are all those entities over which the Group has the power to govern the financial and operating policies, generally accompanying a shareholding of more than one-half of the voting rights. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether the Group controls another entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

Intercompany transactions, balances and unrealised gains on transactions between Group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Investments in subsidiaries are accounted for at cost in the individual financial statements of Pharmaxis Ltd.



## 1. Summary of significant accounting policies (continued)

### (c) Segment reporting

A business segment is a group of assets and operations engaged in providing products or services that are subject to risks and returns that are different to those of other business segments. A geographical segment is engaged in providing products or services within a particular economic environment and is subject to risks and returns that are different from those of segments operating in other economic environments.

### (d) Foreign currency translation

#### (i) Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in Australian dollars, which is Pharmaxis Ltd's functional and presentation currency.

#### (ii) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the income statement, except when deferred in equity as qualifying cash flow hedges and qualifying net investment hedges.

#### (iii) Group companies

The results and financial position of all the Group entities that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet;
- income and expenses for each income statement are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and
- all resulting exchange differences are recognised as a separate component of equity.

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are taken to shareholders' equity. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, a proportionate share of such exchange differences are recognised in the income statement, as part of the gain or loss on sale where applicable.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the foreign entities and translated at the closing rate.

### (e) Revenue recognition

Revenue is measured at the fair value of the consideration received or receivable. Amounts disclosed as revenue are net of returns and trade allowances. Revenue is recognised for the major business activities as follows:

#### (i) Sale of goods

A sale is recorded when goods have been despatched to the customer.

#### (ii) Interest income

Interest income is recognised on a time proportion basis using the effective interest method, see note 1(j).

#### (f) Government grants

Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received and the Company will comply with all attached conditions. When the company receives income in advance of incurring the relevant expenditure, it is treated as deferred income as the company does not control the income until the relevant expenditure has been incurred.

Government grants relating to costs are deferred and recognised in the income statement over the period necessary to match them with the costs that they are intended to compensate.

30 June 2006

## 1. Summary of significant accounting policies (continued)

Government grants relating to the purchase of plant and equipment are included in non-current liabilities as deferred income and are credited to the income statement on a straight-line basis over the expected lives of the related assets.

### (g) Income tax

The income tax expense or revenue for the period is the tax payable on the current period's taxable income based on the national income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences between the tax bases of assets and liabilities and their carrying amounts in the financial statements, and to unused tax losses.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to apply when the assets are recovered or liabilities are settled, based on those tax rates which are enacted or substantively enacted for each jurisdiction. The relevant tax rates are applied to the cumulative amounts of deductible and taxable temporary differences to measure the deferred tax asset or liability. An exception is made for certain temporary differences arising from the initial recognition of an asset or a liability. No deferred tax asset or liability is recognised in relation to these temporary differences if they arose in a transaction, other than a business combination, that at the time of the transaction did not affect either accounting profit or taxable profit or loss.

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

Deferred tax liabilities and assets are not recognised for temporary differences between the carrying amount and tax bases of investments in controlled entities where the parent entity is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

Current and deferred tax balances attributable to amounts recognised directly in equity are also recognised directly in equity.

### (h) Leases

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases (note 22). Payments made under operating leases (net of any incentives received from the lessor) are charged to the income statement on a straight-line basis over the period of the lease.

### (i) Impairment of assets

Intangible assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at each reporting date.

### (j) Cash and cash equivalents

For purposes of the statement of cash flows, cash includes cash on hand, deposits at call and bank accepted commercial bills, which are subject to an insignificant risk of changes in value.

Bank accepted commercial bills are acquired at a discount to their face value. The bills are carried at cost plus a portion of the discount recognised as income on an effective yield basis. The discount brought to account each period is accounted for as interest received.

## 1. Summary of significant accounting policies (continued)

### (k) Trade receivables

Trade receivables are recognised initially at fair value and subsequently measured at amortised cost, less provision for doubtful debts. Trade receivables are due for settlement no more than 30 days from date of invoice.

Collectibility of trade receivables is reviewed on an ongoing basis. Debts which are known to be uncollectible are written off. A provision for doubtful receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of receivables. The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the original effective interest rate. Cash flows relating to short-term receivables are not discounted if the effect of discounting is immaterial. The amount of the provision is recognised in the income statement.

### (l) Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost and net realisable value. Cost comprises direct materials, direct labour and an appropriate proportion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Costs are assigned to individual items of inventory on basis of weighted average costs. Costs of purchased inventory are determined after deducting rebates and discounts. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

### (m) Plant and equipment

Plant and equipment is stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

Depreciation on other assets is calculated using the straight-line method to allocate their cost, net of their residual values, over their estimated useful lives, as follows:

Plant and equipment	5 – 10 years
Computer equipment	4 years
Leasehold improvements	1.5 years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each balance sheet date.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (note 1(i)).

Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in the income statement.

### (n) Intangible assets

#### (i) Patents

Patents have a finite useful life and are carried at cost less accumulated amortisation and impairment losses. Amortisation is calculated using the straight-line method to allocate the cost of the patents over their estimated useful lives, which vary from 12 to 20 years.

#### (ii) Trademarks

Trademarks have a finite useful life and are carried at cost less accumulated amortisation and impairment losses. Amortisation is calculated using the straight-line method to allocate the cost of the trademarks over their estimated useful lives, which are assessed as 20 years.

30 June 2006

## 1. Summary of significant accounting policies (continued)

### (iii) *Research and development*

Research expenditure is recognised as an expense as incurred. Costs incurred on development projects (relating to the design and testing of new or improved products) are recognised as intangible assets when it is probable that the project will be a success considering its commercial and technical feasibility and its costs can be measured reliably. Other development expenditures that do not meet these criteria are recognised as an expense as incurred.

### (iv) *Software*

Software licenses are carried at cost less accumulated amortisation and impairment losses. Amortisation is calculated using the straight-line method to allocate the cost of the software over their estimated useful lives, which vary from 3 to 5 years.

### (o) **Trade and other payables**

These amounts represent liabilities for goods and services provided to the Group prior to the end of financial year which are unpaid. The amounts are unsecured and are usually paid within 30 days of recognition.

### (p) **Employee benefits**

#### (i) *Wages and salaries and annual leave*

Liabilities for wages and salaries, including non-monetary benefits and annual leave expected to be settled within 12 months of the reporting date are recognised in other payables in respect of employees' services up to the reporting date and are measured at the amounts expected to be paid when the liabilities are settled.

#### (ii) *Long service leave*

The liability for long service leave is recognised in the provision for employee benefits and measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on national government bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

#### (iii) *Retirement benefit obligations*

Contributions to defined contribution funds are recognised as an expense as they become payable.

#### (iv) *Share-based payments*

Share-based compensation benefits are provided to employees via the Pharmaxis Employee Option Plan. Information relating to these schemes is set out in note 30. The fair value of options granted under the option plan is recognised as an employee benefit expense with a corresponding increase in equity. The fair value is measured at grant date and recognised over the period during which the employees become unconditionally entitled to the options.

The fair value at grant date is determined using a Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option.

The fair value of the options granted excludes the impact of any non-market vesting conditions (for example, performance targets). Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. At each balance sheet date, the Company revises its estimate of the number of options that are expected to become exercisable. The employee benefit expense recognised each period takes into account the most recent estimate.

The entity has not applied the exemption available under AASB1 paragraph 25B to only recognise an expense on options granted prior to 7th November 2002 and/or vested before 1st January 2005.

#### (v) *Bonus plans*

The Group recognises a liability and an expense for bonuses where contractually obliged or where there is a past practice that has created a constructive obligation.

## 1. Summary of significant accounting policies (continued)

### (vi) Termination benefits

Termination benefits are payable when employment is terminated before the normal retirement date, or when an employee accepts voluntary redundancy in exchange for these benefits. The Group recognises termination benefits when it is demonstrably committed to either terminating the employment of current employees according to a detailed formal plan without possibility of withdrawal or providing termination benefits as a result of an offer made to encourage voluntary redundancy. Benefits falling due more than 12 months after balance sheet date are discounted to present value.

### (q) Contributed equity

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares or options (net of recognised tax benefits) are shown in equity as a deduction from the proceeds. Incremental costs directly attributable to the issue of new shares or options for the acquisition of a business are not included in the cost of the acquisition as part of the purchase consideration.

### (r) Earnings per share

#### (i) Basic earnings per share

Basic earnings per share is calculated by dividing net result after income tax attributable to equity holders of the company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial year.

#### (ii) Diluted earnings per share

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares. At present, the potential ordinary shares are anti-dilutive, and have therefore not been included in the dilutive earnings per share calculations.

### (s) Goods and Services Tax (GST)

Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognised as part of the cost of acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the taxation authority is included with other receivables or payables in the balance sheet.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the taxation authority, are presented as operating cash flow.

### (t) Rounding of amounts

The company is of a kind referred to in Class order 98/0100, issued by the Australian Securities and Investments Commission, relating to the "rounding off" of amounts in the financial report. Amounts in the financial report have been rounded off in accordance with that Class Order to the nearest thousand dollars, or in certain cases, the nearest dollar.

### (u) New accounting standards and UIG interpretations

Certain accounting standards and UIG interpretations have been published that are not mandatory for 30 June 2006 reporting periods. The Group notes that none of these are applicable to their operations.



# Notes to the Financial Statements

30 June 2006

## 2. Revenue

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
<i>Sales revenue</i>			
Sale of goods	8	8	-
<i>Other revenue</i>			
Interest	4,282	4,282	1,702

## 3. Other income

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
Government grants	1,299	1,299	1,219

Government grants comprised the following:

- (i) R&D START program grants of \$444,313 (2005: \$1,179,626).
- (ii) Australian Government's Pharmaceuticals Partnerships Program ('P3') grant of \$848,476 (2005: \$Nil).
- (iii) NSW Department of State and Regional Development commercial grants of \$6,135 (2005: \$40,000).

## 4. Expenses

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
Loss before income tax includes the following specific expenses:			
Depreciation (note 11)			
Plant and equipment	592	592	450
Computer equipment	77	77	39
Leasehold improvements	26	26	47
Total depreciation	695	695	536
Impairment of plant & equipment (note 11)	109	109	-
Amortisation (note 12)			
Patents	91	91	90
Software	6	6	-
Total amortisation	97	97	90
Impairment of intangible assets (note 12)	46	46	-
Net loss on disposal of plant and equipment	40	40	-
Rental expense relating to operating leases	371	371	327
Net foreign exchange losses	5	5	-
Employee benefits expense			
Defined contribution superannuation expense	337	329	196
Other employee benefits expenses	5,498	5,340	3,543

## 5. Income tax expense

	Consolidated	Parent Entity	
	2006	2006	2005
	\$'000	\$'000	\$'000
<b>(a) Numerical reconciliation of income tax expense to prima facie tax payable</b>			
Loss before income tax expense	(17,733)	(17,752)	(10,445)
Tax at the Australian tax rate of 30% (2005 – 30%)	(5,320)	(5,325)	(3,134)
Tax effect of amounts which are not deductible (taxable) in calculating taxable income:			
Share-based payments	337	337	78
Government research tax incentives	(1,556)	(1,556)	(419)
Sundry items	(9)	(9)	27
	(6,548)	(6,553)	(3,448)
Under provision in prior years	(370)	(370)	(413)
Total	(6,918)	(6,923)	(3,861)
Deferred tax benefits not recognised (*)	6,923	6,923	3,861
Income tax expense	5	-	-
(*) Excluding deferred tax benefit of \$2,115,000 relating to items charged to equity not recognised.			
<b>(b) Deferred tax balances</b>			
Deferred tax asset comprises temporary differences attributable to the following:			
Employee benefits	105	105	67
Share capital raising costs	2,313	2,313	806
Revenue in advance	16	16	30
	2,434	2,434	903
Deferred tax assets attributable to temporary differences which are not recognised	(2,434)	(2,434)	(903)
	-	-	-
<b>(c) Tax losses</b>			
Unused tax losses for which no deferred tax asset has been recognised	47,880	47,880	22,830
Potential tax benefit @ 30%	14,364	14,364	6,849
All unused tax losses were incurred by the parent entity.			

# Notes to the Financial Statements

30 June 2006

## 6. Current assets – Cash and cash equivalents

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
Cash at bank and in hand	342	324	80
Deposits at call	349	349	855
Bank accepted commercial bills	97,149	97,149	32,455
	<b>97,840</b>	<b>97,822</b>	<b>33,390</b>

The average interest rate on cash and bank balances is 3.9% (2005: 3.6%).

Bank accepted commercial bills mature in July, August and September 2006.

The weighted average interest rate on the bank accepted commercial bills is 5.8% (2005: 5.6%).

Refer to note 29 for information on financial risks.

## 7. Current assets – Trade and other receivables

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
Trade receivables	7	7	–
Provision for doubtful debts	–	–	–
	<b>7</b>	<b>7</b>	<b>–</b>
Government research grants receivable	400	400	106
Prepayments	781	781	508
Other receivables	183	183	88
	<b>1,371</b>	<b>1,371</b>	<b>702</b>

## 8. Current assets – Inventories

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
Raw materials – at cost	37	37	–
Finished goods – at cost	63	63	–
	<b>100</b>	<b>100</b>	<b>–</b>

## 9. Non-current assets – Receivables

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
Prepayments	284	284	–

## 10. Non-current assets – Other financial assets

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
Shares in subsidiaries (note 24)	-	-	-
Security deposits	272	267	262
	<b>272</b>	<b>267</b>	262

The value of the shares held in subsidiaries is \$2 which has been rounded to \$Nil for the purposes of disclosure. This is valued at cost.

The security deposits are carried at cost plus a portion of the discount recognised as income on an effective yield basis. The discount is brought to account as interest. They mature within 6-12 months and earn interest of 5.9%.

## 11. Non-current assets – Plant and equipment

Consolidated and parent entity	Plant and equipment \$'000	Computer equipment \$'000	Leasehold improvements \$'000	Total \$'000
<b>At 1 July 2004</b>				
Cost	1,848	125	152	2,125
Accumulated depreciation	(557)	(29)	(65)	(651)
Net book amount	1,291	96	87	1,474
<b>Year ended 30 June 2005</b>				
Opening net book amount	1,291	96	87	1,474
Additions	1,432	94	13	1,539
Depreciation charge	(450)	(39)	(47)	(536)
Closing net book amount	2,273	151	53	2,477
<b>At 30 June 2005</b>				
Cost	3,280	219	165	3,664
Accumulated depreciation	(1,007)	(68)	(112)	(1,187)
Net book amount	2,273	151	53	2,477
<b>Year ended 30 June 2006</b>				
Opening net book amount	2,273	151	53	2,477
Additions	1,302	270	-	1,572
Disposals	(25)	(15)	-	(40)
Depreciation charge	(592)	(77)	(26)	(695)
Impairment charge (*)	(109)	-	-	(109)
Closing net book amount	2,849	329	27	3,205
<b>At 30 June 2006</b>				
Cost	4,532	435	162	5,129
Accumulated depreciation	(1,683)	(106)	(135)	(1,924)
Net book amount	2,849	329	27	3,205

(\*) The impairment charge relates to the write-down of an item of plant & equipment which was taken out of service.

Included in opening 1 July 2005 plant and equipment was \$216,000 of capital work in progress, which was capitalised during the financial year.

# Notes to the Financial Statements

30 June 2006

## 12. Non-current assets – Intangible assets

Consolidated and parent entity	Patents	Trademarks	Software	Total
	\$'000	\$'000	\$'000	\$'000
<b>At 1 July 2004</b>				
Cost	1,555	2	–	1,557
Accumulated amortisation	(395)	–	–	(395)
Net book amount	1,160	2	–	1,162
<b>Year ended 30 June 2005</b>				
Opening net book amount	1,160	2	–	1,162
Additions	34	–	–	34
Amortisation charge	(90)	–	–	(90)
Closing net book amount	1,104	2	–	1,106
<b>At 30 June 2005</b>				
Cost	1,589	2	–	1,591
Accumulated amortisation	(485)	–	–	(485)
Net book amount	1,104	2	–	1,106
<b>Year ended 30 June 2006</b>				
Opening net book amount	1,104	2	–	1,106
Additions	31	57	144	232
Impairment charge (*)	(46)	–	–	(46)
Amortisation charge	(91)	–	(6)	(97)
Closing net book amount	998	59	138	1,195
<b>At 30 June 2006</b>				
Cost	1,574	59	144	1,777
Accumulated amortisation and impairment	(576)	–	(6)	(582)
Net book amount	998	59	138	1,195

(\*) The impairment charge relates to the write-down of Patent Family 6 which was allowed to lapse.

## 13. Current liabilities – Trade and other payables

	Consolidated		Parent Entity	
	2006	2006	2006	2005
	\$'000	\$'000	\$'000	\$'000
Trade payables	813	813	757	
Other payables	4,444	4,390	1,530	
Loans from related party	–	56	–	
	5,257	5,259	2,287	

## 14. Current liabilities – Other liabilities

	Consolidated		Parent Entity	
	2006	2006	2006	2005
	\$'000	\$'000	\$'000	\$'000
Deferred government research grants	48	48	103	



## 15. Non-current liabilities – Provisions

	Consolidated		Parent Entity	
	2006	2006	2006	2005
	\$'000	\$'000	\$'000	\$'000
Employee benefits – long service leave	63	63		26
<b>Movements in provisions</b>				
Movements in each class of provision during the financial year are set out below:				
Carrying amount at start of year	26	26		10
Additional provisions recognised	37	37		16
Unused amounts reversed	–	–		–
Carrying amount at end of year	63	63		26

## 16. Non-current liabilities – Other liabilities

	Consolidated		Parent Entity	
	2006	2006	2006	2005
	\$'000	\$'000	\$'000	\$'000
Deferred government research grants	6	6		54

## 17. Contributed equity

	Notes	Parent Entity		Parent Entity	
		2006	2005	2006	2005
		Shares	Shares	\$'000	\$'000
<b>(a) Share capital</b>					
Ordinary shares	(b),(c)				
Fully paid		176,903,592	134,770,092	134,745	54,716

### Movements in ordinary share capital:

Date	Details	Number of shares	Issue price	\$'000
1 July 2004	Opening balance	108,016,000		35,695
1 September 2004	Exercise of employee options	128,000	\$0.1719	22
1 September 2004	Exercise of employee options	96,000	\$ 0.1250	12
18 October 2004	Exercise of employee options	64,000	\$ 0.1250	8
12 November 2004	Private placement	16,200,000	\$ 0.7500	12,150
6 December 2004	Exercise of employee options	84,000	\$ 0.1696	14
14 December 2004	Share purchase plan	4,362,092	\$ 0.7500	3,272
16 December 2004	Private placement	5,800,000	\$ 0.7500	4,350
1 March 2005	Exercise of employee options	20,000	\$ 0.3125	6
	Less: Transaction costs on share issues	–		(813)
30 June 2005	Balance	134,770,092		54,716

# Notes to the Financial Statements

30 June 2006

## 17. Contributed equity (continued)

Date	Details	Number of shares	Issue price	\$'000
5 August 2005	Exercise of employee options	40,000	\$ 0.3125	12
9 September 2005	Exercise of employee options	72,000	\$ 0.3125	23
9 September 2005	Exercise of employee options	100,000	\$ 0.1250	12
6 October 2005	Exercise of employee options	16,000	\$ 0.3125	5
11 November 2005	Public offering on US Nasdaq Global Market	19,500,000	\$ 2.1899	42,703
11 November 2005	Private placement on ASX	19,900,000	\$ 2.2000	43,780
17 November 2005	Exercise of employee options	48,000	\$ 0.3125	15
9 December 2005	Exercise of employee options	7,500	\$ 0.5080	4
31 January 2006	Exercise of employee options	640,000	\$ 0.1250	80
10 February 2006	Exercise of employee options	30,000	\$ 0.3125	9
4 May 2006	Exercise of employee options	300,000	\$ 0.3125	94
6 June 2006	Exercise of employee options	640,000	\$ 0.1250	80
6 June 2006	Exercise of employee options	840,000	\$ 0.3125	263
	Less: Transaction costs on share issue	-		(7,051)
30 June 2006	Balance	176,903,592	\$ 0.8193	134,745

### (b) Ordinary shares

Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the company in proportion to the number of and amounts paid on the shares held.

On a show of hands every holder of ordinary shares present at a meeting in person or by proxy, is entitled to one vote, and upon a poll each share is entitled to one vote.

### (c) Options

Information relating to the Pharmaxis Employee Option Plan, including details of options issued, exercised and lapsed during the financial year and options outstanding at the end of the financial year, is set out in note 30.

## 18. Reserves and accumulated losses

	Consolidated		Parent Entity	
	2006	2006	2006	2005
	\$'000	\$'000	\$'000	\$'000
<b>(a) Reserves</b>				
Share-based payments reserve	2,521	2,521		1,397
Foreign currency translation reserve	1	-		-
	<b>2,522</b>	<b>2,521</b>		1,397
<i>Share-based payments reserve</i>				
Balance 1 July	1,397	1,397		1,137
Option expense	1,124	1,124		260
Balance 30 June	<b>2,521</b>	<b>2,521</b>		1,397

## 18. Reserves and accumulated losses (continued)

	Consolidated	Parent Entity	
	2006	2006	2005
	\$'000	\$'000	\$'000
<i>Foreign currency translation reserve</i>			
Balance 1 July	-	-	-
Currency translation differences arising during the year	1	-	-
Balance 30 June	1	-	-

### (b) Accumulated losses

Movements in accumulated losses were as follows:

	Consolidated	Parent Entity	
	2006	2006	2005
	\$'000	\$'000	\$'000
Balance 1 July	(20,646)	(20,646)	(10,201)
Net loss for the year	(17,733)	(17,752)	(10,445)
Balance 30 June	(38,379)	(38,398)	(20,646)

### (c) Nature and purpose of reserves

(i) *Share-based payments reserve*

The share-based payments reserve is used to recognise the fair value of options granted.

(ii) *Foreign currency translation reserve*

Exchange differences arising on translation of the foreign controlled entity are taken to the foreign currency translation reserve, as described in note 1(d).

## 19. Key management personnel disclosures

### (a) Directors

The following persons were directors of Pharmaxis Ltd during the financial year:

(i) *Chairman – non-executive*

Denis Michael Hanley

(ii) *Executive directors*

Alan Duncan Robertson (Managing Director and Chief Executive Officer)

Brett Charlton (from 1 July 2005 to 20 March 2006)

(iii) *Non-executive directors*

Brigitte Helen Smith

Charles Peter Hunt Kiefel

Carmel Judith Hillyard (from 1 July 2005 to 6 April 2006)

Malcolm John McComas

Peter Craig Farrell (from 15 March 2006)

# Notes to the Financial Statements

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## 19. Key management personnel disclosures (continued)

### (b) Other key management personnel

The following persons also had authority and responsibility for planning, directing and controlling the activities of the Group, directly or indirectly, during the financial year:

<i>Name</i>	<i>Position</i>	<i>Employer</i>
William Butler Cowden	Chief Scientific Officer	Pharmaxis Ltd
John Francis Crapper	Chief Operations Officer	Pharmaxis Ltd
Ian Alexander McDonald	Chief Technical Officer	Pharmaxis Ltd
Brett Charlton	Medical Director	Pharmaxis Ltd
David Morris McGarvey	Chief Financial Officer	Pharmaxis Ltd
Gary Jonathan Phillips	Commercial Director	Pharmaxis Ltd

All of the above persons were also key management persons during the year ended 30 June 2005, including Brett Charlton, who was a Director during 2005.

### (c) Key management personnel compensation

	Consolidated	Parent Entity	
	2006	2006	2005
	\$	\$	\$
Short-term employee benefits	1,761,612	1,761,612	1,326,851
Post-employment benefits	132,118	132,118	91,137
Share-based payments	600,666	600,666	152,708
	<b>2,494,396</b>	<b>2,494,396</b>	1,570,696

The company has taken advantage of the relief provided by Corporations Regulations and has transferred the detailed remuneration disclosures to the Directors' Report. The relevant information can be found in the remuneration report section of the Directors' Report.

### (d) Equity instrument disclosures relating to key management personnel

#### (i) Options provided as remuneration and shares issued on exercise of such options

Details of options provided as remuneration and shares issued on the exercise of such options, together with terms and conditions of the options, can be found in the remuneration report section of the Directors' Report.

## 19. Key management personnel disclosures (continued)

### (ii) Option holdings

The number of options over ordinary shares in the company held during the financial year by each director of Pharmaxis Ltd and other key management personnel of the Group, including their personally related parties, are set out below.

#### 2006

Name	Balance at the start of the year	Granted during the year as compensation	Exercised during the year	Other changes during the year	Balance at the end of the year	Vested and exercisable at the end of the year
<b>Directors of Pharmaxis Ltd</b>						
DM Hanley	1,040,000	40,000	–	–	1,080,000	1,050,000
AD Robertson	2,080,000	150,000	–	–	2,230,000	2,117,500
CPH Kiefel	200,000	20,000	–	–	220,000	155,000
MJ McComas	200,000	20,000	–	–	220,000	155,000
<b>Other key management personnel of the Group</b>						
WB Cowden	1,600,000	100,000	(1,480,000)	–	220,000	145,000
JF Crapper	960,000	100,000	(300,000)	–	760,000	565,000
IA McDonald	200,000	20,000	–	–	220,000	92,500
B Charlton	1,600,000	105,000	(640,000)	–	1,065,000	986,250
DM McGarvey	960,000	100,000	–	–	1,060,000	985,000
GJ Phillips	500,000	105,000	–	–	605,000	463,750

#### 2005

Name	Balance at the start of the year	Granted during the year as compensation	Exercised during the year	Other changes during the year	Balance at the end of the year	Vested and exercisable at the end of the year
<b>Directors of Pharmaxis Ltd</b>						
DM Hanley	1,040,000	–	–	–	1,040,000	–
AD Robertson	2,080,000	–	–	–	2,080,000	–
B Charlton	1,600,000	–	–	–	1,600,000	–
CPH Kiefel	200,000	–	–	–	200,000	–
MJ McComas	200,000	–	–	–	200,000	–
<b>Other key management personnel of the Group</b>						
WB Cowden	1,600,000	–	–	–	1,600,000	–
JF Crapper	960,000	–	–	–	960,000	720,000
IA McDonald	–	200,000	–	–	200,000	–
DM McGarvey	960,000	–	–	–	960,000	840,000
GJ Phillips	500,000	–	–	–	500,000	375,000



# Notes to the Financial Statements

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## 19. Key management personnel disclosures (continued)

### (iii) Share holdings

The numbers of shares in the company held during the financial year by each director of Pharmaxis Ltd and other key management personnel of the Group, including their close family members, are set out below. (Close members of the family of an individual are those family members who may be expected to influence, or be influenced by, that individual in their dealings with the entity).

2006

Name	Balance at the start of the year	Received during the year on the exercise of options	Other changes during the year	Balance at the end of the year
<b>Directors of Pharmaxis Ltd</b>				
<b>Ordinary shares</b>				
DM Hanley	751,325	–	45,000	796,325
AD Robertson	100,000	–	–	100,000
CPH Kiefel	350,000	–	(150,000)	200,000
MJ McComas	139,999	–	–	139,999
BH Smith <sup>(1)</sup>	–	–	–	–
PC Farrell	–	–	101,645	101,645
<b>Other key management personnel of the Group</b>				
<b>Ordinary shares</b>				
WB Cowden	–	1,480,000	(1,460,000)	20,000
JF Crapper	72,000	300,000	(370,000)	2,000
IA McDonald	–	–	–	–
B Charlton	20,000	640,000	–	660,000
DM McGarvey	45,000	–	–	45,000
GJ Phillips	26,664	–	(20,000)	6,664

2005

Name	Balance at the start of the year	Received during the year on the exercise of options	Other changes during the year	Balance at the end of the year
<b>Directors of Pharmaxis Ltd</b>				
<b>Ordinary shares</b>				
DM Hanley	580,000	–	171,325	751,325
AD Robertson	100,000	–	–	100,000
B Charlton	20,000	–	–	20,000
CPH Kiefel	500,000	–	(150,000)	350,000
MJ McComas	100,000	–	39,999	139,999
BH Smith <sup>(1)</sup>	–	–	–	–
CJ Hillyard <sup>(2)</sup>	–	–	–	–
<b>Other key management personnel of the Group</b>				
<b>Ordinary shares</b>				
WB Cowden	–	–	–	–
JF Crapper	72,000	–	–	72,000
IA McDonald	–	–	–	–
DM McGarvey	45,000	–	–	45,000
GJ Phillips	20,000	–	6,664	26,664

## 19. Key management personnel disclosures (continued)

- (1) BH Smith is associated with GBS Venture Partners Ltd, The Australian Bioscience Trust and Bioscience Ventures II. Perpetual Trustees Nominees as trustee of The Australian Bioscience Trust, holds 13,583,010 shares at 30 June 2006 (2005: 16,040,200). GBS Venture Partners Ltd as trustee and manager of Bioscience Venture II, holds 7,481,890 shares at 30 June 2006 (2005: 8,384,800).
- (2) CJ Hillyard resigned as a Director on 6 April 2006. She is associated with CM Capital Investments Pty Ltd, CM Capital Investment Trust No 3, CIBC Australia Fund LLC and the Australia Venture Capital Fund L.P. CM Capital Investments Pty Ltd, as trustee of the CM Capital Investment Trust No 3 held 11,189,044 shares at 30 June 2005. CIBC Australia Fund LLC, as general partner of the Australia Venture Capital Fund L.P. held 3,635,956 shares at 30 June 2005.

### (e) Other transactions with key management personnel

There were no other transactions with key management personnel during the year ended 30 June 2006.

## 20. Remuneration of auditors

During the year the following fees were paid or payable for services provided by the auditor of the parent entity, its related practices and non-related audit firms:

	Consolidated	Parent Entity	
	2006	2006	2005
	\$	\$	\$
<b>(a) Assurance services</b>			
<i>Audit services</i>			
PricewaterhouseCoopers Australian firm			
Audit and review of financial reports and other audit work under the <i>Corporations Act 2001</i>	137,000	137,000	78,000
Audit of US GAAP financial report	20,000	20,000	12,000
Related practices of PricewaterhouseCoopers Australian firm			
Audit of US GAAP financial report	76,176	76,176	61,411
Total remuneration for audit services	233,176	233,176	151,411
<i>Other assurance services</i>			
PricewaterhouseCoopers Australian firm			
Audit of government research grant claims	10,500	10,500	3,000
Audit of Form 20-F, lodged with the United States Securities and Exchange Commission in relation to the listing of the company on NASDAQ	80,879	80,879	50,000
Related practices of PricewaterhouseCoopers Australian firm			
Audit of Form 20-F, lodged with the United States Securities and Exchange Commission in relation to the listing of the company on NASDAQ	353,597	353,597	302,507
Total remuneration for other assurance services	444,976	444,976	355,507
Total remuneration for assurance services	678,152	678,152	506,918
<b>(b) Taxation services</b>			
PricewaterhouseCoopers Australian firm			
International tax consulting and tax advice	25,973	25,973	-
Total remuneration for taxation services	25,973	25,973	-

It is the Group's policy to employ PricewaterhouseCoopers on assignments additional to their statutory audit duties where PricewaterhouseCoopers' expertise and experience with the Group are important.

# Notes to the Financial Statements

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## 21. Contingent liabilities

The company and Group had contingent liabilities at 30 June 2006 in respect of:

### *Government grants*

The company has received three separate Australian Government research grants under the R&D START Program, all three of which have been completed. The Government may require the company to repay all or some of the amount of a particular grant together with interest in either of the following circumstances:

- a) the company fails to use its best endeavours to commercialise the relevant grant project within a reasonable time of completion of the project; or
- b) upon termination of a grant due to breach of agreement or insolvency.

The company continues the development and commercialisation of all three projects funded by the START Program. The total amount received under the START Program at 30 June 2006 was \$4,707,817 (2005: \$4,200,979).

The company received \$848,476 (2005: \$Nil) under the Australian Government's Pharmaceuticals Partnerships Program ('P3') during the financial year. The Government may require the company to repay all or some of the amount of the grant together with interest in any of the following circumstances:

- a) the Government determines that expenditure claimed on research projects do not meet the P3 guidelines; or
- b) upon termination of the grant due to breach of agreement, change in control of the company or insolvency.

### *Other*

The company has entered into an agreement with Macquarie Goodman to underwrite costs incurred as part of a development application for the proposed development of a purpose built facility. In the event that an Agreement of Lease is not entered into between the company and Macquarie Goodman in connection with the proposed development the company will be required to pay \$40,000 toward to the DA submission.

### *Guarantees*

The company's bankers have issued a bank guarantee of \$169,462 in relation to a rental bond for which no provision has been made in the accounts. This bank guarantee is secured by a security deposit held at the bank.

## 22. Commitments

### (a) Capital Commitments

Capital expenditure contracted for at the reporting date but not recognised as liabilities is as follows:

	Consolidated		Parent Entity	
	2006	2006	2005	
	\$'000	\$'000	\$'000	\$'000
Plant and equipment				
Payable: Within one year	396	396		423

### (b) Lease Commitments

*Commitments in relation to leases contracted for at the reporting date but not recognised as liabilities, payable:*

Within one year	389	389	322
Later than one year but not later than five years	1,389	1,389	-
	<b>1,778</b>	<b>1,778</b>	322

## 22. Commitments (continued)

### (i) Operating leases

The Group leases various offices under non-cancellable operating leases expiring within one to five years. The leases have varying terms, escalation clauses and renewal rights. On renewal, the terms of the leases are renegotiated.

### (ii) Other commitments

The company has in place a number of contracts with consultants and contract research organisations in relation to its research and development activities. The terms of these contracts are for relatively short periods of time and allow for the contracts to be terminated with relatively short notice periods. The actual committed expenditure arising under these contracts is therefore not material.

## 23. Related party transactions

### (a) Parent entities

The parent entity within the Group is Pharmaxis Ltd (incorporated in Australia).

### (b) Subsidiaries

Interests in subsidiaries are set out in note 24.

### (c) Key management personnel

Disclosures relating to key management personnel are set out in note 19.

### (d) Transactions with related parties

The following transactions occurred with related parties:

	Consolidated	Parent Entity	
	2006	2006	2005
	\$	\$	\$
Rental income of plant and equipment to subsidiary	-	414	-
Marketing services expenditure paid to subsidiary	-	273,287	-

### (e) Outstanding balances arising from transactions

The following balances are outstanding at the reporting date in relation to transactions with related parties:

	Consolidated	Parent Entity	
	2006	2006	2005
	\$	\$	\$
<i>Current payables</i>			
Subsidiaries	-	55,721	-

### (f) Terms and conditions

All transactions were made on normal commercial terms and conditions and at market rates pursuant to a Contract for Services. Under the contract the parent entity is required to pay for services within 30 days of receipt, with interest penalty clauses applying after 90 days.

Outstanding balances are unsecured and are repayable in cash.

# Notes to the Financial Statements

30 June 2006

## 24. Subsidiaries

The consolidated financial statements incorporate the assets, liabilities and results of the following subsidiary in accordance with the accounting policy described in note 1(b):

Name of entity	Country of incorporation	Class of shares	Equity holding	
			2006 %	2005 %
Pharmaxis UK Limited	United Kingdom	Ordinary	100	–

Pharmaxis UK Limited was incorporated on 3 February 2006. Its results have been consolidated from this date.

## 25. Events occurring after the balance sheet date

No matter or circumstance has arisen since 30 June 2006 that has significantly affected, or may significantly affect:

- (a) the Group's operations in future financial years, or
- (b) the results of those operations in future financial years, or
- (c) the Group's state of affairs in future financial years.

## 26. Financial reporting by segments

The Group operates predominantly in one industry. The principal activities of the Group are the research, development and commercialisation of pharmaceutical products.

The Group operates predominantly in one geographical area, being Australia.

## 27. Reconciliation of loss after income tax to net cash outflows from operating activities

	Consolidated	Parent Entity	
	2006 \$'000	2006 \$'000	2005 \$'000
Loss for the year	(17,733)	(17,752)	(10,445)
Depreciation and impairment of plant & equipment	804	804	536
Amortisation and impairment of intangibles	143	143	90
Non-cash employee benefits expense – share-based payments	1,124	1,124	260
Net (gain) loss on disposal of non-current assets	40	40	–
Change in operating assets and liabilities			
Increase in trade debtors	(7)	(7)	–
Increase in inventories	(100)	(100)	–
Increase in other operating assets	(956)	(951)	(556)
Increase in trade creditors	56	56	514
Increase in other operating liabilities	2,817	2,813	310
Increase in other provisions	37	37	16
Net cash outflow from operating activities	(13,775)	(13,793)	(9,275)



## 28. Earnings per share

	Consolidated	
	2006	2005
	Cents	Cents
<b>(a) Basic earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	(11.1)	(8.4)
<b>(b) Diluted earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	(11.1)	(8.4)
<b>(c) Weighted average number of shares used as the denominator</b>		
Weighted average number of ordinary shares used as the denominator in calculating basic and diluted earnings / (loss) per share	160,349,332	123,933,133

### (d) Information concerning the classification of securities

#### *Options*

Options granted to employees under the Pharmaxis Ltd Employee Option Plan are considered to be potential ordinary shares and have been included in the determination of diluted earnings per share to the extent to which they are dilutive. The options have not been included in the determination of basic earnings per share. Given the entity is currently loss making, the potential ordinary shares are anti-dilutive and have therefore not been included in the diluted earnings per share calculation. Details relating to the options are set out in note 30.

## 29. Financial risk management

### (a) Net fair value of financial assets and liabilities

The directors consider the carrying amount of trade debtors, trade and other accounts payable and employee entitlements to approximate their net fair values.

### (b) Credit risk exposure

The Group manages its credit risk on bank accepted bills by spreading these bills across four major Australian banks.

### (c) Other risk exposures

Liquidity, cashflow and fair value interest rate risks are minimised by maintaining a short term maturity profile on bank accepted bills.

## 30. Share-based payments

### (a) Employee Option Plan

The Pharmaxis Employee Option Plan ('EOP') was approved by shareholders in 1999 and amended by shareholders in June 2003. The maximum number of options available to be issued under the EOP is 15% of total issued shares including the EOP. All employees and directors are eligible to participate in the EOP, but do so at the invitation of the Board. The terms of option issues are determined by the Board. Options are generally granted for no consideration and vest equally over a four year period. For options granted after 1 January 2003 the annual vesting is subject to approval by the Remuneration and Nomination Committee of the Board. The Committee gives its approval for vesting based on the achievement of individual employee's personal annual objectives.

Options granted under the EOP carry no dividend or voting rights. When exercisable, each option is convertible into one ordinary share.

The exercise price is set by the Board. Before the company listed on the Australian Stock Exchange in November 2003, the Board set the exercise price based on its assessment of the market value of the underlying shares at the time of grant. Since listing the exercise price is set as the average closing price of Pharmaxis Ltd shares on the Australian Stock Exchange on the five business days prior to the grant of the options.

# Notes to the Financial Statements

30 June 2006

## 30. Share-based payments (continued)

Set out below are details of options exercised during the year and number of shares issued to employees on the exercise of options.

Year ended 2006			Year ended 2005		
Exercise date	Fair value of shares at issue date	Number	Exercise date	Fair value of shares at issue date	Number
5 August 2005	\$ 1.75	40,000	2 September 2004	\$ 0.58	224,000
9 September 2005	\$ 2.26	72,000	14 October 2004	\$ 0.74	64,000
9 September 2005	\$ 2.20	100,000	2 December 2004	\$ 0.83	84,000
6 October 2005	\$ 2.69	16,000	4 March 2005	\$ 1.25	20,000
17 November 2005	\$ 2.24	48,000			
9 December 2005	\$ 2.01	7,500			
31 January 2006	\$ 2.00	640,000			
10 February 2006	\$ 2.20	30,000			
4 May 2006	\$ 2.44	300,000			
6 June 2006	\$ 2.08	640,000			
6 June 2006	\$ 2.08	840,000			
		2,733,500			392,000

The fair value of shares issued on the exercise of options is the closing price at which the company's shares were traded on the Australian Stock Exchange on the day of the exercise of the options.

There were 7,772,625 vested options at 30 June 2006 (8,792,250 at 30 June 2005). There are no options under escrow (6,720,000 at 30 June 2005). Set out below are summaries of options granted under the plan:

Grant date	Expiry date	Exercise price	Balance at start of the year Number	Granted during the year Number	Exercised during the year Number	Expired during the year Number	Balance at end of the year Number	Vested at end of the year Number
<b>Consolidated and parent entity – 2006</b>								
1 Dec 1999	30 Nov 2009	\$0.1250	2,400,000	–	1,280,000	–	1,120,000	1,120,000
1 July 2000	30 June 2010	\$0.1250	160,000	–	100,000	–	60,000	60,000
1 Sept 2001	30 August 2011	\$0.3125	640,000	–	–	–	640,000	640,000
2 Dec 2001	30 Nov 2011	\$0.1250	160,000	–	–	–	160,000	160,000
12 May 2003	30 June 2012	\$0.3125	4,548,000	–	1,046,000	–	3,502,000	3,502,000
12 May 2003	30 Nov 2012	\$0.3125	480,000	–	–	–	480,000	480,000
12 May 2003	30 April 2013	\$0.3125	216,000	–	–	–	216,000	162,000
1 July 2003	30 June 2013	\$0.3125	960,000	–	300,000	–	660,000	540,000
4 July 2003	3 July 2013	\$0.3125	200,000	–	–	–	200,000	150,000
9 Dec 2003	30 Nov 2013	\$0.3760	500,000	–	–	–	500,000	437,500
25 April 2004	24 April 2014	\$0.5080	30,000	–	7,500	–	22,500	7,500
4 June 2004	3 June 2014	\$0.4260	15,000	–	–	–	15,000	7,500
2 Feb 2005	1 Feb 2015	\$0.8340	275,000	–	–	20,000	255,000	108,750
12 May 2005	11 May 2015	\$1.1470	330,000	–	–	–	330,000	120,000
5 August 2005	4 August 2015	\$1.7900	–	954,500	–	–	954,500	238,625
17 Oct 2005	16 Oct 2015	\$2.7720	–	155,000	–	–	155,000	38,750
13 Feb 2005	12 Feb 2016	\$2.1940	–	320,000	–	10,000	310,000	–
1 June 2006	31 May 2016	\$2.0340	–	111,500	–	–	111,500	–
Total			10,914,000	1,541,000	2,733,500	30,000	9,691,500	7,772,625
Weighted average exercise price			\$ 0.308	\$ 1.990	\$ 0.218	\$ 1.287	\$ 0.597	\$ 0.362

Grant date	Expiry date	Exercise price	Balance at start of the year Number	Granted during the year Number	Exercised during the year Number	Expired during the year Number	Balance at end of the year Number	Vested at end of the year Number
<b>Consolidated and parent entity – 2005</b>								
1 Dec 1999	30 Nov 2009	\$0.1250	2,400,000	–	–	–	2,400,000	2,400,000
1 July 2000	30 June 2010	\$0.1250	384,000	–	224,000	–	160,000	160,000
1 Jan 2001	31 Dec 2010	\$0.1250	96,000	–	96,000	–	–	–
1 Sept 2001	30 August 2011	\$0.3125	640,000	–	–	–	640,000	640,000
2 Dec 2001	30 Nov 2011	\$0.1250	160,000	–	–	–	160,000	160,000
12 May 2003	30 June 2012	\$0.3125	4,640,000	–	72,000	20,000	4,548,000	3,638,000
12 May 2003	30 Nov 2012	\$0.3125	480,000	–	–	–	480,000	480,000
12 May 2003	30 April 2013	\$0.3125	216,000	–	–	–	216,000	108,000
1 July 2003	30 June 2013	\$0.3125	960,000	–	–	–	960,000	720,000
4 July 2003	3 July 2013	\$0.3125	200,000	–	–	–	200,000	100,000
9 Dec 2003	30 Nov 2013	\$0.3760	500,000	–	–	–	500,000	375,000
25 April 2004	24 April 2014	\$0.5080	60,000	–	–	30,000	30,000	7,500
4 June 2004	3 June 2014	\$0.4260	15,000	–	–	–	15,000	3,750
2 Feb 2005	1 Feb 2015	\$0.8340	–	275,000	–	–	275,000	–
12 May 2005	11 May 2015	\$1.1470	–	330,000	–	–	330,000	–
Total			10,751,000	605,000	392,000	50,000	10,914,000	8,792,250
Weighted average exercise price			\$ 0.264	\$ 1.005	\$ 0.159	\$ 0.430	\$ 0.308	\$ 0.257

# Notes to the Financial Statements

30 June 2006

## 30. Share-based payments (continued)

There were 30,000 options forfeited during 2006 (50,000 options during 2005).

The weighted average remaining contractual life of share options outstanding at the end of the period was 6.52 years (2005 – 6.72 years).

### *Fair value of options granted*

The assessed fair value at grant date of options granted during the year ended 30 June 2006 is detailed in the table below. The fair value at grant date is determined using a Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the share price at grant date and expected price volatility of the underlying share and the risk free interest rate for the term of the option.

The model inputs for options granted during the year ended 30 June 2006 are as follows:

Grant date	No. of options granted	Exercise Price	Share Price	Time to expiration (days)	Volatility (%)	Annual interest rate (%)	Option value
5 August 2005	619,500	\$1.790	\$1.790	3,650	50%	5.31%	\$1.2152
5 August 2005	335,000	\$1.790	\$1.790	3,650	50%	5.48%	\$1.6780
17 October 2005	155,000	\$2.772	\$2.772	3,650	50%	5.46%	\$1.8955
13 February 2006	320,000	\$2.194	\$2.194	3,650	50%	5.29%	\$1.4932
1 June 2006	111,500	\$2.034	\$2.034	3,650	50%	5.74%	\$1.3974
	1,541,000						

The options are issued for no consideration.

The expected price volatility is based on the historic volatility (based on the remaining life of the options), adjusted for any expected changes to future volatility due to publicly available information.

### (b) Expenses arising from share-based payment transactions

Total expenses arising from share-based payment transactions recognised during the period as part of employee benefit expense were as follows:

	Consolidated	Parent Entity	
	2006	2006	2005
	\$'000	\$'000	\$'000
Options issued under employee option plan	1,124	1,124	260

### 31. Explanation of transition to Australian equivalents of IFRSs

#### (1) Reconciliation of equity reported under previous Australian Generally Accepted Accounting Principles (AGAAP) to equity under Australian equivalents to IFRSs (AIFRS)

##### (a) At the date of transition to AIFRS: 1 July 2004

Notes	Previous AGAAP \$'000	Effect of transition to AIFRS \$'000	AIFRS \$'000
<b>Parent entity</b>			
Current assets			
	25,217	–	25,217
	148	–	148
	25,365	–	25,365
<b>Non-current assets</b>			
	1,474	–	1,474
	1,162	–	1,162
	260	–	260
	2,896	–	2,896
<b>Total assets</b>			
	28,261	–	28,261
<b>Current liabilities</b>			
	1,448	–	1,448
4(b)	23	48	71
	1,471	48	1,519
<b>Non-current liabilities</b>			
	10	–	10
4(b)	–	101	101
	10	101	111
<b>Total liabilities</b>			
	1,481	149	1,630
<b>Net assets</b>			
	26,780	(149)	26,631
<b>Shareholders' equity</b>			
	35,695	–	35,695
4(a)	–	1,137	1,137
4(a),(b)	(8,915)	(1,286)	(10,201)
	26,780	(149)	26,631

# Notes to the Financial Statements

30 June 2006

## 31. Explanation of transition to Australian equivalents of IFRSs (continued)

(b) At the end of the last reporting period under previous AGAAP: 30 June 2005

	Notes	Previous AGAAP \$'000	Effect of transition to AIFRS \$'000	AIFRS \$'000
<b>Parent entity</b>				
<b>Current assets</b>				
Cash and cash equivalents		33,390	–	33,390
Other		702	–	702
<b>Total current assets</b>		<b>34,092</b>	<b>–</b>	<b>34,092</b>
<b>Non-current assets</b>				
Plant and equipment		2,477	–	2,477
Intangible assets		1,106	–	1,106
Other financial assets		262	–	262
<b>Total non-current assets</b>		<b>3,845</b>	<b>–</b>	<b>3,845</b>
<b>Total assets</b>		<b>37,937</b>	<b>–</b>	<b>37,937</b>
<b>Current liabilities</b>				
Trade and other payables		2,287	–	2,287
Other liabilities – deferred research grants	4(b)	55	48	103
<b>Total current liabilities</b>		<b>2,342</b>	<b>48</b>	<b>2,390</b>
<b>Non-current liabilities</b>				
Provisions		26	–	26
Other liabilities – deferred research grants	4(b)	–	54	54
<b>Total non-current liabilities</b>		<b>26</b>	<b>54</b>	<b>80</b>
<b>Total liabilities</b>		<b>2,368</b>	<b>102</b>	<b>2,470</b>
<b>Net assets</b>		<b>35,569</b>	<b>(102)</b>	<b>35,467</b>
<b>Equity</b>				
Contributed equity	4(a)	54,716	–	54,716
Reserves	4(a)	–	1,397	1,397
Accumulated losses	4(a),(b)	(19,147)	(1,499)	(20,646)
<b>Total equity</b>		<b>35,569</b>	<b>(102)</b>	<b>35,467</b>



## (2) Reconciliation of loss for the year ended 30 June 2005

		Previous AGAAP	Effect of transition to AIFRS	AIFRS
	Notes	\$'000	\$'000	\$'000
Revenue from sale of goods		–	–	–
Cost of sales		–	–	–
<b>Gross profit</b>		–	–	–
Other revenue		1,702	–	1,702
Other income	4(b)	1,172	47	1,219
Other expenses from ordinary activities				
Research & development expenses	4(a)	(9,154)	(115)	(9,269)
Administration expenses	4(a)	(3,105)	(29)	(3,134)
Commercial expenses	4(a)	(847)	(116)	(963)
<b>Profit / (loss) before related income tax expense</b>		(10,232)	(213)	(10,445)
Income tax expense / (credit)		–	–	–
<b>Net profit / (loss)</b>		(10,232)	(213)	(10,445)

## (3) Reconciliation of cash flow statement for the year ended 30 June 2005

The adoption of AIFRSs has not resulted in any material adjustments to the cash flow statement.

### (4) Notes to the reconciliations

#### (a) Share-based payments

Under AASB 2 *Share-based Payment* from 1 July 2004 the Company is required to recognise an expense for those options that were issued to employees under the Pharmaxis Ltd Employee Option Plan. The company has elected not to apply the exemption in relation to share options granted prior to 7 November 2002 and has recorded the appropriate expense for all options. The effect of this is:

(i) *At 1 July 2004*

There has been a decrease in retained earnings of \$1,136,941 and a corresponding increase in reserves.

(ii) *At 30 June 2005*

There has been a decrease in retained earnings of \$1,397,460 and a corresponding increase in reserves.

(iii) *For the year ended 30 June 2005*

There has been an increase in employee benefits expense of \$260,518.

#### (b) Government grants

Under AIFRS, government grants for plant and equipment are recognised as deferred income and amortised into other income over the life of the related plant and equipment. The effect of this is:

(iv) *At 1 July 2004*

There has been an increase in net deferred research grants of \$149,171 and a corresponding decrease in retained earnings.

(v) *At 30 June 2005*

There has been an increase in net deferred research grants of \$101,309 and a corresponding decrease in retained earnings.

(vi) *For the year ended 30 June 2005*

There has been an increase in other revenue of \$47,862.

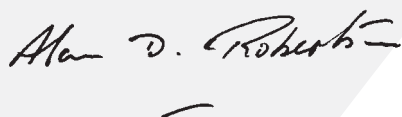
## Directors' Declaration

In the directors' opinion:

- (a) the financial statements and notes set out on pages 52 to 83 are in accordance with the *Corporations Act 2001*, including:
  - (i) complying with Accounting Standards, the *Corporations Regulations 2001* and other mandatory professional reporting requirements; and
  - (ii) giving a true and fair view of the company's and consolidated entity's financial position as at 30 June 2006 and of its performance, as represented by the results of their operations, changes in equity and their cash flows, for the financial year ended on that date; and
- (b) there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable; and
- (c) the audited remuneration disclosures set out in sections A–D of the remuneration report section of the directors' report comply with Accounting Standards AASB 124 *Related Party Disclosures* and the *Corporations Regulations 2001*.

The directors have been given the declarations by the chief executive officer and chief financial officer required by section 295A of the *Corporations Act 2001*.

This declaration is made in accordance with a resolution of the directors.



**Alan D Robertson**  
Director

Sydney  
8 August 2006

## Independent audit report to the members of Pharmaxis Ltd

### Matters relating to the electronic presentation of the audited financial report

This audit report relates to the financial report and remuneration disclosures of Pharmaxis Ltd (the Company) and the Pharmaxis Group (defined below) for the financial year ended 30 June 2006 included on Pharmaxis Ltd web site. The Company's directors are responsible for the integrity of the Pharmaxis Ltd web site. We have not been engaged to report on the integrity of this web site. The audit report refers only to the financial report and remuneration disclosures identified below. It does not provide an opinion on any other information which may have been hyperlinked to/from the financial report or the remuneration disclosures. If users of this report are concerned with the inherent risks arising from electronic data communications they are advised to refer to the hard copy of the audited financial report and remuneration disclosures to confirm the information included in the audited financial report and remuneration disclosures presented on this web site.

### Audit opinion

In our opinion:

the financial report of Pharmaxis Ltd:

gives a true and fair view, as required by the Corporations Act 2001(5) in Australia, of the financial position of Pharmaxis Ltd and the Pharmaxis Group (defined below) as at 30 June 2006, and of their performance for the year ended on that date, and

is presented in accordance with the Corporations Act 2001, Accounting Standards and other mandatory financial reporting requirements in Australia, and the Corporations Regulations 2001;and

Sections A-D of the remunerations disclosures that are contained within the directors' report comply with Accounting Standard AASB 124 Related Party Disclosures (AASB 124) and the Corporations Regulations 2001.

This opinion must be read in conjunction with the rest of our audit report.

### Scope

#### The financial report, remunerations disclosures and directors' responsibility

The financial report comprises the balance sheet, income statement, cash flow statements, statement of changes in equity, accompanying notes to the financial statements, and the directors' declaration for both Pharmaxis Ltd(the company) and the Pharmaxis Group (the consolidated entity), for the year ended 30 June 2006. The consolidated entity comprises both the company and the entities it controlled during that year.

The company has disclosed information about the remuneration of directors and executives (remuneration disclosures) as required by AASB 124, in sections A-D under the heading "remuneration report" in the directors' report, as permitted by the Corporations Regulations 2001.

The directors of the company are responsible for the preparation and true and fair presentation of the financial report in accordance with the Corporations Act 2001. This includes responsibility for the



maintenance of adequate accounting records and internal controls that are designed to prevent and detect fraud and error, and for the accounting policies and accounting estimates inherent in the financial report. The directors are also responsible for the remuneration disclosures contained in the directors' report.

## Audit approach

We conducted an independent audit in order to express an opinion to the members of the company. Our audit was conducted in accordance with Australian Auditing Standards, in order to provide reasonable assurance as to whether the financial report is free of material misstatement and the remuneration disclosures comply with AASB 124 and the Corporations Regulations 2001. The nature of an audit is influenced by factors such as the use of professional judgement, selective testing, the inherent limitations of internal control, and the availability of persuasive rather than conclusive evidence. Therefore, an audit cannot guarantee that all material misstatements have been detected. For further explanation of an audit, visit our website <http://www.pwc.com/au/financialstatementaudit>.

We performed procedures to assess whether in all material respects the financial report presents fairly, in accordance with the Corporations Act 2001, Accounting Standards and other mandatory financial reporting requirements in Australia, a view which is consistent with our understanding of the company's and the consolidated entity's financial position, and of their performance as represented by the results of their operations, changes in equity and cash flows. We also performed procedures to assess whether the remuneration disclosures comply with AASB 124 and the Corporations Regulations 2001.

We formed our audit opinion on the basis of these procedures, which included:

examining, on a test basis, information to provide evidence supporting the amounts and disclosures in the financial report and remuneration disclosures, and

assessing the appropriateness of the accounting policies and disclosures used and the reasonableness of significant accounting estimates made by the directors.

Our procedures include reading the other information in the Annual Report to determine whether it contains any material inconsistencies with the financial report.

While we considered the effectiveness of management's internal controls over financial reporting when determining the nature and extent of our procedures, our audit was not designed to provide assurance on internal controls.

Our audit did not involve an analysis of the prudence of business decisions made by directors or management.

## Independence

In conducting our audit, we followed applicable independence requirements of Australian professional ethical pronouncements and the Corporations Act 2001.



PricewaterhouseCoopers



WHB Seaton

Partner

Sydney  
8 August 2006

# Patents and Patent Applications

The status of the company's patent portfolio is summarised in the following table:

	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)	Prov			

\*G = granted; P = pending; Prov = provisional; PCT = Patent Cooperation Treaty; ROW denotes rest of the world including Japan; A = abandoned

Details of patents and patent applications licensed to, or owned by Pharmaxis Ltd are set out below:

## Patent Family 1 – The Use of Inhaled Mannitol

The invention covered by this family of patents and patent applications generally relates to the use of mannitol and other substances in the form of a dispersible dry powder capable of inducing sputum and promoting airway clearance in conditions where clearance of excess mucus would be advantageous. Included is a test of airway function and susceptibility to asthma based on inhaling an effective amount of mannitol or other substance.

Country	Patent/Application No.	Status	Expires
Australia	682756	Granted – 5 Feb 1998	23 Feb 2015
Canada	2183471	Under examination	23 Feb 2015
Europe (EPO)	95910331.8	Under examination	23 Feb 2015
Japan	7-522021	Under examination	23 Feb 2015
Malaysia	PI9603590	Granted	23 Feb 2015
New Zealand	281522	Granted	23 Feb 2015
P.R. China	95191808.7	Granted	25 Feb 2015
Republic of Korea	96-704666	Granted	23 Feb 2015
Singapore	34525	Granted	19 Dec 2015
The Philippines	I-54034	Granted	17 Mar 2024
USA	5,817,028	Granted	06 Oct 2015
Vietnam	SC0131/96	Granted	23 Feb 2015

This series of patents and patent applications are held in the name of Sydney South West Area Health Service and stem from an initial Australian provisional patent application PM4114 filed 25-Feb-1994. Subsequently, complete applications were filed via a PCT application (PCT/AU/95/00086; 23-Feb-1995).

## Patent Family 2 – Phosphosugar-based anti-inflammatory and/or immunosuppressive drugs

The invention covered by this family of patents and patent applications generally relates to a method for treating inflammatory or immune-mediated conditions in patients by administering a phosphosugar (mainly mannose-6-phosphate and fructose-6-phosphate) as well as oligo- and polysaccharides that contain such phosphosugars. These agents act as antagonists at mannose phosphate receptors by competitive inhibition of the binding of the natural ligand for these receptors. This treatment targets 'delayed hypersensitivity' types of immune reactions and their attendant inflammatory processes, and the patent is directed specifically to the treatment of arthritis, inflammatory diseases of the central nervous system, and the rejection of organ transplants.

Country	Patent/Application No.	Status	Expires
Australia	627500	Granted – 21 Dec 1992	18 Aug 2009
Europe		Granted – 30 June 1996	17/18 Aug 2009
Japan	509079/89	Granted – 03 Dec 1999	18 Aug 2009
USA	5,506,210	Issued – 09 Apr 1996	09 Apr 2013

This family of patents is owned by The Australian National University ('ANU') and claims priority to Australian Provisional application P19942/88 filed on 19 Aug 1988. Subsequently, complete applications were based on a PCT application (PCT/AU89/00350) filed 18 Aug 1989).

## Patent Family 3 – Novel phosphosugars and phosphosugar-containing compounds having anti-inflammatory activity

These patents are for substituted D-mannoside-6-phosphate compounds that have anti-inflammatory activity and their use in treating inflammatory diseases, particularly cell-mediated inflammatory diseases. The patent discloses use of these compounds to suppress experimental autoimmune encephalomyelitis in the rat (a model of multiple sclerosis) and two different types of delayed-type hypersensitivity responses in mice. Issued claims in the U.S. patent cover some of these novel phosphosugar compositions and methods of treating cell-mediated inflammation in a human or non-human mammalian patient by administering these compositions.

Country	Patent/Application No.	Status	Expires
Australia	728393	Granted 26 Apr 2001	17 Oct 2017
USA	6,294,521	Issued 25 Sep 2001	18 Oct 2017

The above family of patents are held in the name of the ANU and stem from a priority Australian provisional patent application PO 3098/96 filed 18 October 1996.



#### Patent Family 4 – Novel compounds and methods

This family of patent applications relates generally to novel phosphotetrahydropyran (mannose-6-phosphate derivatives) compounds and their use in treating diseases that are dependent upon T lymphocyte migration. These compounds were shown to inhibit (a) T lymphocyte migration across rat brain endothelial cell layers *in vitro*; (b) lymphocyte migration into lymphatic and extralymphatic tissues *in vivo*; and (c) delayed hypersensitivity-type immune responses and development of T cell-mediated autoimmune disease *in vivo* in animal models. In particular, the present invention relates to the use of the above compounds in the treatment of T lymphocyte mediated inflammatory diseases in animals and man, such as rheumatoid arthritis, multiple sclerosis, *etc.*

Country	Patent/Application No.	Status	Expires
Australia	2001270356	Granted	11 Jul 2021
Canada	2415214	Pending	11 Jul 2021
Europe	01949109.1	Pending	11 Jul 2021
New Zealand	523565	Granted	11 Jul 2021
Japan	2002-509335	Lodged	11 Jul 2021
USA	6878690	Granted	11 Jul 2021

These applications stem from Australian Provisional Patent Application No. PQ8723/00 filed on 11 July 2000. Complete applications were based on a PCT application (PCT/AU01/00831) filed on 11 July 2001.

#### Patent Family 5 – Novel phosphotetrahydropyrans and methods

The present invention relates generally to novel phosphotetrahydropyran compounds, primarily derivatives of mannose-6-phosphate, and their use in treating diseases or disorders that are mediated at least in part by T lymphocyte emigration from blood to tissues. These compounds are said to be improved inhibitors as compared to the compounds in Patent Family 4. Pharmaceutical compositions containing these compounds are used in methods to treat T lymphocyte mediated inflammatory and autoimmune diseases in animals and man, including rheumatoid arthritis, multiple sclerosis, acute disseminated encephalomyelitis, psoriasis, Crohn's disease, T cell-mediated dermatitis, stromal keratitis, uveitis, thyroiditis, sialitis or type I diabetes.

Country	Application No.	Status	Expires
USA	60/761,754	Under examination	
Canada	2525328	Request examination by May 20 2009	
New Zealand	544085	Examination is automatic	
Australia	2004240938	Request examination by May 20 2009	
Europe	04752819.5	Proceeding to examination	

These applications stem from U.S. Provisional Patent Application No. 60/471,716 filed on 20 May 2003. Complete applications were based on a PCT application (PCT/US2004/015876) filed on 19 May 2004.

### Patent Family 6 – Novel Cannabinoid CB-2 Receptor Agonists and Uses Thereof

This patent application relates to compounds and pharmaceutical compositions comprising novel cannabinoid CB<sub>2</sub> receptor agonists that have a number of biological and pharmacological activities, including bronchial, immunomodulatory and analgesic. These compounds are therefore useful for the treatment of inflammatory conditions, immune disorders and cell proliferative disorders, as well as in pain management, either alone or in combination with known agents for these conditions.

Country	Application No.	Status	Expires
All countries	PCT/US2004/027809	Abandoned	No longer relevant

The US provisional application was filed in the name of Pharmaxis Pty Ltd on 28-Aug-2003. The application was abandoned ahead of its entry into the National Phase. The patent was abandoned because the molecules were no longer considered to be of development calibre and had been replaced with compounds of a similar nature but with more improved properties (patent family 7).

### Patent Family 7 – Novel Anti-inflammatory Agents and Uses Thereof

This patent relates to a series of compounds and pharmaceutical compositions comprising novel inhibitors of tumour necrosis factor (TNF). The compounds are useful for the treatment of inflammatory conditions, immune disorders and cell proliferative disorders, as well as in pain management, either alone or in combination with known agents for these conditions.

Country	Application No.	Status	Expires
USA	Serial No. 60/761,754	Provisional Application	20 years from filing date

The U.S. provisional application was filed in the name of Pharmaxis Pty Limited on 25 January 2006 and the non-provisional and/or the international application must be filed by no later than January 25 2007 in order to claim priority from this provisional application.

## Shareholder Information

The shareholder information set out below was applicable as at 15 August 2006.

### A. Distribution of equity securities

Analysis of numbers of equity security holders by size of holding:

	Class of equity security	
	Ordinary shares	
	Shares	Options
1 – 1000	442	
1,001 – 5,000	1,470	1
5,001 – 10,000	809	6
10,001 – 100,000	1,202	30
100,001 and over	118	16
	4,041	53

There were 39 holders of less than a marketable parcel of ordinary shares.

### B. Equity security holders

*Twenty largest quoted equity security holders*

The names of the twenty largest holders of quoted equity securities are listed below:

	Ordinary shares	
	Number held	Percentage of issued shares
ANZ Nominees Limited	22,998,300	13%
Perpetual Trustees Nominees Ltd	13,583,010	8%
CM Capital Investments Pty Ltd	11,189,044	6%
National Nominees Limited	9,816,783	6%
GBS Venture Partners Ltd	7,481,890	4%
Equity Trustees Limited	6,818,764	4%
Mooroolbark Technology Pty Ltd	6,400,000	4%
Patch International Inc	6,091,937	3%
Westpac Custodian Nominees Limited	3,770,998	2%
CIBC Australia VC Fund LLC	3,635,956	2%
JP Morgan Nominees Australia Ltd	3,508,097	2%
The Australian National University	2,900,000	2%
Cogent Nominees Pty Limited	2,241,789	1%
Sayers Investments (ACT) Pty Limited	1,442,220	1%
Litster & Associates Pty Ltd	1,165,854	1%
Citicorp Nominees Pty Limited	1,146,324	1%
AGIO Capital Corporation Ltd	995,000	1%
KFT Investments P/L	970,000	1%
UBS Nominees Pty Ltd	917,669	1%
Citicorp Nominees Pty Limited	843,682	0%

## Shareholder Information

### *Unquoted equity securities*

	Number on issue	Number of holders
Options issued under the Pharmaxis Ltd Employee Option Plan	10,223,500	53

### **C. Substantial holders**

Substantial holders in the company are set out below:

	Number held	Percentage
Orbis Global Equity Fund Limited	19,766,000	11%
CM Capital Investments Pty Ltd	14,825,000	8%
Perpetual Trustees Nominees Limited as trustee of the Australian Bioscience Trust and GBS Venture Partners Ltd as Manager of the Australian Bioscience Trust	14,307,220	8%
Acorn Capital Limited	9,750,932	6%

### **D. Voting rights**

The voting rights attaching to each class of equity securities are set out below:

(a) Ordinary shares

On a show of hands every member present at a meeting in person or by proxy shall have one vote and upon a poll each share shall have one vote.

(b) Options

No voting rights.

## Target Diseases

### How do the lungs clear mucus?

The inside lining of our airways is covered by millions of fine hair-like structures called cilia, which are in turn covered by a thin layer of mucus, secreted by the lungs to defend against germs, dust particles and other foreign bodies.

In lung cells, salt moves through ion channels in the cell membrane to the airway surface. The chloride and sodium combination pulls water into the lungs to create a thin fluid layer that coats the airway surface and keeps the cilia moist so they can do their job of moving foreign particles along the airway and out of the lungs. The cilia move continuously and propel the overlying blanket of salt, water and mucus up to the throat, where secretions are swallowed or expelled as sputum (this process is called mucociliary clearance).

This constant process, which is barely noticeable in healthy people, helps keep the airways clean, allows the passage of clean, warm air through the lungs, and removes any foreign bodies from the airways, preventing infection.

People with respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) and cystic fibrosis are generally affected by a breakdown in the natural mechanism of cleansing, hydrating, and protecting the mucus lining their airways. They face the ongoing challenge of clearing excessive and thickened secretions from their congested lungs, usually by constant coughing.

## Asthma

### What is asthma?

Asthma is a serious condition in which the small airways of the affected person's lungs constrict suddenly when they are exposed to certain triggers, such as dust mites, pollen, exercise, or even dry air. During an asthma 'attack', the person's airway lining rapidly becomes inflamed and swollen, the muscles around the airways tighten, and excess mucus is produced as the body reacts to the trigger. This reaction causes reduced airflow into and out of the lungs, and the person has to gasp for breath.

Asthma is a major public health problem affecting 52 million people around the world, including 2 million Australians and 15 million Americans. The disease is usually life-long and claims around 400 lives in Australia each year and 4,500 lives in the US. Recent studies have shown that the incidence of asthma in Australian children is increasing.

The disease has a major impact on the quality of life of asthmatics and their families, with many sufferers requiring daily medication and modifications in their lifestyle. In addition to the human price, asthma is a major burden on the healthcare system. For example, the cost to the US healthcare system is US\$15 billion per year.

### How is asthma currently managed?

The effective diagnosis, monitoring and management of asthma remain key challenges for doctors and asthmatics.

The primary method currently used to diagnose asthma has remained unchanged for many years, with a diagnosis arrived at through a detailed history and physical examination of the patient.

Exercise challenge tests and methacholine inhalation tests are procedures used most frequently in clinical laboratories to evaluate airway responsiveness. While these tests can indicate the presence of asthma, they are not sensitive or specific enough for asthma, nor do they give a precise or objective measure of the seriousness of the patient's condition. As a consequence, under-diagnosis and misdiagnosis of asthma continue to be serious medical issues that impact extensively on people's health and quality of life.

There are a number of therapeutic options to treat the symptoms of asthma, including inhalers that expand the airways, and preventative measures such as anti-inflammatory medications.

The absence of an accurate test not only hinders the diagnosis of asthma, but also makes it difficult for doctors to monitor the severity of their patients' asthma to ensure they receive the most appropriate dose of medication.

Many asthma sufferers have poor control of their disease, placing an over reliance on bronchodilators to control their asthma symptoms. At the other extreme, many people with asthma have few outward symptoms and can become less diligent with their asthma management.

Much of the deterioration in the quality of life of asthma sufferers could be prevented through correct early diagnosis of the disease, appropriate treatment, and effective ongoing monitoring.

### Chronic Obstructive Pulmonary Disease (COPD)

Chronic Obstructive Pulmonary Disease or COPD encompasses a number of serious conditions affecting the lungs (pulmonary system), including emphysema, chronic bronchitis and bronchiectasis.

More than 30 million people are affected with COPD worldwide. COPD is responsible for the deaths of more than 100,000 people a year in the US and Western Europe alone, making it the fourth leading cause of death after heart disease, cancer and stroke. The disease costs the US healthcare system US\$40 billion each year.

A key therapeutic goal for clinicians treating these patients is to assist the natural process of keeping the mucus hydrated and clearing it from the lungs. Current management of COPD generally involves bronchodilators and steroids. However, only one in five patients respond positively to steroids and it is impossible to determine which patients will respond to steroids without conducting a trial.

Maintaining a reasonable quality of life for COPD sufferers and their families is also a challenge; they have to deal with problems associated with breathing difficulties, respiratory infections, poor sleep, general discomfort, lifestyle limitations, and the gradual deterioration of lung function over the years.

### Bronchiectasis

#### What is bronchiectasis?

Bronchiectasis is a progressive lung disease in which the small airway walls are dilated and usually chronically inflamed, with resulting poor clearing of the increased mucus production. Chronic inflammation of the walls of the airway is common in all types of bronchiectasis. This is often a result of a vicious cycle of bacterial infection, in which damage to the lungs further predisposes the lung to more infections. The body repairs the damaged lung tissue by forming tough, fibrous material, which leads to changes that impair normal lung structure and function.

Effects include:

- reduced lung capacity;
- poor gas-exchange;
- changes of the organisation of blood vessels; and,
- overall increased blood flow through the lungs.

These changes can ultimately lead to heart failure. Recurrent lung infections commonly reduce patients' quality of life; progressive respiratory insufficiency is the most common cause of death.

Bronchiectasis affects more than half a million people worldwide. Most cases of bronchiectasis develop during childhood, and can be a result of infections such as pneumonia or the inhalation of noxious substances.

#### How is bronchiectasis currently managed?

Treatment today is aimed at controlling infections, secretions, airway obstructions and complications. Regular, daily postural drainage to remove bronchial secretions is a routine part of treatment for sufferers.

Early diagnosis and treatment of bronchiectasis and the infections that occur are very important in managing the disease. As ineffective mucus clearance is a major element of bronchiectasis, medications similar to those for chronic bronchitis are utilised, including inhaled bronchodilators to dilate the airways. Although antibiotics can be used to some effect to clear infections, there are no therapeutic products available to effectively clear excess mucus secretions and improve the quality of life of sufferers.

### Chronic bronchitis

#### What is chronic bronchitis?

Patients with chronic bronchitis experience persistent airway inflammation and airflow obstruction, with symptoms including a chronic cough producing mucus, and shortness of breath. Due to the difficulties they have in clearing mucus from their lungs, sufferers are prone to periodic bacterial infections where their cough worsens, mucus production increases, and breathing becomes more difficult. These episodes damage and scar the bronchial lining and contribute to continued chronic inflammation and immune-mediated cell damage as the body struggles to fight the infections. This cycle of infection and internal scarring causes a progressive decline in the patient's lung function, reducing their quality of life.



The disease is caused by inhaling some form of lung irritant repeatedly for many years, most commonly cigarette smoke. Chronic bronchitis is slow to develop and is often not diagnosed until the sufferer is in their 40s or 50s. The exact prevalence in the community is unknown but may be as high as 10 per cent of people over the age of 45.

### How is chronic bronchitis currently managed?

Conventional treatment of chronic bronchitis includes various general supportive measures such as:

- giving up smoking;
- limiting exposure to dust and chemicals;
- avoiding sudden temperature changes;
- undertaking chest physiotherapy and deep-breathing exercises; and,
- increasing fluid intake to keep the bronchial secretions thin.

While there are a number of medications that dilate the airways (bronchodilators) and reduce airway inflammation in chronic bronchitis sufferers, there are few therapeutic products available to effectively clear excess mucus secretions. This presents a major medical challenge, as ineffective mucus clearance is a major cause of infection and progression of the disease.

## Cystic Fibrosis

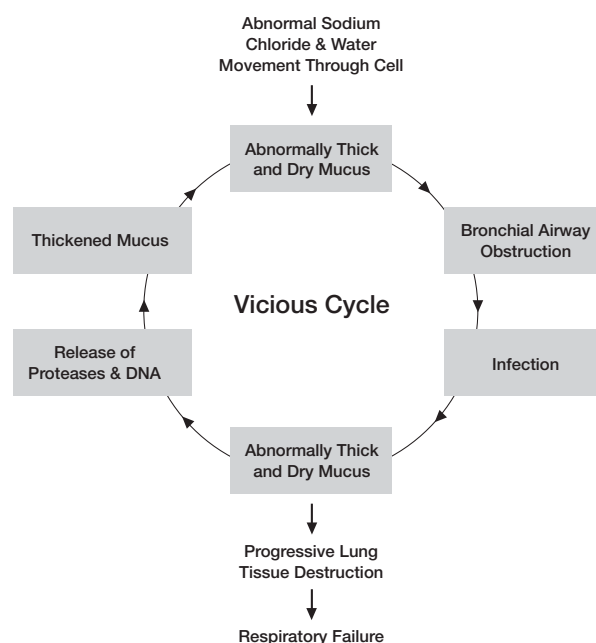
### What is cystic fibrosis?

Cystic fibrosis is an inherited, life-limiting disease that affects the body's exocrine glands, which produce mucus, saliva, sweat and tears. In cystic fibrosis, a genetic mutation disrupts the delicate balance of sodium, chloride and water within cells, causing the exocrine glands to secrete fluids that are poorly hydrated and therefore thicker and stickier than fluids in people without cystic fibrosis. This leads to chronic problems in various systems of the body, particularly the lungs and pancreas, and the digestive and reproductive systems.

In the lungs of a cystic fibrosis patient, the thick mucus and the thinning of the airway surface liquid make it nearly impossible for the cilia to clear bacteria from the airway. This severely impairs the natural airway-clearing processes and increases the potential for bacteria to be trapped, leading to respiratory infections that may require hospitalisation. Impairments in these vital lung defence mechanisms (see 'How do the lungs clear mucus?' earlier in this section) typically begin in early childhood and often result in chronic secondary infections, leading to progressive lung dysfunction and deterioration.

Although the life expectancy of cystic fibrosis sufferers has increased over the past few decades due to better management of the disease, the median life expectancy today for patients with cystic fibrosis is only 31 years of age.

There are 33,000 diagnosed cystic fibrosis patients in the US and 75,000 in the eight major pharmaceutical markets. In Australia, 2,500 people suffer from the disease, 20 per cent of whom are children under five years of age.



### **How is cystic fibrosis currently managed?**

Currently, there is no cure for cystic fibrosis. The goal for doctors treating cystic fibrosis sufferers is to hydrate, break down and move the excessive, sticky mucus secretions to improve lung function and reduce the number and severity of secondary lung infections. Cystic fibrosis sufferers and their carers are generally able to manage the condition at home using a combination of exercise, daily physiotherapy, postural drainage, and chest percussion (to assist the sufferer to expel mucus from their lungs). Depending on the severity of the condition, caring for a person with cystic fibrosis can take several hours of at-home treatment every day.

Medications to treat cystic fibrosis are limited, and few are very effective or convenient. Nebulised medications, delivered by aerosol or a facemask, are used to make the mucus less thick and sticky and open up the airways. Antibiotics may also be required to treat secondary infections. There have been no therapeutic advances to help clear congested lungs for patients with cystic fibrosis in the past ten years.

### **Multiple Sclerosis**

#### **What is Multiple Sclerosis?**

Multiple sclerosis is a chronic, debilitating disease of the central nervous system, thought to be the result of an autoimmune reaction. The immune system attacks and damages the protective protein sheath or myelin that insulates the nerve cells and helps speed the conduction of nerve signals to the brain and spinal cord. Damaged myelin is eventually replaced by scar-like tissue, which causes nerve signals to be slowed or halted.

The progression, symptoms and severity of the disease vary greatly between patients, although it is most often characterised by unpredictable 'attacks' or flare-ups in symptoms, followed by periods of remission. Most patients experience muscle weakness in their hands and feet and difficulty with coordination and balance. Other symptoms may include blurred vision, bladder and bowel problems, extreme tiredness, slurred speech and tremors. About half of sufferers have difficulties with concentration, attention, memory, and judgment, but intellectual and language abilities are generally spared.

The majority of sufferers do not become severely disabled, but, in the worst cases, multiple sclerosis can cause partial or complete paralysis and render a person unable to write, speak, or walk. Although the disease reduces their quality of life, most people with multiple sclerosis have a normal life expectancy. Multiple sclerosis affects more women than men, and the average age of onset is 20-40 years. About 1.1 million people in the developed world have multiple sclerosis, including 15,000 Australians.

#### **How is multiple sclerosis currently managed?**

Although there are treatments aimed at delaying the progression of multiple sclerosis and relieving the symptoms, there is no cure. The goals of therapy are threefold:

- to improve recovery from attacks;
- to prevent or lessen the number of relapses; and,
- to halt disease progression.

In the past, steroids were the principal medications for multiple sclerosis; other drugs such as beta interferon are now preferred. However, current treatments have limited effectiveness, cause side effects, and are given by injection, which most patients find unpleasant. New, more effective therapies that address the underlying cause of multiple sclerosis are required.

## Glossary of Terms

<b>ADEC</b>	Australian Drug Evaluation Committee
<b>ADR</b>	American Depositary Receipts (ADRs) are commonly used to facilitate the holding and trading of foreign securities by US residents which would otherwise be prohibited by US securities laws.
<b>agonist</b>	A molecule capable of combining with a biochemical receptor on a cell and initiating the same response as occurs naturally
<b>airway responsiveness</b>	The degree to which airways react to a stimulus. Usually used to describe the degree of airway constriction that will be caused by exposure to a stimuli
<b>analgesic</b>	Relieving pain; a pain-relieving drug
<b>antagonist</b>	A chemical that acts within the body to reduce the physiological activity of another chemical substance i.e. opposing the action of a drug or a substance occurring naturally in the body by combining with and blocking its receptor
<b>Aridol™</b>	Aridol™ is a patented, dry powder formulation of mannitol delivered to the lungs through an inhaler. Aridol™ is applied as a bronchial provocation test to accurately diagnose the presence and severity of bronchial hyperresponsiveness or over-sensitivity, which is characteristic of asthma.
<b>asthma</b>	Refer to disease information earlier in this section
<b>ASX</b>	Australian Stock Exchange
<b>autoimmune</b>	Having the property whereby immune cells respond to tissues in ones' own body, that is, the body no longer recognises all cells as being its own, and rejects some
<b>beta interferon</b>	A protein released by some cells in response to a viral infection. The protein can be synthesised and used in the treatment of multiple sclerosis.
<b>blinding/blindness</b>	The term 'blind' refers to a lack of knowledge of the identity of the trial treatment. Blinding avoids bias in trial execution and in interpretation of results and is achieved by disguising the identity of trial medications (e.g. a placebo should look, taste and behave identically to the active drug). In a 'single blind' trial the patient is unaware, but the physician is informed of the allotment. In a 'double blind' trial, both patient and physician are unaware.
<b>breakdown products</b>	Products that result from the disintegration or decomposition of a substance in the body
<b>bronchial hyper-responsiveness or over-sensitivity</b>	When a person's bronchial tubes (tubes that lead to the left and right lung) are abnormally responsive or sensitive to triggers and react by narrowing and becoming inflamed
<b>bronchial provocation test</b>	A lung test that provokes a temporary narrowing of the bronchial tubes in the lungs
<b>bronchiectasis</b>	Refer to disease information earlier in this section
<b>Bronchitol™</b>	Bronchitol™ is a patented, dry powder formulation of mannitol delivered to the lungs through an inhaler. Bronchitol™ is designed for the treatment of diseases such as COPD and cystic fibrosis.
<b>bronchodilator</b>	A substance that acts to dilate or expand the bronchial airway passages, making it easier for patients to breathe
<b>carcinogenicity</b>	Potential to cause cancer
<b>central nervous system</b>	System of nerves of the brain and spinal cord

## Glossary of Terms

<b>chemoattractant</b>	A chemical agent that induces movement of cells in the direction of its highest concentration
<b>chest percussion</b>	Form of physiotherapy/massage that involves tapping the patient's chest and back with light, rapid blows to help them expel mucus from their lungs
<b>chronic</b>	A disease or condition of long duration or frequent recurrence; in some instances, it may slowly become more serious over time
<b>chronic bronchitis</b>	Refer to disease information earlier in this section
<b>chronic obstructive pulmonary disease</b>	Refer to disease information earlier in this section
<b>cilia</b>	Millions of fine hair-like structures that cover the inside lining of our airways and move continuously to propel secretions up to the throat (also refer to mucociliary clearance)
<b>ciliated cell</b>	An epithelial cell which has cilia on its external surface. Found in the lungs and other airway passages such as bronchi and nose.
<b>clinical trial</b>	Refer to explanation/diagram later in this section
<b>Cooperative Research Centre for Asthma and Airways (CRCAA)</b>	The CRCAA (formerly the Cooperative Research Centre for Asthma) is an Australian research cooperative that was expanded in 2006 to include all airways diseases. It focuses on three core areas of airways research: diagnosis and monitoring, new treatments, and assessing the consequences of air quality.
<b>COPD</b>	Chronic obstructive pulmonary disease. Refer to disease information earlier in this section
<b>corticosteroids</b>	Any of the steroid hormones produced by the adrenal cortex or their synthetic equivalents. Corticosteroids are used clinically for hormonal replacement therapy, for suppression of glands such as the anterior pituitary, as anti-cancer and anti-allergic and anti-inflammatory agents, and to suppress the immune response. They may be injected, taken as pills, inhaled via a puffer or rubbed on to the skin.
<b>cystic fibrosis (CF)</b>	Refer to disease information earlier in this section
<b>direct challenge test</b>	The process of directly stimulating receptors in the lung walls and inducing a constriction or narrowing of the airways by administering a substance to the airways that acts directly on the airway wall and testing the response by spirometry. Examples include methacholine and histamine.
<b>dose response curve</b>	A dose response curve illustrates the relation between the amount of a drug or other chemical administered to a person or an animal and the degree of response it produces.
<b>dosing phase</b>	Refer to explanation/diagram later in this section
<b>endothelial</b>	An endothelial cell layer refers to the layer of cells that lines the blood vessels and airways
<b>epithelial mast cells</b>	Mast cells are a variety of leukocytes or white blood cells containing granules that store a variety of inflammatory chemicals including histamine and serotonin. Mast cells play a central role in inflammatory and immediate allergic reactions. The release of mediators from the cell is known as degranulation and may be induced by the presence of a specific antigen (allergen). Epithelial mast cells are those found in the epithelium (the membranous tissue composed of one or more layers of cells separated by very little intercellular substance and forming the covering of most internal and external surfaces of the body and its organs. Skin and the lung linings are two examples of epithelium.)

<b>eucapnic hyperpnoea</b>	Eucapnic (adjective) is defined as a normal healthy level of carbon dioxide (CO <sub>2</sub> ). Hyperpnoea is abnormally fast breathing.
<b>European Medicines Agency (EMA)</b>	The EMA is an agency that coordinates the evaluation and supervision of medicinal products throughout the European Union.
<b>exercise challenge test</b>	A test in which patients undertake a physical activity, such as exercise, running or bike riding, and the body's response to the activity is measured. It can be used to determine if a patient is asthmatic by measuring the degree of bronchial constriction that is induced during a period of exercise.
<b>exocrine glands</b>	Glands that produce mucus, saliva, sweat and tears
<b>FDA</b>	United States of America's Food and Drug Administration
<b>flare or flare-up</b>	A period of worsening symptoms
<b>GMP</b>	Good Manufacturing Practice – set of principles and procedures which, when followed by manufacturers of therapeutic goods, helps ensure that the products manufactured will have the required quality
<b>goblet cell</b>	A mucus-secreting epithelial cell that is distended with secretion, so called because of its histological shape.
<b>head-to-head trial</b>	A clinical trial in which a test compound is evaluated against another compound
<b>hypertonic saline</b>	A solution with a higher salt concentration than in normal cells of the body and the blood. A salt solution containing more than 0.9% salt is hypertonic.
<b>indirect challenge test</b>	The process of indirectly inducing a constriction or narrowing of the airways by causing cells in the airways to release molecules that subsequently act on the airway, and testing the response by spirometry. Mannitol mimics an allergen challenge or asthma attack. The attack can be controlled by administering increasing doses and the response at each dose is measured. Other examples include exercise and hypertonic saline.
<b>International Committee on Harmonisation (ICH)</b>	An international body that provides test guidelines that cover the manufacture of drug substances, the manufacture of the dosage form, and the safety testing that must be conducted before evaluation in humans can proceed
<b>in vitro</b>	In an artificial environment, outside the living body e.g. in a test tube
<b>in vivo</b>	In the living body of a plant or animal, or in real life
<b>leukocytes</b>	Immune cells; white blood cells
<b>ligand</b>	A molecule that binds to cell receptors
<b>lung function</b>	Ability of a person to move air in and out of their lungs. A measure often used is termed FEV <sub>1</sub> , which is the volume of air that can be forcibly expelled from the lungs in one second
<b>lymphocyte</b>	A type of white blood cell found in the body's lymph, a clear fluid that flows through the body and has an important function in defending the body against disease
<b>mannitol</b>	Mannitol is a naturally occurring sugar alcohol used variously as a food additive, a therapeutic product, and a sweetener.
<b>marketing authorisation</b>	The legal authority granted to an individual or company to sell a product
<b>meta-analysis</b>	Pooling and examining data from a number of studies

## Glossary of Terms

<b>methacholine inhalation test</b>	A test used in the diagnosis of asthma. Methacholine is inhaled as a vapour and causes bronchial constriction in asthmatic patients.
<b>mucociliary clearance</b>	A constant, natural process where the cilia lining the lungs move continuously and propel the overlying blanket of salt, water and mucus up to the throat, where secretions are swallowed or expelled as sputum. This helps keep the airways clean, allows the passage of clean, warm air through the lungs, and removes any foreign bodies from the airways, preventing infection.
<b>mucosal hydration</b>	The natural process of keeping mucus hydrated to prevent it becoming thick and sticky i.e. maintaining the correct balance of water
<b>mucus</b>	Thin, slippery substance secreted by the lungs (and other organs in the body) to defend against germs, dust particles and other foreign bodies
<b>multi-centre study</b>	Study conducted simultaneously in a number of clinics, hospitals, etc
<b>multiple sclerosis (MS)</b>	Refer to disease information earlier in this section
<b>myelin</b>	The protective protein sheath that insulates the nerve cells and helps speed the conduction of nerve signals to the brain and spinal cord
<b>NASDAQ</b>	National Association of Securities Dealers Automated Quotation system (US)
<b>nebulised medication</b>	Medication delivered to the lungs of patients in fine spray by aerosol or face mask
<b>oral medication</b>	Medication taken by mouth e.g. tablets, liquids
<b>orphan drug</b>	A product intended for the diagnosis, prevention and treatment of a rare disease (orphan disease) or condition where current therapy would be improved or no therapy exists.
<b>osmotic balance</b>	Osmosis is the passage of water from a region of high water concentration through a semi-permeable membrane, such as a cell, lung or intestinal wall, to a region of low water concentration. Osmotic balance is when there is no tendency for water to flow across the membrane.
<b>P3</b>	Pharmaceuticals Partnerships Program (Australian Federal government grant program)
<b>pathogen</b>	Disease-causing microorganism
<b>PBS</b>	Pharmaceutical Benefits Scheme (Australian government program that reduces the cost of some drugs to patients)
<b>PCT</b>	Patent Cooperation Treaty
<b>PEP mask</b>	A mask worn over the nose and mouth, which pumps air into the lungs (positive expiratory pressure)
<b>pharmaco-economic evaluation</b>	Evaluation of the potential of a new pharmaceutical product to produce cost savings to a national economy
<b>pharmacokinetic profile</b>	How a drug interacts in the body in terms of its absorption, distribution, metabolism, and excretion
<b>phase III registration study</b>	Refer to explanation/diagram later in this section
<b>phase II clinical trial</b>	Refer to explanation/diagram later in this section
<b>pilot clinical study</b>	Refer to explanation/diagram later in this section

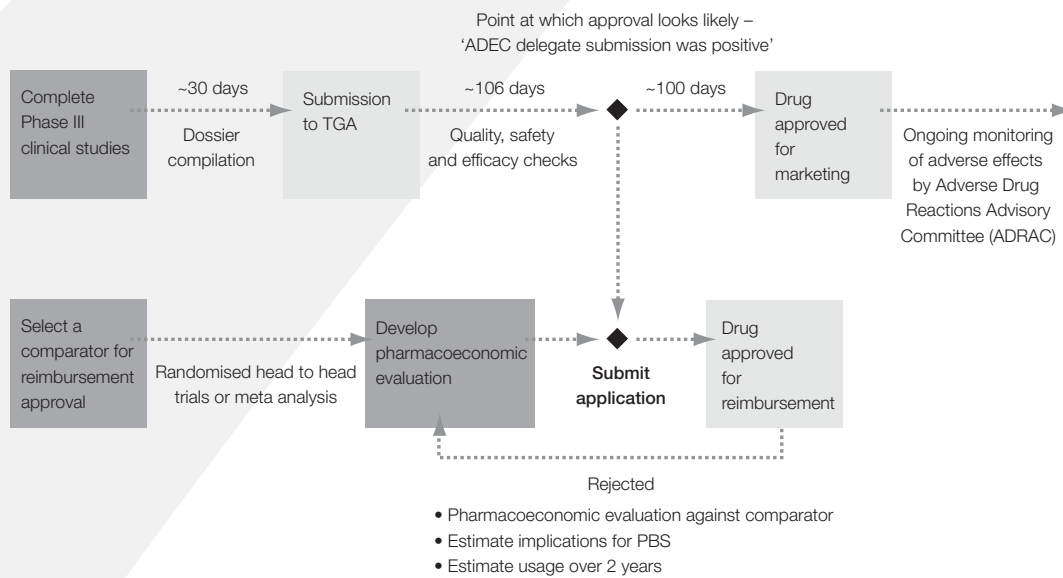


<b>placebo</b>	An inert or innocuous substance used especially in controlled experiments to test and compare the efficacy of another, active, substance
<b>postural drainage</b>	A method of draining the lungs in which the patient is placed in an inverted position so that fluids are drawn by gravity
<b>pre-clinical</b>	Prior to being administered to volunteers or patients
<b>primary cilia dysplasia</b>	Dysplasia means a cell is abnormally shaped or abnormally functioning. Ciliary dysplasia is a genetic disease where the cilia do not function properly.
<b>pro-drug</b>	An inactive precursor of a drug, converted into its active form in the body by normal metabolic processes.
<b>protease</b>	An enzyme that breaks the internal bonds of a protein
<b>psoriasis</b>	A chronic skin disease characterised by red patches covered with white scales
<b>pulmonary function</b>	Refer to lung function, above
<b>pulmonary system</b>	Lungs
<b>pyran</b>	A sugar derivative
<b>PXS64</b>	A compound being developed by Pharmaxis to target the underlying disease processes of multiple sclerosis
<b>PXS74</b>	A compound being investigated by Pharmaxis for its effects on asthma
<b>R&amp;D</b>	Research and development
<b>relapse</b>	A recurrence of symptoms of a disease after a period of improvement or remission
<b>remission</b>	Period when the symptoms of the patient's disease are not present
<b>respiratory failure</b>	A clinical term used to define the inability of the lungs to function
<b>respiratory insufficiency</b>	A clinical term used to define a failure to adequately provide sufficient oxygen to the body, or remove excess carbon dioxide
<b>rheology</b>	The study of the flow of materials that behave in an interesting or unusual manner
<b>rheumatoid arthritis</b>	Refer to disease information earlier in this section
<b>safety profile</b>	Evidence gathered that indicates a substance is safe to be administered to people
<b>secondary lung infections</b>	Infection coming after, or as a result of, an initial or primary infection
<b>selective inhibitor</b>	A substance that is used to stop a specific biochemical reaction
<b>spirometer; spirometry test</b>	A device used to measure the amount of air a patient can expel from their lungs in one second
<b>sputum microbiology</b>	A measure of lung infections
<b>statistical significance</b>	A mathematical test that indicates that groups being compared are different
<b>steroid</b>	Numerous natural or synthetic compounds that contain a 17-carbon 4-ring system and can modify reactions in the body
<b>submucosal glands</b>	The glands situated in the connective tissue beneath the mucous membrane.
<b>synthesis, synthetic compound</b>	A substance that is made by a series of chemical or biochemical reactions
<b>T-cells</b>	Immune cells that attach themselves to other cells

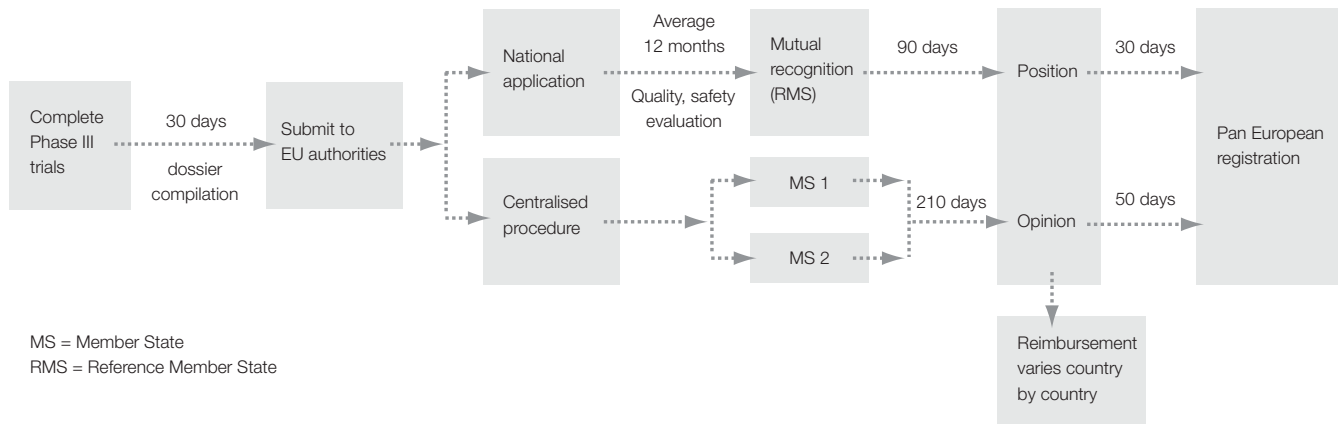
# Glossary of Terms

<b>therapeutic</b>	Medicinal, curative
<b>TGA</b>	Australia's Therapeutic Goods Administration
<b>toxicology study</b>	Investigation into the adverse effects of a substance in an animal or human
<b>Tumour Necrosis Factor (TNF)</b>	A small molecular-weight protein produced primarily by immune cells. It is a key protein responsible for initiating inflammation
<b>viscosity</b>	A physical property of fluids that determines the internal resistance to shear forces (the resistance a material has to change in form)

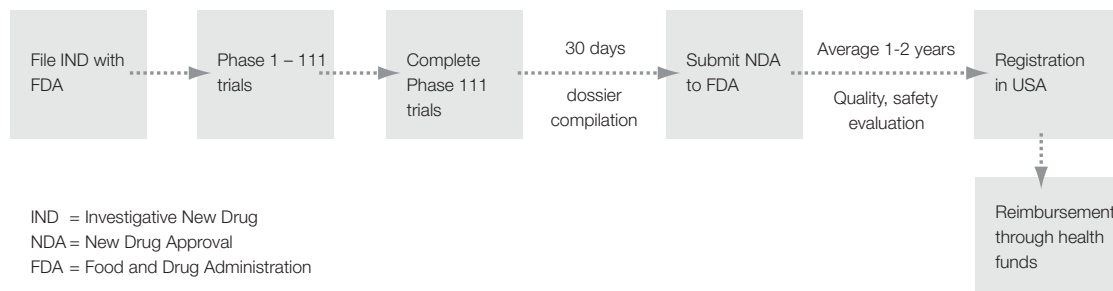
## Drug registration and reimbursement process in Australia



### European registration



### USA registration



# Guide to the Clinical Trial, Regulation and Approval Process

The development of human therapeutic products is a highly regulated process. Evaluation and testing for safety and efficacy proceed through laboratory (research), animal (pre-clinical) and human (clinical) stages of development. Pharmaxis conducts its preclinical safety evaluation in accordance with the guidelines provided by the International Committee on Harmonisation, which provides test guidelines applicable to the major pharmaceutical territories of the world.

These guidelines cover the manufacture of the drug substance, the manufacture of the dosage form, and the safety testing that must be conducted before evaluation in humans can proceed.

Clinical testing involves a three-phase process.

- In **phase I**, clinical trials are conducted with a small number (typically 10-50) of healthy subjects to determine the early safety profile and pharmacokinetic profile (pattern of drug distribution and metabolism).
- In **phase II**, clinical trials with groups of patients with a specified disease (typically 100-200) to determine preliminary effectiveness, optimal dosages and expanded evidence of safety. This is intended to show that the drug is effective in different patient populations under a variety of doses.
- In **phase III**, the Company conducts large-scale (typically >1,000), multi-centre, comparative clinical trials with patients with the target disease to provide sufficient data to statistically evaluate the effectiveness and safety of the product. During these clinical studies, the manufacture of the drug will be refined and an optimal formulation will be selected. Additional safety studies will be required, including long-term toxicology studies (possibly of 12 months' duration) and carcinogenicity studies. The Company also undertakes a detailed study of the pharmacology of the drug to identify any breakdown products and the routes of excretion from the body.
- The Company's therapeutic and diagnostic products require regulatory approval by government agencies before the Company can start testing in humans, and marketing.

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Pharmaxis shares are listed on the  
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