### pharmaxis

# Improving lives through innovative medicine



2007 Annual Report

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Our Mission To build an internationally successful pharmaceutical business by bringing innovative medicines to patients.

### Notice of meeting

The Annual General Meeting of Pharmaxis Ltd will be held at the Intercontinental Sydney, Corner of Bridge and Phillip Streets, Sydney, on Monday, 5 November, 2007 at 2.30pm.

Seven years ago, Pharmaxis was founded on an important Australian research discovery.

Today, Pharmaxis is on the cusp of bringing innovative medicine to millions of people worldwide, touching and improving their lives as it does so.

In this year's Annual Report, we highlight just some of the stories that illustrate why we are committed to bringing our therapeutic advances for respiratory and immune diseases to patients.

We also show how we are building an internationally successful pharmaceutical business; one that's built to last.

Welcome to our journey.



## Rebounding from bronchiectasis

Keen amateur basketballer Paul Kingsley was considering giving up the game he loves after severe bronchiectasis left him sidelined.

'I was spending more time off the court than on because of my bronchiectasis,' says 48-year-old Paul, who's been playing competition basketball since he was 21.

'I was constantly coughing throughout the game; three minutes out of five I'd be coughing up a lung.'

Paul was diagnosed with bronchiectasis a year ago after 'trying every antibiotic known to man' to treat what some doctors thought was the flu.

Fortunately the diagnosing doctor recommended Paul be placed on the Phase III trial of Bronchitol for bronchiectasis. Within a few weeks of using Bronchitol he was back in the game, breathing much easier.

'My lung capacity and peak flow were the best results I'd had in years,' recalls Paul. 'As soon as I started on it I knew I wanted to stay on it because it was making such a difference.'

'But before Bronchitol, nothing worked. I was told to live with it by the doctors,' explains Paul.

For Paul, the benefits of Bronchitol aren't just being felt on the basketball court.

'My wife was ready to divorce me or kick me out into another room because of my coughing,' he recalls with a smile. 'So the outcome on Bronchitol has been excellent as she's not going to divorce me for that just yet!'

### Quality of life impact of bronchiectasis

Bronchiectasis causes significant disruption to sufferers' day-to-day lives. Mucus accumulation affects their ability to breathe, exercise, sleep and lead a normal life – ultimately reducing life expectancy.

## Building for Success

### Going global

Aridol is available in Australia and Sweden, and set to be marketed in 13 other European countries, including:

- Germany France United Kingdom Italy Netherlands Belgium Denmark Greece
- , Spain, Finland, Ireland, Norway, Portugal

Pharmaxis continues to deliver quality outcomes to position the company for future growth



### 200

 Pharmaxis licenses patents for respiratory products from technology developed by Royal Prince Alfred Hospital, Sydney



### 2003

- Listed on Australian Securities
   Exchange
- Manufacturing facility licensed by TGA; production begins
- Awarded \$6 million AusIndustry R&D Start Grant to develop new cystic fibrosis treatments



### 2004

- Aridol Phase III and Bronchitol bronchiectasis Phase II clinical trials completed
- Awarded Pharmaceuticals Partnership Program grant of \$16 million

2007 Milestones

July 06 Pharmaxis' first commercial supply of Aridol to US

September 06 European headquarters established in UK October 06 Swedish approval of Aridol November 06 Bronchitol receives fast track status from US FDA for cystic fibrosis

### 59

## Clinical studies of Aridol led by independent investigators

### 362

## Patients involved in world's largest bronchiectasis trial





- Aridol approved for sale and marketing in Sweden and Australia
- First European distributors appointed
- European Medicines Agency grants Bronchitol Orphan Drug status for cystic fibrosis
- US Aridol Phase III clinical trial completed



### 2007

- Phase III Bronchitol trial successfully completed – world's largest study in bronchiectasis
- EU approval of Aridol 14
   European countries set to market
- European headquarters established



- Bronchitol Phase II clinical trial in CF completed
- Tripled manufacturing capacity
- US FDA grants Bronchitol Orphan Drug status for bronchiectasis and cystic fibrosis
- NASDAQ listing of Pharmaxis

Product Pipeline			Cli	nical Trial Phas	ses		
Respiratory diseases	Research	Preclinical	Phase I	Phase II	Phase III	Registration	Market
Aridol – asthma (Aus)	•	•	•	•	•	•	
Aridol – asthma (Europe)	•	•	•	•	•	•	
Aridol – asthma (USA)	•	•	•	•	•		
Aridol – COPD	•	•	•	•		_	
Bronchitol – bronchiectasis	•	•	•	•	•		
Bronchitol – cystic fibrosis	•	•	•	•			
Bronchitol – chronic bronchitis		•	•				

Immune disorders		
PXS25/64 – multiple sclerosis	•	
PXS74 – asthma	•	

COPD = Chronic Obstructive Pulmonary Disease - a fatal disease of the lungs, related to smoking.

November 06 US Phase III trial shows Aridol successful in diagnosing asthma patients

Aridol endorsed in global asthma guidelines

June 06 – April 07 Spanish, Dutch, Italian & Greek Aridol distributors appointed March 07 Phase II clinical trial demonstrates role for Aridol in COPD April 07 Phase III cystic fibrosis trial begins in Europe & Australia June 07 European Union approval of Aridol August 07
Phase III bronchiectasis trial successfully completed



We are now at the edge of bringing significant advances in treating respiratory diseases to patients worldwide.





Becoming the first Australian pharmaceutical company to bring a new medicine – Aridol – from discovery to market is an historic achievement of which we should all be proud.

But we have a greater ambition, which is summed up succinctly by the great American essayist, Ralph Waldo Emerson:

'To know even one life has breathed easier because you have lived – that is to have succeeded.'

This credo mirrors Pharmaxis' underlying philosophy and objectives. From the outset, we have been strongly committed to bringing quality products to market in areas where there is large patient demand because of a lack of effective therapies.

Placing patients first by bringing new medicines to market in areas of unmet need is, I believe, the foundation of building a sustainable and profitable business. If we can do that, then we will have succeeded and both patients and shareholders will surely benefit.

Already we have been given the remarkable opportunity to help people with limited treatment options. Under the Therapeutic Goods Administration's highly valuable Special Access Scheme, we have been supplying one of our products to over 50 patients with breathing difficulties associated with lung congestion. This opportunity to help is a great reward for all at Pharmaxis who have worked hard on the development of Bronchitol and our other products.

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 complete control and understanding of the manufacturing process is essential for a full return to our shareholders and on our investment in product development.

## \$76 million end of year cash position

### A year of solid progress

In the year we are leaving behind, we have accomplished a great deal with solid progress being achieved on all three major fronts:

- › Aridol for asthma management
- Bronchitol for improving mucus clearance
- The discovery of new medicines

We are now at the edge of bringing significant advances in treating respiratory diseases to patients worldwide and changing the way respiratory medicine is conducted. We finished the year with a good cash position of \$76 million and put a number of important milestones behind us, of which the most significant were the European approval of Aridol, the completion of a U.S. Phase III Aridol trial and, subsequent to year end, the completion of a Phase III Bronchitol trial.

As you will learn from this Annual Report on our business, considerable risk has been taken out of the product development and we are now ready to embark on the next phase of our growth. We can do this with some confidence, having navigated the Aridol regulatory review process successfully and being well through the Bronchitol clinical development process.



The next phase will ensure we are able to meet the anticipated demand for Bronchitol and will involve commissioning of new manufacturing equipment.

Therefore, we have been working on the design and construction of a new facility that will allow us to meet the Bronchitol demand – at least in the short to medium term. The building will be suitable to house a manufacturing facility capable of producing 269 million capsules of Bronchitol per year, sufficient for over 40,000 patients.

recruitment of 360 patients. Our Phase III clinical trial in 250 subjects with cystic fibrosis is expected to close recruitment in the middle of 2008. We never take patient participation for granted, particularly when they have a chance of receiving inactive placebo. To help compensate, in both the above studies, patients are guaranteed to receive Bronchitol at the end of the formal study period and practically every eligible patient has taken up this option.

The building will be capable of producing 269 million capsules of Bronchitol per year.

A little further from home, but also important in our international development, is our European office located in the United Kingdom. This group looks after our European clinical interests and manages our relationships with our European distributors. Our team there has expanded during the year and is now making major contributions to the business. In a similar vein, we have plans to establish a U.S. presence to help manage our clinical trials and other commercial interests in America. In the forthcoming year, we expect to initiate two Phase III clinical trials in the U.S in bronchiectasis and cystic fibrosis. It is my strong preference to control as much of this process as possible and, while we work extensively with contract research organisations, there is no substitute for having a strong local presence to ensure the trial is run efficiently and well.

### **Bronchitol development**

Running clinical trials not without its challenges and there is an inordinate number of activities requiring careful orchestration. The greatest unknown, and in many ways the greatest challenge, is patient recruitment. The Bronchitol Phase III trial in subjects with bronchiectasis took 10 months and 22 hospitals to reach its target

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 preliminary data from the first Phase III bronchiectasis clinical trial has reported and Bronchitol performed very well indeed. We look forward to next year, with a great deal of anticipation, as we complete the Bronchitol Phase III trial in subjects with cystic fibrosis.

In addition to these studies, 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.

### Aridol growth

The misdiagnosis of asthma is common, particularly in the primary care setting and, as with any wrong diagnosis, this brings treatment difficulties for both the patient and the physician. Our first product Aridol, for the diagnosis and management of asthma, has been well accepted by physicians and patients alike. It is a product that has to be marketed by education, requiring a change in the way that difficult-to-treat asthma patients are managed and therefore will take time to gain solid sales traction. It is a true world-first

product, being the only indirect lung function challenge test ever to be approved for helping asthma patients anywhere in the world, and this no doubt reflects what was a painfully slow European approval process. We are looking forward to opening up and consolidating these European markets over the coming year.

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 we now have four different international companies using Aridol to identify those patients most likely to respond to their experimental therapies. This side of the Aridol business is expected to grow over the coming years and is important for the long term health of Aridol. In addition, within our own research laboratories, we have an active programme looking for new asthma treatments.

### Looking ahead

We are now generating revenue from the sale of our products. Although Australia represents a small percentage of world sales, ours is a sophisticated market and many of the dynamics are replayed in other territories. Lessons learned here can be quickly adopted in other territories. On the clinical front, we hope to be able to commence two Phase III trials for Bronchitol in the U.S and to report a successful Phase III clinical study in patients with cystic fibrosis.

It is my great pleasure to present our 2007 Annual Report. I thank you for your support and look forward to another year of major progress for your company.

Alan Robertson
Chief Executive Officer

Ala D. Roberton



From its beginning, Pharmaxis has believed in its ability to successfully navigate these processes and achieve approval of its life-enhancing products, and in so doing, generate benefits and value for patients and shareholders.

While each year has seen us progress towards these objectives, over the past 12 months we have significantly advanced our opportunity to reach our goals.

### Achieving major milestones

The completion of our Phase III clinical trial of Bronchitol in patients with bronchiectasis was an important moment in the company's history, as it provides strong evidence that Bronchitol is effective.

Another milestone was the European approval for the marketing of Aridol, demonstrating Pharmaxis' ability to bring a product to international markets. The completion of the US Phase III clinical trial of Aridol was a similarly notable achievement, representing the final step before we apply for our first United States marketing approval.

With a Phase III clinical trial of Bronchitol in patients with cystic fibrosis underway and recruiting strongly, and the US Phase III trials for both bronchiectasis and cystic fibrosis in advanced planning, we are

moving steadily towards having a suite of products approved for marketing on a global basis.

I believe Pharmaxis now has the skills and resources to pursue these opportunities to completion.

companies and larger international corporations. All non-executive directors of the company are now independent.

On behalf of all of your Board and shareholders I warmly congratulate management and staff for their

We are moving steadily towards having a suite of products approved for marketing on a global basis.

### **Board transformation**

Consistent with the growth and development of the company, the Board has continued a process of transformation, initiated in 2006. Director Brigitte Smith retired at the 2006 annual members' meeting and has since been replaced by Dr John Villiger. Ms Smith contributed significantly to the development of Pharmaxis in its formative years, and on behalf of Pharmaxis shareholders I thank Ms Smith for her contribution during that crucial period.

The Board's extensive capabilities now include industry, technology, international, scientific, business and financial expertise in both rapidly growing start-up

achievements over the past 12 months. I believe together we can continue to progress Bronchitol and Aridol and potentially other products towards worldwide market approvals, and thus continue towards our goals to provide benefits and value to patients and shareholders.

Danis M Hanley

Denis M Hanley Chairman



### Caring for the kids

As one of Australia's leading paediatric respiratory physicians

Dr Peter Cooper knows the joy and heartbreak of treating

children with cystic fibrosis.

'You develop a strong bond with the kids and their families as you watch them grow up,' says Peter, who heads the cystic fibrosis department of The Children's Hospital at Westmead, Sydney.

The life expectancy of people born with cystic fibrosis is gradually increasing with improvements in therapy; sufferers now live to an average age of 37 years.

Peter says while his patients are fully aware of their inevitable decline, they make the best of their lives.

'It's a privilege to help these young people with an incurable disease live their lives as fully as they can,' he says.

With no new treatments in over a decade, Peter believes cystic fibrosis deserves a higher profile and attention from pharmaceutical companies.

'Some of the existing therapies aren't always well tolerated, so anything that could improve their daily quality of life would be good.

'A drug that can enhance mucus production and clearance would significantly improve their outcomes.'

Peter says the Phase II results of Pharmaxis' Bronchitol offer cause for optimism.

'The results are encouraging; Bronchitol is another potentially very useful way of clearing secretions.'

Peter says cystic fibrosis specialists and thousands of patients with the disease are keenly anticipating the results of the Phase III trial of Bronchitol in cystic fibrosis, due in 2008.

75,000 Worldwide cystic fibrosis patient population

37 Average years life expectancy

### **Bronchitol**Review

Pharmaxis is on the cusp of transformational growth, following positive results from the Phase III trial of Bronchitol in bronchiectatic patients.



Bronchitol is a therapeutic agent designed to improve airway mucus clearance and lung hygiene.

The trial found that Bronchitol delivered a highly significant improvement in users' quality of life, as assessed by the St George Respiratory Questionnaire, a patient reported outcome tool for measuring health-related quality of life.

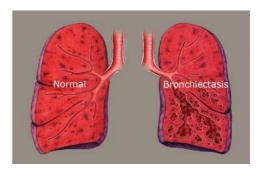
In addition, there was a highly significant difference in mucus clearance at the end of the study for patients receiving Bronchitol versus those patients receiving placebo.

Removal of mucus in the lungs is critical for bronchiectasis patients, as mucus accumulation affects their ability to breathe, exercise, sleep and lead a The largest study of bronchiectatic patients ever undertaken in the world, the trial of 362 patients was conducted at 22 hospitals across Australia, New Zealand and the United Kingdom.

The completion of this study and the achievement of its primary endpoints is a major advance towards our goal of having Bronchitol available for patients with bronchiectasis.

We will be discussing the study results with relevant regulatory agencies, with the intention of seeking agreement to file a marketing application in Australia and Europe as soon as possible. We have already applied to the FDA to begin a sixmonth Phase III trial.

Full study results will also be submitted for presentation at an upcoming international scientific meeting.



Bronchiectasis destroys lung tissue and is notoriously difficult to manage.

## This study is a major advance towards our goal of having Bronchitol available for patients with bronchiectasis.

normal life - ultimately leading to premature death. More than 600,000 people worldwide suffer from bronchiectasis, and there are no effective drugs proven to assist with mucus clearance in this patient group. Bronchitol has the potential to be the first targeted medication for this patient group in over 20 years, giving sufferers worldwide the chance to breathe easier.

### Cystic fibrosis trials advance

Major strides were made this year in bringing Bronchitol closer to market to treat cystic fibrosis (CF), with three separate trials progressing steadily.

The most important of these is an international Phase III trial, that seeks to demonstrate that Bronchitol is effective and safe in improving the lung function and quality of life of patients with CF. The study follows a successful Phase II trial showing that Bronchitol significantly improves lung function and wellbeing in CF patients.

### 2007 Bronchitol Milestones

### **Bronchiectasis**

 Phase III clinical trial finds Bronchitol effective in treating bronchiectasis

### Cystic fibrosis

- Bronchitol receives fast track status from US FDA for cystic fibrosis
- Phase III European and Australia trial begins
- > Phase II dosing study begins in Argentina

### 2008 Outlook

### **Bronchiectasis**

- Begin marketing discussion with Australian and European regulators
- > Commence US Phase III trial

### Cystic fibrosis

- > Commence US Phase III clinical trial
- > Report Phase II dosing study

## people worldwide suffer from bronchiectasis

Subjects will be treated with Bronchitol for six months, with full enrolment expected by mid 2008.

The six month trial is being conducted in over 30 hospitals across Australia and Europe and is the final clinical step before Pharmaxis seeks approval to market Bronchitol for CF in Europe and Australia.

If successful, Bronchitol would fulfil an important unmet medical need. More than 75,000 people in the major world markets are affected with CF, including 2,500 Australians. There have been no treatment advances in over a decade, and no products are approved to improve lung hydration.

The second trial underway is a Phase II study to determine the optimal dosing of Bronchitol for CF. The trial started in Canada last year and was opened up to additional clinical centres in Argentina earlier this year. It is due to report in early 2008.

The third trial, an investigator-led Phase II study in children with CF, is in its final stages. This trial involves three different treatment regimens, and is expected to report in early 2008. While not on the regulatory approval path, this is an important study for children with CF. It will provide us with useful information on how Bronchitol works with, and compares to, the market leading agent to help clear mucus.

### **US FDA fast-tracks Bronchitol**

Based on last year's positive Phase II trial results, the US Food and Drug Administration (FDA) in November 2006 granted Bronchitol fast track status for CF. The FDA fast-tracks the New Drug Application process if a therapy can potentially address an unmet medical need for a life-threatening disease.

Designation as a fast-track product will speed the process of bringing this potentially life-saving drug to CF sufferers. A complete NDA submission is expected to be made to the FDA in 2008. The FDA and European Medicines Agency have both previously granted Bronchitol orphan drug status for treating cystic fibrosis.

### COPD potential investigated

Bronchitol has potential applications in acute exacerbations of COPD, and clinical work in this area is underway. Bronchitol is designed to help clear congested chests during a worsening of COPD symptoms and to improve the disease management. There are more than 30 million COPD sufferers in the developed world and it is the fourth leading cause of death in the U.S.

### What is bronchiectasis?

Bronchiectasis is an incurable, degenerative and chronic lung condition affecting more than 600,000 people worldwide, including 20,000 Australians. Clinically, it is defined as a permanent dilation of the lower airways arising from chronic bronchial inflammation or infection. The most common signs and symptoms are chronic cough, copious mucus and chronic fatigue, all leading to a low quality of life.

### What is cystic fibrosis?

Cystic fibrosis (CF) is a life-threatening inherited disease affecting 75,000 people worldwide. It causes thick, sticky mucus to build up and clog the lungs and pancreas, making breathing and digesting food very difficult. Most individuals die from lung failure, with life expectancy of 33 to 37 years. There have been no treatment advances in over a decade.

### How does Bronchitol work?

Pharmaxis is developing Bronchitol for the management of chronic lung diseases, including bronchiectasis, cystic fibrosis and COPD. Bronchitol is a dry powdered formulation of mannitol, administered twice daily directly to the patient's lungs through a small handheld inhaler. Bronchitol hydrates the lungs, helps restore normal lung clearance, and allows patients to clear mucus more effectively. It breaks the vicious cycle of infection, inflammation and mucus production that leads to further damage of lung tissue, long term disability and increased mortality.



### Something to smile about

The future life course of 24-year-old Russell Agland hangs on the result of the Aridol asthma test he is about to take.

Russell is trying to enter the police force, and this is his third attempt to prove he has his asthma under control.

'Becoming a policeman is all I've ever wanted to do, but having asthma has held me back,' says Russell, talking about the police force's strict physical entry criteria.

Aridol is approved in Australia to diagnose the presence of asthma in users, by detecting airway inflammation. Patients inhale increasing doses of Aridol via a hand-held inhaler, and their lung capacity is measured after each dose. People with asthma will temporarily experience a reduction in the amount of air they can exhale.

Both patients and healthcare professionals report that they find Aridol easy to use. 'I think it's faster and more pleasant than saline tests,' says Russell.

Alison Boynton, the senior scientist administering the Aridol challenge test at Liverpool Hospital's respiratory department, agrees.

'With other tests, patients can close the back of their throats and don't get the right dosage,' she says.

'Coming in a kit form, Aridol is easier to use and there's no cleanup time, whereas other test's equipment need to be scrubbed and sterilised.'

So, the results for Russell? He passed, with flying colours, and he's now on track to fulfil his lifelong dream of becoming an investigating policeman.

### 52 million People affected by asthma in

People affected by asthma in the seven major pharmaceutical markets Countries that have approved

Aridol for marketing

### **Aridol**Review

2007 saw the company's first product, Aridol, approved for marketing in 14 European countries.



This landmark achievement provides an important new disease management tool to millions of asthma sufferers across Europe.

It is also important validation of Pharmaxis' capability to bring a product from concept to global markets.

Aridol detects airway inflammation and assists in the diagnosis and management of asthma. A simple-to-use airways inflammation test, Aridol is administered as a dry powder in a hand-held inhaler. Doctors can use the results of this test to identify airway hyper-responsiveness – a hallmark of asthma.

### Going global

First launched in Australia in May 2006, Aridol reached a long-awaited milestone when it was approved by Sweden in January 2007.

Sweden's acceptance of Aridol enabled Pharmaxis to apply for wider European approval of the drug via the European Union Mutual Recognition Procedure.

Following a significant drug registration process, in June 2007 Pharmaxis gained approval in the chosen 13 European countries to authorise the marketing of Aridol for the detection of airway reactivity in patients with asthma and other respiratory diseases.

The approving countries include Germany, France, the United Kingdom, Italy, the

Netherlands, Belgium, Denmark, Greece, Spain, Finland, Ireland, Norway and Portugal.

Some European markets will require pricing approval, while in others Aridol can be promoted immediately as a hospital product without reimbursement.

In Sweden, Aridol has received excellent support from key opinion leaders and our distribution partners are confident of gaining market penetration in the coming year.

Aridol is a major advance in the diagnosis and management of asthma. Research shows asthma and its severity is misdiagnosed in around 30% of cases, leading to poor control of symptoms and sometimes unnecessary pharmacological treatment and healthcare system costs.

### World first

Aridol is now the first and only approved Europe-wide lung function test and the world's first approved indirect challenge test for asthma.

Distribution partners have been established for most countries, with further distributors pending. Partner companies have established networks in respiratory markets, experience in new product launches, relationships with Aridol target customers, and knowledge of local processes required to successfully launch a new provocation test.

Pharmaxis is working closely with its European partners to ensure a successful launch of Aridol.

### Moving into Asia

In July 2007 Pharmaxis took its first step into the Asian market, filing for Korean marketing approval of Aridol.

Korea was chosen as the first Asian country to submit a marketing application because of its high number of asthmatics and acceptance of bronchial provocation tests in managing respiratory disease.

With an estimated 2.5 million asthma sufferers and another 185,000 asthmatics being diagnosed every year, Korea represents an opportunity for growing global Aridol sales.

### 2007 Aridol Milestones

- > European marketing approval in 13 countries
- > Registration and launch in Sweden
- > US Phase III trial completed
- > Distributors for EU appointed
- > Endorsed in global and Australian guidelines

### 2008 Outlook

- Launch Aridol in 13 European countries using distribution partners
- Lodge New Drug Application with US FDA
- Grow Aridol in Australia
- Build Aridol's long term potential by exploring new clinical applications

## Revenue from Aridol sales increased each quarter.

## Aridol is the world's first approved indirect lung challenge test for asthma

### Steady sales growth

Aridol is promoted in Australia through a contract Pharmaxis sales team based across four states. Since its launch in Australia in May 2006, more than 80% of laboratories in Australia now offer Aridol testing. Sales momentum is building, with strong growth in re-orders demonstrating those who have tried Aridol are converting from other provocation tests.

Internationally, Aridol is attracting increasing interest from pharmaceutical and biopharmaceutical companies wishing to use the product as part of their clinical trial process in bringing new anti-asthma medications to the market.

### **US NDA**

The efforts of our marketing group are ensuring that Aridol is well positioned for the future. Pharmaxis has been actively planning for building a US presence that will have the capability to manage our expanding US clinical and regulatory interests, and prepare us for the selling and marketing of both Aridol and Bronchitol in the US.

The next critical milestone in this journey will be the filing of a New Drug Application to the US FDA.

### **Expert endorsement**

During the year, Aridol was included in global and Australian official guidelines for managing asthma.

The product's inclusion in three influential guidelines: the US Asthma Management Guidelines, the GINA

Report on Global Strategy for Asthma Management and Prevention, and the Australian Asthma Management Handbook, followed extensive independent scientific and clinical review.

In addition, the product is now accepted by key occupational, industry and sporting authorities, including the Swedish Army, the World Anti-Doping Agency, the Australian Thoracic Society, the Australian Defence Force and NSW Police.

Aridol's endorsement by global experts adds weight to the body of evidence accelerating the product's acceptance by physicians worldwide.



## **Discovery** and Development

This year marked a number of significant achievements and developments in Pharmaxis' drug discovery journey.

The company's research was centralised in its laboratories in North Ryde, Sydney; and the research team and the drug discovery and development pipeline were strategically realigned.

The focus of all research efforts remains unchanged: we seek to discover new medicines to treat inflammatory and immune disorders such as multiple sclerosis, rheumatoid arthritis and asthma.

Our strategy also takes advantage of high quality science being undertaken in Australian academic and institutional laboratories, with research alliances forged with several leading institutions during the year.

### 2007 Highlights

### PXS25 and PXS64 – new medicine to treat inflammatory disease

The latest pre-clinical results indicate that clinical proof-of-concept for PXS25 and PXS64 may be more readily evaluated in inflammatory diseases other than

### PXS2076 and PXS74 – for rheumatoid arthritis and asthma

Both compounds have shown promising activities in models of arthritis and asthma, however, neither compound has the robust properties required for development as a pharmaceutical. We are working on identifying a therapeutic target for PXS2076 and on improved variants of PXS74.

### A promising new drug discovery program – inhibition of SSAO/VAP-1

Over the past few years an exciting new avenue has emerged to discover new medicines for the treatment of the large family of inflammatory diseases. SSAO is a protein that has been studied extensively for over 20 years but only very recently has its critical role in our immune defence, and in the development of many inflammatory diseases been understood.

SSAO/VAP-1 is now recognized as a new target for the design of novel medicines to treat asthma, rheumatoid

## We seek to discover new medicines to treat inflammatory and immune disorders

multiple sclerosis. We are exploring these avenues with further pre-clinical efficacy studies in models of asthma and other lung inflammatory conditions. In parallel, we are optimising the manufacturing process and are undertaking significant safety studies in preparation for clinical testing, which is now projected for 2008.

arthritis, colitis and other inflammatory conditions. Pharmaxis scientists are discovering new, potential medicines which act by inhibition of SSAO/VAP-1.



### Collaborations with leading Australian research groups

Australia is fortunate to have internationally renowned biology research teams in areas of basic biology related to asthma, cancer, diabetes and viral infection, as well as the emerging technology of structural biology.

Structural biology is a powerful alternative to traditional screening methods for identifying leads for drug discovery. The technology bombards protein crystals with x-ray beams to determine the three-dimensional structure of proteins. These extremely precise images of the site in a protein where drugs can bind help chemists design new compounds with some confidence. This is expected to significantly reduce the time currently taken to bring new therapies to patients.

Capitalising on the promise of this emerging field, Pharmaxis has entered into two collaborations with structural biology groups in Sydney and Melbourne.

University of Sydney. We were awarded funding from the Australian government in the form of an Australian Research Council Linkage grant to undertake a three-year study to crystallise and determine the three-dimensional structure of human SSAO/VAP-1 bound to known inhibitors of the enzyme. We will use this information to guide our SSAO/VAP-1 drug discovery project.

### CSIRO Molecular and Health

Technologies, Melbourne. Pharmaxis and CSIRO have entered into the first phase of an agreement to determine the three-dimensional structures of a large number of proteins involved in the inflammatory process. Proteins will be studied to determine which ones offer the best prospect for crystallisation and, of these, which ones will be best suited for drug discovery. CSIRO and Pharmaxis will determine whether to move to a second drug discovery agreement after receiving the first phase results.



Situated close to the current premises at 20-24 Rodborough Road Frenchs Forest, the 7,600 square metre purpose-built facility will accommodate all of Pharmaxis' activities in one location, including research, manufacturing, clinical, sales and marketing and administration. The new facility, which will be leased from the developer, has been designed to allow modular expansion and capacity can be doubled by installing new manufacturing equipment. The initial capital expenditure to expand our manufacturing capacity is approximately \$17 million.

### Manufacturing capacity boosted

In anticipation of growing Aridol sales worldwide and the expected launch of Bronchitol, the two-storey building will initially expand the company's manufacturing capacity more than 20-fold through the installation of a new spray dryer.

Successful quality control testing of the dryer has been undertaken in Denmark, as well as additional testing to meet the US FDA's Chemistry Manufacturing and Controls Guidelines.

The upgraded manufacturing facility will comply with the world's most stringent requirements and will assist both Aridol and Bronchitol to be registered in the US, the world's largest pharmaceutical market.

### Business systems upgraded

During the year Pharmaxis implemented the Navision business reporting and control platform that positions the company for global expansion. This formed the basis of improvements to the Company's financial reporting and control systems and procedures and enabled Pharmaxis to comply with Australian and US (Sarbanes Oxley) internal control requirements at 30 June 2007.

## Aridol kits manufactured in 2007

Utilising technology to match and exceed industry best practices, the new management platform will assist with meeting compliance obligations associated with Sarbanes Oxley and TGA and FDA manufacturing requirements.

The new headquarters will expand the company's manufacturing capacity 20-fold

Board of Directors



Denis Hanley AM MBA FCPA

- , Independent Chairman since 2001
- Mr Hanley brings more than 36 years' experience in managing and growing technology-based businesses. He spent 14 years with global medical company Baxter, including as managing director of its Australian operations, and founded Memtec Ltd, which grew into a NYSE-listed business with 1700 employees.

Alan D Robertson BSc PhD

- Chief Executive Officer since 1999
   Executive Director since 2000
- Dr Robertson has more than 20 years' experience in drug discovery and product development with leading pharmaceutical companies, including Wellcome, Faulding and Amrad. The co-inventor of 18 patents, Alan discovered the migraine medicine Zomig, which is marketed worldwide by AstraZeneca.



Peter Farrell AM DSc PhD

Non-Executive Director since 2006

Dr Farrell adds vast international experience to the Board, having spent more than 20 years developing and commercialising medical products globally. Following international roles at Baxter Healthcare, Dr Farrell founded Resmed.



### Board of Directors and Senior Management

Pharmaxis is led by talented and highlyexperienced individuals, who together are transitioning the organisation from an early stage research firm to a world-class specialist pharmaceutical company.



John Villiger BSocSc PhD

Non-Executive Director since 2006

Dr Villiger brings strong insights into developing new medicines for global markets, having held senior global roles at Roche and created a successful NASDAQ-listed pharmaceutical company, The Medicines Company.

Malcolm J McComas BEC LLB

Non-Executive Director since 2003

Mr McComas is a company director and former lawyer with more than 20 years' investment banking experience. He was a director of Grant Samuel, Managing Director of Investment Banking at County NatWest (now Citigroup), and a senior executive with Morgan Grenfell (now Deutsche Bank).



Charles PH Kiefel BCom FCA

Non-Executive Director since 2003

Mr Kiefel's decades of experience in finance and investment banking bring significant value to the Board. He has held global roles at Lazard Bros, and senior leadership positions with Ord Minnett and ANZ.



, Chief Financial Officer since 2002 Company Secretary since 2002

Mr McGarvey has 19 years' experience as Chief Financial Officer of successful Australian-based international technology businesses. He held senior roles at Memtec and later US Filter.



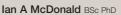




Brett Charlton MBBS PhD

Medical Director since 1998

Dr Charlton is responsible for the company's clinical trials program. A medical researcher and specialist in autoimmune disease, he has over 15 years' experience in clinical trial design and management. Dr Charlton co-founded Pharmaxis and has written more than 60 scientific papers.



· Chief Scientific Officer since 2006

Dr McDonald oversees research and development at Pharmaxis. He has strong credentials in managing drug discovery and design, having led teams in Europe and USA over 25 years. Under his leadership, six compounds have been developed and evaluated in clinical trials, and he is an inventor on 38 US patents.



John F Crapper BSc MBA

Chief Operations Officer since 2003

Mr Crapper heads manufacturing at Pharmaxis, ensuring the company's operations meet Australian and international requirements. He has 32 years' manufacturing and operations experience, including as Australian Managing Director of Memcor, a world leader in microfiltration membranes and systems.



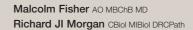
Gary Phillips BPharm MBA

Director since 2003

Mr Phillips heads the company's commercial activities, drawing on his extensive track record in marketing and sales in Australia, Europe and Asia. With 22 years' operational experience across the pharmaceutical sector, he was previously CEO of Novartis Australia and Ciba Geigy in Hungary.



Sandra Anderson BSc DSc PhD FANZSRS Norbert Berend AM MBBS MD FRACP



### Financial History

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

		Year ended 30 June			
	2007	2006	2005	2004	2003
	A\$	A\$	A\$	A\$	A\$
		(in the	ousands, except p	per share data)	
Income Statements					
Revenue from sale of goods	205	8			
Cost of sales	(49)	(2)			
Gross profit	156	6			
Interest	5,278	4,282	1,702	1,075	284
Grant income	2,152	1,299	1,219	1,152	779
Other income				48	43
Expenses					
Research & development	(23,840)	(16,978)	(9,269)	(6,301)	(2,051)
Administration	(3,240)	(4,386)	(3,134)	(2,461)	(1,103)
Commercial	(4,666)	(1,951)	(963)		
Loss before income tax	(24,160)	(17,728)	(10,445)	(6,486)	(2,048)
Income tax expense	(19)	(5)			
Loss for the year	(24,179)	(17,733)	(10,445)	(6,486)	(2,048)
	Cents	Cents	Cents	Cents	Cents
Earnings per share:					
Basic and diluted earnings / (loss) per share	(13.6)	(11.1)	(8.4)	(7.1)	(3.9)
			As at 30 Ju	une	
	2007	2006	2005	2004	2003
	A\$	A\$	<b>A</b> \$	A\$	A\$
Balance Sheets					
Cash and cash equivalents	76,182	97,840	33,390	25,217	7,384
Plant & equipment	3,521	3,205	2,477	1,474	1,515
Total Assets	82,648	104,267	37,937	28,261	10,495
Total liabilities	6,089	5,379	2,470	1,630	802
Total shareholders' equity	76,559	98,888	35,467	26,631	9,693
Share Data					
Ordinary shares on issue	177,949	176,904	134,770	108,016	11,200
Converting preference shares					46,816
Options over ordinary shares on issue	9,836	9,692	10,914	10,751	9,024



### Corporate Governance

### 2007 Review

The Board reviews and updates the Corporate Governance Framework as required and at least annually. The Pharmaxis Corporate Governance Framework was in compliance with ASX Recommendations for the 2007 year.

During 2007 a director representing a major shareholder retired and Dr John Villiger was appointed to the board. All non-executive directors are now independent and similarly the Remuneration and Nomination Committee consists exclusively of independent directors.

The business and management systems that support the Corporate Governance Framework are regularly reviewed and updated in line with the growth of the business:

- During the current year the Company installed a financial and management system that provides comprehensive management and oversight of the Company's financial and IT risks. This system was validated, reviewed and tested and is the basis of the Company being able to comply with Australian and U.S. (Sarbanes Oxley) internal control requirements as at 30 June 2007
- The Company has introduced a comprehensive employee manual

### **ASX Disclosures**

The Pharmaxis Corporate Governance Framework and supporting policies are available on the Pharmaxis website. The disclosures required by the ASX Recommendations are set out below. For ease of reference, this section is structured in line with those 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. This is disclosed on the Pharmaxis website.

### 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

The Board consists of five non-executive directors all of whom are independent and one executive director. 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.

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. Dr Peter Farrell was appointed to the Committee in October 2006, at which time the committee consisted of two independent directors, and the chief executive officer who had been temporarily appointed to the Committee in May 2006 to fill a vacancy. Dr John Villiger was appointed to the Committee in June 2007 at which time Dr Robertson resigned his temporary appointment and the Committee consisted entirely of independent directors. The chairman of the Committee is an independent director.

		Relevant Skills & Experience	Initially Appointed
Denis Hanley	Independent Chairman	Leading expert in management of technology- based growth businesses developing; 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
Peter Farrell	Independent director	More than 20 years experience developing and commercialising medical products overseas and in Australia	16 March 2006
John Villiger	Independent director	More than 30 years experience of the complete healthcare product lifecycle in international healthcare companies	15 November 2006
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 Resigned 26 October 2007

The Remuneration & Nomination Committee consists of:

	Meetings Held	Meetings Attended
Denis Hanley — Chairman	5	5
Peter Farrell – appointed 26 October 2006	3	3
John Villiger – appointed 7 June 2007	1	1
Brigitte Smith - resigned 26 October 2006	2	2
Alan Robertson – resigned 7 June 2007	4	4

### 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.

A copy of the Code of Conduct is available on the Pharmaxis website.

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.

### 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
Malcolm McComas - Chairman	BEc. LLB FSIA AICD	4	4
Charles Kiefel	BCom. FCA FAICD	4	4
Denis Hanley	MBA FCPA FAICD	4	4

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

The Pharmaxis Audit Committee Charter is available on the Pharmaxis website.

### 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
- Medical Director
- Commercial Director

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 spirit and intent of 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 Pharmaxis Continuous Disclosure and Shareholder Communication Policy is available on the Pharmaxis website.

Pharmaxis provides shareholders with quarterly updates of the Company's progress across all areas of the business (in addition to continuous disclosure requirements), complies with the spirit and intent of the voluntary Code of Best Practice for Reporting by Life Science Companies issued by AusBiotech and the ASX, and utilises 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 to the Board 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:
  - a) 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.
  - b) 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 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 by the Committee prior to discussion at a full Board meeting to agree on the implementation of any recommendations.

### 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

### Corporate Governance

### Individual Directors

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 Chief Financial Officer and 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 separate discussions as considered necessary by either.

### Key Executives

The Remuneration and Nomination Committee is specifically responsible for reviewing the ongoing performance of the Chief Executive Officer (CEO). The Committee is also responsible for setting and approving performance of senior executives in relation to bonus payments and options. In June of each year the Committee:

- approves individual milestones/objectives for the CEO and senior executives for the coming financial year, the milestones being based on the Company's business plan approved by the Board
- evaluates CEO performance compared to milestones/objectives set at the beginning of the year and approves the payment of any bonus and/or the grant and vesting of any options related to the CEO's performance
- in relation to Senior Executives, reviews recommendations, considers and approves the payment of any bonus and/or the grant and vesting of any options based on performance of milestones/objectives for the current fiscal 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. The Company's Annual Report on Form 20-F, filed with the US Securities and Exchange Commission and available on the Pharmaxis website, also discusses remuneration of directors and senior executives.

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 executive remuneration includes a variable component such as the vesting of options or bonus payments linked to the achievement of performance targets.

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 approved by shareholders 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 2007

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

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

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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 9th August 2007. 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



### **Directors' Report**

30 June 2007

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 2007.

### **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

Peter Farrell

Charles Kiefel

Malcolm McComas

Alan Robertson

Brigitte Smith was a director from the beginning of the financial year until her resignation on 26 October 2006.

John Villiger was appointed a director on 15th November 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

**Bronchitol** 

The Group is developing Bronchitol for the management of chronic obstructive lung diseases including bronchiectasis, cystic fibrosis and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patients clear mucus more effectively.

Major milestones achieved during the year include:

- Completion of a 362 subject, 22 site international Phase III clinical trial of Bronchitol in bronchiectasis
- Commencement of a 250 subject international Phase III clinical trial of Bronchitol in cystic fibrosis
- Fast Track designation of Bronchitol by the U.S. Food and Drug Administration

### Aridol

Aridol is the Group's first product. It is a simple-to-use airways inflammation test administered as a dry powder in a hand-held inhaler. Doctors can use the results of this test to identify airway hyper-responsiveness – a hallmark of asthma.

Major milestones achieved during the year include:

- Aridol received marketing approval from the Swedish regulatory agency. Subsequently the European European Mutual
  Recognition Procedure successfully completed its evaluation of Aridol allowing the issue of marketing authorizations in
  Germany, France, the United Kingdom, Italy, the Netherlands, Belgium, Denmark, Greece, Spain, Finland, Ireland, Norway
  and Portugal
- Successful completion and reporting of a 502 subject, 30 site Phase III clinical trial of Aridol in the United States which will enable the filing of a New Drug Application with the U.S. Food and Drug Administration
- · Filing of new drug applications for Aridol in Switzerland and Korea
- The appointment of marketing and distribution partners in Greece, Italy, the Netherlands and Spain
- First sales of Aridol to Europe and also to a pharmaceutical company in the U.S., for use in clinical trials of a new asthma therapy it is developing

### Other milestones:

- Design work commenced on a new facility to incorporate expanded production capacity as well as all of the Group's research, sales and administration functions. Specifications for the new spray dryer, the key component of the production expansion were completed, negotiations with the supplier advanced and manufacture of the spray dryer commenced
- The Group's research laboratories were consolidated at North Ryde, following closure of the facilities based at the Australian National University earlier in the year

### Financial Highlights

	Consolidated		
	2007	2006	
	\$'000	\$'000	
Revenue from sale of goods	205	8	
Cost of sales	(49)	(2)	
Gross profit	156	6	
Government research grants	2,152	1,299	
Interest income	5,278	4,282	
Other expenses from ordinary activities			
Research & development expenses	(23,840)	(16,978)	
Administration expenses	(4,666)	(4,391)	
Commercial expenses	(3,240)	(1,946)	
Loss before income tax	(24,160)	(17,728)	
Income tax expense	(19)	(5)	
Loss for the year	(24,179)	(17,733)	
Backlog of outstanding sales orders	33	113	
Cash and bank accepted commercial bills	76,182	97,840	
Net assets	76,559	98,888	

### Revenue from continuing operations:

Aridol was launched in Australia in June 2006, and was approved for sale in Sweden in October 2006 and an additional 13 European countries in June 2007. Approximately 60 percent of sales for the 2007 fiscal year were in Australia where the average quarter on quarter increase was 28 percent. The other 40 percent of sales were split approximately evenly between Sweden and a US biopharmaceutical company which is using Aridol in a series of clinical trials of a new asthma treatment they are developing. Gross margin was 76 percent of sales.

### Grant income:

Approximately 90 percent of grant income in 2007 derives from the Pharmaceuticals Partnerships Program (P3) grant awarded to the Group in April 2004. This grant payable to Pharmaxis is 30 percent of the increase of eligible R&D expenditure over a base amount derived from average base year expenditures. The increase in the P3 grant in 2007 correlates with the increased level of research expenditure in 2007. The Group also received an Export Market Development Grant in 2007 which totalled \$150,000. The remainder of the grant income relates to amortization of a deferred portion of a R&D Start Grant for the development of new treatments for cystic fibrosis that concluded in December 2005.

### Interest:

The increase in interest income is attributable to the greater level of funds invested during fiscal 2007. The Group started the current fiscal year with \$98 million of cash and bank accepted bills of exchange. By contrast the Group started the 2006 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.

### Research & development expenses:

Research & development expenses for 2007 were \$23.8 million, an increase of 40 percent compared to 2006. There are five components to the research & development expenses:

### Directors' Report

30 June 2007

The research unit based at the John Curtin School of Medical Research within the Australian National University accounted for 1 percent of our total research and development expenditure in the current year. This unit was closed during the year following the expansion of the Group's research unit at North Ryde.

During the financial year we expanded the Group's drug discovery unit based at North Ryde. This unit accounted for approximately 5 percent of our total research and development expenditure in the current year. It is focused on autoimmune and respiratory drug discovery. The combined expenditure of the North Ryde facilities and the Australian National University increased by approximately 10 percent in the current year and accounted for approximately 2 percent of the increase in overall research & development expenditure during the current year.

The preclinical development unit located at the Frenchs Forest facility accounted for approximately 10 percent of our total research and development expenditure in current year and increased by approximately 22 percent compared to the 2006 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 95 percent of expenditure in the current year related to Bronchitol long term safety studies. This area of research accounted for approximately 6 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 58 percent of our total research and development expenditure in the current year and increased by approximately 34 percent compared to the 2006 financial year. The clinical unit designs and manages the clinical trials run by Pharmaxis. The majority of the unit's expenditures relate to hospital and other services associated with the conduct and analysis of clinical trials. This increase in expenditure reflects the number of clinical trials ongoing during fiscal 2007. This area of research accounted for approximately 51 percent of the increase in overall research & development expenditure during the current year.

The manufacturing facility at Frenchs Forest is predominantly 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 26 percent of our total research and development expenditure in the current year and increased by approximately 80 percent compared to the 2006 financial year, reflecting additional manufacturing capacity/productivity research and product stability studies required to support registration applications. This area of expenditure accounted for approximately 41 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 2007 financial year were \$3.2 million, an increase of approximately 67 percent over the 2006 financial year. The commercial launch of Aridol in Australia and preparation for the full commercial launch in Europe resulted in additional one time expenses over and above the first full year. Costs were associated with the hiring of a sales and marketing team late in the 2006 financial year in Australia and Europe and with obtaining detailed global market information related to bronchiectasis.

### Administration expenses:

Administration expenses include accounting, administration, office, recruitment, legal and public company costs.

Administration expenses for the current year were \$4.6 million, an increase of 5 percent over the prior comparable period.

### Income tax expense:

Income tax expense relates to income generated by the Group's UK subsidiary which was incorporated during the 2006 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 issue of shares subsequent to the exercise of employee options contributed \$0.4 million. Together with pre-existing funds the Group ended the year with \$76 million in cash and bank accepted commercial bills.

Capital expenditure for the 2007 financial year of \$1.2 million compares to \$1.6 million in 2006. Expenditure was predominantly related to QC laboratory capacity and equipment. Other expenditure related to computer equipment and additional research equipment for the North Ryde laboratories.

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

No matter or circumstance has arisen since 30 June 2007 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 the reporting of a 362 subject international Phase III clinical trial of Bronchitol in bronchiectasis which is expected in the September quarter and the completion of an agreement for the supply of an additional spray dryer 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 2007

### 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
Chairman – non-exec	cutive			
Denis M Hanley MBA, FCPA, FAICD	6 years. Age 60. Extensive experience in developing and commercialising new Australian technology including 14 years as CEO of Memtec Ltd which grew from a small enterprise	Chairman Chairman of Remuneration and Nomination Committee Member of Audit Committee	767,997	1,120,000
	Mr Hanley is non-executive chairman of CathRx Ltd, and a non-executive director of Universal Biosensors In both Australian listed companies. Mr Hanley is also executive chairman of PFM Cornerstone Limited.	10,		
Executive				
Alan D Robertson BSc, PhD	,	Managing Director and Chief Executive Officer	-	2,380,000
	Dr Robertson is a non-executive director of Patrys Ltd, an Australian listed company.			
Non-executive				
Peter C Farrell DSc, PhD	• • • • • • • • • • • • • • • • • • • •	Member of Remuneration and Nomination Committee	101,645	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	
Non-executive					
Charles PH Kiefel BCom, FCA, FAICD	Non-executive director for 4 years.  Age 52. 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).	Member of Audit Committee	200,000	68,957	
Malcolm J McComas BEc, LLB, FSIA, AICD SF FINSIA	Non-executive director for 4 years. Age 53.  More than 20 years investment banking experience and 5 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 and County NatWest, and a senior executive with Morgan Grenfell (now Deutsche Bank).  Mr McComas is currently non-executive chairman of Sunshine Heart Inc.	Chairman of Audit Committee	126,666	240,000	
John Villiger DSc, PhD	Non-executive director appointed 15 November 2006. Age 53. More than 20 years experience in developing new products for global markets. Dr Villiger held various senior positions in product development at Roche from 1986 to 1996 in New Zealand and Switzerland, including International project director and head of global project management. He oversaw the development of Roche's pharmaceutical portfolio, managing over 50 development programs and teams in Switzerland, the UK, USA and Japan.	Member of Remuneration and Nomination Committee	-	-	

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## 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 Securities 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 2007, and the number of meetings attended by each director was:

	Boa	rd	Meetings of Committees			
	Meetings		Audit		Remune Nomir	
	Α	В	Α	В	Α	В
DM Hanley	7	7	4	4	5	5
AD Robertson	7	7			4	4
CPH Kiefel	7	7	4	4		
MJ McComas	7	7	4	4		
BH Smith	3	3			2	2
PC Farrell	7	5			3	3
J Villiger	4	4			1	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

#### 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 2007 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. When last adjusted in 2006, 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
- as from August 2006 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 award date using the same methodology as used to determine the amounts expensed in the financial statements. Options are granted under the Pharmaxis Ltd Employee Option Plan. As the options are granted in substitution for current year cash compensation they vest at the later of award or shareholder approval. Options issued to nonexecutive directors prior to August 2006 vest over a four year period

The other non-executive director during the year was BH Smith. She is a principal of a venture capital firm that manages funds which are significant shareholders of the company. Ms Smith was paid a cash fee of \$10,174 for the four months until her retirement from the Board.

Independent directors are issued options on becoming a director of the Company, subject to shareholder approval, and vest over four years.

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 \$600,000 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 percent
- 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 commensurate with the responsibilities and contribution of the executive. An executive's pay is also reviewed on promotion.

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#### 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 5 highest paid executives of the entity:

Name	Position	Employer
Brett Charlton	Medical Director	Pharmaxis Ltd
John Francis Crapper	Chief Operations Officer	Pharmaxis Ltd
lan Alexander McDonald	Chief Scientific Officer	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.

# Key management personnel of Pharmaxis Ltd and the Group

2007	Sh	nort-term bene	efits	Post- employment benefits	Long- term benefits	Share- based payment	
Name	Cash salary and fees	Cash bonus	Non- monetary benefits	Super- annuation	Long service benefits	Options	Total
Namo	\$	\$	\$	\$	\$	\$	\$
Non-executive directors							
DM Hanley Chairman	66,644	_	_	5,998	_	71,575	144,217
CPH Kiefel	6,987	_	-	629	-	75,944	83,560
MJ McComas	42,985	_	-	_	_	37,893	80,878
PC Farrell	40,688	_	_	_	_	157,141	197,829
BH Smith	10,174	_	_	_	_	_	10,174
J Villiger	35,000	_	_	_	_	-	35,000
Sub-total non- executive directors	202,478	_	_	6,627	_	342,553	551,658
Executive directors							
AD Robertson	329,025	93,500	_	29,612	8,205	161,843	622,185
Other key management personnel							
B Charlton	251,125	40,000	_	22,601	6,264	119,240	439,230
JF Crapper	235,750	40,000	_	21,218	4,554	105,568	407,090
IA McDonald	184,756	20,000	_	16,628	1,359	97,181	319,924
DM McGarvey	261,375	40,000	_	23,524	5,516	100,525	430,940
GJ Phillips	260,775	40,000	_	23,470	4,413	106,072	434,730
Totals	1,725,284	273,500	-	143,680	30,311	1,032,982	3,205,757

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# Key management personnel of Pharmaxis Ltd and the Group (continued)

2006	Sh	ort-term bene	fits	Post- employment benefits	Long- term benefits	Share- based payment	
Name	Cash salary and fees \$	Cash bonus \$	Non- monetary benefits \$	Super- annuation \$	Long service benefits \$	Options \$	Total \$
Non-executive directors							
DM Hanley Chairman	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
Sub-total non- executive directors	224,890	_	_	9,402	_	82,640	316,932
Executive directors							
AD Robertson	270,500	92,400	_	24,345	4,876	139,722	531,843
Other key management personnel							
WB Cowden <sup>1</sup>	147,087	20,000	_	13,238	1,828	67,678	249,831
JF Crapper	208,750	40,000	_	18,788	1,795	73,023	342,356
IA McDonald	177,625	18,750	_	15,986	_	83,841	296,202
B Charlton	215,000	40,000	_	19,350	4,100	95,236	373,686
DM McGarvey	226,750	42,500	_	20,408	2,453	67,678	359,789
GJ Phillips	222,250	40,000	_	20,003	953	73,488	356,694
Totals	1,692,852	293,650	_	141,520	16,005	683,306	2,827,333

<sup>&</sup>lt;sup>1</sup> W B Cowden ceased to be a member of key management personnel effective 30 June 2006.

# Remuneration subject to risk

Of the total amount of remuneration paid to the Chief Executive Officer and other key management personnel, both the payment of the bonus and the granting and vesting of options (excluding sign on options) are subject to the individual employee performance. Part E of the Remuneration Report highlights the risk associated with the bonus this year.

#### 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 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 2007, 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.

Brett Charlton, Medical Director

- Term of agreement 30 June 2008.
- Effective 1 January 2007, 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.

John Francis Crapper, Chief Operations Officer

- Term of agreement 30 June 2008.
- Effective 1 January 2007, 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.

lan Alexander McDonald, Chief Scientific Officer

- Term of agreement 30 June 2008.
- Effective 1 January 2007, 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 2007, 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.

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Gary Jonathan Phillips, Commercial Director

- Term of agreement 30 June 2008.
- Effective 1 January 2007, 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 percent 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. From listing until 31 August 2006 the exercise price was set as the average closing price of Pharmaxis Ltd shares on the Australian Securities Exchange on the 5 business days prior to the grant of the options. From 1 September 2006 the exercise price is set as the average of the volume weighted average price of Pharmaxis Ltd shares on the Australian Securities Exchange on the 5 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:

Grant date	Expiry date	Exercise price	Value per option at grant date	Number of options granted	Number of option grantees	Date exercisable
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.

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	25% at each of 30 June 2004, 2005, 2006 and 2007, subject to Remuneration and Nomination Committee annual approval.
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.

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## 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
15 August 2006	14 August 2016	\$1.9170	\$1.3277	505,000	5	25% at each of 30 June 2007, 2008, 2009 and 2010, 255,000 of which are subject to Remuneration and Nomination Committee annual approval.
26 October 2006	14 August 2016	\$1.9170	\$1.3167	278,957	5	25% at each of 30 June 2007, 2008, 2009 and 2010, 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 op	tions granted	Number of options vested during the year		
	during t	he year			
	2007	2006	2007	2006	
Directors of Pharmaxis Ltd					
DM Hanley Chairman	40,000	40,000	50,000	110,000	
AD Robertson	150,000	150,000	75,000	277,500	
CPH Kiefel	48,957	20,000	103,957	55,000	
MJ McComas	20,000	20,000	75,000	55,000	
PC Farrell	220,000	_	70,000	_	
J Villiger <sup>1</sup>	_	_	_	_	
BH Smith	_	_	_	_	
Other key management personnel of the	Company				
JF Crapper	100,000	100,000	170,000	145,000	
IA McDonald	100,000	20,000	67,500	42,500	
B Charlton	105,000	105,000	52,500	146,250	
DM McGarvey	100,000	100,000	50,000	145,000	
GJ Phillips	100,000	105,000	113,750	88,750	

On 15 November 2006 the Board announced that it had resolved to grant 200,000 options to Dr John Villiger 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 2007 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 2007 included:

(a) options are granted for no consideration, 25% vesting at each of 30 June 2007, 2008, 2009 and 2010, subject to Remuneration and Nomination Committee annual approval

(b) exercise price: \$1.917

(c) grant date: 15 August 2006 and 26 October 2006

(d) expiry date: 14 August 2016

(e) share price at grant date: \$1.917 (15 August 2006) and \$3.00 (26 October 2006)

(f) expected price volatility of the company's shares: 50%

(g) risk-free interest rate: 5.93% (15 August 2006) and 5.73% (26 October 2006)

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		
		2007	2006	
Directors of Pharmaxis Ltd				
CPH Kiefel	19 June 2007	150,000	_	
	29 June 2007	50,000	_	
Other key management perso	onnel of the Group			
JF Crapper	23 April 2007	300,000	300,000	
B Charlton	7 December 2006	110,000	640,000	

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
19 October 2006	\$0.3125
19 October 2006	\$1.7900
7 December 2006	\$0.3125
23 April 2007	\$0.3125
19 June 2007	\$0.3125
29 June 2007	\$0.3125

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

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#### 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 2007.

Cash bonus			Options							
Name	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	-	-	2007 2006 2003	100 100 100	- - -	2007 to 2009	- - -	- 36,456 -		
AD Robertson	85	15	2007 2006 2003	100 100 100	- - -	2008 to 2010 2007 to 2009	- - -	148,129 188,775 –		
CPH Kiefel	_	-	2007 2006 2003	100 100 100	- - -	2007 to 2009 2007	- - -	- 18,228 8,395		
MJ McComas	-	-	2007 2006 2004	100 100 100	- - -	2007 to 2009 2007	- - -	- 18,228 8,405		
PC Farrell	-	_	2007 2007	100 100	- -	2008 to 2010	- -	213,060		
J Villiger	_	_	_	_	_	_	_	_		
JF Crapper	80	20	2007 2006 2004	100 100 100	- - -	2008 to 2010 2007 to 2009 2007	- - -	99,578 90,410 20,172		
IA McDonald	80	20	2007 2006 2005	100 100 100	- - -	2008 to 2010 2007 to 2009 2007 to 2009	- - -	99,578 18,228 70,065		
B Charlton	80	20	2007 2006 2003	100 100 100	- - -	2008 to 2010 2007 to 2009	- - -	104,556 95,697 –		
DM McGarvey	80	20	2007 2006 2003	100 100 100	- - -	2008 to 2010 2007 to 2009	- - -	99,578 91,140 -		
GJ Phillips	80	20	2007 2006 2004	100 100 100	- - -	2008 to 2010 2007 to 2009 2007	- - -	99,578 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 2007 have been achieved by all executives.

Share-based compensation: Options

Further details relating to options are set out below.

	А	В	С	D	Е
Name	Remuneration	Value at	Value at	Value at	Total of
	consisting	grant date	exercise date	lapse date	columns B-D
	of options	\$	\$	\$	\$
DM Hanley	50%	52,668	_	_	52,668
AD Robertson	26%	197,505	_	_	197,505
CPH Kiefel	91%	64,461	33,580	_	98,041
MJ McComas	47%	26,334	_	_	26,334
PC Farrell	79%	310,414	_	_	310,414
BH Smith	_	_	_	_	_
J Villiger	_	_	_	_	_
JF Crapper	26%	132,770	50,430	_	183,200
IA McDonald	31%	132,770	_	_	132,770
B Charlton	28%	139,409	18,469	_	157,878
DM McGarvey	24%	132,770	_	_	132,770
GJ Phillips	25%	132,770	_	_	132,770

- 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. Not permitted under Pharmaxis Corporate Governance Framework

# 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 5 most highly remunerated officers of the company as part of their remuneration are set out in Section D above.

30 June 2007

## Shares under option

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

		Issue price	Number under
Date options granted	Expiry date	of shares	option
1 December 1999	30 November 2009	\$0.1250	1,120,000
1 July 2000	30 June 2010	\$0.1250	_
1 September 2001	30 August 2011	\$0.3125	640,000
2 December 2001	30 November 2011	\$0.1250	100,000
12 May 2003	30 June 2012	\$0.3125	3,050,000
12 May 2003	30 November 2012	\$0.3125	480,000
12 May 2003	30 April 2013	\$0.3125	16,000
1 July 2003	30 June 2013	\$0.3125	360,000
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	240,000
12 May 2005	11 May 2015	\$1.1470	320,000
5 August 2005	4 August 2015	\$1.7900	790,000
17 October 2005	16 October 2015	\$2.7720	70,000
13 February 2006	12 February 2016	\$2.1940	270,000
1 June 2006	31 May 2016	\$2.0340	96,500
15 August 2006	14 August 2016	\$1.9170	617,250
26 October 2006	14 August 2016	\$1.9170	278,957
20 September 2006	19 September 2016	\$1.8918	47,500
26 October 2006	15 March 2016	\$2.0680	200,000
14 December 2006	13 December 2016	\$3.0710	72,500
18 June 2007	17 June 2017	\$3.3155	237,500
			9,743,707

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 2007 on the exercise of options granted under the Pharmaxis Employee Option Plan. On 19 July 2007, the company issued 72,000 shares at \$0.3125 each, 5,000 shares at \$1.79 each and 2,500 shares at \$1.917 each upon the exercise of options granted under the Pharmaxis Employee Option Plan on 12 May 2003, 5 August 2005 and 15 August 2006 respectively. No amounts are unpaid on any of the shares.

	Issue price	Number of
Date options granted	of shares	shares issued
12 May 2003	\$ 0.3215	580,000
5 August 2005	\$ 1.7900	35,625
2 February 2005	\$ 0.8340	7,500
12 May 2005	\$ 1.1470	2,500
2 December 2001	\$ 0.1250	60,000
1 July 2003	\$ 0.3215	300,000
1 July 2000	\$ 0.1250	60,000
		1,045,625

#### Insurance of officers

During the financial year, Pharmaxis Ltd paid a premium of \$115,015 to insure the directors and officers of the Group for the policy year ended 26 September 2007.

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 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 APES110, 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.

Ala D. Robertia

30 June 2007

#### 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

9 August 2007



# **Auditor's Independence Declaration**

As lead auditor for the audit of Pharmaxis Ltd for the year ended 30 June 2007, 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.

WHB Seaton

Partner

PricewaterhouseCoopers

Sydney 9 August 2007

# **Income Statements**

For the year ended 30 June 2007

		Consc	olidated	Paren	t Entity
		2007	2006	2007	2006
	Notes	\$'000	\$'000	\$'000	\$'000
Revenue from continuing operations					
Revenue from sale of goods	2	205	8	205	8
Cost of sales		(49)	(2)	(49)	(2)
Gross profit		156	6	156	6
Other revenue	2	5,278	4,282	5,278	4,282
Other income	3	2,152	1,299	2,152	1,299
Other expenses from ordinary activities	4				
Research & development expenses		(23,840)	(16,978)	(23,865)	(16,978)
Commercial expenses		(3,240)	(1,946)	(3,303)	(1,970)
Administration expenses		(4,666)	(4,391)	(4,672)	(4,391)
Loss before income tax		(24,160)	(17,728)	(24,254)	(17,752)
Income tax expense	5	(19)	(5)	-	_
Loss for the year		(24,179)	(17,733)	(24,254)	(17,752)
				0 1	
Earnings per share:	9.5	Cents	Cents	Cents	Cents
Basic earnings / (loss) per share	28	(13.6)	(11.1)	(13.7)	(11.1
Diluted earnings / (loss) per share	28	(13.6)	(11.1)	(13.7)	(11.1

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

# **Balance Sheets**

As at 30 June 2007

		Cons	solidated	Parent Entity	
	Notes	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
ASSETS					
Current assets					
Cash and cash equivalents	6	76,182	97,840	76,095	97,822
Trade and other receivables	7	1,026	1,371	1,020	1,371
Inventories	8	79	100	79	100
Total current assets		77,287	99,311	77,194	99,293
Non-current assets		<u> </u>		· · · · · · · · · · · · · · · · · · ·	
Receivables	9	221	284	216	284
Other financial assets	10	380	272	378	267
Plant and equipment	11	3,521	3,205	3,504	3,205
ntangible assets	12	1,239	1,195	1,239	1,195
Total non-current assets		5,361	4,956	5,337	4,95
Total assets		82,648	104,267	82,531	104,244
LIABILITIES					
Current liabilities					
Trade and other payables	13	5,944	5,257	5,945	5,259
Other liabilities	14	6	48	6	48
Current tax liabilities		24	5	_	-
Total current liabilities		5,974	5,310	5,951	5,307
Non-current liabilities					
Provisions	15	115	63	115	63
Other liabilities	16		6	_	6
Total non-current liabilities		115	69	115	69
Total liabilities		6,089	5,379	6,066	5,376
Net assets		76,559	98,888	76,465	98,868
EQUITY					
Contributed equity	17	135,108	134,745	135,108	134,745
Reserves	18 (a)	4,009	2,522	4,009	2,52
Accumulated losses	18 (b)	(62,558)	(38,379)	(62,652)	(38,398
Total equity		76,559	98,888	76,465	98,868

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

# Statements of Changes in Equity

For the year ended 30 June 2007

		Cons	olidated	Parer	nt Entity
	Notes	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Total equity at the beginning of the financial year		98,888	35,467	98,868	35,467
Exchange differences on translation of foreign operations	18 (a)	(1)	1	-	_
Net income recognised directly in equity		(1)	1	-	_
Loss for the year		(24,179)	(17,733)	(24,254)	(17,752)
Total recognised income and expense for the year		(24,180)	(17,732)	(24,254)	(17,752)
Contributions of equity, net of transaction costs	17 (a)	363	80,029	363	80,029
Employee share options	18 (a)	1,488	1,124	1,488	1,124
Total equity at the end of the financial year		76,559	98,888	76,465	98,868

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 2007

		Cons	olidated	Parer	nt Entity	
	Notes	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000	
Cash flows from operating activities						
Receipts from customers						
inclusive of goods and services tax)		191	1	191	1	
Payments to suppliers and employees						
inclusive of goods and services tax)		(28,458)	(18,960)	(28,559)	(18,978)	
		(28,267)	(18,959)	(28,368)	(18,977)	
Research grant receipts from government		2,292	902	2,292	902	
nterest received		5,278	4,282	5,278	4,282	
Net cash outflow from operating activities	27	(20,697)	(13,775)	(20,798)	(13,793)	
Cash flows from investing activities						
Payments for plant and equipment		(1,182)	(1,572)	(1,133)	(1,572)	
Proceeds from disposal of plant and equipment		52	_	33	_	
Payments for intangible assets		(192)	(232)	(192)	(232)	
Net cash outflow from investing activities		(1,322)	(1,804)	(1,292)	(1,804)	
Cash flows from financing activities						
Proceeds from issues of shares		363	87,080	363	87,080	
Share issue transaction costs			(7,051)	_	(7,051)	
Net cash inflow from financing activities		363	80,029	363	80,029	
Net (decrease) / increase in cash and cash equiva Cash and cash equivalents at the beginning	lents	(21,656)	64,450	(21,727)	64,432	
of the financial year  Effects of exchange rate changes on cash and		97,840	33,390	97,822	33,390	
cash equivalents		(2)	_	_	_	
Cash and cash equivalents at the						
oaon and caon equivalento at the						

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

# Notes to the Financial Statements

30 June 2007

## 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 IFRS

Australian Accounting Standards include AIFRS. Compliance with AIFRS ensures that the consolidated financial statements and notes of Pharmaxis Ltd comply with International Financial Reporting Standards (IFRS). The parent entity financial statements and notes also comply with IFRS 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*.

#### Early adoption of standards

The Group has elected to apply the following pronouncement to the annual reporting period beginning 1 July 2006:

- revised AASB 101 Presentation of Financial Statements (issued October 2006)

This includes applying the pronouncement to the comparatives in accordance with AASB 108 Accounting Policies, Changes in Accounting Estimates and Errors. No adjustments to any of the financial statements were required for the above pronouncement, but certain disclosures are no longer required and have therefore been omitted.

#### 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 2007 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.

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.

#### (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

Sales revenue is measured at the fair value of the consideration received or receivable. Revenue from the sale of goods is recorded when goods have been dispatched and title passes to the customer.

# (ii) Interest income

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

30 June 2007

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

#### (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 recognises the income only when 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.

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.

#### (i) 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.

#### (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 the 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.

#### (I) 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 the 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.

## Notes to the Financial Statements

30 June 2007

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

#### (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.

#### (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 and receipt of a valid invoice.

#### (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 underling 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.

#### (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.

#### (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 receivable 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 AASB interpretations

Certain new accounting standards and AASB interpretations have been published that are not mandatory for the year ended 30 June 2007 reporting period. The Group's assessment of the impact of these new standards and interpretations is set out below.

## Notes to the Financial Statements

30 June 2007

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

(i) AASB 2007-4 Amendments to Australian Accounting Standards arising from ED 151 and Other Amendments was issued in April 2007

This standard reinstates some of the options that exist in the international board's pure IFRS which were removed by the AASB when it promulgated Australian equivalents (AIFRS) in Australia. It also removes some of the additional disclosure requirements added to AIFRS by the AASB. The significant options reinstated are the option to use the indirect method of presenting cash flow statements and the option to use proportionate consolidation for accounting for investments in joint venture entities.

The Group intends to prepare the cashflow statements using the direct method. Proportionate consolidation is not applicable as the group has no investments in joint ventures.

- (ii) AASB 7 Financial Instruments: Disclosures and AASB 2005-10 Amendments to Australian Accounting Standards [AASB 132, AASB 101, AASB 114, AASB 114, AASB 117, AASB 133, AASB 139, AASB 1, AASB 4, AASB 1023 & AASB 1038]
  - AASB 7 and AASB 2005-10 are applicable to annual reporting periods beginning on or after 1 January 2007. The Group has not adopted the standards early. Application of the standards will not affect any of the amounts recognised in the financial statements, but will impact the type of information disclosed in relation to the group's financial instruments.
- (iii) AASB-I 11 AASB 2 Group and Treasury Share Transactions and AASB 2007-1 Amendments to Australian Accounting Standards arising from AASB Interpretation 11
  - AASB-I 11 and AASB 2007-1 are effective for annual reporting periods commencing on or after 1 March 2007. AASB-I 11 addresses whether certain types of share-based payment transactions should be accounted for as equity-settled or as cash settled transactions and specifies the accounting in a subsidiary's financial statements for share-based payment arrangements involving equity instruments of the parent. The Group will apply AASB-I 11 from 1 July 2007, but it is not expected to have any impact on the Group's financial statements.
- (iv) AASB 8 Operating Segments and AASB 2007-3 Amendments to Australian Accounting Standards arising from AASB 8

AASB 8 and AASB 2007-3 are effective for annual reporting periods commencing on or after 1 January 2009. AASB 8 will result in a significant change in the approach to segment reporting, as it requires adoption of a 'management approach' to reporting on the financial performance. The information being reported will be based on what the key decision-makers use internally for evaluating segment performance and deciding how to allocate resources to operating segments.

The Group has not yet decided when to adopt AASB 8. Application of AASB 8 may result in different segments, segment results and different types of information being reported in the segment note of the financial report. However, it will not affect any of the amounts recognised in the financial statements.

## 2. Revenue

	Consc	Consolidated		Parent Entity	
	2007	2006	2007 \$'000	2006 \$'000	
	\$'000	\$'000			
Sales revenue					
Sale of goods	205	8	205	8	
Other revenue					
nterest	5,278	4,282	5,278	4,282	

# 3. Other income

	Consc	Consolidated		Parent Entity	
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000	
Government grants	2,152	1,299	2,152	1,299	

Government grants comprised the following:

- (i) R&D START program grants of \$47,862 (2006: \$444,313).
- (ii) Australian Government's Pharmaceuticals Partnerships Program ('P3') grants of \$1,954,592 (2006: \$848,476).
- (iii) Export Market Development grants of \$150,000 (2006: \$6,135 NSW DSRD).

Refer Note 21 for additional information on the nature and extent of grants recognised and conditions associated with the grants.

# 4. Expenses

	Consc	olidated	Paren	t Entity
	2007	2006	2007	2006
	\$'000	\$'000	\$'000	\$'000
Loss before income tax includes the following specific expenses:				
Depreciation (note 11)				
Plant and equipment	631	592	629	592
Computer equipment	109	77	108	77
Leasehold improvements	51	26	51	26
Total depreciation	791	695	788	695
Impairment of plant & equipment (note 11)	-	109	_	109
Amortisation (note 12)				
Patents	92	91	92	91
Trademarks	3	_	3	_
Software	53	6	53	6
Total amortisation	148	97	148	97
Impairment of intangible assets (note 12)	_	46	_	46
Net loss on disposal of plant and equipment	24	40	14	40
Rental expense relating to operating leases	459	371	426	371
Net foreign exchange losses	47	5	49	5
Employee benefits expense				
Defined contribution superannuation expense	454	337	423	329
Other employee benefits expenses	9,007	5,498	8,400	5,340
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# Notes to the Financial Statements

30 June 2007

# 5. Income tax expense

	Cons	olidated	Parer	nt Entity
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
(a) Numerical reconciliation of income tax expense				
to prima facie tax payable				
Loss before income tax expense	(24,160)	(17,728)	(24,254)	(17,752)
Tax at the Australian tax rate of 30% (2006 - 30%)	(7,248)	(5,320)	(7,276)	(5,325)
Tax effect of amounts which are not deductible (taxable)				
in calculating taxable income:				
Share-based payments	446	337	446	337
Government research tax incentives	(1,900)	(1,556)	(1,900)	(1,556)
Sundry items	8	(9)	8	(9)
	(8,694)	(6,548)	(8,722)	(6,553)
Under provision in prior years	(251)	(370)	(251)	(370)
Difference in overseas tax rates	(9)	_	_	_
Total	(8,954)	(6,918)	(8,973)	(6,923)
Deferred tax benefits not recognised	8,973	6,923	8,973	6,923
Income tax expense	19	5	_	_
(b) Deferred tax balances				
Deferred tax asset comprises temporary differences				
attributable to the following:				
Interest and Grant receivables	(231)	_	(231)	_
Employee benefits	156	105	150	105
Share capital raising costs	1,637	2,313	1,637	2,313
Revenue in advance	2	16	2	16
	1,564	2,434	1,558	2,434
Deferred tax assets attributable to temporary				
differences which are not recognised	(1,564)	(2,434)	(1,558)	(2,434)
		_	-	_
(c) Tax losses				
Unused tax losses for which no deferred tax asset				
has been recognised	79,219	47,880	79,219	47,880
Potential tax benefit @ 30%	23,766	14,364	23,766	14,364

All unused tax losses were incurred by the parent entity.

# 6. Current assets - Cash and cash equivalents

	Consolidated		Parent Entity	
	2007	2006	2007	2006
	\$'000	\$'000	\$'000	\$'000
Cash at bank and in hand	693	342	606	324
Deposits at call	1,994	349	1,994	349
Bank accepted commercial bills	73,495	97,149	73,495	97,149
	76,182	97,840	76,095	97,822

The weighted average interest rate on cash and bank balances is 5.1% (2006: 3.9%).

Bank accepted commercial bills mature in July, August and September 2007. The weighted average interest rate on the bank accepted commercial bills is 6.30% (2006: 5.8%).

Refer to note 29 for information on financial risks.

## 7. Current assets - Trade and other receivables

	Consolidated		Parent Entity	
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Trade receivables	34	7	34	7
Provision for doubtful debts		_	_	_
	34	7	34	7
Government research grants receivable	407	400	407	400
Prepayments	386	781	386	781
Other receivables	199	183	193	183
	1,026	1,371	1,020	1,371

## 8. Current assets - Inventories

	Consolidated		Parent Entity	
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Raw materials – at cost	61	37	61	37
Work-in-progress – at cost	15	_	15	-
Finished goods – at cost	3	63	3	63
	79	100	79	100

# 9. Non-current assets - Receivables

	Consc	Consolidated		Entity
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Other receivables	5	_	_	_
Prepayments	216	284	216	284
	221	284	216	284

30 June 2007

# 10. Non-current assets - Other financial assets

	Consc	Consolidated		Entity
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Shares in subsidiaries (note 24)	_	_	_	_
Security deposits	380	272	378	267
	380	272	378	267

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

The security deposits are held at fair value.

# 11. Non-current assets - Plant and equipment

Consolidated	Plant and equipment \$'000	Computer equipment \$'000	Leasehold improvements \$'000	Total \$'000
At 1 July 2005				
Cost	3,280	219	165	3,664
Accumulated depreciation	(1,007)	(68)	(112)	(1,187)
Net book amount	2,273	151	53	2,477
Year ended 30 June 2006				
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
At 30 June 2006				
Cost	4,532	435	162	5,129
Accumulated depreciation and impairment	(1,683)	(106)	(135)	(1,924)
Net book amount	2,849	329	27	3,205
Year ended 30 June 2007				
Opening net book amount	2,849	329	27	3,205
Additions	808	182	192	1,182
Disposals	(74)	(1)	_	(75)
Depreciation charge	(631)	(109)	(51)	(791)
Closing net book amount	2,952	401	168	3,521
At 30 June 2007				
Cost	5,223	614	354	6,191
Accumulated depreciation and impairment	(2,271)	(213)	(186)	(2,670)
Net book amount	2,952	401	168	3,521

<sup>\*</sup> The impairment charge relates to the write-down of an item of plant & equipment which was taken out-of-service.

# 12. Non-current assets – Intangible assets

Consolidated and parent	Patents	Trademarks	Software	Total
	\$'000	\$'000	\$'000	\$'000
At 1 July 2005				
Cost	1,589	2	_	1,591
Accumulated amortisation	(485)	_	_	(485)
Net book amount	1,104	2	_	1,106
Year ended 30 June 2006				
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
At 30 June 2006				
Cost	1,574	59	144	1,777
Accumulated amortisation and impairment	(576)	_	(6)	(582)
Net book amount	998	59	138	1,195
Year ended 30 June 2007				
Opening net book amount	998	59	138	1,195
Additions	34	6	152	192
Amortisation charge	(92)	(3)	(53)	(148)
Closing net book amount	940	62	237	1,239
At 30 June 2007				
Cost	1,608	65	296	1,969
Accumulated amortisation and impairment	(668)	(3)	(59)	(730)
Net book amount	940	62	237	1,239

 $<sup>^{\</sup>star}\,$  The impairment charge relates to the write-down of Patent Family 6 which was allowed to lapse.

# 13. Current liabilities - Trade and other payables

	Cons	Consolidated		t Entity
	2007	2006	2007	2006
	\$'000	\$'000	\$'000	\$'000
Trade payables	2,654	813	2,625	813
Other payables	3,290	4,444	3,113	4,390
Trade payables to subsidiary		-	207	56
	5,944	5,257	5,945	5,259

30 June 2007

14. Current liabilities	<ul> <li>Other liabilities</li> </ul>
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	Consolidated		Parent Entity	
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Deferred government research grants	6	48	6	48

# 15. Non-current liabilities - Provisions

	Consolidated		Parent Entity	
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Employee benefits – long service leave	115	63	115	63

# 16. Non-current liabilities - Other liabilities

	Consolidated		Parent Entity	
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Deferred government research grants	_	6	-	6

# 17. Contributed equity

		P		Pare	ent Entity
		2007	2006	2007	2006
	Notes	Shares	Shares	\$'000	\$'000
(a) Share capital					
Ordinary shares	(b),(c)				
Fully paid		177,949,217	176,903,592	135,108	134,745

# Movements in ordinary share capital:

Wovernerite in Grainary	luly 2005 Opening balance 134,770,092 54			
Date	Details		Issue price	\$'000
1 July 2005	Opening balance	134,770,092		54,716
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

## Movements in ordinary share capital:

Date	Details	Number of shares	Issue price	\$'000
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		134,745
19 July 2006	Exercise of employee options	56,000	\$ 0.3125	18
19 July 2006	Exercise of employee options	1,500	\$ 1.7900	3
4 September 2006	Exercise of employee options	10,000	\$ 0.3125	3
19 October 2006	Exercise of employee options	60,000	\$ 0.1250	7
19 October 2006	Exercise of employee options	160,000	\$ 0.3125	50
19 October 2006	Exercise of employee options	25,000	\$ 1.7900	45
6 November 2006	Exercise of employee options	10,000	\$ 0.3125	3
27 November 2006	Exercise of employee options	2,500	\$ 1.1470	3
27 November 2006	Exercise of employee options	10,000	\$ 0.3125	3
27 November 2006	Exercise of employee options	1,500	\$ 1.7900	3
7 December 2006	Exercise of employee options	1,875	\$ 1.7900	3
7 December 2006	Exercise of employee options	110,000	\$ 0.3125	34
7 December 2006	Exercise of employee options	2,500	\$ 0.8340	2
7 December 2006	Exercise of employee options	1,250	\$ 1.7900	2
16 January 2007	Exercise of employee options	3,000	\$ 1.7900	5
23 January 2007	Exercise of employee options	1,500	\$ 1.7900	3
26 February 2007	Exercise of employee options	5,000	\$ 0.8340	4
18 April 2007	Exercise of employee options	12,000	\$ 0.3125	4
23 April 2007	Exercise of employee options	300,000	\$ 0.3125	94
5 June 2007	Exercise of employee options	12,000	\$ 0.3125	4
19 June 2007	Exercise of employee options	150,000	\$ 0.3125	47
21 June 2007	Exercise of employee options	60,000	\$ 0.1250	7
29 June 2007	Exercise of employee options	50,000	\$ 0.3125	16
		177,949,217		135,108

# (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.

# Notes to the Financial Statements

30 June 2007

# 18. Reserves and accumulated losses

	Cons	olidated	Parer	Parent Entity	
	2007	2006	2007	2006	
	\$'000	\$'000	\$'000	\$'000	
(a) Reserves					
Share-based payments reserve	4,009	2,521	4,009	2,521	
Foreign currency translation reserve		1	-	_	
	4,009	2,522	4,009	2,521	
Share-based payments reserve					
Balance 1 July	2,521	1,397	2,521	1,397	
Option expense	1,488	1,124	1,488	1,124	
Balance 30 June	4,009	2,521	4,009	2,521	
Foreign currency translation reserve					
Balance 1 July	1	_	_	-	
Currency translation differences arising during the year	(1)	1	-	_	
Balance 30 June		1	_	_	
(b) Accumulated losses					
Movements in accumulated losses were as follows:					
Balance 1 July	(38,379)	(20,646)	(38,398)	(20,646)	
Net loss for the year	(24,179)	(17,733)	(24,254)	(17,752)	
Balance 30 June	(62,558)	(38,379)	(62,652)	(38,398)	

# (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 director

Alan Duncan Robertson (Managing Director and Chief Executive Officer)

### (iii) Non-executive directors

Brigitte Helen Smith (resigned 26 October 2006)

Charles Peter Hunt Kiefel

Malcolm John McComas

Peter Craig Farrell

John Villiger (appointed 15 November 2006)

### (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:

Name	Position	Employer
John Francis Crapper	Chief Operations Officer	Pharmaxis Ltd
lan Alexander McDonald	Chief Scientific 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 2006. W B Cowden (Chief Scientific Officer) ceased to be a member of key management personnel effective 30 June 2006.

### (c) Key management personnel compensation

	Consolidated		Parent Entity	
	2007	2006	2007	2006
	\$	\$	\$	\$
Short-term employee benefits	1,796,306	1,761,612	1,796,306	1,761,612
Post-employment benefits	137,053	132,118	137,053	132,118
Long-term benefits	30,311	16,005	30,311	16,005
Share-based payments	690,429	600,666	690,429	600,666
	2,654,099	2,510,401	2,654,099	2,510,401

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.

30 June 2007

### 19. Key management personnel disclosures (continued)

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

(i) Options provided as remuneration and shares issued on exercise of such optionsDetails 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.

### (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.

2007	Balance at the start of	Granted during the year as	Exercised during the	Other changes during	Balance at the end of	Vested and exercisable at the end
Name	the year	compensation	year	the year	the year	of the year
Directors of Pharmaxis Ltd						
DM Hanley	1,080,000	40,000	_	_	1,120,000	1,100,000
AD Robertson	2,230,000	150,000	_	_	2,380,000	2,192,500
CPH Kiefel	220,000	48,957	(200,000)	_	68,957	58,957
MJ McComas	220,000	20,000	_	_	240,000	230,000
PC Farrell	_	220,000	_	_	220,000	70,000
J Villiger	_	_	_	_	_	-
Other key management perso	onnel of the Gr	roup				
JF Crapper	760,000	100,000	(300,000)	_	560,000	435,000
IA McDonald	220,000	100,000	_	_	320,000	160,000
B Charlton	1,065,000	105,000	(110,000)	_	1,060,000	928,750
DM McGarvey	1,060,000	100,000	_	_	1,160,000	1,035,000
GJ Phillips	605,000	100,000	_	_	705,000	577,500
				0.11		
2006	Balance at	Granted during the	Exercised	Other changes	Balance at	Vested and exercisable
	the start of	year as	during the	during	the end of	at the end
Name	the year	compensation	year	the year	the year	of the year
Directors of Pharmaxis Ltd						
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
Other key management perso	onnel of the Gr	roup				
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

 $<sup>^{\</sup>ast}\,$  W B Cowden ceased to be a member of key management personnel effective 30 June 2006.

### (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).

2007		Received during		
	Balance at the	the year on the	Other changes	Balance at the
Name	start of the year	exercise of options	during the year	end of the year
Directors of Pharmaxis Ltd				
Ordinary shares				
DM Hanley	774,661	_	10,000	784,661
AD Robertson	100,000	-	-	100,000
CPH Kiefel	200,000	200,000	(200,000)	200,000
MJ McComas	139,999	-	-	139,999
BH Smith <sup>1</sup>	-	-	-	_
P Farrell	101,645	-	-	101,645
J Villiger	_	_	_	_
Other key management per	rsonnel of the Group			
Ordinary shares				
JF Crapper	2,000	300,000	(300,000)	2,000
IA McDonald	-	-	-	_
B Charlton	660,000	110,000	(750,000)	20,000
DM McGarvey	45,000	-	-	45,000
GJ Phillips	6,664		6,664	

2006		Received during		
Name	Balance at the start of the year	the year on the exercise of options	Other changes during the year	Balance at the end of the year
Directors of Pharmaxis L	td			
Ordinary shares				
DM Hanley	734,661	_	40,000	774,661
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>	_	_	_	_
P Farrell	_	_	101,645	101,645
Other key management p	personnel of the Group			
Ordinary shares				
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	

 $<sup>^{\</sup>ast}\,$  W B Cowden ceased to be a member of key management personnel effective 30 June 2006.

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### 19. Key management personnel disclosures (continued)

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, held 14,307,220 shares as at 30 June 2006.
GBS Venture Partners Ltd as trustee and manager of Bioscience Venture II, held 7,481,890 shares as at 30 June 2006.
BH Smith was not a director as at 30 June 2007.

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

There were no other transactions with key management personnel during the year ended 30 June 2007.

### 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:

	Cons	solidated	Parent Entity	
	2007	2006	2007	2006
	\$	\$	\$	5
a) Assurance services				
udit services				
ricewaterhouseCoopers Australian firm				
Audit and review of financial reports and				
other audit work under the Corporations Act 2001	149,425	137,000	149,425	137,000
Audit of US GAAP financial report	30,000	20,000	30,000	20,000
Related practices of PricewaterhouseCoopers Australian firm				
Audit of US GAAP financial report	83,340	76,176	83,340	76,176
Ion-PricewaterhouseCoopers audit firm for the audit of the				
nancial report of Pharmaxis Pharmaceuticals Limited	20,104	_	-	-
otal remuneration for audit services	282,869	233,176	262,765	233,176
Other assurance services				
ricewaterhouseCoopers Australian firm				
Audit of government research grant claims	6,500	10,500	6,500	10,500
Review of the December 2006 US GAAP interim				
financial statements including December 2005				
comparatives for the filing of the shelf F-3 document	22,175	_	22,175	-
Purchasing & payables process review	18,500	_	18,500	-
Sarbanes Oxley readiness review	43,092	_	43,092	-
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
Related practices of PricewaterhouseCoopers Australian firm				
Review of Shelf F-3 document	61,542	_	61,542	-
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
otal remuneration for other assurance services	151,809	444,976	151,809	444,976

	Cons	olidated	Parent Entity	
	2007	<b>2007</b> 2006	2007	2006
	\$	\$	\$	\$
(b) Non-audit services				
Taxation services				
PricewaterhouseCoopers Australian firm				
International tax consulting and tax advice	9,986	25,973	9,986	25,973
Tax compliance services	12,000	_	12,000	_
Total remuneration for taxation services	21,986	25,973	21,986	25,973
Total remuneration for non-audit services	21,986	25,973	21,986	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.

### 21. Contingent liabilities

The parent entity and Group had contingent liabilities at 30 June 2007 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 2007 was \$4,707,817 (2006: \$4,707,817).

The company received \$1,954,592 (2006: \$848,476) 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 does 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 Goodman International 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 Goodman International 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 \$177,168 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.

The company's bankers have issued a bank guarantee of GBP40,000 in relation to corporate credit card facilities provided by an overseas affiliate of the banker to Pharmaxis Pharmaceuticals Limited. This bank guarantee is secured by a deposit held at the bank.

30 June 2007

### 22. Commitments

### (a) Capital Commitments

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

	Consolidated		Parent Entity	
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
	<b>4</b> 000	Ψ σσσ	<u> </u>	Ψ
Plant and equipment				
Payable: Within one year	85	396	85	396
(b) Lease Commitments				
Commitments in relation to leases contracted for at the reporting date but not recognised as liabilities payable:				
Within one year	401	389	401	389
Later than one year but not later than five years	1,071	1,389	1,071	1,389
	1,472	1,778	1,472	1,778

### (i) Operating leases

The Group leases various premises 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	
	2007 \$	2006	2007 \$	2006
Rental income of plant and equipment to subsidiary	-	-	_	414
Marketing, clinical and administration services expenditure paid to subsidiary		_	1,157,829	273,287

### (e) Outstanding balances arising from transactions

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

	Conso	Consolidated		t Entity
	2007	2006	2007	2006
	\$	\$	\$	\$
Current payables				
Subsidiaries	_	_	206,622	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.

### 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
			2007	2006
			%	%
Pharmaxis Pharmaceuticals Limited	United Kingdom	Ordinary	100	100

Pharmaxis Pharmaceuticals Limited (previously known as Pharmaxis UK Limited) was incorporated on 3rd 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 2007 that has significantly affected, or may significantly affect:

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

### 26. Financial reporting by segments

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

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

30 June 2007

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

	Cons	olidated	Parent Entity	
	2007	2006	2007	2006
	\$'000	\$'000	\$'000	\$'000
Loss for the year	(24,179)	(17,733)	(24,254)	(17,752)
Depreciation and impairment of plant & equipment	791	804	788	804
Amortisation and impairment of intangibles	148	143	148	143
Non-cash employee benefits expense-share based payments	1,488	1,124	1,488	1,124
Net loss on disposal of non-current assets	24	40	14	40
Change in operating assets and liabilities				
Increase in trade debtors	(27)	(7)	(27)	(7)
Decrease / (increase) in inventories	21	(100)	21	(100)
Decrease / (increase) in other operating assets	327	(956)	334	(951)
Increase in trade creditors	1,841	56	1,812	56
(Decrease) / increase in other operating liabilities	(1,183)	2,817	(1,174)	2,813
Increase in other provisions	52	37	52	37
Net cash outflow from operating activities	(20,697)	(13,775)	(20,798)	(13,793)

### 28. Earnings per share

	Consolidated	
	2007	2006
	Cents	Cents
(a) Basic earnings per share		
Loss attributable to the ordinary equity holders of the company	(13.6)	(11.1)
(b) Diluted earnings per share		
Loss attributable to the ordinary equity holders of the company	(13.6)	(11.1)
(c) Weighted average number of shares used as the denominator		
Weighted average number of ordinary shares used as the denominator		
in calculating basic and diluted earnings / (loss) per share	177,285,390	160,349,332

### (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 and other receivables, 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 three 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 percent 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. Once vested, the options remain exercisable for up to 10 years from the grant date or termination of employment (whichever is earlier). 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.

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 2007			Year ended 2006			
Exercise date	Fair value of shares at issue date	Number	Exercise date	Fair value of shares at issue date	Number	
19 July 2006	\$ 1.75	56,000	5 August 2005	\$ 1.75	40,000	
19 July 2006	\$ 1.75	1,500	9 September 2005	\$ 2.26	72,000	
4 September 2006	\$ 2.04	10,000	9 September 2005	\$ 2.20	100,000	
19 October 2006	\$ 2.70	60,000	6 October 2005	\$ 2.69	16,000	
19 October 2006	\$ 2.70	160,000	17 November 2005	\$ 2.24	48,000	
19 October 2006	\$ 2.70	25,000	9 December 2005	\$ 2.01	7,500	
6 November 2006	\$ 2.91	10,000	31 January 2006	\$ 2.00	640,000	
27 November 2006	\$ 3.32	2,500	10 February 2006	\$ 2.20	30,000	
27 November 2006	\$ 3.32	10,000	4 May 2006	\$ 2.44	300,000	
27 November 2006	\$ 3.32	1,500	6 June 2006	\$ 2.08	640,000	
7 December 2006	\$ 3.08	1,875	6 June 2006	\$ 2.08	840,000	

30 June 2007

### 30. Share-based payments (continued)

Year ended 2007			Year ended 2006			
	Fair value of shares at			Fair value of shares at		
Exercise date	issue date	Number	Exercise date	issue date	Number	
7 December 2006	\$ 3.08	110,000				
7 December 2006	\$ 3.08	2,500				
7 December 2006	\$ 3.08	1,250				
16 January 2007	\$ 2.99	3,000				
23 January 2007	\$ 3.00	1,500				
26 February 2007	\$ 3.32	5,000				
18 April 2007	\$ 3.60	12,000				
23 April 2007	\$ 3.46	300,000				
5 June 2007	\$ 3.45	12,000				
19 June 2007	\$ 3.30	150,000				
21 June 2007	\$ 3.26	60,000				
29 June 2007	\$ 3.30	50,000				
		1,045,625			2,733,500	

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 7,826,645 vested options at 30 June 2007 (7,772,625 at 30 June 2006). There are no options under escrow (Nil at 30 June 2006). Set out below are summaries of options granted under the plan:

Expiry date	Exercise price	Balance at start of the year	Granted during the year	Exercised during the year	Forfeited during the year	Balance at end of the year	Vested at end of the year
		Number	Number	Number	Number	Number	Number
and Parent Entity	<i>y</i> – 2007						
30 Nov 2009	\$ 0.1250	1,120,000	_	_	_	1,120,000	1,120,000
30 June 2010	\$ 0.1250	60,000	_	60,000	_	_	-
30 Aug 2011	\$ 0.3125	640,000	_	_	_	640,000	640,000
30 Nov 2011	\$ 0.1250	160,000	_	60,000	_	100,000	100,000
30 June 2012	\$ 0.3125	3,502,000	_	380,000	_	3,122,000	3,122,000
30 Nov 2012	\$ 0.3125	480,000	_	_	_	480,000	480,000
30 April 2013	\$ 0.3125	216,000	_	200,000	_	16,000	16,000
30 June 2013	\$ 0.3125	660,000	_	300,000	_	360,000	360,000
3 July 2013	\$ 0.3125	200,000	_	_	_	200,000	200,000
30 Nov 2013	\$ 0.3760	500,000	_	_	_	500,000	500,000
24 April 2014	\$ 0.5080	22,500	_	_	_	22,500	15,000
3 June 2014	\$ 0.4260	15,000	_	_	_	15,000	11,250
1 Feb 2015	\$ 0.8340	255,000	_	7,500	7,500	240,000	147,500
11 May 2015	\$ 1.1470	330,000	_	2,500	7,500	320,000	185,000
4 Aug 2015	\$ 1.7900	954,500	_	35,625	118,875	800,000	400,000
16 Oct 2015	\$ 2.7720	155,000	_	_	85,000	70,000	35,000
12 Feb 2016	\$ 2.1940	310,000	_	_	40,000	270,000	67,500
	30 Nov 2009 30 June 2010 30 Aug 2011 30 Nov 2011 30 June 2012 30 Nov 2012 30 April 2013 30 June 2013 30 June 2013 30 June 2013 24 April 2014 3 June 2014 1 Feb 2015 11 May 2015 4 Aug 2015 16 Oct 2015	And Parent Entity – 2007  30 Nov 2009 \$ 0.1250  30 June 2010 \$ 0.1250  30 Aug 2011 \$ 0.3125  30 Nov 2011 \$ 0.3125  30 June 2012 \$ 0.3125  30 Nov 2012 \$ 0.3125  30 April 2013 \$ 0.3125  30 June 2013 \$ 0.3125  30 Nov 2013 \$ 0.3125  30 Nov 2013 \$ 0.3125  30 Nov 2013 \$ 0.325  31 June 2014 \$ 0.4260  1 Feb 2015 \$ 0.8340  11 May 2015 \$ 1.7900  16 Oct 2015 \$ 2.7720	Expiry date	Expiry date	Expiry date	Expiry date         Exercise price         start of the year         during the year         the year         humber           and Parent Entity - 2007	Expiry date         Exercise price         start of the year the year         during the year the year         during the year the year         during the year         during the year         during the year         during the year         the year         humber         Number         Number

Grant date	Expiry date	Exercise price	Balance at start of the year	Granted during the year	Exercised during the year	Forfeited during the year	Balance at end of the year	Vested at end of the year
			Number	Number	Number	Number	Number	Number
Consolidated a	and Parent Entity	· – 2007						
1 June 2006	31 May 2016	\$ 2.0340	111,500	_	_	15,000	96,500	24,125
15 Aug 2006	14 Aug 2016	\$ 1.9170	_	649,500	_	22,250	627,250	156,813
26 Oct 2006	14 Aug 2016	\$ 1.9170	_	278,957	_	_	278,957	166,457
20 Sept 2006	19 Sept 2016	\$ 1.8918	_	72,500	_	25,000	47,500	11,875
26 Oct 2006	15 Mar 2016	\$ 2.0680	_	200,000	_	_	200,000	50,000
14 Dec 2006	13 Dec 2016	\$ 3.0710	_	80,000	_	7,500	72,500	18,125
18 Jun 2007	17 Jun 2017	\$ 3.3155	_	237,500	_	_	237,500	_
Total			9,691,500	1,518,457	1,045,625	328,625	9,835,707	7,826,645
Weighted avera	ge exercise price		\$ 0.597	\$ 2.215	\$ 0.347	\$ 2.113	\$ 0.823	\$ 0.512
Consolidated a	and parent entity	- 2006						
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 Aug2011	\$ 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 Aug 2005	4 Aug 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 2006	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 avera	ge exercise price		\$ 0.308	\$ 1.990	\$ 0.218	\$ 1.287	\$ 0.597	\$ 0.362

There were 328,625 options forfeited during 2007 (30,000 options during 2006).

The weighted average remaining contractual life of share options outstanding at the end of the period was 6.01 years (2006 – 6.52 years).

Fair value of options granted

The assessed fair value at grant date of options granted during the year ended 30 June 2007 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 weighted average 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.

30 June 2007

### 30. Share-based payments (continued)

The model inputs for options granted during the year ended 30 June 2007 are as follows:

Grant date	No. of options granted	Exercise Price	Share Price	Time to expiration (days)	Volatility (%)	Annual interest rate (%)	Option value
15 August 2006	649,500	\$ 1.9170	\$ 1.90	3,650	50%	5.93%	\$ 1.3277
20 September 2006	72,500	\$ 1.8918	\$ 1.85	3,650	50%	5.62%	\$ 1.2993
26 October 2006	278,957	\$ 1.9170	\$ 3.00	3,650	50%	5.73%	\$ 1.3167
26 October 2006	200,000	\$ 2.0680	\$ 3.00	3,650	50%	5.73%	\$ 1.4204
14 December 2006	80,000	\$ 3.0710	\$ 3.10	3,650	50%	5.73%	\$ 2.1093
18 June 2007	237,500	\$ 3.3155	\$ 3.30	3,650	50%	6.27%	\$ 2.3107
	1,518,457						

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:

	Consc	Consolidated		t Entity
	2007 \$'000	2006 \$'000	2007 \$'000	2006 \$'000
Options issued under employee option plan	1,488	1,124	1,488	1,124

## **Directors' Declaration**

In the directors' opinion:

- (a) the financial statements and notes set out on pages 52 to 82 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 2007 and of its performance 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

Ala D. Kobertin

Director

Sydney

9 August 2007



Independent auditor's report

to the members of Pharmaxis Limited

### PricewaterhouseCoopers ABN 52 780 433 757

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# Report on the financial report and the AASB 124 Remuneration disclosures contained in the directors' report

We have audited the accompanying financial report of Pharmaxis Ltd (the company), which comprises the balance sheet as at 30 June 2007, and the income statement, statement of changes in equity and cash flow statement for the year/period ended on that date, a summary of significant accounting policies, other explanatory notes and the directors' declaration for both Pharmaxis Ltd and the Pharmaxis Ltd Group (the consolidated entity). The consolidated entity comprises the company and the entities it controlled at the year's end or from time to time during the financial year.

We have also audited the remuneration disclosures contained in the directors' report. As permitted by the *Corporations Regulations 2001*, the company has disclosed information about the remuneration of directors and executives ("remuneration disclosures"), required by Accounting Standard AASB 124 *Related Party Disclosures*, under the heading "remuneration report" in pages 36 to 45 of the directors' report and not in the financial report.

Directors' responsibility for the financial report and the AASB 124 Remunerations disclosures contained in the directors' report

The directors of the company are responsible for the preparation and fair presentation of the financial report in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001*. This responsibility includes establishing and maintaining internal control relevant to the preparation and fair presentation of the financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances. In Note 1(a), the directors also state, in accordance with Accounting Standard AASB 101 *Presentation of Financial Statements*, that compliance with the Australian equivalents to International Financial Reporting Standards ensures that the financial report, comprising the financial statements and notes, complies with International Financial Reporting Standards

The directors of the company are also responsible for the remuneration disclosures contained in the directors' report.

Auditor's responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. These Auditing Standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement. Our responsibility is to also express an opinion on the remuneration disclosures contained in the directors' report based on our audit.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report and the remuneration disclosures contained in the directors' report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report and the remuneration disclosures contained in the directors' report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial report and the remuneration disclosures contained in the directors' report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report and the remuneration disclosures contained in the directors' report.

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

For further explanation of an audit, visit our website http://www.pwc.com/au/financialstatementaudit.

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

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions.

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) for the financial year ended 30 June 2007 included on the 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 above. It does not provide an opinion on any other information which may have been hyperlinked to/from the financial report or 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.

Independence

In conducting our audit, we have complied with the independence requirements of the Corporations Act 2001.

Auditor's opinion on the financial report

In our opinion:

- (a) the financial report of Pharmaxis Ltd is in accordance with the Corporation Act 2001, including:
  - giving a true and fair view of the company's and consolidated entity's financial position as at 30 June 2007and of their performance for the year ended on that date; and
  - (ii) complying with Australian Accounting Standards (including the Australian Accounting Interpretations) and the Corporations Regulations 2001; and
- (b) the consolidated financial statements and notes also comply with International Financial Reporting Standards as disclosed in Note 1(a).

Auditor's opinion on the AASB 124 Remuneration disclosures contained in the directors' report

In our opinion, the remuneration disclosures that are contained in pages 36 to 45 of the directors' report comply with Accounting Standard AASB 124.

Pricewaterhouse Coopers

WHB Seaton Partner Sydney 9 August 2007

## **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	Р	G	P/G <sup>1</sup>
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	Р	Р	G/P
Patent Family 5 - Novel pyrans and methods (PXS25)	NP	NP	NP	NP
Patent Family 7 - Novel inhibitors of TNF (PXS2076)	Prov			

G = granted; P = pending; Prov = provisional; PCT = patent cooperation treaty; NP = national phase ROW = rest of the world including Japan; (1) Aridol granted in Japan

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	Granted	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.

### Patents and Patent Applications

### 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	Request examination by May 20 2009	
New Zealand	544085	Under examination		
Australia	2004240938	Request examination	by May 20 2009	
Europe	04752819.5	Under examination		
Singapore	200507071-9	Under 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 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 2007 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 31 August 2007.

### 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	793		
1,001 – 5,000	1,923	3	
5,001 - 10,000	913	8	
10,001 – 100,000	1,225	42	
100,001 and over	122	15	
	4,976	68	

There were 123 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	27,088,202	15.22	
National Nominees Limited	17,008,251	9.55	
HSBC Custody Nominees (Australia) Limited	11,035,881	6.2	
GBS Venture Management Pty Ltd	9,382,551	5.27	
J P Morgan Nominees Australia Limited	6,484,888	3.64	
GBS Venture Partners Ltd	4,906,559	2.76	
CM Capital Investments Pty Ltd	4,640,455	2.61	
Cogent Nominees Pty Limited	4,338,251	2.44	
KFT Investments Pty Ltd	3,124,864	1.76	
CS Fourth Nominees Pty Ltd	2,764,983	1.55	
The Australian National University	2,650,000	1.49	
Equity Trustees Limited	2,154,701	1.21	
Citicorp Nominees Pty Limited	2,031,525	1.14	
CIBC Australia VC Fund LLC	1,674,872	0.94	
Sayers Investments (ACT) Pty Limited	1,335,348	0.75	
Citicorp Nominees Pty Ltd	856,162	0.48	
UBS Nominees Pty Ltd	822,501	0.46	
HSBC Custody Nominees (Australia) Limited-Gsco ECA	800,661	0.45	
Mr Joseph James Pagliaro	800,000	0.45	
Turnbull Bros Orchard Pty Ltd	800,000	0.45	

### Unquoted equity securities

	Number on issue	Number of holders
Options issued under the Pharmaxis Ltd Employee Option Plan	11,628,207	68

### C. Substantial holders

Substantial holders in the company are set out below:

	Number held	Percentage	
Orbis Global Equity Fund Limited	26,129,674	15%	
Acorn Capital Limited	9,680,390	5%	
Platypus Asset Management Pty Limited	9,655,050	5%	
GBS Venture Partners Ltd as Manager of the Australian Bioscience Trust	9,382,551	5%	

### 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.

### **Background Information**

### **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 lung function improves with inhaled 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.

### **Background Information**

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

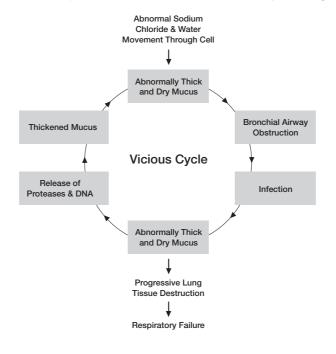
### What is cystic fibrosis?

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

ADEC Australian Drug Evaluation Committee

ADR 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.

agonist A molecule capable of combining with a biochemical receptor on a cell and initiating

the same response as occurs naturally

airway responsiveness

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

analgesic Relieving pain; a pain-relieving drug

antagonist 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

Aridol™ 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.

asthma Refer to disease information earlier in this section

ASX Australian Stock Exchange

autoimmune 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

beta interferon 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.

**blinding/blindness**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.

breakdown products Products that result from the disintegration or decomposition of a substance

in the body

bronchial hyper-responsiveness

or over-sensitivity

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

bronchial provocation test

A lung test that provokes a temporary narrowing of the bronchial tubes in the lungs

bronchiectasis Refer to disease information earlier in this section

**Bronchitol™** Bronchitol™ is a patented, dry powder formulation of mannitol delivered to the lungs

through an inhaler. Bronchito  $\hspace{-0.1em}^{\text{\tiny TM}}$  is designed for the treatment of diseases such as

COPD and cystic fibrosis.

bronchodilator A substance that acts to dilate or expand the bronchial airway passages, making

it easier for patients to breathe

carcinogenicity Potential to cause cancer

central nervous system System of nerves of the brain and spinal cord

**chemoattractant** A chemical agent that induces movement of cells in the direction of its highest

concentration

**chest percussion** 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

**chronic** A disease or condition of long duration or frequent recurrence; in some instances,

it may slowly become more serious over time

**chronic bronchitis** Refer to disease information earlier in this section

chronic obstructive

pulmonary disease

Refer to disease information earlier in this section

cilia 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)

ciliated cell An epithelial cell which has cilia on its external surface. Found in the lungs and other

airway passages such as bronchi and nose.

clinical trial Refer to explanation/diagram later in this section

Cooperative Research Centre for Asthma and Airways (CRCAA)

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.

COPD Chronic obstructive pulmonary disease. Refer to disease information earlier in

this section

corticosteroids 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.

cystic fibrosis (CF) Refer to disease information earlier in this section

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.

dose response curve 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.

dosing phase Refer to explanation/diagram later in this section

endothelial An endothelial cell layer refers to the layer of cells that lines the blood vessels

and airways

epithelial mast cells 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.)

eucapnic hyperpnoea Eucapnic (adjective) is defined as a normal healthy level of carbon dioxide (CO<sub>2</sub>).

Hyperphoea is abnormally fast breathing.

### Glossary of Terms

European Medicines Agency (EMEA) The EMEA is an agency that coordinates the evaluation and supervision of medicinal

products throughout the European Union.

exercise challenge test

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.

**exocrine glands** Glands that produced mucus, saliva, sweat and tears

FDA United States of America's Food and Drug Administration

flare or flare-up A period of worsening symptoms

GMP 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

goblet cell A mucus-secreting epithelial cell that is distended with secretion, so called because

of its histological shape.

head-to-head trial A clinical trial in which a test compound is evaluated against another compound

hypertonic saline 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.

indirect challenge test

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.

International Committee on Harmonisation (ICH)

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

in vitro In an artificial environment, outside the living body e.g. in a test tube

in vivo In the living body of a plant or animal, or in real life

leukocytes Immune cells; white blood cells

ligand A molecule that binds to cell receptors

lung function Ability of a person to move air in and out of their lungs. A measure often used is

termed  $\ensuremath{\mathsf{FEV}}_1$ , which is the volume of air that can be forcibly expelled from the lungs

in one second

lymphocyte 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

mannitol Mannitol is a naturally occurring sugar alcohol used variously as a food additive,

a therapeutic product, and a sweetener.

marketing authorisation The legal authority granted to an individual or company to sell a product

meta-analysis Pooling and examining data from a number of studies

methacholine inhalation test

A test used in the diagnosis of asthma. Methacholine is inhaled as a vapour and

causes bronchial constriction in asthmatic patients.

mucociliary clearance 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.

mucosal hydration The natural process of keeping mucus hydrated to prevent it becoming thick and

sticky i.e. maintaining the correct balance of water

mucus Thin, slippery substance secreted by the lungs (and other organs in the body)

to defend against germs, dust particles and other foreign bodies

multi-centre study Study conducted simultaneously in a number of clinics, hospitals, etc

multiple sclerosis (MS)

Refer to disease information earlier in this section

myelin The protective protein sheath that insulates the nerve cells and helps speed the

conduction of nerve signals to the brain and spinal cord

NASDAQ National Association of Securities Dealers Automated Quotation system (US)

**nebulised medication** Medication delivered to the lungs of patients in fine spray by aerosol or

face mask

oral medication Medication taken by mouth e.g. tablets, liquids

orphan drug 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.

osmotic balance 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.

P3 Pharmaceuticals Partnerships Program (Australian Federal government grant program)

**pathogen** Disease-causing microorganism

PBS Pharmaceutical Benefits Scheme (Australian government program that reduces the cost

of some drugs to patients)

PCT Patent Cooperation Treaty

PEP mask A mask worn over the nose and mouth, which pumps air into the lungs (positive

expiratory pressure)

pharmaco-economic evaluation Evaluation of the potential of a new pharmaceutical product to produce cost savings

to a national economy

pharmacokinetic profile How a drug interacts in the body in terms of its absorption, distribution, metabolism,

and excretion

phase III registration study

Refer to explanation/diagram later in this section

phase II clinical trial

Refer to explanation/diagram later in this section

pilot clinical study Refer to explanation/diagram later in this section

placebo An inert or innocuous substance used especially in controlled experiments to test

and compare the efficacy of another, active, substance

postural drainage A method of draining the lungs in which the patient is placed in an inverted position

so that fluids are drawn by gravity

pre-clinical Prior to being administered to volunteers or patients

### Glossary of Terms

primary cilia dysplasia Dysplasia means a cell is abnormally shaped or abnormally functioning. Ciliary

dysplasia is a genetic disease where the cilia do not function properly.

pro-drug An inactive precursor of a drug, converted into its active form in the body by normal

metabolic processes.

protease An enzyme that breaks the internal bonds of a protein

psoriasis A chronic skin disease characterised by red patches covered with white scales

pulmonary function Refer to lung function, above

**pulmonary system** Lungs

**pyran** A sugar derivative

PXS64 A compound being developed by Pharmaxis to target the underlying disease processes

of multiple sclerosis

PXS74 A compound being investigated by Pharmaxis for its effects on asthma

**R&D** Research and development

relapse A recurrence of symptoms of a disease after a period of improvement or remission

remission Period when the symptoms of the patient's disease are not present respiratory failure A clinical term used to define the inability of the lungs to function

respiratory insufficiency A clinical term used to define a failure to adequately provide sufficient oxygen to the

body, or remove excess carbon dioxide

**rheology** The study of the flow of materials that behave in an interesting or unusual manner

rheumatoid arthritis Refer to disease information earlier in this section

safety profile Evidence gathered that indicates a substance is safe to be administered to people

secondary lung infections Infection coming after, or as a result of, an initial or primary infection selective inhibitor

A substance that is used to stop a specific biochemical reaction

spirometer; spirometry test

A device used to measure the amount of air a patient can expel from their lungs

in one second

**sputum microbiology** A measure of lung infections

statistical significance A mathematical test that indicates that groups being compared are different

steroid Numerous natural or synthetic compounds that contain a 17-carbon 4-ring system

and can modify reactions in the body

**submucosal glands**The glands situated in the connective tissue beneath the mucous membrane.

synthesis, synthetic compound A substance that is made by a series of chemical or biochemical reactions

T-cells Immune cells that attach themselves to other cells

therapeutic Medicinal, curative

TGA Australia's Therapeutic Goods Administration

toxicology study Investigation into the adverse effects of a substance in an animal or human

Tumour Necrosis Factor (TNF) A small molecular-weight protein produced primarily by immune cells. It is a key

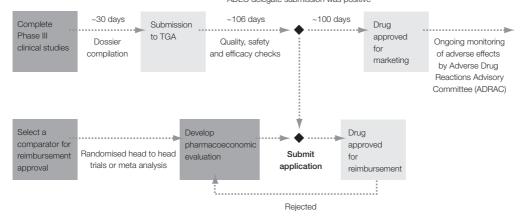
protein responsible for initiating inflammation

viscosity A physical property of fluids that determines the internal resistance to shear forces

(the resistance a material has to change in form)

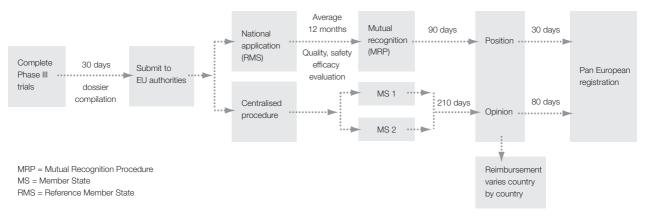
### Drug registration and reimbursement process in Australia

Point at which approval looks likely – 'ADEC delegate submission was positive'

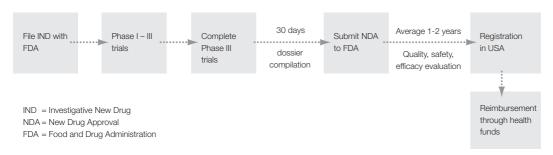


- Pharmacoeconomic evaluation against comparator
- Estimate implications for PBS
- Estimate usage over 2 years

### 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.

# Corporate Directory

### **Directors**

Denis Hanley - Chairman Alan Robertson - CEO Peter Farrell Charles Kiefel Malcolm McComas John Villiger

### Company Secretary and Chief Financial Officer

David McGarvey

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HSBC Bank Australia Ltd Westpac Banking Corporation

### **Patent Attorney**

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### Stock Exchange Listings

Pharmaxis shares are listed on the Australian Securities Exchange (Code: PXS)

Pharmaxis American Depositary Receipts (ADRs) are listed on the National Association of Securities Dealers Automated Quotation system (NASDAQ) Global Market (Code: PXSL)

### **Share Registry**

Computershare Investor Services Pty Ltd Level 3, 60 Carrington Street Sydney NSW 2000 Australia

Telephone: 1300 855 080 Fax: +61 3 9473 2500 www.computershare.com

Shareholders can access information and services relevant to their holding from the Pharmaxis website under Investor Information/Shareholder Services

### **American Depositary Receipts** Registrar and Transfer Agent:

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