

pharmaxis

# New Therapies for Respiratory Diseases

2008 Statutory Annual Report



This Statutory Annual Report will be lodged with the Australian Securities Exchange and the Australian Securities and Investments Commission and is available from our website [www.pharmaxis.com.au](http://www.pharmaxis.com.au).

This Statutory Annual Report will also form part of an annual regulatory filing which we make in the United States. As a result, this Statutory Annual Report includes more information than we have typically included in prior years and the presentation and style of this Statutory Annual Report differs from prior years.

Information contained in or otherwise accessible through the websites mentioned in this Statutory Annual Report does not form part of the report unless specifically stated to incorporate the information by reference. All other references in this Statutory Annual Report to websites are inactive textual references and the information contained therein is not incorporated by reference into this Statutory Annual Report.

In this Statutory Annual Report, the terms 'we,' 'our,' 'us,' 'Pharmaxis', 'Group' and 'Company' refer to Pharmaxis Ltd ABN 75 082 811 630 and its subsidiaries unless the context clearly means just Pharmaxis Ltd.

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# Section



## 1.1 Important Information

### Forward Looking Statements

This Statutory Annual Report contains statements that constitute 'forward-looking statements' within the meaning of section 21E of the United States Securities Exchange Act of 1934, as amended ('Securities Exchange Act'). The United States Private Securities Litigation Reform Act of 1995 provides a 'safe harbour' for forward-looking information to encourage companies to provide prospective information about themselves without fear of litigation so long as the information is identified as forward-looking and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those projected in the information.

Forward-looking statements appear in a number of places in this Statutory Annual Report. In some cases, you can identify forward-looking statements by terminology such as 'may,' 'will,' 'should,' 'expects,' 'plans,' 'anticipates,' 'believes,' 'estimates,' 'predicts,' 'potential,' or 'continue,' or the negative of these terms or other comparable terminology. These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we are under no duty to update or revise any of our forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this Statutory Annual Report.

### Currency of Presentation

We publish our consolidated financial statements in Australian dollars. In this Statutory Annual Report, unless otherwise stated or the context otherwise requires, references to 'dollar amounts', '\$', 'AUD' or 'A\$' are to Australian dollars. References to 'US\$', 'USD' or 'US dollars' are to United States dollars.

Certain Australian dollar amounts have been translated into US dollars at specified rates. The amounts have been translated into U.S. dollars from Australian dollars based upon the noon buying rates in New York City as determined by the Federal Reserve Bank of New York on 30 June 2008, which was A\$1.00 to US\$0.9562. These translations are merely for the convenience of the reader and should not be construed as representations that the Australian dollar amounts actually represent such U.S. dollar amounts or could be converted into U.S. dollars at the rate indicated.

Exchange Rate information is presented in Section 4.2.10 of this report.

## 1.2 Information on Pharmaxis

### 1.2.1 History and Development of Pharmaxis

Pharmaxis Ltd is a public company limited by shares which is domiciled in Australia and operates under, and is subject to, Australian law. Our Australian Company Number is 082 811 630 and our Australian Business Number is 75 082 811 630.

We were incorporated under Australian law on 29 May, 1998 under the name 'Praxis Pharmaceuticals Australia Pty Ltd.' On 6 June, 2002, we changed our name to 'Pharmaxis Pty Ltd.' On 5 September, 2003, we changed our name to 'Pharmaxis Ltd' to reflect the change of company type from a proprietary company limited by shares to a public company limited by shares undertaken at that time. Our ordinary shares are quoted on the Australian Securities Exchange ('ASX') and our American Depositary Shares ('ADS') are quoted on the Nasdaq Global Market. Each ADS represents 15 ordinary shares.

In November 2003 we completed an initial public offering in Australia of 50 million of our ordinary shares and received A\$22.9 million after payment of underwriting fees and offering expenses. In November 2005 we completed a public offering in the U.S. of 1.3 million ADSs and a simultaneous placement in Australia of 19.9 million ordinary shares and received A\$79.4 million after payment of underwriting fees and offering expenses. We have completed other share (and ADS) issues which are described in Section 2.2.5 – Liquidity and Capital Resources.

Our principal place of business is Unit 2, 10 Rodborough Road, Frenchs Forest, NSW 2086, Australia, and our primary telephone number is +61 2 9454 7200.

## 1.2.2 Business Overview

### (i) Introduction

We are a specialty pharmaceutical company focused on the development of new products for the diagnosis and treatment of chronic respiratory and immune disorders.

#### **Bronchitol**

We are developing Bronchitol, our proprietary inhaled dry powder mannitol formulation, for the treatment of cystic fibrosis, or CF; for the treatment of chronic obstructive pulmonary disease, or COPD, an umbrella term for diseases such as bronchiectasis and chronic bronchitis; and for the treatment of other acute and chronic pulmonary conditions.

#### ***Bronchitol for Cystic fibrosis***

- In August 2008 we completed enrolment for a Phase III clinical trial of Bronchitol in patients with CF in Europe and Australia being conducted according to a clinical trial protocol agreed with the European Medicines Agency, or EMEA. The efficacy component of the clinical trial is scheduled to report in the first half of 2009.
- In 2005 we completed a Phase II clinical trial of Bronchitol in patients with CF and demonstrated a statistically significant improvement in lung function relative to placebo over a two week treatment period.
- In April 2008 we reported initial results from a Phase II clinical trial of Bronchitol in children with CF and demonstrated an improvement in lung function over a three month treatment period.
- In August 2008 we commenced a further Phase III clinical trial of Bronchitol for the treatment of CF to be conducted according to a clinical trial protocol agreed with the U.S. Food and Drug Administration, or the FDA, under its Special Protocol Assessment (SPA) procedure.
- In August 2008 we reported a Phase II dose ranging clinical trial of Bronchitol in patients with CF which demonstrated a dose dependent improvement in lung function.
- The FDA has granted Orphan Drug designation to Bronchitol for the treatment of bronchiectasis and for CF patients at risk of developing bronchiectasis. The EMEA has granted Orphan Drug designation to Bronchitol for the treatment of CF.

#### ***Bronchitol for Bronchiectasis***

- In 2007 we reported a Phase III clinical trial of Bronchitol for bronchiectasis conducted in Europe and Australia. The study demonstrated a significant improvement in quality of life after 13 weeks of treatment with Bronchitol as assessed by the St George Respiratory Questionnaire, a significant improvement in quality of life compared to placebo and a significant change in mucus clearance on patients receiving Bronchitol versus those patients receiving placebo.
- In August 2008, we reported the results from an open label 12 month safety trial in subjects with bronchiectasis. This trial was an extension of the trial described above. The trial demonstrated that Bronchitol was safe and well tolerated when administered twice per day for 12 months without any serious adverse events attributed to treatment. Based on this study we are preparing to apply for marketing approval of Bronchitol for the treatment of bronchiectasis in Australia during the third quarter of 2008.
- In June 2008 we reached agreement with the FDA on the clinical trial design for a Phase III registration clinical trial of Bronchitol for the treatment of bronchiectasis, having previously agreed on the clinical trial design with the EMEA.
- In 2004 we completed a Phase II clinical trial of Bronchitol in bronchiectasis patients and demonstrated a clinically meaningful increase in patients' quality of life relative to placebo following two weeks of treatment.

#### ***Bronchitol for Other Pulmonary Indications***

- Bronchitol has potential application to other pulmonary conditions such as chronic bronchitis and patients within hospital intensive care units.

## 1.2.2 Business Overview (Continued)

### Aridol

We have developed Aridol, as a novel tool for the detection of airway hyperresponsiveness and to assist in the diagnosis and management of asthma and chronic obstructive pulmonary disease, or COPD. The Aridol test mimics the bronchoconstriction that can occur in inflamed airways from time to time in people with asthma. Airway hyperresponsiveness is one of the hallmarks of untreated or poorly controlled asthma. Aridol may also be used to determine the minimum effective doses of inhaled corticosteroid required for optimum control of asthma.

- We received marketing approval in Australia in March 2006 and commenced commercial supply of Aridol in Australia in June 2006.
- In June 2007 we successfully completed the E.U. mutual recognition procedure which permitted marketing approvals of Aridol by Germany, France, the United Kingdom, Italy, the Netherlands, Belgium, Denmark, Greece, Finland, Ireland, Norway, Sweden and Portugal. Individual country marketing certificates were issued from June 2007 to June 2008 at which time Italy, Spain, France and Belgium were still being processed.
- We received marketing approval in Korea in January 2008.
- In August 2006 we completed a pivotal U.S. Phase III clinical trial to determine the selectivity and specificity of Aridol as a test for the detection of airway hyperresponsiveness in patients diagnosed with exercise induced asthma. Based on this study and an earlier Phase III clinical trial that was the basis of marketing approval in Australia and Europe, we have met with the FDA, and are preparing to apply for marketing approval of Aridol in the U.S.
- In 2007 we reported the commencement of an independent investigator led asthma management study being conducted by the U.S. Asthma Clinical Research Network.
- We have previously reported independent investigator clinical trials assessing the role of Aridol in determining those patients with COPD who will respond to treatment with inhaled corticosteroids.

### Preclinical Pipeline

Our preclinical pipeline is focused on novel treatments for inflammatory and immune disorders, including asthma and other pulmonary conditions. During the next twelve months PXS25 is scheduled to commence Phase I clinical trials and PXS4159 is scheduled to complete preclinical studies. PXS25 is an inhibitor of the mannose 6 phosphate receptor and PXS4159 is an inhibitor of semicarbazide sensitive amine oxidase/vascular adhesion protein-1.

### (ii) Lung Disease Overview

Our lead product and product candidates are for the diagnosis or treatment of chronic respiratory diseases, including asthma, cystic fibrosis and COPD, including bronchiectasis and chronic bronchitis and other chronic and acute pulmonary conditions. Several of these diseases share similar biology and pathology, such as the airway inflammation in both asthma and chronic bronchitis, as well as difficulty with normal clearance of lung mucus in patients with cystic fibrosis and bronchiectasis.

#### *Lung Congestion*

The inside lining of the airways is covered by millions of fine hair-like structures called cilia, which are in turn covered by a surface liquid and a thin layer of mucus, secreted by the lungs to defend against germs, dust particles and other extraneous matter. The cilia move continuously and propel the mucus up towards the throat. This constant process, which is unnoticeable in healthy people, cleans the airways, permits clean air to pass freely through the lungs and removes bacteria, thereby limiting infectious episodes.

Patients with COPD or with CF are generally affected by a breakdown in natural mechanisms of creating, hydrating, and clearing this mucus. These patients face the ongoing challenge of clearing excessive and thickened secretions from their congested lungs, usually by constant coughing. 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.



## ***Cystic Fibrosis***

CF is an inherited, progressive and fatal disease that affects epithelial surfaces including the airways, pancreas, sweat ducts, reproductive system and intestinal tract. The lungs of CF patients produce copious amounts of thick, tenacious secretions which are not cleared effectively by the lungs. Such changes are known to be present from birth and inevitably result in airway obstruction and bacterial infection. This generally leads to progressive lung deterioration, and eventually respiratory failure, the primary cause of death in adult CF patients.

According to the U.S. Cystic Fibrosis Foundation, there are about 30,000 diagnosed CF patients in the U.S. and 70,000 worldwide. While this patient population is relatively small, the problem of sputum clearance is common to all sufferers and is a chronic lifelong problem. According to the literature, annual direct healthcare cost associated with the disease in the United States amount to over U.S.\$0.5 billion.

There is no cure for CF. Maintaining a reasonable quality of life for these patients is a significant challenge. Problems include breathing difficulties, respiratory infections, poor sleep, general discomfort, lifestyle limitations and gradual deterioration of lung function over time. Although the life expectancy of CF sufferers has increased dramatically over the past few decades due to better management of the disease, according to the U.S. Cystic Fibrosis Foundation, the predicted median age of survival in 2006 was 37 years of age.

Physicians seek to improve lung function and reduce the number and severity of secondary lung infections by hydrating and breaking down the excessive, sticky mucus secretions, allowing it to be cleared from the lungs. Management of CF includes exercise, daily physiotherapy, postural drainage and chest percussion and can take several hours of at-home treatment every day. Medications to treat CF 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, and are also often used to prevent infection.

Dornase alfa, marketed by Genentech in the U.S., is the most widely used therapeutic for chronic use in CF to aid sputum clearance. According to Genentech, U.S. sales of dornase alfa were approximately U.S.\$266 million in 2007. We estimate that dornase alfa has a market penetration in developed countries and the seven major pharmaceutical markets of the U.S., Germany, France, United Kingdom, Italy, Spain and Japan of about 30%. Although dornase alfa demonstrates lung function improvement in CF patients, similar benefit was not shown in other respiratory conditions, including bronchiectasis. Further, in previous clinical trials, dornase alfa provided no increase in sputum clearance. Dornase alfa is unstable and is delivered by a nebulizer. Solutions have to be prepared by the patient before administration, the treatment periods are long and all equipment has to be sterilized after use.

## ***Chronic Obstructive Pulmonary Disease***

Chronic Obstructive Pulmonary Disease, or COPD, encompasses a number of serious conditions affecting the lungs, including emphysema, chronic bronchitis and bronchiectasis and other chronic and acute pulmonary conditions. According to the World Health Organization, or WHO, 80 million people suffer from moderate to severe COPD and 3 million died due to it in 2005. The WHO predicts that by 2030, it will be the third largest cause of mortality worldwide.

Since COPD is not diagnosed until it becomes clinically apparent, prevalence and mortality data greatly underestimate the socioeconomic burden of COPD.

According to Datamonitor, there are 16 million people diagnosed with COPD in the U.S., and more than 30 million people are affected with COPD in the seven major pharmaceutical markets. In 2005 there were more than 10 million physician office visits and two million hospitalizations per year. The disease was estimated to cost the U.S. healthcare system U.S.\$30 billion in 2000. According to a report by Datamonitor, worldwide sales in 2004 of the top seven respiratory therapeutics indicated for COPD were U.S.\$4.8 billion.

### 1.2.2 Business Overview (Continued)

Management of COPD generally involves bronchodilators and steroids. However, only an estimated 20%-25% of patients respond positively to steroids and it is currently not practical to determine in advance which patients will respond to steroids. We believe that only half of moderate and severe COPD patients achieve an adequate treatment outcome. Therefore, as with asthma, we believe there is room to improve both the diagnosis and management of COPD.

#### ***Bronchiectasis***

In this condition the bronchial tubes become enlarged and distended, and the cilia do not function normally. Many patients with cystic fibrosis and asthma may also have bronchiectasis. For other patients, bronchiectasis is a result of infections such as pneumonia, or the chronic inhalation of noxious substances although in over half the case, the underlying cause is never identified. The condition results in poor clearing of mucus and predisposes the lung to more infections. The body repairs damaged lung tissue by forming tough, fibrous material, which leads to reduced lung function, lower lung efficiency, changes of the organization of blood vessels and increased blood flow through the lungs. These changes impair normal lung function and can ultimately lead to heart failure. Recurrent lung infections commonly reduce patients' quality of life and progressive respiratory insufficiency is the most common cause of death from this disease. Based on research carried out for us by Datamonitor and Frost & Sullivan, we estimate that there are about 600,000 people worldwide seeking treatment for bronchiectasis. A report in *Clinical Pulmonary Medicine* published in 2005 (Volume 12, Number 4, page 205) indicates that over 110,000 people in the U.S. may be receiving treatment for bronchiectasis, resulting in an annual additional medical-care expenditure of \$630 million.

Bronchiectasis treatment is aimed at controlling infections, increasing secretions, reducing airway obstructions and minimizing complications. Daily drainage to remove bronchial secretions is a routine part of treatment. Physicians often prescribe medications similar to those for chronic bronchitis, including inhaled bronchodilators to dilate the airways. Although antibiotics can be used to some effect to clear infections, no currently approved products effectively clear excess mucus secretions and improve the quality of life of these patients. Furthermore, because of the serious damage to lung tissue present in these patients, medications generally do not provide substantial improvement in lung function.

#### ***Chronic Bronchitis***

Patients with chronic bronchitis experience persistent airway inflammation and airflow obstruction, with symptoms including a chronic mucus-producing cough 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 lung function, reducing quality of life and ultimately causing death.

Many of the deaths associated with chronic bronchitis are included in the COPD figure that now accounts for over 100,000 deaths a year in the U.S. The disease is predominately caused by inhaling some form of lung irritant repeatedly for many years, usually cigarette smoke. Chronic bronchitis is slow to develop and is often not diagnosed until the sufferer is in their 40s or 50s.

Management 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 airway and reduce airway inflammation, for 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.

Treatments for chronic bronchitis include anti-cholinergic agents, steroids, antibiotics and oxygen. Anticholinergic agents, also known as antimuscarinics, are bronchodilators used for the relief of acute symptoms in both asthma

and COPD, but tend to be more effective in COPD. Inhaled corticosteroids are less likely to cause systemic side effects than oral corticosteroids, and have been shown to be effective in asthmatics. However, the role of these agents in the management of COPD remains unclear. According to a recent scientific report (Chest, 2004, 126, 1815) there are no indications that early treatment with inhaled corticosteroids modifies a rapid decline in lung function or respiratory symptoms and quality of life.

## **Asthma**

Asthma is a chronic inflammatory disease of the lungs where the airways narrow in response to a variety of stimuli. Published estimates indicate that this disease affects over 20 million people in the U.S. and approximately 51 million people in the seven major pharmaceutical markets of the U.S., Germany, France, United Kingdom, Italy, Spain and Japan. Based on published studies, we estimate that each year in the U.S., 4.7 out of every 1,000 people under the age of 16 are newly diagnosed with asthma and two out of every 1,000 people aged 16 to 44 are newly diagnosed with the disease.

Many patients with asthma are not currently diagnosed with the disease. Sufferers and even physicians often attribute common asthma symptoms, such as cough and breathlessness, to smoking, lack of fitness or old age. Moreover, according to a recent publication, 34% of individuals diagnosed as asthmatic by their primary care physician do not have the disease. Even when accurately diagnosed, many patients do not receive the most appropriate therapy according to published guidelines. Physicians can underestimate the severity of the disease, and prescribe only bronchodilators, whereas the addition of an inhaled corticosteroid is the recommended course of action according to the Global Initiative for Asthma, or GINA, guidelines. We estimate that only about 30% of asthma patients in the U.S. receive inhaled corticosteroids despite evidence that uncontrolled asthma is common. Poorly controlled asthma can lead to irreversible damage to the airways. Therefore, the goal of treatment is to provide sufficient anti-inflammatory medication to control inflammation and airway remodeling. However, using high doses of medication can lead to unwanted side effects. Hence, selecting the right dose for individual patients remains a clinical problem.

To diagnose asthma and to evaluate patient response to treatment, pulmonary specialists may, for example, introduce an aerosolized substance directly into the lungs, and subsequently test lung function. The tests fall into two categories. The first category, known as 'direct' challenge tests, use either histamine or methacholine to directly cause airway narrowing. These substances act on receptors on bronchial smooth muscle to cause contraction. The second category, known as 'indirect' challenge tests, involve stimuli such as exercise, rapid breathing of dry air, or inhalation of salt solutions or adenosine monophosphate. This more closely mimics an asthmatic process, and can cause the release of chemicals from inflammatory cells within the lungs, resulting in airway contraction and narrowing.

The only FDA-approved direct test is Provocholine® (methacholine), marketed by Methapharm Inc. We believe that the disadvantage of direct tests are that the airway narrowing caused by histamine or methacholine is not dependent on the presence of inflammatory cells. Moreover, a positive response is not specific for identifying asthma and can occur in healthy people with no symptoms, smokers, and those with other diseases of the lung. Despite these limitations, we believe that over 200,000 direct tests are performed each year in the U.S., based on information reported by Solucient LLC in 2003. However, this represents only a small fraction of the potential market.

We believe that the indirect tests have a much lower false positive rate for asthma and increased sensitivity. However, each of them suffers from limitations. For example, tests involving exercise and rapid breathing of dry air require a lengthy period of time to complete and they require complicated equipment. Furthermore, these tests are limited to identifying exercise induced asthma and are not useful for determining the severity of airway inflammation. Hypertonic saline, which is delivered by a nebuliser during administration of the test, is uncomfortable for the patient, determination of the administered dose is difficult and this procedure is unsuitable for managing anti-inflammatory drug treatment. Adenosine monophosphate is unstable, also delivered by a nebuliser and its use is restricted to specialist research laboratories.

## 1.2.2 Business Overview (Continued)

### (iii) Bronchitol Development

We are developing Bronchitol, our proprietary inhaled mannitol formulation, for the treatment of chronic respiratory diseases, including cystic fibrosis and COPD, including bronchiectasis and chronic bronchitis and other chronic and acute pulmonary conditions. Mannitol is accepted as a food additive in the U.S. and is included in the FDA Inactive Excipients Guide for drug products. We manufacture mannitol into a dry respirable powder and incorporate it into a capsule. The compound is delivered to a patient's lungs via a pocket-sized inhaler.

In a 12 week Phase III clinical trial involving 362 bronchiectasis patients sponsored by us, Bronchitol demonstrated a significant improvement in quality of life and a highly significant improvement in mucus clearance relative to placebo. In a 12 month extension to this study, Bronchitol was proven to be safe with no serious adverse events attributed to treatment. In a Phase II clinical trial sponsored by us and involving 60 patients with bronchiectasis, Bronchitol provided a statistically-significant increase in patients' quality of life relative to placebo and a highly statistically significant reduction in the symptoms of the disease following two weeks treatment.

In a 2 week Phase II trial involving 39 cystic fibrosis patients sponsored by us, Bronchitol provided a statistically significant reduction in airway obstruction and a statistically significant improvement in lung function measurement of 7% as determined by the change in Forced Expiratory Volume in 1 second, known as FEV<sub>1</sub>.

In a small second Phase II trial in children with cystic fibrosis supported by us, Bronchitol improved lung function by 7% as determined by FEV<sub>1</sub> measurement following a 3 month treatment period.

In a Phase II trial sponsored by us and comparing four different doses of Bronchitol in 49 cystic fibrosis patients a clear dose related effect in improving lung function was recorded with the top dose of 400 mg improving lung function by a statistically significant 139mls or 8.6%.

We have an exclusive, worldwide license from Sydney South West Area Health Service to certain key intellectual property and patents relating to the use and formulation of Bronchitol.

#### ***Mechanism and Early Data***

Bronchitol increases mucociliary clearance in asthmatic and healthy subjects. We have shown that a single inhalation of Bronchitol increases the clearance of mucus both acutely and over a 24 hour period in patients with bronchiectasis, and acutely in patients with cystic fibrosis.

In an investigator-sponsored 19 patient, single-dose Phase II clinical trial of Bronchitol in patients diagnosed with bronchiectasis, an increase in whole lung mucus clearance was observed over a 75 minute period beginning at the onset of intervention and this increase was statistically significant ( $p < 0.005$ ). There was an almost doubling of mucus clearance after Bronchitol treatment and most of this was in the central and intermediate regions of the lung. Over a 24 hour period after Bronchitol intervention the increase in mucus clearance was approximately 30% over control and this was statistically significant ( $p < 0.0001$ ).

#### ***Bronchitol for CF***

In August 2005, we announced results from a Company sponsored Phase II clinical trial involving 39 patients with cystic fibrosis. The placebo-controlled trial was conducted at eight sites in Australia and New Zealand. Patients were treated for two weeks with either Bronchitol or placebo. After a two week washout period where patients received neither drug nor placebo, patients who previously received Bronchitol were treated with placebo, and vice versa. This crossover trial design allows each patient to act as their own control. The primary endpoint was change in Forced Expiratory Volume in 1 second, known as FEV<sub>1</sub>. This is a quantitative measure of the volume of air a patient can exhale in one second, and is the most frequently used measure of the degree of airway obstruction. The secondary endpoints included quality of life, sputum microbiology, the physical properties of the sputum, safety and additional lung function measurements. At the end of the treatment period, patients receiving Bronchitol had significantly better lung function compared to placebo as measured by FEV<sub>1</sub> and for the maximum mid-expiratory flow, or MMEF, another measure of airway function. Approximately half the subjects were using dornase alfa during the trial.

In this trial, Bronchitol had a positive impact on lung function. Patients who received Bronchitol had a 7% improvement in FEV<sub>1</sub> as compared to placebo (p=0.008). An improvement of 7% in this indication is considered to be clinically relevant. MMEF increased by 15% while on Bronchitol treatment and this increase was significant compared to control (p<0.01). The MMEF reflects function in small airways and is an early abnormality in cystic fibrosis. Respiratory symptoms determined from a Likert scale self-assessment after Bronchitol treatment were significantly improved as compared to placebo (p<0.02).

In August 2005, the FDA granted Orphan Drug designation to Bronchitol for the treatment of cystic fibrosis. In November 2005, the European Medicines Agency, or EMEA, granted Orphan Drug designation to Bronchitol for the treatment of cystic fibrosis. In November 2006, Bronchitol was awarded 'Fast Track' designation by the FDA for cystic fibrosis, making Bronchitol eligible to apply for accelerated approval.

In April 2008, we reported the results of a Company supported investigator-led Phase II clinical trial comparing the effect on lung function of Bronchitol as compared to dornase alfa in children. Both Bronchitol and dornase alfa improved lung function by 7% although the patient numbers were too small to draw a statistically definitive conclusion.

In August 2008 we also reported results from a Company sponsored Phase II dose-ranging clinical trial to determine optimal dosing. The trial was an open, randomized comparison of 400mg, 240mg, 120mg and 40 mg of Bronchitol involving 48 patients with cystic fibrosis conducted at 12 centres across Canada and Argentina. Bronchitol was administered twice a day for 14 days. The primary end point was a dose dependent change in FEV<sub>1</sub> and Forced Vital Capacity, known as FVC. The secondary endpoints included other spirometry and quality of life measures. The trial demonstrated a dose dependent improvement in lung function as measured by FVC and FEV<sub>1</sub>.

Change in FEV <sub>1</sub>	Change in FVC	
400 mg treatment group	8.6%*	7.9%*
240 mg treatment group	4.6%	3.9%
120 mg treatment group	1.9%	1.5%
40 mg treatment group	(1.6%)	(0.6%)

\*p=0.0005 relative to 40 mg dose

Secondary measures showed a positive effect for 400 mg Bronchitol on MMEF and the respiratory domain of the cystic fibrosis quality of life questionnaire. Additionally, no serious adverse events emerged during treatment periods and the adverse event profile was similar across all doses.

In August 2008 we completed enrolment in a pivotal Phase III clinical trial in the E.U. and Australia, to provide the basis for applications for marketing authorization in the E.U. and other countries outside of the U.S.. The protocol for the clinical trial was designed with scientific advice from the EMEA. The clinical trial is being conducted in 325 subjects with cystic fibrosis over a 6 month treatment period. The primary endpoint was change in Forced Expiratory Volume in 1 second, known as FEV<sub>1</sub>. Additional endpoints of the trial included a reduction in exacerbation frequency and other lung function measurements. The data from this trial will not be available until the first half of 2009.

We have agreed a clinical trial protocol with the U.S. FDA under its Special Protocol Assessment procedure for a Phase III trial with Bronchitol in cystic fibrosis. This trial will be the second of two required by the FDA before a New Drug Application (NDA) can be submitted for Bronchitol to treat cystic fibrosis. The clinical trial will be conducted in 250 subjects with cystic fibrosis over a 6 month treatment period and will study a similar patient population to the first Phase III trial. The primary endpoint is to be change in Forced Expiratory Volume in 1 second, known as FEV<sub>1</sub>. Additional endpoints of the trial included a reduction in exacerbation frequency, quality of life and other lung function measurements. The trial is due to commence recruitment during the third quarter of 2008 and data from this trial will not be available until 2010.

We believe that the addressable annual market for Bronchitol in CF is the 70,000 diagnosed CF patients in the major pharmaceutical markets.

## 1.2.2 Business Overview (Continued)

### *Bronchitol for Bronchiectasis*

In 2004 we completed a proof of concept Phase II clinical trial of Bronchitol in 60 bronchiectasis subjects. We began this comparator-controlled, crossover design trial at a single centre in Sydney and later expanded it to include four centres in Australia and New Zealand. This trial was designed to explore the safety and efficacy of Bronchitol in bronchiectasis patients. Patients received 400 mg of Bronchitol or comparator, twice a day for 14 days. In this trial, the comparator was a mannitol formulation with a larger (non-respirable) particle size, which we anticipated to be most similar in patient experience to active Bronchitol, yet was intended not to enter the lungs to any significant degree. Endpoints of the study were to evaluate the effect of Bronchitol treatment on patient quality of life using a self-assessment known as the Likert scale, the St. Georges Hospital Respiratory Questionnaire, or SGRQ, which is another self assessed measure of quality of life, sleep quality as measured by the self assessed Epworth scale, exercise tolerance as measured by the 6 minute walk test, lung function as measured by two tests known as spirometry and flow oscillometry, sputum microbiology, the physical properties of sputum, the volume of sputum production over 24 hours and the safety profile of Bronchitol. The SGRQ includes changes in three components, symptom, activity and impact, as well as an overall score. Improvement in quality of life measures is indicated by a reduction in score.

Versus baseline, treatment with Bronchitol led to a significant reduction in the Likert scale score of 6.1 ( $p=0.03$ ). Versus baseline and comparator, there was a statistically significant improvement in the Epworth sleep score ( $p<0.02$  versus comparator). For patients receiving Bronchitol, 38% went from an unclear chest to a clear chest as compared to 17% on comparator ( $p<0.05$ ). There were no statistically significant changes on lung function as measured by standard spirometry. Flow oscillometry showed a significant effect of Bronchitol compared to comparator ( $p<0.05$ ). Flow oscillometry is considered to reflect changes in small airways.

However, the effect of Bronchitol was most pronounced in the 75% of patients who entered the study with an unclear chest, which indicates the most serious problems with normal clearance of lung mucus. There was a mean decrease of 10.2 in Likert scale score during Bronchitol treatment, compared to a mean decrease of 3.6 for placebo ( $p<0.005$  versus placebo). Treatment with Bronchitol led to a significant improvement in the impact component of the SGRQ compared to comparator in those patients with an unclear chest. The improvement was clinically significant at 6.9 points. There was also a trend for an effect on the total score versus comparator but this did not reach significance ( $p=0.15$ ). Compared to baseline, the overall score showed a strong trend with a clinically significant reduction of 5.6 ( $p=0.055$ ).

In August 2007 we completed a Phase III clinical trial of Bronchitol in 362 bronchiectasis subjects. This comparator-controlled double blinded trial was conducted over 22 sites in the United Kingdom, Australia and New Zealand. The trial was designed to evaluate the safety of Bronchitol and its impact on quality of life and mucus clearance. In this trial, the comparator was a mannitol formulation with non respirable particle size, which we anticipated to be most similar in patient experience to active Bronchitol, yet was intended not to enter the lungs to any significant degree. Primary efficacy endpoints of the study were to evaluate the effect of Bronchitol treatment on patient quality of life using a self-assessed questionnaire, known as the St. Georges Hospital Respiratory Questionnaire, or SGRQ, which is a patient reported outcome tool for measuring health-related quality of life, and 24 hour mucus clearance. The SGRQ includes changes in three components, symptom, activity and impact, as well as an overall score. Improvement in quality of life measures is indicated by a reduction in score. Additional endpoints included exercise tolerance, antibiotic use, exacerbation rate, cough frequency and lung function as determined by spirometry readings.

Subjects were administered drug or comparator over a twelve week period and the randomization was 2:1 in favor of the treatment arm. Following conclusion of the formal efficacy component, a proportion of the trial subjects were recruited to an open label extension of the trial for a total treatment period of twelve months.

Treatment with Bronchitol led to an overall improvement in quality of life versus baseline ( $p < 0.001$ ) and an overall improvement in quality of life versus the comparator ( $p < 0.05$ ). The change in quality of life was clinically significant at 4.1 units at the mid-point of the study and 3.9 units at the end of the study. Additionally, there was a difference in sputum volume between the two groups of subjects, with the Bronchitol treated group producing 30% more mucus over the 24 hour collection periods and this difference was statistically significant ( $p < 0.001$ ).

In addition to the primary efficacy analysis, clinical trial subjects that had been assigned to the drug treatment arm used less antibiotics over the first six week period than their counterparts on the comparator arm and this difference was significant ( $p < 0.05$ ).

There were no serious adverse events attributable to treatment and there was no statistical difference in the number or nature of adverse events in the two treatment groups.

No therapies to enhance mucus clearance in bronchiectasis patients have been approved in over 20 years in the U.S. In June 2008, we reached agreement with the FDA under its Special Protocol Assessment procedure and with the EMEA on the protocol for a Phase III trial with Bronchitol in bronchiectasis to provide the basis for application for marketing authorization in the U.S. and the E.U.

In February 2005, the FDA granted Orphan Drug designation to Bronchitol for the treatment of bronchiectasis. We are currently supplying Bronchitol in Australia on an individual, named patient basis under a TGA-administered compassionate use program known as the Special Access Scheme. This program allows patients access to unapproved drugs where there are limited treatment options. In June 2008 we announced the extension of this named patient basis program to qualifying patients in other parts of the world.

We believe that an effective daily treatment for the estimated 600,000 people worldwide affected by bronchiectasis represents a significant market opportunity.

#### ***Bronchitol for Other Pulmonary Indications***

Most asthmatics with mucus hypersecretion have difficulty in clearing their secretions such that mucus plugs and airway obstruction are commonly present and this can present clinical challenges. A recent study (*Respirology*, 2007, 12, 683) indicates that Bronchitol may be beneficial in enhancing clearance of mucus in asthmatics. The expected long term effect would be a reduction in mucus plug formation and an improvement in lung function in asthmatics with mucociliary dysfunction.

Pilot data in patients with chronic bronchitis have shown that Bronchitol may also be beneficial in improving mucociliary and cough clearance in these patients. We indirectly supported a small, investigator-sponsored Phase II clinical trial to determine the effects of Bronchitol on mucus clearance over a two hour period, and the effects on rate of clearance of a radiolabelled tracer over a 24 hour period. The trial was not powered nor suitably controlled for statistical analysis, but provided encouraging data.

We plan to conduct additional Phase II clinical trials in patients with chronic bronchitis. The objective of these trials will be to determine if Bronchitol assists in clearing mucus after an exacerbation requiring hospitalization and whether Bronchitol has the ability to lengthen the time to and, reduce the frequency of, subsequent exacerbations requiring hospitalisation.

We also plan to conduct additional clinical trials to determine the effects of Bronchitol on mucus clearance in patients admitted to hospital intensive care units.

## 1.2.2 Business Overview (Continued)

### (iv) Aridol

We have initially developed Aridol as a more accurate and precise proprietary tool for physicians to use in the diagnosis and management of asthma and COPD. Physicians do not currently have rapid, accurate, safe and inexpensive tests to evaluate the presence or severity of these diseases. Aridol is a proprietary dry powder formulation of mannitol, delivered to the lungs through an inhaler. Mannitol is an osmotic agent which causes the release of certain mediators from inflammatory cells, which in turn cause a bronchoconstriction. This process mimics the changes that often occur in the airways of people with asthma. Asthma patients who are not receiving adequate doses of anti-inflammatory medicine, such as an inhaled corticosteroid, experience airway narrowing and a drop in lung capacity when given the Aridol test. In contrast, healthy people or well-controlled asthma patients do not experience this narrowing and reduction in lung capacity. In 2004 we completed a 646 subject, 12 centre, Phase III clinical trial of Aridol. Based on the Phase III data, we have received marketing approval in Australia. In June 2007 we successfully completed the E.U. mutual recognition procedure which permitted marketing approvals of Aridol by Germany, France, the United Kingdom, Italy, the Netherlands, Belgium, Denmark, Greece, Spain, Finland, Ireland, Norway, Sweden and Portugal. Individual country marketing certificates were issued from June 2007 to June 2008 at which time Italy, France, Spain and Belgium were still being processed.

We received marketing approval in Korea in January 2008. In October 2006 we completed a 500 participant, 30 centre, Phase III clinical trial designed to allow approval in the U.S. Based on this study and the earlier Phase III clinical trial that was the basis of marketing approval in Australia and Europe, we intend to file a New Drug Application (NDA) with the FDA in the third quarter of 2008.

Aridol is the subject of 48 peer-reviewed publications in international journals. We believe that Aridol is superior to direct tests such as methacholine because Aridol is an indirect challenge test that relies on mediators released by inflammatory cells to cause a bronchoconstriction, thereby making Aridol a more accurate predictor of airway inflammation. We believe that Aridol's high degree of sensitivity and specificity for airway inflammation, combined with its ease of use, will make it possible for physicians to:

- diagnose asthma more accurately and objectively, and measure disease severity, with a high correlation to in-depth patient assessment by a pulmonary specialist physician;
- monitor the effectiveness of treatment, with a negative Aridol test indicating good control of asthma and a positive test indicating active airway inflammation and the need for more or different medication;
- determine the minimum required dose of steroids to achieve adequate disease control in a given patient, and predict the risk of exacerbation when reducing the steroid dose.

We have an exclusive, worldwide license from Sydney South West Area Health Service to certain key intellectual property and patents relating to the use and formulation of Aridol.

### **Aridol for Asthma**

In our Phase II and Phase III clinical trials, patients used a dry powder inhaler to take progressively higher doses of Aridol (from 5 mg to 635 mg, nine steps in all). After each inhalation the patient's lung capacity is determined by a spirometer, an instrument to measure airflow and lung capacity. The Aridol test is stopped when a patient has a 15% fall in lung capacity, indicating the presence of active airway inflammation. Only those patients with active airway inflammation will experience a drop in lung capacity. On average, the procedure takes 17 minutes for a positive test and 26 minutes for a negative test. The only equipment required is a standard spirometer to record lung capacity.

A large number of investigator-sponsored, open-label Phase I and Phase II clinical trials have been conducted with Aridol. The results show that use of Aridol can identify subjects with asthma who are also responsive to inhaled salt solutions, inhaling dry air and exercise. Aridol also identifies both adults and children with currently active asthma who are responsive to methacholine, as well as others who are not responsive to methacholine. The Aridol test demonstrates good repeatability in both adults and children, and responses are rapidly reversible using a standard dose of bronchodilator. Furthermore, Aridol can provide an assessment of the effectiveness of inhaled steroids in controlling the disease. Finally, Aridol response correlates with the symptoms and signs of exercise induced asthma, indicating that a negative response to Aridol may be a useful end point signifying adequate asthma control.



In 2004 we completed a 12 centre, 646 subject, Phase III clinical trial of Aridol to identify airway hyperresponsiveness in asthmatic patients, and to support filing for marketing authorization in Australia and the European Union. Airway hyperresponsiveness is a hallmark of untreated or poorly controlled asthma, and over time can lead to long-term changes in the lungs. This trial included asthmatic patients who were currently treating their disease, patients with symptoms suggestive of asthma but without a clinical diagnosis, and healthy volunteers, including both children and adults. The goals of this trial were to:

- compare Aridol to hypertonic saline in identifying airway hyper-responsiveness in asthmatic subjects and non-asthmatic subjects;
- compare Aridol to standard clinical assessment in diagnosing asthma;
- compare asthma severity as determined by our Aridol test to the Severity of Asthma (Asthma Management Handbook 2002);
- evaluate the advantages of Aridol versus hypertonic saline with respect to simplicity, safety and patient and health care convenience; and
- further evaluate the safety profile of Aridol.

The primary endpoint was a comparison of the sensitivity and specificity of Aridol to that for an unapproved test, hypertonic saline, which is widely used in Australia. A secondary endpoint was a comparison of the sensitivity and specificity of Aridol to that of physician diagnosis. Sensitivity is a measure of the percentage of people correctly identified as having airway hyperresponsiveness by the test. Specificity is a measure of the percentage of people correctly identified as lacking airway hyperresponsiveness.

In this trial, sensitivity of Aridol against hypertonic saline was 81%, and specificity was 87%. This means that 81% of patients identified as having airway hyper-responsiveness by the hypertonic saline test were also identified as positive by the Aridol test and 87% of patients classified as lacking airway hyper-responsiveness were also identified as negative by Aridol. Conversely, the sensitivity of hypertonic saline against Aridol was 88%, and specificity was 79%. These numbers indicate good agreement between the two tests ( $p < 0.01$ ).

In comparison to physician diagnosis, Aridol had a sensitivity of 58%, and specificity was 94%. Significantly, of the 42% of patients identified as asthmatic by physician diagnosis, but lacking airway hyper-responsiveness as determined by Aridol, 85% were using inhaled corticosteroids at the time of the clinical trial. When the subjects who were Aridol negative and were using inhaled corticosteroids were removed from the analysis versus physician diagnosis, sensitivity was 89% and specificity was 95%. The increase in sensitivity underscores the utility of Aridol in managing patients on inhaled corticosteroid medication.

As a result of this trial, we have received marketing approval in Australia, Korea, Germany, the United Kingdom, the Netherlands, Denmark, Greece, Finland, Ireland, Norway, Portugal and Sweden. We have filed for the issue of marketing authorizations in France, Italy, Spain and Belgium subsequent to our successful completion of the E.U. mutual recognition procedure. We have also filed for marketing approval in Switzerland and several smaller Asian markets.

We have established a sales force based in Australia and have completed our first two years of sales of Aridol in Australia. We have appointed independent marketing partners in Scandinavia, Switzerland, Italy, Greece, Spain, Portugal, the Netherlands and Korea and established an office in the United Kingdom to manage these partners and to manage European sales and marketing in the UK, Ireland and France. We have appointed an independent marketing partner in Korea and established an office in China to manage Asian sales and marketing partners. We intend to establish additional marketing partnerships in select E.U. and Asian territories and other jurisdictions for this product. We are supporting a number of investigator-sponsored trials to provide the basis for a rapid uptake of Aridol in the marketplace.

In the U.S., unlike Australia and Europe, a product, methacholine, is approved by the FDA to identify airway hyper-responsiveness in asthmatic patients. Based on discussions with the FDA, we undertook a 500 subject Phase III clinical trial comparing Aridol with methacholine and exercise challenge in patients with suspected asthma. The primary endpoint was to compare the sensitivity and specificity of Aridol to identify exercise-induced bronchoconstriction. We completed this trial in October 2006. In this group with predominantly very mild symptoms, Aridol was able to identify patients with exercise induced bronchoconstriction in 58% of cases

## 1.2.2 Business Overview (Continued)

(sensitivity). In comparison methacholine, an approved lung function test in the U.S., identified 54% of cases. The difference between the two tests was not statistically significant. Aridol also had similar specificity to methacholine, (66% versus 70% respectively) in subjects without exercise induced bronchoconstriction. In addition Aridol was proven to have an acceptable safety profile and to cause less bronchoconstriction than methacholine ( $p < 0.05$ ). Based on this study and the earlier Phase III clinical trial that was the basis of marketing approval in Australia and Europe, we intend to file a New Drug Application (NDA) with the FDA. We have established an office in the U.S.A. to manage sales and marketing of Aridol in North America.

Our initial target market for Aridol are the lung function testing laboratories and specialist physicians that manage those asthmatic patients that have poor control of their disease. Because current use of objective lung function testing is low, we plan to focus initial Aridol marketing efforts on physician education regarding asthma diagnosis and disease control. We believe physicians who commonly diagnose asthma based only on patient history of asthma symptoms leads to sub-optimal control of this disease, falling far short of the goals of current clinical guidelines. We are also planning development and marketing efforts in new areas where challenge testing could be useful given the availability of an accurate, valid and easy to use test like Aridol. These include monitoring asthma therapy and assessing asthma prevalence in the community.

### Aridol for COPD

We are also exploring the use of Aridol in the management of COPD. Treatment of COPD is difficult but approximately 20%-25% of patients with COPD can have a positive clinical outcome with the administration of inhaled steroids. A long standing problem is that there is no effective test to identify those people that will respond clinically to inhaled steroids. A publication by Jörg Leuppi and colleagues has shown that in an investigator-sponsored, Phase II clinical trial, those patients with COPD that have a positive response to an Aridol challenge test are likely to benefit from inhaled corticosteroids treatment. In this trial, all patients had a positive response to inhaled histamine (a lung challenge test) whereas only 23% had a response to inhaled Aridol. After three months treatment with steroids, only those patients who recorded a positive Aridol challenge test had an improvement in their lung capacity. The difference in response to treatment between the two groups was highly statistically significant ( $p = 0.001$ ). In March 2007 we reported the results of a Phase II clinical trial to determine if Aridol is a practical test to guide treatment of inhaled corticosteroids in COPD patients in the primary care setting. In subjects with a positive Aridol challenge test, treatment with inhaled corticosteroids led to a statistically significant improvement in airway hyper-responsiveness as judged by a subsequent Aridol challenge test.

### (v) Drug Development

We currently conduct a number of different research programs including PXS25 and PXS4159.

#### PXS25

PXS25 is an inhibitor of the cation-independent mannose-6-phosphate/insulin-like growth factor-II receptor (CI-M6P/IGF2R). According to the type of ligand, CIM6PR/IGF2R may modulate a large panel of biological pathways, such as cell migration, wound healing, angiogenesis and cell growth inhibition,

PXS25 has been developed as a selective and stable antagonist of CIM6PR/IGF2R and has been studied in a variety of models of human disease. Our preclinical studies indicate that PXS25 is able to inhibit inflammatory cell ingress to selected organs including the lungs and may be useful in addressing clinical conditions such as COPD or fibrotic disorders of the lung.

In our animal studies, PXS25 demonstrated significant activity when administered by injection. However, the oral bioavailability of PXS25 is low in several species of animals. Therefore, we have developed PXS64, an orally available prodrug of PXS25 which is metabolized to active PXS25 once absorbed by the body.

The preclinical safety assessment of PXS25 as an intravenous formulation have been completed and initial Phase I clinical trials to determine the safety and pharmacokinetic properties of PXS25 are in preparation.

Additional preclinical research studies are in progress to determine the most appropriate clinical indication for PXS25 and the most appropriate route of delivery. Additional preclinical safety studies will be required if PXS25 is delivered to the lungs to treat fibrotic disorders of the lung and additional preclinical safety studies will be required if PXS25 is to be delivered orally via its prodrug PXS64.

## PSX4159

PXS4159 is a potent and selective inhibitor of semicarbazide sensitive amine oxidase (SSAO) which is also known as vascular adhesion protein-1 (VAP1). SSAO/VAP-1 plays a key role in inflammation.

The soluble products from SSAO/VAP-1 are highly reactive and include hydrogen peroxide and reactive aldehyde. The concentration of SSAO/VAP-1 circulating in the blood is increased in several inflammatory diseases, including congestive heart failure, inflammatory liver disease, and diabetes. The soluble products which form when SSAO/VAP-1 reacts with substrates are highly reactive and include hydrogen peroxide and reactive aldehyde.

SSAO/VAP-1 plays a role in the transmigration of leukocytes out of the blood stream into sites of inflammation. It has been reported in the scientific and patent literature that inhibition of the amine oxidase enzymatic activity of SSAO/VAP-1 in animal models of inflammatory diseases leads to amelioration of disease symptoms. Rheumatoid arthritis, lung inflammation, multiple sclerosis, liver inflammation and ocular inflammation disease models have been studied in this manner.

In a series of preclinical studies, PXS4159 has been shown to effectively inhibit the oxidase activity of SSAO/VAP-1 when administered to animals and to suppress inflammation in an animal model of lung disease, is effectively absorbed following oral administration and is well tolerated. On this basis, we have selected PXS4159 as our preferred development candidate and have commenced the scale up manufacture and pre-clinical safety studies necessary to evaluate the compound in humans.

### (vi) Our Strategy

Our objective is to build a specialty pharmaceutical company focused on respiratory and inflammatory/autoimmune indications. Key aspects of our strategy include:

- *Focus on attractive product opportunities in our core therapeutic areas.* We are developing products that address severe, chronic and acute respiratory and inflammatory diseases where there are limitations to current treatment and the patient population is treated by a relatively concentrated physician audience.
- *Successfully complete the clinical development of Bronchitol in two initial indications.* In the use of Bronchitol for cystic fibrosis we have recently successfully completed our Phase II clinical trial program, completed recruitment of our first Phase III clinical trial (in Europe and Australia) and initiated our second Phase III clinical trial (in the U.S.). In the use of Bronchitol for bronchiectasis we have successfully completed our first Phase III clinical trial, have agreed the protocol for a second Phase III clinical trial with the FDA and EMEA, and we are preparing to file a marketing application with the Australian TGA.
- *Increase manufacturing capacity.* We have a TGA approved manufacturing plant sufficient for the current commercial requirements of Aridol. A purpose built manufacturing, research and office facility is currently being constructed for us which we will equip with manufacturing capacity sufficient for our launch of Bronchitol into global markets.
- *Complete the international approval and commercial launch of Aridol.* We have received marketing authorization of Aridol in Europe, Australia and Korea. Based on our pre-IND meeting with the FDA, the completed U.S. clinical trial of Aridol and the earlier Phase III clinical trial that was the basis of marketing approval in Korea, Australia and Europe, we intend to file a New Drug Application (NDA) with the FDA. The commercial launch of Aridol continues throughout Europe and Asia as country specific marketing and pricing approvals are obtained.
- *Develop sales and marketing capabilities in select markets.* We intend to retain commercial rights to our products in indications and territories where we believe we can effectively market them with a small specialized sales force. For all other indications and territories, we intend to pursue strategic collaborations.
- *Continue to expand and progress our R&D pipeline.* We have a number of current research and development programs and will continue to build and strengthen our product pipeline and commercial capabilities, and we may acquire complementary technology and drug development candidates from research institutes, universities and private and public companies. These acquisitions may take the form of collaborations, licensing arrangements or outright purchase of intellectual property, research groups or corporate entities.

## 1.2.2 Business Overview (Continued)

### (vii) Sales and Marketing

We have a sales and marketing group in Australia and have appointed marketing and distribution partners for certain European and Asian territories with respect to the marketing and sale of Aridol. We have established offices in the United Kingdom, the U.S. and China to manage local marketing and distribution partners and/or undertake direct marketing to pulmonary specialists and third parties. In order to commercialize any of our other respiratory product candidates, we must further develop these capabilities internally or through collaborations with third parties. We intend to retain commercial rights to market our products to pulmonary specialists in the U.S. and Europe and may enter into sales, marketing and distribution agreements for other parts of the world. Because the U.S. and European pulmonary specialist market is relatively concentrated, we believe we can effectively target it with a small specialized sales force. We may pursue strategic collaborations to commercialize our products in other territories and on a worldwide basis for indications treated by large physician populations, such as asthma or chronic bronchitis.

### (viii) Manufacturing

We manufacture both Aridol and Bronchitol in our production facility located in Sydney, Australia, under conditions of current Good Manufacturing Practice, known as cGMP. Our manufacturing facility consists of a warehouse, adjoining office space, a cGMP laboratory for quality control and quality assurance, and clean rooms. Final packing of both Aridol and Bronchitol in foil packs is performed by a third party. The inhaler used in conjunction with both Aridol and Bronchitol is manufactured by a third party in Italy and is supplied to us on a non-exclusive basis through a standard supply agreement.

We believe that our manufacturing facility has ample operating capacity to produce adequate Aridol and Bronchitol to undertake the full clinical trial program through submission of an NDA in the U.S. for those product candidates and to support the commercial demand of Aridol two years after international launch. We have entered into an agreement concerning the lease of a purpose built manufacturing, warehousing and office facility. Construction of the new facility is underway and is expected to complete in the first quarter of 2009. We have entered an agreement for the construction of a spray dryer, being the key piece of production equipment to be housed in the new facility and are continuing to enter into agreements for other pieces of equipment which will be required to increase capacity.

Our cGMP facilities have been inspected and licensed by the Therapeutic Goods Administration. Our facilities and those of any third-party manufacturers will be subject to periodic inspections confirming compliance with applicable law of jurisdictions in which we have approved product. Our new facility must be cGMP certified before we can manufacture our drugs for commercial sale. Failure to comply with these requirements could result in the shutdown of our existing facilities or the assessment of fines or other penalties or an inability to supply product from our new facility.

Mannitol is the key raw material required for the manufacture of both Aridol and Bronchitol. cGMP grade mannitol is available from a number of suppliers. Inhalers are also available from a number of suppliers.

We have outsourced the manufacturing of cGMP grade PXS25 for preclinical and clinical trials as our manufacturing facilities are not suitable for the production of PXS25. Our contract manufacturers have the capacity to produce adequate PXS25 for clinical trials.

We have outsourced the manufacturing of cGMP grade PXS4159 for preclinical trials as our manufacturing facilities are not suitable for the production of PXS4159. Our contract manufacturers have the capacity to produce adequate PXS4159 for clinical trials.

### (ix) Competition

We operate in highly competitive segments of the biotechnology and pharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than do we. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. These companies also have significantly greater research capabilities than do we. In addition, many

universities and private and public research institutes are active in respiratory and autoimmune disease research, some in direct competition with us. We also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We are aware of many of our competitors in each of the markets we target. These products include approved and marketed products as well as products in development. We expect Aridol, to compete with direct bronchial provocation tests such as methacholine (Provocholine®) and histamine. We expect Bronchitol for CF to compete with or to be used in conjunction with Pulmozyme and other mucolytic agents and bronchodilators. Although it has little market penetration, Mucomyst®, marketed by AstraZeneca, is used by some physicians to treat bronchiectasis, other forms of COPD and CF. Numerous other potential competing therapeutic products are in clinical treatment and preclinical development, including new antibiotic preparations and new agents to restore salt balance. In each of our development programs addressing indications for which there are therapies available, we intend to complete clinical trials designed to evaluate the potential advantages of our drug candidates as compared to, or in conjunction with, the current standard of care. Key differentiating elements affecting the success of all of our drug candidates are likely to be their efficacy, convenience and side-effect profile compared to commonly used therapies.

## **(x) Intellectual Property**

We patent the technology, inventions and improvements that we consider important to the development of our business. As of 31 July 2008, we owned or had exclusive rights to 20 issued U.S. and foreign patents and 14 pending U.S. and foreign patent applications. Of these, 11 issued patents and three pending applications relate to Aridol and Bronchitol. The last of these issued patents are due to expire in 2021. One pending application relates to PXS25 and PXS64 and has now entered the national phase and one provisional application relates to PXS4159. The remaining patents and applications relate to other aspects of our technology or other drug discovery programs that have not yet entered a full development program. If available to us, we intend to seek patent term extension for our eligible patents, including under the Hatch-Waxman Act, which provides up to five years of patent extension.

We have the exclusive worldwide rights from Sydney South West Area Health Service for certain key intellectual property and patents relating to the use of respirable dry powders for the assessment of bronchial hyper-responsiveness, a condition consistent with active asthma, for monitoring steroid use in asthma patients, and enhancing mucus clearance in diseases such as cystic fibrosis, bronchiectasis and chronic bronchitis. These exclusive rights, which form the basis for patent protection of both Aridol and Bronchitol, derive from one issued U.S. and eight issued foreign patents. The U.S. and most of the foreign patents covering Aridol and Bronchitol are due to expire in 2015. The latest expiring in any territory is 2021. The U.S. and European patents may be eligible for extension by up to an additional five years, however, we cannot guarantee that any such extension would be granted.

We also have an exclusive worldwide license from ANU Enterprises Pty Ltd. (formerly Anutech Pty Ltd.) to develop and commercialize intellectual property relating to the treatment of inflammatory or immune-mediated conditions in patients by administering a phosphosugar. These exclusive rights derive from two issued U.S. and four issued foreign patents covering the E.U. member states and Australia, as well as other major territories. The last of these patents are due to expire in 2017. The U.S. patents may be eligible for extension by up to an additional five years however we cannot guarantee that any such extension would be granted.

Our ability to build and maintain our proprietary position for our technology and drug candidates will depend on our success in obtaining effective claims and enforcing those claims once granted. The patent positions of biopharmaceutical companies like ours are generally uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Some countries in which we may sell our product candidates or license our intellectual property may fail to protect our intellectual property rights to the same extent as the protection that may be afforded in the U.S. or Australia. Some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, the European Union, Australia or elsewhere. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex

## 1.2.2 Business Overview (Continued)

nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the U.S, the E.U. or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection.

We may not be able to develop patentable products or be able to obtain patents from pending patent applications. Even if patents are issued, those patents can be challenged by our competitors who can argue such patents are invalid. Patents also will not protect our products if competitors devise ways of making these product candidates without legally infringing our patents. The U.S. Federal Food, Drug and Cosmetic Act and FDA regulations and policies and equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, non-infringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes.

In addition, patent applications filed before 29 November 2000 in the U.S. are maintained in secrecy until patents issue. Later filed U.S. applications and patent applications in most foreign countries generally are not published until at least 18 months after they are filed. Scientific and patent publication often occurs long after the date of the scientific discoveries disclosed in those publications. Accordingly, we cannot be certain that we were the first to invent the subject matter covered by any patent application or that we were the first to file a patent application for any inventions.

The status of the Company's patent portfolio is summarized in the following table:

	USA	Europe	Australia	ROW
Patent Family 1 – Aridol and Bronchitol	G	P	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	P	P	G/P
Patent Family 5 – Novel pyrans and methods (PXS25)	NP	NP	NP	NP
Patent Family 7 – Novel inhibitors of TNF (PXS2076)	Prov			
Patent Family 8 – Novel inhibitors of SSAO/VAP-1 (PXS4159)	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	Granted	23 Feb 2015
Europe (EPO)	95910331.8	Under examination	23 Feb 2015
Japan	3979660	Granted	23-Feb-2015
	2006-317693	Under examination	
	2009-317692	Under examination	
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 February 1994. Subsequently, complete applications were filed via a PCT application (PCT/AU/95/00086) filed on 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 poly-saccharides 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 August 1988. Subsequently, complete applications were based on a PCT application (PCT/AU89/00350) filed on 18 August 1989.

## 1.2.2 Business Overview (Continued)

### ***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 auto-immune 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 on 18 October 1996.

### ***Patent Family 4 – Novel Compounds and Methods***

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

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

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

### ***Patent Family 5 – Novel Phosphotetrahydropyrans and Methods***

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



Country	Application No.	Status	Expires
USA	60/761,754	Under examination	20 years from filing date
Canada	2525328	Request examination by 20 May, 2009	20 years from filing date
New Zealand	544085	Under examination	20 years from filing date
Australia	2004240938	Request examination by 20 May, 2009	20 years from filing date
Europe	04752819.5	Under examination	20 years from filing date
Singapore	200507071-9	Under examination	20 years from filing date

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 tumor necrosis factor (TNF). The compounds are useful for the treatment of treat 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 28 January 2008 and the non-provisional and/or the international application must be filed by no later than 28 January 2009 in order to claim priority from this provisional application.

**Patent Family 8 – Novel Inhibitors of SSAO/VAP-1**

This patent relates to a series of compounds and pharmaceutical compositions comprising novel inhibitors of SSAO/VAP-1. The compounds are useful for the treatment of inflammatory conditions, immune disorders and cell proliferative disorders, either alone or in combination with known agents for these conditions.

Country	Application No.	Status	Expires
USA	Serial No. 60/689,634	Provisional Application	20 years from filing date

The U.S. provisional application was filed in the name of Pharmaxis Ltd on 21 November 2007 and the non-provisional and/or the international application must be filed by no later than 21 November 2008 in order to claim priority from this provisional application.

## 1.2.2 Business Overview (Continued)

### (xi) Government Regulation and Product Approval

Regulation by governmental authorities is a significant factor in the development, manufacture and marketing of pharmaceuticals. All of our products will require regulatory approval by regulatory authorities prior to commercialization and will be subject to a variety of regulations governing clinical trials and commercial sales and distribution of our product throughout the world. In particular, pharmaceutical drugs are subject to rigorous preclinical testing and clinical trials and other premarketing approval requirements by regulatory authorities. Regulatory authorities often also govern or impact upon the manufacturing, safety, labeling, storage, record-keeping and marketing of pharmaceutical products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources. Regulatory approval, when and if obtained for any of our product candidates, may be limited in scope which may significantly limit the indicated uses for which our product candidates may be marketed. Further, approved drugs and manufacturers are subject to ongoing review and discovery of previously unknown problems that may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

The approval process varies from country to country, and the time may be longer or shorter than that required in other countries. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. The following describes the typical regulatory framework applicable in North American, European and Australian jurisdictions.

#### ***Preclinical Studies***

Before testing any compounds with potential therapeutic value in human subjects, stringent government requirements for preclinical data must be satisfied. Preclinical testing includes both in vitro and in vivo laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Preclinical testing results obtained from studies in several animal species, as well as from in vitro studies, are typically submitted to the regulatory authority and reviewed by the regulatory authority prior to the commencement of human clinical trials. These preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial trials in human volunteers.

#### ***Clinical Trials***

If a company wants to test a new drug in humans, it must typically first apply to and receive approval from the relevant local regulatory authority. In addition, an institutional review board typically comprised in part of physicians at the hospital or clinic where the proposed trials will be conducted must review and approve the trial protocol and monitor the trial on an ongoing basis. The local regulatory authority typically retains the ability to impose a clinical hold on proposed or ongoing clinical trials, which can result in substantial delay and expense.

#### ***Clinical Trial Phases***

Clinical trials typically are conducted in three sequential phases, phases I, II and III, with phase IV trials potentially conducted after marketing approval. These phases may be compressed, may overlap or may be omitted in some circumstances.

- *Phase I clinical trials.* After receiving approval from the relevant local regulatory authority phase I human clinical trials can begin. These trials evaluate a drug's safety profile, and the range of safe dosages that can be administered to healthy volunteers and/or patients, including the maximum tolerated dose that can be given to a trial subject with the target disease or condition. Phase I trials also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and duration of its action.
- *Phase II clinical trials.* Phase II clinical trials typically are designed to evaluate the potential effectiveness of the drug in patients and to further ascertain the safety of the drug at the dosage given in a larger patient population.
- *Phase III clinical trials.* In phase III clinical trials, the drug is usually tested in a controlled, randomized trial comparing the investigational new drug to an approved form of therapy in an expanded and well defined patient population and at multiple clinical sites. The goal of these trials is to obtain definitive statistical evidence of safety and effectiveness of the investigational new drug regime as compared to an approved standard therapy in defined patient populations with a given disease and stage of illness.

All clinical trials for our products have been conducted in accordance with the ICH (International Conference on Harmonization) guidance so that we can apply for marketing authorization in multiple jurisdictions.

### ***New Drug Application/Marketing Authorisation Application***

After completion of clinical trials, if there is substantial evidence that the drug is safe and effective, a new drug application (NDA) or marketing authorization application (MAA), is prepared and submitted for the relevant local regulatory authority to review. The NDA/MAA must contain all of the essential information on the drug gathered to that date, including data from preclinical and clinical trials, and the content and format of an NDA/MAA must conform with all regulatory authority regulations and guidelines. Accordingly, the preparation and submission of an NDA/MAA is a major undertaking for a company.

In some countries the regulatory authority will review NDAs/MAAs submitted before accepting them for filing and may request additional information from the sponsor rather than accepting an NDA/MAA for filing. Once the submission is accepted for filing, the regulatory authority begins an in-depth review of the NDA/MAA. The time to review and respond to the NDA/MAA varies by country and may involve referring of the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved.

### ***Other Regulatory Requirements***

Any products we manufacture or distribute are subject to pervasive and continuing regulation by regulatory agencies including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are typically subject to periodic unannounced inspections by the regulatory authorities for compliance with current GMP regulations which impose procedural and documentation requirements upon us and any third party manufacturers we utilize.

Regulatory authorities closely regulate the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the relevant regulatory agency. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by regulatory authorities. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. Regulatory authorities do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict manufacturer's communications on the subject of off-label use.

Regulatory authority policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates or approval of new indications for our existing products. We cannot predict the likelihood, nature or extent of adverse governmental regulations that might arise from future legislative or administrative action.

### ***Regulation in the U.S.***

#### ***Preclinical Studies***

Before testing any compounds with potential therapeutic value in human subjects, in the United States, stringent government requirements for preclinical data must be satisfied. Preclinical testing includes both in vitro and in vivo laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. Preclinical testing results obtained from studies in several animal species, as well as from in vitro studies, are submitted to the FDA as part of an investigational new drug application, or IND, and are reviewed by the FDA prior to the commencement of human clinical trials. These preclinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial trials in human volunteers.

## 1.2.2 Business Overview (Continued)

### *New Drug Application*

After completion of clinical trials, if there is substantial evidence that the drug is safe and effective, a new drug application, or NDA, is prepared and submitted for the FDA to review. The NDA must contain all of the essential information on the drug gathered to that date, including data from preclinical and clinical trials, and the content and format of an NDA must conform with all FDA regulations and guidelines. Accordingly, the preparation and submission of an NDA is a major undertaking for a company.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information from the sponsor rather than accepting an NDA for filing. In such an event, the NDA must be submitted with the additional information and, again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Typically, the FDA takes ten months to review and respond to the NDA. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation, but gives great weight to it. If the FDA evaluations of both the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which usually contains a number of conditions that must be satisfied in order to secure final approval. If the FDA's evaluation of the NDA submission or manufacturing facility is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter.

The FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates or approval of new indications for our existing products. We cannot predict the likelihood, nature or extent of adverse governmental regulations that might arise from future legislative or administrative action, either in the United States or abroad.

We received orphan drug designation for Bronchitol from the FDA in August 2005 for the treatment of CF for patients at risk for developing bronchiectasis in the U.S. Bronchiectasis is a major risk for CF patients. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the applicant, the therapeutic agent and the designated orphan use are disclosed publicly by the FDA. The European Medicines Agency in November 2006 has likewise granted orphan drug designation for Bronchitol in the treatment of CF in Europe.

Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. The FDA may permit additional companies to market a drug for the designated condition if such companies can demonstrate clinical superiority. More than one product may also be approved by the FDA for the same orphan indication or disease as long as the products are different drugs. As a result, even if Bronchitol is approved to treat CF and receives orphan drug status, the FDA can still approve other drugs for use in treating the same indication or disease covered by Bronchitol, which could create a more competitive market for us. Moreover, if a competitor obtains approval of the same drug for the same indication or disease before us, we would be blocked from obtaining approval for our product for seven years, unless our product can be shown to be clinically superior.

### ***Regulation in the E.U.***

Under E.U. regulatory systems, marketing authorizations may be submitted either under a centralized procedure, a mutual recognition procedure or a decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for a joint assessment of safety and efficacy by a number of E.U. member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the member state

approving the first marketing authorization within the E.U. submits an application for recognition to other E.U. member states. Within 90 days of receipt of the application and the first member state's report of the assessment of the drug, the other member states are supposed to recognize the marketing authorization of the first member state or refer the application to the Committee for Human Medicinal Products, or CHMP, for arbitration, if one or more member states believe there is a potential serious risk to public health, and the member states cannot reach agreement on the approval of the product. The CHMP is a scientific expert committee of the European Medicines Agency, or EMEA. The EMEA is responsible for the protection of public health in the E.U. through the coordination and evaluation and supervision of medicinal products, including administering the centralized procedure and performing a more limited role in the mutual recognition procedures. After member states agree to mutual recognition of the first marketing authorization, national marketing authorizations must still be issued in each member state which recognized it, including approval of translations, labeling and the like.

### **Regulation in Australia**

In Australia, the relevant regulatory body responsible for the pharmaceutical industry is the Therapeutics Goods Administration, or TGA. The TGA maintains the Australian system of controls, safety, efficacy and availability of therapeutic goods used in Australia or exported from Australia.

Any products we manufacture in Australia or distribute in, or export from, Australia are subject to pervasive and continuing regulation by the TGA. Our products are subject to pre-market evaluation and approval by the TGA and must be entered on the Australian Register of Therapeutic Goods prior to commercial manufacture or sale. Our manufacturing facilities must be licensed by the TGA and our products must be manufactured in accordance with international standards of Good Manufacturing Practice. The TGA carries out a range of ongoing assessment and monitoring activities, including sampling, adverse event reporting, surveillance activities, and response to public inquiries and undertakes assessments of products for export. The TGA also regulates the advertising, labeling, product appearance and guidelines of our products.

The TGA's policies may change and additional governmental regulations may be enacted which could prevent or delay the regulatory approval of our product candidates or approval of new indications of our existing products. We cannot predict the likelihood, nature and extent or adverse governmental regulations that might arise from future legislative or administrative action.

In addition to regulations in Europe, Australia and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our products.

### **(xii) Employees**

As of 30 June 2008, we had 86 full time equivalent employees and full time contractors. A total of 35 of our employees and full time contractors are engaged in research and development, 35 are engaged in manufacturing which has a significant research component, with the remainder involved in administrative and marketing functions. We believe relations with our employees are generally good. None of our employees are covered by a collective bargaining agreement. For further details, see Section 1.6.2 of the Statutory Annual Report.

### **(xiii) Legal Proceedings**

We are not involved in any legal, arbitration or governmental proceedings which may have, or have had in the recent past, significant effects on our financial position or profitability. We are also not aware of any pending legal, arbitration or governmental proceedings against us which may have significant effects on our financial position or profitability.

### **(xiv) Research Grant Funding**

We have a research grant with the Commonwealth of Australia that assisted us in funding certain of our research programs.

Under our AusIndustry P3 Pharmaceuticals Partnerships Program funding deed with the Commonwealth of Australia, subject to certain conditions, the Commonwealth of Australia agreed to pay us a total amount of \$6.1 million between the July 2004 and June 2008 for eligible pharmaceutical research and development activities undertaken by us in relation to the development of new treatments for autoimmune diseases and the development of new treatments for chronic respiratory diseases. The grant concluded at 30 June, 2008 and no further funding is available thereunder. For details regarding this research grant, see Section 4.2.5 of this Statutory Annual Report.

### 1.2.3 Organisational Structure

We have two wholly owned subsidiaries:

- (i) Pharmaxis Pharmaceuticals Limited, incorporated under the laws of England and Wales.
- (ii) Pharmaxis, Inc., incorporated under the laws of the State of Delaware, U.S.

### 1.2.4 Property, Plant and Equipment

As of 30 June, 2008 we leased approximately 19,000 square feet of manufacturing, warehouse and office space at 10 Rodborough Road, Frenchs Forest, NSW 2086, Sydney, Australia. Our lease was renewed in June 2006 for a further five years, with an option to renew for a further five years thereafter. From 1 July 2002 to 30 June, 2008, we spent approximately A\$5 million related to the establishment of this manufacturing facility.

As of 30 June, 2008 we license approximately 2,000 square feet of research laboratory and office space at Building 34, 1 Rivett Road, Riverside Corporate Park, North Ryde, Sydney, Australia. Our lease is terminable at one month's notice by either party. Our research staff based at this site will relocate to our new facility at Frenchs Forest once it is completed in early 2009.

We will require additional space and facilities as our business expands. In particular, we will require additional manufacturing capabilities. We have therefore entered into an agreement concerning the lease of a custom designed manufacturing, warehousing and office facility of approximately 75,000 square feet. The facility is being constructed to our specifications. Once the lease commences, the lease will have a term of 15 years, with two options to renew of a further five years each and the option to break the lease at ten years but with financial penalties attached. We anticipate spending approximately A\$20 million to fitout this facility and acquire additional and expanded production equipment.

## 1.3 Corporate Governance

### 1.3.1 Introduction

We have adopted a Corporate Governance Framework. In preparing the framework, we have been mindful of the revised Corporate Governance Principles and Recommendations (second edition) issued by ASX Limited's Corporate Governance Council in August 2007 ('ASX Governance Principles'). Compliance with the recommendations set out in the ASX Governance Principles are not mandatory however departures from the recommendations are required to be disclosed in our Statutory Annual Report. ASX Listing Rule 12.7 requires that we must comply with the recommendation in relation to the composition, operation and responsibility of our audit set out in Principle 4 of the ASX Governance Principles. We have also adopted certain corporate governance requirements arising as a result of our ADS's being quoted on the Nasdaq Global Market.

The Board reviews and updates our Corporate Governance Framework as required and at least annually.

This statement reflects our corporate governance framework, policies and procedures as at 12 August 2008. The documents referred to in this section, are available for viewing in the corporate governance section of our website (unless otherwise stated) at [www.pharmaxis.com.au](http://www.pharmaxis.com.au)

### 1.3.2 ASX Disclosures

A description of our Corporate Governance Framework and supporting policies are available on our website. The disclosures required by the ASX Governance Principles are set out below. For ease of reference, this section is structured within the context of the ASX Governance Principles.

***Principle 1: Lay Solid Foundations for Management and Oversight***

*Companies should establish and disclose the respective roles and responsibilities of board and management.*

***Recommendation 1.1***

*Companies should establish the functions reserved to the board and those delegated to senior executives and disclose those functions.*

This is disclosed on our website.

## **Recommendation 1.2 & 1.3**

*Companies should disclose the process for evaluating the performance of senior executives and provide the information required in the guide to Principle 1.*

The performance of our Chief Executive Officer and Senior Executive Officers was evaluated in the current year in accordance with the process described below.

The Remuneration and Nomination Committee is specifically responsible for reviewing the ongoing performance of the Chief Executive Officer ('CEO') and ensuring there is an appropriate process to review the performance of Senior Executive Officers and for setting and approving performance objectives of Senior Executive Officers in relation to bonus payments and options. In June of each year the Remuneration and Nomination Committee:

- approves individual milestone objectives for the CEO and Senior Executive Officers for the coming financial year, the milestones being based on our business plan approved by the Board;
- evaluates the performance of the CEO compared to milestone 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 Executive Officers, reviews recommendations, considers and approves the payment of any bonus and/or the grant and vesting of any options based on performance of milestone objectives for the current financial year.

## **Principle 2: Structure the Board to Add Value**

*Companies should have a board of an effective composition, size and commitment to adequately discharge its responsibilities and duties.*

### **Recommendation 2.1**

*A majority of the board should be independent directors.*

Our Board of Directors currently consists of six directors, including five non-executive directors, one of whom is the non-executive chairman. Details of the skills, experience and expertise of each of our directors are set out in the Section 1.4.1 of this Statutory Annual Report.

Under our constitution, the number of Directors will not, unless otherwise determined by an ordinary resolution of our shareholders, be less than three or more than nine. A Director need not be a shareholder of us. Only a person over the age of 18 may be appointed as a director.

We regard our five non-executive Directors, Messrs. McComas, Farrell, Villiger, Delaat and Hanley as independent for the purposes of the ASX Governance Principles. The Board regularly assesses director independence having regard to the criteria outlined in the ASX Governance Principles. 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 or Committee fees.

We do not regard Dr. Robertson as an independent Director as he is an executive officer.

The Board has an agreed procedure for Directors and Board Committees to obtain independent professional advice at the Company's expense.

### **Recommendation 2.2**

*The chair should be an independent director.*

The Chairman of our Board is an independent director. Our Corporate Governance Framework requires the Chairman to be independent.

### **Recommendation 2.3**

*The roles of the chair and the chief executive officer should not be exercised by the same individual.*

The role of Chairman and Chief Executive Officer are exercised by different individuals. Our Corporate Governance Framework requires the Chairman to be a different individual to the Chief Executive Officer.

### 1.3.2 ASX Disclosures (continued)

#### *Recommendation 2.4*

*The board should establish a nomination committee.*

We have a Remuneration and Nomination Committee. The combined role is considered appropriate for a company of our size. A copy of the Remuneration and Nomination Committee Charter is available on our website. The purpose of our Remuneration and Nomination Committee is:

- monitor the ongoing development of the Board consistent with our growth and development;
- make recommendations for the appointment and removal of Directors to the Board;
- assist the Board evaluate the performance and contribution of individual directors, the Board and Board Committees; and
- assist the Board in establishing remuneration policies and practices that enable us to attract, retain and motivate executives and Directors who will pursue our long-term growth and success.

The Remuneration and Nomination Committee consisted entirely of independent directors during the financial year ended 30 June 2008. The chairman of the Remuneration and Nomination Committee is an independent Director.

The names of the members of the Remuneration and Nomination Committee, the number of meetings held in the financial year ended 30 June 2008 and the number of meetings attended by each member is detailed in Section 1.4.2 of this Statutory Annual Report.

#### *Recommendation 2.5*

*Companies should disclose the process for evaluating the performance of the board, its committees and individual directors.*

Our Remuneration and Nomination Committee is responsible for overseeing the process for evaluating the performance of the Board, Board Committees and individual Directors. Evaluations were conducted in the current year in accordance with the process described below.

Our Remuneration and Nomination Committee conducts an annual survey of Directors.

A Board performance survey is used to:

- review our current corporate governance practices and identify any requirements that required to be changed;
- 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; and
- examine ways of assisting the Board in performing its duties more effectively and efficiently.

The Board performance surveys are collated by the Company Secretary and discussed at a subsequent Board meeting where the implementation of recommendations is agreed.

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; and
- review their committee charter annually, and recommend changes to the Board.

An individual director performance survey is used 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/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.



**Principle 3: Promote Ethical and Responsible Decision-making**

*Companies should actively promote ethical and responsible decision-making.*

**Recommendation 3.1**

*Companies should establish a code of conduct and disclose the code or a summary of the code as to:*

- *the practices necessary to maintain confidence in the company's integrity*
- *the practices necessary to take into account their legal obligations and the reasonable expectations of their stakeholders*
- *the responsibility and accountability of individuals for reporting and investigating reporting and investigating reports of unethical practices.*

A copy of our Code of Conduct is available on our website.

**Recommendation 3.2**

*Companies should establish a policy concerning trading company securities by directors, senior executives and employees, and disclose the policy or a summary of that policy.*

A copy of our Share Trading Policy is available on our website.

**Principle 4: Safeguard Integrity in Financial Reporting**

*Companies should have a structure to independently verify and safeguard the integrity of their financial reporting.*

**Recommendation 4.1**

*The board should establish an audit committee.*

We have an Audit Committee.

**Recommendation 4.2**

*The audit committee should be structured so that it:*

- *consists only of non-executive directors;*
- *consists of a majority of independent directors;*
- *is chaired by an independent chair, who is not chair of the board; and*
- *has at least three members.*

The structure of our Audit Committee complies with the above recommendation. Our Audit Committee is responsible for:

- the integrity of the financial reporting process and all other financial information published by the us;
- the integrity of the our financial reporting system, including the management of risk and systems of internal control;
- our internal and external audit process, including appointing the external auditor and overseeing the independence of the external auditor; and
- our process for monitoring compliance with laws and regulations and our own Code of Conduct.

The members of our Audit Committee are Messrs. McComas (chairman), Hanley and Delaat. Mr. Kiefel was a member of the Audit Committee until his retirement from the Board in December 2007. Dr. Villiger was a member of the Audit Committee following the retirement of Mr. Kiefel up until Mr. Delaat was appointed to the Board and the Audit Committee in June 2008.

The names of the members of the Audit Committee, their qualifications, the number of meetings held in the financial year ended 30 June 2008 and the number of meetings attended by each member is detailed in Section 1.4.2 of this Statutory Annual Report.

### 1.3.2 ASX Disclosures (continued)

#### *Recommendation 4.3*

*The audit committee should have a formal charter.*

Our Audit Committee Charter is available on our website. The Audit Committee Charter provides information on procedures for the selection and appointment of our external auditor.

#### **Principle 5: Make Timely and Balanced Disclosure**

*Companies should promote timely and balanced disclosure of all material matters concerning the company.*

#### *Recommendation 5.1*

*Companies should establish written policies designed to ensure compliance with ASX Listing Rule disclosure requirements and to ensure accountability at a senior executive level for that compliance and disclose those policies or a summary of those policies.*

We have a Continuous Disclosure and Shareholder Communications Policy, which is available on our website.

We have a Disclosure Committee to oversee the implementation of the policies and procedures in relation to communications with the market.

The Disclosure Committee consists of the:

- Chief Executive Officer;
- Chief Financial Officer/Company Secretary;
- Chairman of the Board;
- Medical Director; and
- Commercial Director.

#### **Principle 6: Respect the Rights of Shareholders**

*Companies should respect the rights of shareholders and facilitate the effective exercise of those rights.*

#### *Recommendation 6.1*

*Companies should design a communications policy for promoting effective communication with shareholders and encouraging their participation at general meetings and disclose their policy or a summary of that policy.*

Our Continuous Disclosure and Shareholder Communication Policy is available on our website. In addition to our continuous disclosure and statutory reporting requirements, we provide shareholders with quarterly updates of our progress across all areas of the business and utilize our website to disclose useful and relevant information about us.

#### **Principle 7: Recognise and Manage Risk**

*Companies should establish a sound system of risk oversight and management and internal control.*

#### *Recommendation 7.1*

*Companies should establish policies for the oversight and management of material business risks and disclose a summary of those policies.*

The Audit Committee is responsible to the Board for oversight of material business risks and internal controls.

Our Risk Management Statement is available on our website and provides an overview of our risk profile, management strategies and internal controls. Section 2.4 of this Statutory Annual Report also contains details of the material business risks relevant to us.

## **Recommendation 7.2**

*The board should require management to design and implement the risk management and internal control system to manage the company's material business risks and report to it on whether those risks are being managed effectively. The board should disclose that management has reported to it as to the effectiveness of the company's management of its material business risks.*

The Audit Committee, as part of its oversight in this area, requires management to establish appropriate systems and procedures to manage our material business risks and to report on the effective management of those risks. Management has provided the Board in the current year with a report that attested to the effective management of our material business risks.

## **Recommendation 7.3**

*The board should disclose whether it has received assurance from the chief executive officer and the chief financial officer that the declaration provided in accordance with section 295A of the Corporations Act is founded on a sound system of risk management and internal control and that the system is operating effectively in all material respects in relation to financial reporting risks.*

This recommendation is a requirement of our Corporate Governance Framework as well as U.S. securities legislation. The Board has received such assurances in writing from the chief executive officer and chief financial officer.

## **Principle 8: Remunerate Fairly and Responsibly**

*Companies should ensure that the level and composition of remuneration is sufficient and reasonable and that its relationship to performance is clear.*

## **Recommendation 8.1**

*The board should establish a remuneration committee.*

We have a Remuneration and Nomination Committee. A copy of our Remuneration and Nomination Committee Charter is available on our website.

As noted above, our Remuneration and Nomination Committee consists of Mr. Hanley, Dr. Farrell and Dr. Villiger all of whom are independent directors. None of our executive officers serve as a member of the board of directors or compensation committee of any entity that has one or more executive officers who serve on our Board of Directors or Remuneration and Nomination Committee.

## **Recommendation 8.2**

*Companies should clearly distinguish the structure of non-executive directors' remuneration from that of executive directors and senior executives.*

As non-executive Directors assess individual and Company performance, their remuneration does not have any variable incentive component. Only the Executive Director and Senior Executive Officer remuneration includes a variable component such as the vesting of options or bonus payments linked to the achievement of performance targets.

Note that Directors, Senior Executive Officers and other persons designated by the Board are not permitted to trade in derivatives of our securities without the written consent of the Board. For further details in relation to our remuneration framework, refer to the Remuneration Report set out in Section 1.5 of this Statutory Annual Report.

### 1.3.3 Corporate Governance Requirements Arising from Our U.S. Listing – the Sarbanes-Oxley Act of 2002, SEC Rules and the Nasdaq Global Market Marketplace Rules.

Our shares in the form of ADRs are quoted on the Nasdaq Global Market. The Sarbanes-Oxley Act of 2002, as well as related new rules subsequently implemented by the SEC, require companies which are considered to be foreign private issuers in the U.S, such as us, to comply with various corporate governance practices. In addition, Nasdaq has made certain changes to its corporate governance requirements for companies that are listed on the Nasdaq Global Market. These changes allow us to follow Australian 'home country' corporate governance practices in lieu of the otherwise applicable Nasdaq corporate governance standards, as long as we disclose each requirement of Rule 4350 that we do not follow and describe the home country practice we follow in lieu of the relevant Nasdaq corporate governance standards. We intend to take all actions necessary to maintain compliance with applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, rules adopted by the SEC and listing standards of Nasdaq. We follow Australian corporate governance practices in lieu of the corporate governance requirements of the Nasdaq Marketplace Rules in respect of:

- Nasdaq requirement under Rule 4350(f) that a quorum consist of holders of 33 1/3% of the outstanding ordinary shares – The ASX Listing Rules do not have an express requirement that each issuer listed on ASX have a quorum of any particular number of the outstanding ordinary shares, but instead allow a listed issuer to establish its own quorum requirements. Our quorum is currently five persons who are entitled to vote. We believe this quorum requirement is consistent with the requirements of the ASX and is appropriate and typical of generally accepted business practices in Australia.
- The Nasdaq requirements under Rules 4350(c)(1) and (2) relating to director independence, including the requirements that a majority of the board of directors must be comprised of independent directors and that independent directors must have regularly scheduled meetings at which only independent directors are present – The Nasdaq and ASX definitions of what constitute an independent director are not identical and the requirements relating to the roles and obligations of independent directors are not identical. The ASX, unlike Nasdaq, permits an issuer to establish its own materiality threshold for determining whether a transaction between a director and an issuer affects the director's status as independent and it does not require that a majority of the issuer's board of directors be independent, as long as the issuer publicly discloses this fact. In addition, the ASX does not require that the independent directors have regularly scheduled meeting at which only independent directors are present. We believe that our Board composition is consistent with the requirements of the ASX and that it is appropriate and typical of generally accepted business practices in Australia.
- The Nasdaq requirements under Rule 4350(d) (other than Rule 4350(d)(2)(A)(ii), which we will comply with) relating to the composition of the audit committee and the audit committee charter – The Nasdaq and ASX audit committee requirements are not identical. Moreover, differences in the requirements of Nasdaq and ASX also arise because of the differences in the definitions of who constitutes an independent director, as discussed above. Issuers listed in the top 300 of the S&P ASX All Ordinaries, such as us, are required to establish an audit committee consisting only of non-executive directors, a majority of independent directors, an independent chairman, and at least three members, and adopt a formal audit committee charter which sets out the roles and responsibilities, composition, structure and membership requirements of the audit committee. We have an audit committee and audit committee charter that are consistent with the requirements of the ASX Listing Rules and which we believe are appropriate and typical of generally accepted business practices in Australia. We also comply and will continue to comply with Nasdaq Rule 4350(d)(3) relating to audit committees responsibilities and authority required by SEC Rule 10A-3(b)(2)-(5).
- The Nasdaq requirements under Rules 4350(c)(3) and (4) that compensation of an issuer's officers must be determined, or recommended to the Board for determination, either by a majority of the independent directors, or a compensation committee comprised solely of independent directors, and that director nominees must either be selected, or recommended for the Board's selection, either by a majority of the independent directors, or a nominations committee comprised solely of independent directors. The Nasdaq compensation committee requirements are not identical to the Australian Securities Exchange remuneration and nomination committee requirements. Issuers listed on the ASX are recommended under applicable listing standards to establish a remuneration committee consisting of a majority of independent directors and an independent chairperson, or publicly disclose that it has not done so. We have a Remuneration and Nomination Committee that is consistent with the requirements of the ASX and which we believe is appropriate and typical of generally accepted business practices in Australia.

## 1.4 Directors Report

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 2008.

### 1.4.1 Information on Directors

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

*Alan D. Robertson, Ph.D. (age 52)*, has been our Chief Executive Officer since December 1999 and a member of our Board of Directors since July 2000. Dr. Robertson has more than two decades of experience in drug discovery and product development with leading pharmaceutical companies, including spending 8 years with Wellcome plc in London and thereafter with two Australian companies, Faulding Ltd and Amrad Ltd. Dr. Robertson has been actively involved in the discovery, development and marketing of various compounds, including new treatments for migraine and cardiovascular disease. Dr. Robertson is the co-inventor of 18 patents and author of more than 35 scientific papers, and was the inventor of the migraine therapeutic Zomig that is marketed worldwide by AstraZeneca. Dr. Robertson holds a B.Sc. and a Ph.D. in Synthetic Organic Chemistry from the University of Glasgow.

*Denis M. Hanley (age 61)* has been the Chairman of our Board of Directors since October 2001. From 1983 to 1997, Mr. Hanley served as Chief Executive Officer of Memtec Limited, a leader in the design and manufacture of microfiltration membrane systems. From 1971 to 1982, Mr. Hanley held various positions within Baxter Healthcare, most recently as Australian Managing Director. Mr. Hanley has served on the Australian Industry Research and Development Board and various technology councils and roundtables. Mr. Hanley serves on the board of directors of Universal Biosensors, Inc., CathRx Ltd and PFM Cornerstone Limited, and was a member of the Australian Government's Cooperative Research Centre Committee. Mr. Hanley holds an M.B.A. with high distinction from the Harvard Graduate School of Business Administration, where he was named a Baker Scholar. Mr Hanley is Chairman of the Remuneration and Nomination Committee and a member of the Audit Committee.

*Peter C. Farrell, Ph.D. (age 66)* has been a member of our Board of Directors since March 2006. Dr. Farrell has more than two decades of experience in developing and commercializing medical products in the U.S., Europe, Japan and Australia. Dr. Farrell began his commercial career with Baxter Healthcare, Inc. in Japan as Director and Vice President of Research and Development, then as Managing Director of the Baxter Center for Medical Research. He left Baxter in 1989 to establish ResMed, Inc., a company that develops treatments for sleep-disordered breathing and respiratory failure. Dr. Farrell is currently founding Chairman and Chief Executive Officer of ResMed Inc. Dr. Farrell serves on the Executive Councils of Harvard Medical School and the University of California at San Diego, and is visiting Professor at the University of Sydney. Dr. Farrell has written more than 150 papers covering topics from engineering applications in medicine to focusing technology to meet business objectives. Dr. Farrell holds bachelor and masters degrees in chemical engineering from the University of Sydney and the Massachusetts Institute of Technology, a Ph.D. in bioengineering from the University of Washington, Seattle and a Doctor of Science from the University of New South Wales for research related to dialysis and renal medicine. Dr Farrell is a member of our Remuneration and Nomination Committee.

*Malcolm J. McComas (age 53)* has been a member of our Board of Directors since July 2003. Mr. McComas is an experienced company director and has more than two decades of experience in investment banking, particularly in equity and debt finance, mergers and acquisitions, and privatizations. From 1999 to 2004, Mr. McComas was a director of Grant Samuel, the corporate advisor, property services and funds management group and currently serves as a consultant. During 1998, Mr. McComas served as a Managing Director at Salomon Smith Barney. From 1988 to 1998, Mr. McComas served as a Managing Director at County NatWest. Mr. McComas serves as a non-executive director of Falkiner Global Investors Limited and Ocean Capital Limited and as non-executive chairman of Sunshine Heart Inc. Mr. McComas holds a Bachelor of Economics and a Bachelor of Laws from Monash University. Mr McComas is chairman of our Audit Committee.

#### 1.4.1 Information on Directors (continued)

*John Villiger, Ph.D. (age 54)* has been a member of our Board of Directors since November 2006. Dr. Villiger co-founded The Medicines Company, a Nasdaq listed company in 1996. Dr. Villiger was Senior Vice President of Development until February 2006. The Medicines Company has a significant marketed product with two other products in late stage clinical development. From 1986 to 1996 Dr. Villiger held various positions in product development at Roche in both New Zealand and Switzerland, including International Project Director from 1991 to 1995 and Head of Global Project Management from 1995 to 1996. As Head of Global Project Management, he oversaw the development of Roche's pharmaceutical portfolio, with programs in Switzerland, the UK, U.S. and Japan. Dr. Villiger holds a Ph.D. in psychopharmacology from the University of Otago. Dr Villiger is a member of our Remuneration and Nomination Committee and served on our Audit Committee from December 2007 to June 2008.

*William L. Delaat (age 57)* was appointed a member of our Board of Directors on June 23, 2008. Mr Delaat has 35 years experience in the global pharmaceutical industry, most recently as the managing director of the Australian subsidiary of Merck & Co., a position he held from 1997 until his retirement in 2008. During his career Mr Delaat has held executive positions in both Europe and Australia for Merck and AstraZeneca. Mr Delaat is experienced in sales and marketing and has been responsible for international product launches and commercialisation of respiratory products. Mr Delaat is chairman of the Australian pharmaceutical industry's peak body, Medicines Australia, and is chairman of the Pharmaceuticals Industry Council. Mr Delaat holds a Bachelor of Science, Physiology & Chemistry from the University of London. Mr Delaat is a member of our Audit Committee.

*Charles Kiefel* was a member of our Board of Directors from the beginning of the financial year until his resignation in December 2007.

There are no family relationships between any of our Senior Executive Officers or Directors.

#### 1.4.2 Meetings 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 2008, and the number of meetings attended by each Director was:

	Board Meetings		Meetings of Committees			
			Audit		Remuneration & Nomination	
	A	B	A	B	A	B
DM Hanley	9	9	3	3	4	4
AD Robertson	9	9				
CPH Kiefel	6	6	2	1		
MJ McComas	9	7	3	2		
PC Farrell	9	7			4	3
J Villiger	9	9	1	1	4	4
WL Delaat	0	0	0	0		

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

#### 1.4.3 Indemnification and Insurance of Directors

Our Constitution provides that, except to the extent prohibited by the Corporations Act 2001, each of our officers shall be indemnified out of our funds against any liability incurred by such person in his or her capacity as an officer in defending any legal proceedings, whether civil or criminal, in which judgment is given in such person's favor or where such officer is acquitted in connection with any application under the *Corporations Act 2001* and relief is granted to such officer by a court.

We have entered into Deeds of Access to Documents and Indemnity agreements to indemnify our Directors and certain of our executive officers and to provide contractual indemnification in addition to the indemnification provided for in our Constitution. We believe that these provisions and agreements are necessary to attract and retain qualified directors and executive officers. Our Constitution also permits us, to the extent permitted by law, to secure insurance on behalf of any officer for any liability arising out of his or her actions.

At present, there is no pending litigation or proceeding involving any of our Directors, officers, employees or agents where indemnification by us will be required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

We maintain directors' and officers' liability insurance providing for the indemnification of our Directors and officers against certain liabilities incurred as a director or officer, including costs and expenses associated in successfully defending legal proceedings. We intend to continue to maintain this insurance in the future. During the financial year, we paid a premium of \$144,000 to insure the directors and officers of the Group for the policy year ended 26 September 2008. 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.

#### **1.4.4 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 the New York Stock Exchange.

#### **1.4.5 Principal Activities**

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

#### **1.4.6 Review and Results of Operations**

A review of the operations of the Group for the financial year ended 30 June 2008 is set out in Section 2.2 of this Statutory Annual Report.

#### **1.4.7 Remuneration Report**

Refer to Section 1.5 of this Statutory Annual Report.

#### **1.4.8 Dividends**

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

We have never declared or paid any cash dividends on our ordinary shares and we do not anticipate paying any cash dividends in the foreseeable future. Dividends may only be paid out of our profits. Payment of cash dividends, if any, in the future will be at the discretion of our Board of Directors or, if our Directors do not exercise their power to issue dividends, our shareholders in a general meeting may exercise the powers.

#### **1.4.9 Significant Changes in the State of Affairs**

The Australian share placement and share purchase plan increased cash funds by A\$59.2 million after deducting associated expenses. Together with pre-existing funds the Group ended the year with A\$111.8 million in cash and bank accepted commercial bills. Capital expenditure for the 2008 financial year of A\$5.1 million compares to A\$1.3 million in 2007. Expenditure was predominantly related to the fit out of a new facility being constructed for us and additional manufacturing equipment to be housed in the new facility. Refer also to Section 2.2.5 of this Statutory Annual Report.

#### **1.4.10 Matters Subsequent to the End of the Financial Year**

No matter or circumstance has arisen since 30 June 2008 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.

#### **1.4.11 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 are set out in Section 2.2 of this Statutory Annual Report.

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.

#### **1.4.12 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.

#### **1.4.13 Rounding**

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.

#### **1.4.14 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 19 to the Annual Financial Report included in Section 3 of this Statutory Annual Report.

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 decision making capacity for the Company, acting as advocate for the Company or jointly sharing economic risk and rewards.



## 1.4.15 Auditors' Independence Declaration

A copy of the auditors' independence declaration as required under section 307C of the *Corporations Act 2001* is below.

### Auditor's Independence Declaration

As lead auditor for the audit of Pharmaxis Ltd for the year ended 30 June 2008, 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.



**Mark Dow**  
Partner  
PricewaterhouseCoopers  
  
Sydney  
12 August 2008

## 1.4.16 Auditor

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

## 1.4.17 Resolution of the Board

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



**Alan D Robertson**  
Director  
  
Sydney  
12 August 2008

## 1.5 Remuneration Report

### Remuneration Report

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

- 1.5.1. Principles used to determine the nature and amount of remuneration paid to Directors and Senior Executive Officers
- 1.5.2. Details of remuneration paid to Directors and Senior Executive Officers
- 1.5.3. Service agreements with Senior Executive Officers
- 1.5.4. Share based compensation paid to Directors and Senior Executive Officers
- 1.5.5. Additional information on compensation paid to Directors and Senior Executive Officers
- 1.5.6. Employee option plan.

We make our remuneration disclosures to meet both Australian and applicable U.S. requirements. Wherever possible this report has been prepared to meet the requirements of both jurisdictions with a single disclosure. However in certain instances additional disclosures are required to address specific differing jurisdictional disclosures for format or content. Where additional disclosures are required to address U.S. requirements, we have sought to provide explanations of the basis of presentation.

#### 1.5.1 Principles Used to Determine the Nature and Amount of Remuneration Paid to Directors and Senior Executive Officers

As a company building a specialty pharmaceutical business, we require 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 Senior Executive Officer remuneration includes a mix of short and long-term components. Remuneration of Executive Directors and Senior Executive Officers 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 2008 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 senior executives 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 chairman;
- 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 our Employee Option Plan. As the options are granted in substitution for current year cash compensation they vest at the latter of award or shareholder approval. Options issued to Non-Executive Directors prior to August 2006 vest over a four year period.

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 Senior Executive Officers:**

There are four components to the remuneration of Executive Directors and Senior Executive Officers:

- a base salary paid in cash or packaged at the executive's discretion within Australian Fringe Benefit's Tax, or FBT, guidelines as a total cost package;
- superannuation of 9 percent of base salary;
- 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; and
- options under our 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 which 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 us.

Base pay for the Chief Executive Officer and Senior Executive Officers 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.

#### *Termination payments*

Termination payments apply only to Executive Directors and Senior Executive Officers. The employment contracts for each of the Executive Directors and Senior Executive Officers can be terminated immediately by us for serious misconduct and with three months notice without cause. Unless otherwise required by law, no additional payments apply on termination.

#### *Pharmaxis Ltd Employee Option Plan*

Information on the Pharmaxis Ltd Employee Option Plan is set out in Note 29 to the Annual Financial Report included in Section 3 of this Statutory Annual Report and Section 1.5.6 of this Statutory Annual Report.

### 1.5.2 Details of Remuneration Paid to Directors and Senior Executive Officers

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

The Senior Executive Officers and the Chief Executive Officer of the Group and the entity are:

<i>Name</i>	<i>Position</i>	<i>Employer</i>
Alan Duncan Robertson	Chief Executive Officer	Pharmaxis Ltd
Brett Charlton	Medical Director	Pharmaxis Ltd
John Francis Crapper	Chief Operations Officer	Pharmaxis Ltd
Ian Alexander McDonald	Chief Technical Officer	Pharmaxis Ltd
David Morris McGarvey	Chief Financial Officer and Company Secretary	Pharmaxis Ltd
Gary Jonathan Phillips	Commercial Director	Pharmaxis Ltd

Included in the above are the five highest remunerated Group and entity executives.

The payment of cash bonuses are dependent on the satisfaction of performance conditions as discussed in Section 1.5.1 of this Statutory Annual Report, 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.

# Section 1

2008	Short-term benefits			Post-employment benefits	Long-term benefits	Share-based payment	Total A\$
	Cash salary or Directors' fees A\$	Cash bonus/incentive A\$	Non-monetary benefits A\$	Super-annuation A\$	Long service leave A\$	Options value <sup>1</sup> A\$	
<i>Non-Executive Directors</i>							
DM Hanley <i>Chairman</i>	106,558	–	–	9,590	–	10,082	126,230
WL Delaat <sup>3</sup>	1,250	–	–	–	–	–	1,250
CPH Kiefel <sup>2</sup>	19,878	–	–	1,789	–	5,041	26,708
MJ McComas	65,574	–	–	–	–	5,041	70,615
PC Farrell	60,251	–	–	–	–	88,164	148,415
J Villiger	67,917	–	–	–	–	212,790	280,707
<b>Sub-total Non-Executive Directors</b>	<b>321,428</b>	<b>–</b>	<b>–</b>	<b>11,379</b>	<b>–</b>	<b>321,118</b>	<b>653,925</b>
<i>Executive Director</i>							
AD Robertson	353,476	90,750	–	31,813	17,247	340,187	833,473
<i>Senior Executive Officers</i>							
B Charlton	263,681	37,500	–	23,731	13,163	275,470	613,545
JF Crapper	247,538	37,500	–	22,278	10,712	265,368	583,396
IA McDonald	202,000	45,000	–	18,180	5,929	263,863	534,972
DM McGarvey	277,944	45,000	–	25,015	12,948	265,368	626,275
GJ Phillips	269,063	45,000	–	24,216	10,447	266,281	615,007
<b>Totals</b>	<b>1,935,130</b>	<b>300,750</b>	<b>–</b>	<b>156,613</b>	<b>70,445</b>	<b>1,997,655</b>	<b>4,460,593</b>

<sup>1</sup> The fair value of options granted was estimated on the date of each grant using the Black-Scholes option pricing model and recognised as option expense and remuneration over the vesting period.

<sup>2</sup> Mr Kiefel retired as a Director on 19 December 2007.

<sup>3</sup> Mr Delaat was appointed as a Director on 23 June 2008.

### 1.5.2 Details of Remuneration Paid to Directors and Senior Executive Officers (continued)

2007	Short-term benefits			Post-employment benefits	Long-term benefits	Share-based payment	Total A\$
	Cash salary or Directors' fees A\$	Cash bonus/incentive A\$	Non-monetary benefits A\$	Super-annuation A\$	Long service leave A\$	Options value <sup>1</sup> A\$	
<i>Non-Executive Directors</i>							
DM Hanley <i>Chairman</i>	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 <sup>2</sup>	10,174	–	–	–	–	–	10,174
J Villiger	35,000	–	–	–	–	–	35,000
<b>Sub-total Non-Executive Directors</b>	<b>202,478</b>	<b>–</b>	<b>–</b>	<b>6,627</b>	<b>–</b>	<b>342,553</b>	<b>551,658</b>
<i>Executive Directors</i>							
AD Robertson	329,025	93,500	–	29,612	8,205	161,843	622,185
<i>Senior Executive Officers</i>							
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
<b>Totals</b>	<b>1,725,284</b>	<b>273,500</b>	<b>–</b>	<b>143,680</b>	<b>30,311</b>	<b>1,032,982</b>	<b>3,205,757</b>

<sup>1</sup> The fair value of options granted was estimated on the date of each grant using the Black-Scholes option pricing model and recognised as option expense and remuneration over the vesting period.

<sup>2</sup> Ms Smith retired as a Director in October 2006.

*Remuneration subject to risk*

Of the total amount of remuneration paid to the Chief Executive Officer and other Senior Executive Officers, both the payment of the bonus and the granting and vesting of options (excluding sign on options) are subject to the individual employee performance. Section 1.5.5 of the Remuneration Report highlights the risk associated with the bonus this year.

### 1.5.3 Service Agreements with Senior Executive Officers

The following Executive Directors and Senior Executive Officers have employment agreements with us. Each of these agreements provides for the provision of performance-related cash incentives and participation, when eligible, in our Employee Option Plan. These agreements also contain certain confidentiality, intellectual property and non competition provisions that serve to protect our intellectual property rights and other proprietary information.

The employment agreements can only be terminated by us without notice if for serious misconduct. For any other termination without cause, we are required to provide the employee three months advance notice. During the above noted notice periods, the employee is entitled to his base salary and other benefits. Upon termination, the employee is also entitled to payment of any accrued annual leave benefits.

In addition to their respective base salaries, each of the following Senior Executive Officers may be awarded an annual performance bonus upon satisfaction of certain milestones upon the sole discretion of our Remuneration and Nomination.

Other material terms of each of these agreements are identified below.

Senior Executive Officer	Contract Expiry Date <sup>1</sup>	Annual Base Salary Effective 1 January 2008 <sup>2</sup> \$	Superannuation Contributions at 9% of Base Salary <sup>3</sup> \$
Alan D. Robertson, Ph.D. <i>Chief Executive Officer and Managing Director</i>	30 June 2011	A\$353,903	A\$31,851
Brett Charlton, Ph.D. <i>Medical Director</i>	30 June 2011	A\$270,113	A\$24,310
John F. Crapper <i>Chief Operations Officer</i>	30 June 2011	A\$253,575	A\$22,822
Ian A. McDonald, Ph.D. <i>Chief Scientific Officer</i>	30 June 2010	A\$204,000	A\$18,360
David M. McGarvey, C.A., C.P.A. <i>Chief Financial Officer and Company Secretary</i>	30 June 2011	A\$281,138	A\$25,302
Gary J. Phillips <i>Head of Commercial Development</i>	30 June 2011	A\$275,625	A\$24,806

<sup>1</sup> Subject to earlier termination by us, the terms of a Senior Executive Officer's employment will last until the date stated, unless the term of the employment agreement is either extended or the Senior Executive Officer enters into a new employment agreement with us;

<sup>2</sup> Annual base salaries may be subject to increase upon review annually by our Remuneration and Nomination Committee; and

<sup>3</sup> We make superannuation fund contributions equal to 9% of the annual base salary per year for the benefit of the Senior Executive Officer.

#### 1.5.4 Share Based Compensation Paid to Directors and Senior Executive Officers

##### *Options Granted to Directors and Senior Executive Officers under the Employee Option Plan*

Our Employee Option Plan is described in Section 1.5.6 of this Statutory Annual Report. For options granted to Senior Executive Officers and employees 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.

The terms and conditions of each grant of options affecting remuneration of Directors and Senior Executive Officers in 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 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.
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.



Grant date	Expiry date	Exercise price	Value per option at grant date	Number of options granted	Number of option grantees	Date exercisable
10 August 2007	9 August 2017	\$3.3890	\$1.6678	1,400,000	6	25% at each of 30 June 2008, 2009, 2010 and 2011, subject to Remuneration and Nomination Committee annual approval.
5 November 2007	9 August 2017	\$3.3890	\$1.6932	150,000	1	25% at each of 30 June 2008, 2009, 2010 and 2011, subject to Remuneration and Nomination Committee annual approval.
5 November 2007	14 November 2016	\$3.2258	\$1.6117	200,000	1	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.*

*Our Corporate Governance Framework prohibits Directors and Senior Executive Officers from trading in Pharmaxis derivatives, without the written consent of the Pharmaxis Board.*

#### **Option Grants in 2008 to Directors and Senior Executive Officers**

Details of options over our ordinary shares provided as remuneration to each of our Directors and each of our Senior Executive Officers are set out below. When exercisable, each option is convertible into one of our ordinary shares. Options are issued at a zero purchase price. Vesting details are set out in the subsequent table. Further information on the options is set out in this Remuneration Report and in Note 29 to the Annual Financial Report in Section 3 of this Statutory Annual Report.

#### 1.5.4 Share Based Compensation Paid to Directors and Senior Executive Officers (continued)

Name	Options granted during the year				Number of options vested during the year	
	2008			2007	2008	2007
	Expiration Date	Exercise Price	Number	Number		
<b>Directors of Pharmaxis Ltd</b>						
DM Hanley <i>Chairman</i>	-	-	-	40,000	<b>10,000</b>	50,000
AD Robertson <i>Chief Executive Officer</i>	<b>9 Aug 2017</b>	<b>\$3.3890</b>	<b>300,000</b>	150,000	<b>150,000</b>	75,000
CPH Kiefel	-	-	-	48,957	<b>5,000</b>	103,957
MJ McComas	-	-	-	20,000	<b>5,000</b>	75,000
PC Farrell	-	-	-	220,000	<b>50,000</b>	70,000
J Villiger	<b>14 Nov 2016</b>	<b>\$3.2258</b>	<b>200,000</b>	-	<b>50,000</b>	-
WL Delaat <sup>1</sup>	-	-	-	-	-	-
BH Smith <sup>2</sup>	-	-	-	-	-	-
<b>Senior Executive Officers</b>						
JF Crapper	<b>9 Aug 2017</b>	<b>\$3.3890</b>	<b>250,000</b>	100,000	<b>112,500</b>	170,000
IA McDonald	<b>9 Aug 2017</b>	<b>\$3.3890</b>	<b>250,000</b>	100,000	<b>130,000</b>	67,500
B Charlton	<b>9 Aug 2017</b>	<b>\$3.3890</b>	<b>250,000</b>	105,000	<b>115,000</b>	52,500
DM McGarvey	<b>9 Aug 2017</b>	<b>\$3.3890</b>	<b>250,000</b>	100,000	<b>112,500</b>	50,000
GJ Phillips	<b>9 Aug 2017</b>	<b>\$3.3890</b>	<b>250,000</b>	100,000	<b>113,750</b>	113,750

<sup>1</sup> On 24 June 2008 the Board announced that it had resolved to grant 200,000 options to Mr Will Delaat under the Employee Option Plan subsequent to his appointment to the Board. The option grant is subject to shareholder approval which will be sought at the 2008 Annual General Meeting.

<sup>2</sup> Ms BH Smith retired as a Director in October 2006.

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 to Directors and Senior Executive Officers during the year ended 30 June 2008 included:

- (a) options are granted for no consideration, 25% vesting at each of 30 June 2008, 2009, 2010 and 2011, subject to Remuneration and Nomination Committee annual approval
- (b) exercise price: \$3.389 and \$3.2258
- (c) grant date: 10 August 2007 and 5 November 2007
- (d) expiry date: 9 August 2017 and 14 November 2016
- (e) share price at grant date: \$3.389 (10 August 2007) and \$4.20 (5 November 2007)
- (f) expected price volatility of the Company's shares: 40.81%
- (g) risk free interest rate: 6.14% (10 August 2007) and 6.55% (5 November 2007)

The model inputs for options granted to Directors and Senior Executive Officers 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 2007
- (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: 50.00%
- (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 Senior Executive Officers 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	
		2008	2007
<b>Directors of Pharmaxis Ltd</b>			
CPH Kiefel	20 December 2007	<b>58,957</b>	–
	19 June 2007	–	150,000
	29 June 2007	–	50,000
<b>Senior Executive Officers of the Group</b>			
JF Crapper	23 April 2007	–	300,000
B Charlton	9 November 2007	<b>400,000</b>	–
	7 December 2006		110,000

The amounts paid per ordinary share by each Director and Senior Executive Officer on the exercise of options at the date of exercise were as follows:

#### 1.5.4 Share Based Compensation Paid to Directors and Senior Executive Officers (continued)

Exercise date	Amount paid per share
7 December 2006	\$0.3125
23 April 2007	\$0.3125
19 June 2007	\$0.3125
29 June 2007	\$0.3125
9 November 2007	\$0.3125
20 December 2007	\$1.7900
20 December 2007	\$1.9170

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

#### **Options Granted to Directors and Senior Executive Officers under the Employee Option Plan since 30 June 2008**

On 12 August 2008 the Board of Directors resolved to grant under the Pharmaxis Employee Option Plan 750,000 options to Senior Executive Officers, 200,000 options to the Executive Director and 729,500 options to other employees. The options have an exercise price of \$1.8170 and expire 11 August 2018. The grant of options to the Executive Director requires shareholder approval and such approval will be sought at the 2008 Annual General Meeting.

#### **Details of Option Values**

The numbers of options to purchase our ordinary shares held at 12 August 2008 by each Director of Pharmaxis and each of the Senior Executive Officers are listed below. When exercisable, each option is convertible into one ordinary share of Pharmaxis. Options are issued at a zero purchase price.

Name	Number of Securities	Exercise Price A\$	Expiration Date	Vesting
<i>Directors</i>				
AD Robertson <sup>2</sup> <i>Chief Executive Officer</i>	1,120,000	0.1250	30 November 2009	280,000 at each of 30 June 2000, 2001, 2002 and 2003
	960,000	0.3125	30 June 2012	240,000 at each of 30 June 2003, 2004, 2005 and 2006
	150,000	1.790	4 August 2015	37,500 at each of 30 June 2006, 2007, 2008 and 2009 <sup>1</sup>
	150,000	1.917	14 August 2016	37,500 at each of 30 June 2007, 2008, 2009 and 2010 <sup>1</sup>
	300,000	3.389	9 August 2017	75,000 at each of 30 June 2008, 2009, 2010 and 2011 <sup>1</sup>
DM Hanley <i>Chairman</i>	640,000	0.3125	30 August 2011	640,000 at 30 August 2002
	400,000	0.3125	30 June 2012	100,000 at each of 30 June 2003, 2004, 2005 and 2006
	40,000	1.790	4 August 2015	10,000 at each of 30 June 2006, 2007, 2008 and 2009
	40,000	1.917	14 August 2016	40,000 at 26 October 2006
PC Farrell	200,000	2.068	15 March 2016	50,000 at each of 30 June 2007, 2008, 2009 and 2010
	20,000	1.917	14 August 2016	20,000 at 26 October 2006

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Name	Number of Securities	Exercise Price A\$	Expiration Date	Vesting
<i>Directors</i>				
J Villiger	200,000	3.226	14 November 2016	50,000 at each of 30 June 2007, 2008, 2009, 2010
MJ McComas	200,000	0.3125	3 July 2013	50,000 at each of 30 June 2004, 2005, 2006 and 2007
	20,000	1.790	4 August 2015	5,000 at each of 30 June 2006, 2007, 2008 and 2009
	20,000	1.917	14 August 2016	20,000 at 26 October 2006
WL Delaat <sup>3</sup>	–	–	–	–
<i>Senior Executive Officers</i>				
B Charlton	80,000	0.3125	30 June 2012	480,000 at 30 June 2003
	370,000	0.3125	30 June 2012	120,000 at each of 30 June 2003, 2004, 2005 and 2006
	105,000	1.790	4 August 2015	26,250 at each of 30 June 2006, 2007, 2008 and 2009 <sup>1</sup>
	105,000	1.917	14 August 2016	26,250 at each of 30 June 2007, 2008, 2009 and 2010 <sup>1</sup>
	250,000	3.389	9 August 2017	62,500 at each of 30 June 2008, 2009, 2010 and 2011 <sup>1</sup>
	150,000	1.817	11 August 2008	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>
JF Crapper	180,000	0.3125	30 June 2013	480,000 at 1 July 2004
	180,000	0.3125	30 June 2013	120,000 at each of 30 June 2004, 2005, 2006 and 2007 <sup>1</sup>
	100,000	1.7900	4 August 2015	25,000 at each of 30 June 2006, 2007, 2008 and 2009 <sup>1</sup>
	100,000	1.917	14 August 2016	25,000 at each of 30 June 2007, 2008, 2009 and 2010 <sup>1</sup>
	250,000	3.389	9 August 2017	62,500 at each of 30 June 2008, 2009, 2010 and 2011 <sup>1</sup>
	150,000	1.817	11 August 2008	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>

#### 1.5.4 Share Based Compensation Paid to Directors and Senior Executive Officers (continued)

Name	Number of Securities	Exercise Price A\$	Expiration Date	Vesting
<i>Senior Executive Officers</i>				
IA McDonald	50,000	1.1470	11 May 2015	50,000 at 3 April 2006
	150,000	1.1470	11 May 2015	37,500 at each of 30 June 2006, 2007, 2008 and 2009 <sup>1</sup>
	20,000	1.7900	4 August 2015	5,000 at each of 30 June 2006, 2007, 2008 and 2009 <sup>1</sup>
	100,000	1.917	14 August 2016	25,000 at each of 30 June 2007, 2008, 2009 and 2010 <sup>1</sup>
	250,000	3.389	9 August 2017	62,500 at each of 30 June 2008, 2009, 2010 and 2011 <sup>1</sup>
	150,000	1.817	11 August 2008	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>
DM McGarvey	480,000	0.3125	30 June 2012	120,000 at each of 30 June 2003, 2004, 2005 and 2006 <sup>1</sup>
	480,000	0.3125	30 November 2012	480,000 at 1 December 2003
	100,000	1.7900	4 August 2015	25,000 at each of 30 June 2006, 2007, 2008 and 2009 <sup>1</sup>
	100,000	1.917	14 August 2016	25,000 at each of 30 June 2007, 2008, 2009 and 2010 <sup>1</sup>
	250,000	3.389	9 August 2017	62,500 at each of 30 June 2008, 2009, 2010 and 2011 <sup>1</sup>
	150,000	1.817	11 August 2008	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>
GJ Phillips	250,000	0.3760	30 November 2013	62,500 at each of 30 June 2004, 2005, 2006 and 2007 <sup>1</sup>
	250,000	0.3760	30 November 2013	250,000 at 1 December 2004
	105,000	1.7900	4 August 2015	26,250 at each of 30 June 2006, 2007, 2008 and 2009 <sup>1</sup>
	100,000	1.917	14 August 2016	25,000 at each of 30 June 2007, 2008, 2009 and 2010 <sup>1</sup>
	250,000	3.389	9 August 2017	62,500 at each of 30 June 2008, 2009, 2010 and 2011 <sup>1</sup>
	150,000	1.817	11 August 2008	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>

<sup>1</sup> Vesting is subject to approval of the Remuneration and Nomination Committee.

<sup>2</sup> On 12 August 2008 the Board resolved to issue 200,000 options to Dr Alan Robertson under the Employee Option Plan. The option grant is subject to shareholder approval which will be sought at the 2008 Annual General Meeting.

<sup>3</sup> On 23 June 2008 the Board resolved to issue 200,000 options to Mr. WL Delaat on his appointment to the Board under the Employee Option Plan subsequent to his appointment to the Board. The option grant is subject to shareholder approval which will be sought at the 2008 Annual General Meeting.

## 1.5.5 Additional Information on Compensation Paid to Directors and Senior Executive Officers

### *Details of Director and Senior Executive Officer 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. 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 2008.

Name	Cash bonus		Options					
	Paid %	Forfeited %	Year granted	Vested %	Forfeited %	Financial years in which options may vest	Minimum total value of grant yet to vest \$	Maximum total value of grant yet to vest \$
DM Hanley	–	–	2006	25	–	2009	–	4,298
AD Robertson	82.5	17.5	2008	25	–	2009 to 2011	–	263,064
			2007	25	–	2009 to 2010	–	45,267
			2006	25	–	2009	–	16,118
CPH Kiefel	–	–	2006	25	–	–	–	–
MJ McComas	–	–	2006	25	–	2009	–	2,149
PC Farrell	–	–	2007	25	–	2009 to 2010	–	65,109
J Villiger	–	–	2008	25	–	2009-2010	–	109,550
W L Delaat	–	–	–	–	–	–	–	–
JF Crapper	75	25	2009	–	–	2009 to 2012	–	272,550
			2008	25	–	2009 to 2011	–	207,647
			2007	25	–	2009 to 2010	–	28,662
			2006	25	–	2009	–	7,782
IA McDonald	90	10	2009	–	–	2009 to 2012	–	272,550
			2008	25	–	2009 to 2011	–	207,647
			2007	25	–	2009 to 2010	–	28,662
			2006	25	–	2009	–	7,202
B Charlton	75	25	2009	–	–	2009 to 2012	–	272,550
			2008	25	–	2009 to 2011	–	207,647
			2007	25	–	2009 to 2010	–	30,096
			2006	25	–	2009	–	11,282
DM McGarvey	90	10	2009	–	–	2009 to 2012	–	272,550
			2008	25	–	2009 to 2011	–	207,647
			2007	25	–	2009 to 2010	–	28,662
			2006	25	–	2009	–	7,782
GJ Phillips	90	10	2009	–	–	2009 to 2012	–	272,550
			2008	25	–	2009 to 2011	–	207,647
			2007	25	–	2009 to 2010	–	28,662
			2006	25	–	2009	–	8,171

### 1.5.5 Additional Information on Compensation Paid to Directors and Senior Executive Officers (continued)

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 Remuneration and Nomination Committee has determined that performance targets set by the Committee in relation to options vesting at 30 June 2008 have been achieved by all executives.

#### **Share Based Compensation Paid to Directors and Senior Executive Officers: Options**

Further details relating to options granted to Directors and Senior Executive Officers are set out below.

Name	A Remuneration consisting of options	B Value at grant date \$	C Value at exercise date \$	D Value at lapse date \$
DM Hanley	–	–	–	–
AD Robertson	51%	504,150	–	–
CPH Kiefel	–	–	131,152	23,300
MJ McComas	–	–	–	–
PC Farrell	–	–	–	–
WL Delaat	–	–	–	–
J Villiger	83%	322,340	–	–
JF Crapper	57%	416,950	–	–
IA McDonald	61%	416,950	–	–
B Charlton	55%	416,950	1,631,000	–
DM McGarvey	54%	416,950	–	–
GJ Phillips	54%	416,950	–	–

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 difference between the market price of shares and the exercise price of options at exercise date 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 because a vesting condition was not satisfied. The value is determined at the time of lapsing, but assuming the condition was satisfied.

#### **Loans to Directors and executives**

Nil. Not permitted under Pharmaxis Corporate Governance Framework.



## 1.5.6 Pharmaxis Ltd Employee Option Plan

Our Employee Option Plan was adopted in 1999 and amended in June 2003. Any person considered to be an employee of us, by our Board of Directors including Executive Directors and Non-Executive Directors are eligible to participate in the our Employee Option Plan, but do so at the invitation of our Board of Directors. Under the Employee Option Plan, the Board of Directors may issue options to purchase our ordinary shares on such terms, including the issue price, the exercise price and the vesting conditions, as it determines. The maximum number of options available to be issued under our Employee Option Plan at any given time is 15% of our total issued shares and other securities convertible into shares at such time, or such number as is consistent with any Listing Rules or laws or regulations that apply to us.

Any vesting conditions determined by our Board of Directors must be satisfied before the employee options vest and become exercisable. Options are generally granted for no consideration. Options granted to executives and employees vest in equal tranches over a four-year period. For options granted after January 1, 2003, the annual vesting is subject to approval by the Remuneration and Nomination Committee of our Board of Directors. The Remuneration and Nomination Committee gives its approval for vesting based on the achievement of individual employee's personal annual objectives. Independent Non-Executive Directors are granted options on joining the Board and commencing in the 2006 financial year, are allowed to package their remuneration to include options. Options are granted under our Employee Option Plan. Options granted to Non-Executive Directors upon joining the Board and options granted before June 2006 vest over a period of approximately four years. Other options granted to Non-Executive Directors vest in the year of grant. If a takeover offer is made for us, all options which have not yet vested, vest.

When exercisable, each option issued under our Employee Option Plan entitles the holder to subscribe for one fully paid ordinary share. Each ordinary share issued on exercise of an option will rank equally with all other ordinary shares then issued.

The exercise price of the employee options is set by our Board of Directors. Before we listed on the Australian Securities Exchange in November 2003, our Board of Directors set the exercise price based on its assessment of the market value of the underlying shares at the time of grant. From listing on the Australian Securities Exchange, the exercise price is set by our Board of Directors as the average closing price of our ordinary shares on the Australian Securities Exchange during the five business days prior to the grant of the options. From September 1, 2006 the exercise price is set by our Board of Directors as the average of the volume weighted average price of our shares on the Australian Securities Exchange on the five business days prior to the grant of the options.

The employee options lapse on such date as determined by the Board of Directors at the time of grant. If an option holder ceases to be regarded as an employee by our Board of Directors, all of his or her options which have not yet vested lapse and all options which have already vested lapse, if not exercised, within 30 days of such determination. If an employee is terminated for cause, dishonesty or fraud, his or her options lapse immediately on ceasing to be an employee. If an employee dies, all options which have not vested lapse and all options which have vested, lapse on the date 12 months after the death of the employee (to the extent that they are not exercised by the estate of the former employee).

The employee options which have not been exercised do not confer a right to notices of general meetings (except as may be required by law) or a right to attend, speak or vote at general meetings.

A holder of employee options may only participate in new issues of securities with respect to options which have been exercised and ordinary shares issued prior to the record date.

In the event of a consolidation, subdivision or similar reconstruction of our issued share capital, the number of shares to which a holder of options is entitled on exercise of an option will be adjusted in the same proportion as our issued share capital is consolidated, subdivided or reconstructed (as applicable) and an appropriate adjustment will be made to the exercise price with the effect that the total amount payable on an exercise of all options by each holder will not change.

If any pro-rata offer is made by us to at least all holders of shares, the exercise price of the relevant employee options will be reduced according to a formula set out in the Employee Option Plan and consistent with the Listing Rules of the Australian Securities Exchange.

### 1.5.6 Pharmaxis Ltd Employee Option Plan (continued)

If we make a bonus issue of ordinary shares to our shareholders, the number of ordinary shares over which the employee options are exercisable may be increased by the number of shares the relevant option holder would have received if the option had been exercised prior to the record date of the bonus issue.

If we make a return of capital to our shareholders generally, the exercise price of the employee options will be proportionately reduced by the amount of the return of capital.

Except by transmission on death or with the prior written consent of our Board of Directors, employee options may not be transferred, encumbered, assigned or otherwise disposed of by the relevant employee. Shares issued upon exercise of options are freely transferable and we seek quotation of any such shares on the Australian Securities Exchange.

Our Employee Option Plan may be amended with any necessary approvals under the *Corporations Act 2001* and the Listing Rules of the Australian Securities Exchange. The *Corporations Act 2001* and the Listing Rules of the Australian Securities Exchange prevail over the Employee Option Plan to the extent of any inconsistency. Our Employee Option Plan is administered by the Board of Directors and the Remuneration and Nomination Committee.

Summaries of options granted under our Employee Option Plan during 2007 and 2008 are provided in Note 29 to the Annual Financial Report included in Section 3 of this Statutory Annual Report.

#### **Shares Under Option**

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

Date options granted	Expiry date	Issue price of shares	Number under option
Total unissued ordinary shares under option at 30 June 2008 – refer Note 29 to the Annual Financial Report included in Section 3 of this Statutory Annual Report			11,536,250
Options granted during the period from 1 July 2008 to 12 August 2008:			
12 August 2008	11 August 2018	\$1.8170	1,479,500
Options exercised (shares issued) during the period from 1 July 2008 to 12 August 2008:			
25 April 2004	24 April 2014	\$0.5080	(22,500)
Options lapsed during the period from 1 July 2008 to 12 August 2008:			
5 August 2005	4 August 2015	\$0.7900	(7,500)
15 August 2006	14 August 2016	\$1.9170	(3,000)
10 August 2007	9 August 2017	\$3.3890	(2,000)
23 June 2008	22 June 2018	\$1.5990	(10,000)
			12,970,750

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 of our ordinary shares were issued during the year ended 30 June 2008 on the exercise of options granted under our Employee Option Plan. No amounts are unpaid on any of the shares.

<b>Date options granted</b>	<b>Issue price of shares</b>	<b>Number of shares issued</b>
12 May 2003	\$0.3215	632,000
5 August 2005	\$1.7900	24,376
2 February 2005	\$0.8340	5,000
12 May 2005	\$1.1470	15,000
13 February 2006	\$2.1940	10,000
1 June 2006	\$2.0340	2,250
15 August 2006	\$1.9170	7,125
26 October 2006	\$1.9170	48,957
20 September 2006	\$1.8918	1,250
		745,958

## **1.6 Senior Management, Employees and Scientific Advisory Board**

### **1.6.1 Executive Director and Senior Executive Officers**

The following table presents information about our Executive Director and Senior Executive Officers as of 15 August 2008.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Alan D. Robertson, Ph.D.	52	Chief Executive Officer and Managing Director
Brett Charlton, Ph.D.	52	Medical Director
John F. Crapper	56	Chief Operations Officer
Ian A. McDonald, Ph.D.	61	Chief Scientific Officer
David M. McGarvey.	52	Chief Financial Officer and Company Secretary
Gary J. Phillips	47	Head of Commercial Development

The business address for our Senior Executive Officers and Directors is c/o Pharmaxis Ltd, Unit 2, 10 Rodborough Road, Frenchs Forest, NSW Australia 2086.

#### **Executive Director and Senior Executive Officers**

*Alan D. Robertson, Ph.D.*, Refer to Section 1.4.1 of this Statutory Annual Report.

*Brett Charlton, Ph.D.* is a co-founder of Pharmaxis and has been our Medical Director and was a member of our Board of Directors from June 1998 to March 2006. Dr. Charlton is the author of more than 60 scientific papers and has over 15 years of experience in clinical trial design and management. Dr. Charlton was founding Medical Director of the National Health Sciences Centre and established its Clinical Trials Unit. Prior to joining us, Dr. Charlton held various positions with the Australian National University, Stanford University, the Baxter Centre for Medical Research, Royal Melbourne Hospital, and the Walter and Eliza Hall Institute. Dr. Charlton holds a M.B.B.S. with honors from the University of New South Wales and a Ph.D. from the University of New South Wales.

### 1.6.1 Executive Director and Senior Executive Officers (continued)

*John F. Crapper* has been our Chief Operations Officer since July 2003. Mr. Crapper has over three decades of experience in manufacturing and operations. From 1987 to 2003, Mr. Crapper held various positions within the Memtec Limited/Memcor organization most recently as Senior Vice-President and General Manager of Memcor International, and Managing Director of Memcor Australia Pty Ltd, a leader in the design and manufacture of microfiltration membranes and systems. During his 15 years at Memcor, Mr. Crapper managed the scale-up of manufacturing equipment and processes from the Company's research and development group, created full-scale production operations, and managed the establishment of Quality Assurance and Enterprise Resource Planning systems. From 1980 to 1987, Mr. Crapper served as Operations Director of the Animal Health Division at Syntex Pharmaceutical. From 1971 to 1980, Mr. Crapper served as Production Manager at VR Laboratories, a private veterinary pharmaceutical company. Mr. Crapper holds a B.S. in Applied Chemistry from the University of Technology, Sydney and an M.B.A from Macquarie University.

*Ian A. McDonald, Ph.D.* has been our Chief Scientific Officer since September 2006, having previously served as Chief Technical Officer from his joining us in April 2005. Dr. McDonald has over 25 years of experience in managing drug discovery and design teams in Europe and the U.S. From 2002 to 2004, Dr. McDonald served as Vice President of Drug Discovery at Structural GenomiX, Inc. (now SGX Pharmaceuticals Inc.). From 2001 to 2002, Dr. McDonald served as Vice President of Drug Discovery at Structural Bioinformatics Inc. (now Cengent Therapeutics). From 1993 to 2000, Dr. McDonald served as Director, then Vice President of Chemistry at SIBIA Neuroscience (now part of Merck Research Laboratories) and was responsible for medicinal and bio-chemistry research. From 1978 to 1993, Dr. McDonald served in various capacities as a research chemist at Merrell Dow (now part of Sanofi-Aventis). Dr. McDonald is the co-inventor of 39 U.S. patents and co-author of 77 peer-reviewed manuscripts and book chapters. Dr. McDonald holds B.S. and Ph.D. degrees in Organic Chemistry from the University of Western Australia.

*David M. McGarvey, C.A., C.P.A.* has been our Chief Financial Officer and Company Secretary since December 2002. Mr. McGarvey has two decades of experience in overseeing the financial affairs of different Australian companies. From 1998 to 2002, Mr. McGarvey served as Chief Financial Officer of the Filtration and Separations Group of U.S. Filter Corporation where he managed over 20 merger and acquisition transactions, including the sale of the Filtration and Separations Group to Pall Corporation in 2002. From 1985 to 1997, Mr. McGarvey served as Chief Financial Officer of Memtec Limited. While at Memtec, Mr. McGarvey oversaw the U.S. listing of Memtec on the Nasdaq Global Market and the New York Stock Exchange and managed numerous international merger and acquisition transactions, including the acquisition of Memtec by U.S. Filter. From 1975 to 1985, Mr. McGarvey held various positions at PricewaterhouseCoopers. Mr. McGarvey holds a B.A. in Accounting from Macquarie University and was admitted to the Institute of Chartered Accountants in Australia in 1981, and to the membership of CPA Australia in 1993.

*Gary J. Phillips* has been our Commercial Director since December 2003. Mr. Phillips has over two decades of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia. From 1998 to 2003, Mr. Phillips held various positions within Novartis Asia, most recently as Chief Executive Officer of Novartis Pharmaceuticals Australia Pty Ltd, where he successfully launched leading oncology and ophthalmology products and relaunched newly acquired primary care products. From 1992 to 1998, Mr. Phillips served as Chief Executive Officer at Ciba Geigy in Hungary. Mr. Phillips holds a B. Pharm. in Pharmacy with honors from Nottingham University in the U.K. and an M.B.A. from Henly Management College.

### 1.6.2 Employees

The table below presents certain information regarding our employees and full time contractors as of 30 June 2006, 2007 and 2008, respectively.

As at 30 June	2008	2007	2006
Research and development	35	27	29
Manufacturing	35	26	20
Commercial	11	9	10
Administration	5	6	6
	<b>86</b>	<b>68</b>	<b>65</b>

Our main office facility at Frenchs Forest, Sydney was established in November 2002. We also have a research group of seven based in North Ryde, Sydney; an office in the United Kingdom where we base a commercial team of two and a clinical research team of four; an office in the United States of four; a representative office of two in China; and three sales staff based around Australia. Until December 2006 we also had a research group based at the Australian National University (ANU), Canberra.

Each of our full time employees enter into an agreement with us. We also engage casual employees from time to time who enter into contracts of employment with us. Outside of the United States we do not have any 'at will' employees, as this concept is not customary in Australia or the United Kingdom. We may only terminate the employment of any of our employees in accordance with the relevant employee's contract of employment. Our standard contract of employment for full time and part time employees provides that we can terminate the employment of an employee without notice for serious misconduct or with between one to three months notice without cause (as set out in the relevant employee's contract of employment). Our standard contracts of employment for casual employees provide that we can terminate the employment of a casual employee without notice. For a summary of the key terms of employment of each of our Senior Executive Officers, see Section 1.5.3 - Service Agreements with Senior Executive Officers. Minimum notice periods may be prescribed for certain of our employees under applicable Australian law. The notice periods in our contracts of employment are equal to or exceed the minimum requirements.

None of our full time employees are represented by any collective bargaining unit. Our employees are subject to certain minimum standards and conditions of employment under the laws applicable in the jurisdiction in which they are employed.

We believe that we maintain good relations with all of our employees and contractors.

### 1.6.3 Scientific Advisory Board

The members of our Scientific Advisory Board play an important role advising us in their areas of expertise.

*Sandra Anderson, B.Sc., Ph.D., D.Sc., FANZSRS*, is an expert in the diagnosis and treatment of asthma. She is a world authority in the measurement, management and mechanisms of exercise-induced asthma, and has developed a variety of tests for identifying asthma, including Aridol. A prolific author and the recipient of numerous awards for her work, Dr. Anderson is Principal Hospital Scientist in the Department of Respiratory Medicine of the Royal Prince Alfred Hospital, Sydney. She is a Vice President of Asthma NSW and Co-Chairman of their Research Advisory Committee. Dr. Anderson has served on various international taskforces and committees and is currently part of an independent panel of the International Olympic Committee Medical Commission. She is actively engaged in our development, participating in technical presentations to various opinion leaders and regulatory authorities around the world. Dr. Anderson holds a Bachelor of Science in Physiology from the University of Sydney and a Ph.D. in Medicine from the University of London.

*Norbert Berend, M.B., B.S., M.D., FRACP* is Director of the Woolcock Institute of Medical Research at Royal Prince Alfred Hospital, Sydney and is internationally recognized for his work in chronic obstructive pulmonary disease. Dr. Berend is active in national and international peer groups, is a member of the COPD Guidelines Working Party, and serves on the Respiratory Clinical Expert Reference Committee of the NSW Department of Health. In addition, he is a Senior Investigator for the Cooperative Research Centre, or CRC, for Asthma and a Director of the CRC for Chronic Inflammatory Diseases and is the author of more than 95 publications on airways disease, emphysema and infection in COPD. Dr. Berend was a principal investigator at one site participating in the Aridol trial as well as serving on trial related safety committees.

*Malcolm Fisher, A.O., M.B., Ch.B., M.D.* is renowned for his work in critical care medicine, having received numerous awards and being named an officer in the Order of Australia. Based in Sydney, Dr. Fisher is a Staff Specialist in the Intensive Care Unit of Royal North Shore Hospital, and Area Director of Intensive Care and Clinical Professor in Intensive Care Medicine in the Departments of Medicine and Anaesthesia at the University of Sydney. He is a past President of the World Federation of Intensive and Critical Care Medicine Societies, and its Australasian chapter, ANZICS. He is the author of two books and more than 130 scientific articles.

*Richard J.I. Morgan, C.Biol., MIBiol. DRCPATH* has more than 25 years' experience in pharmaceutical research and development, and has been involved in the development of a large number of successful, marketed pharmaceutical products. He has held senior management positions within preclinical safety (a vital precursor to human clinical trials), including Head of Toxicology at the pharmaceutical company Wellcome and International Head of Toxicology and Preclinical Outsourcing for GlaxoWellcome (later GlaxoSmithKline). He has been responsible for evaluating the preclinical safety of more than 100 new chemical entities, ranging from anti-infectives and anti-parasitics to cancer compounds and vaccines. He currently advises U.K. and Australian companies on toxicology and preclinical discovery and development. Mr. Morgan consults to Pharmaxis on the preclinical safety aspects of developing products.

### 1.6.4 Retirement Benefits

We contribute to standard defined contribution superannuation and pension funds on behalf of all employees at rates competitive in each country where we operate.

We contributed A\$337,000, A\$454,000 and A\$594,000 for the financial years ended 30 June 2006, 30 June 2007 and 30 June 2008.

# Section



## 2.1 Four Year Summary Financial Information

### Selected Financial Data

The following table presents our selected financial data for the dates and periods indicated. This data should be read together with Operating and Financial Review and Prospects in Section 2.2 of this Statutory Annual Report. The income statement data for the years ended 30 June 2006, 2007 and 2008, and the balance sheet data as at 30 June 2007 and 2008, were derived from our audited financial statements and related notes thereto included elsewhere in this Statutory Annual Report. The income statement data for the years ended 30 June 2005, and the balance sheet data as at 30 June 2005 and 2006, are derived from our audited financial statements and related notes thereto which are not included in this report. All financial information was prepared in accordance with Australian equivalents to International Financial Reporting Standards (AIFRS) and in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and are presented in Australian dollars (except as otherwise noted). Our financial year ends on 30 June. We designate our financial year by the year in which that financial year ends; e.g., financial year 2008 refers to our financial year ended 30 June 2008.

Summary Financial Data for the year ended 30 June 2004 has been omitted because financial statements prepared in accordance with AIFRS and IFRS were not required to be prepared at the time we adopted IFRS and such financial data cannot be provided without unreasonable expense or effort.

Year Ended 30 June	2008 A\$	2007 A\$	2006 A\$	2005 A\$	2008 U.S.\$ <sup>1</sup>
<i>In thousands except per share and footnote data</i>					
<b>Income Statement Data:</b>					
<b>Revenue from continuing operations</b>					
Revenue from sale of goods	527	205	8	–	504
Cost of sales	(129)	(49)	(2)	–	(123)
<b>Gross profit</b>	<b>398</b>	156	6	–	<b>381</b>
Other revenue – interest income	7,402	5,278	4,282	1,702	7,078
Other income	1,576	2,152	1,299	1,219	1,507
<b>Other expenses from ordinary activities:</b>					
Research and development	(19,996)	(23,840)	(16,978)	(9,269)	(19,120)
Commercial expenses	(4,557)	(3,240)	(1,946)	(963)	(4,357)
Administration expenses	(5,231)	(4,666)	(4,391)	(3,134)	(5,001)
<b>Loss before income tax</b>	<b>(20,408)</b>	(24,160)	(17,728)	(10,445)	<b>(19,512)</b>
Income tax expense	(32)	(19)	(5)	–	(31)
<b>Loss for the year</b>	<b>(20,440)</b>	(24,179)	(17,733)	(10,445)	<b>(19,543)</b>
	<b>Cents</b>	<b>Cents</b>	<b>Cents</b>	<b>Cents</b>	<b>Cents</b>
Basic and diluted loss per share	(10.8)	(13.6)	(11.1)	(8.4)	(10.3)
Weighted average number of ordinary shares used in calculating basic and diluted net loss per share <sup>2</sup>	189,335	177,285	160,349	123,933	189,340



- <sup>1</sup> The amounts have been translated into U.S. dollars from Australian dollars based upon the noon buying rates in New York City as determined by the Federal Reserve Bank of New York on 30 June 2008, which was A\$1.00 to U.S.\$0.9562. These translations are merely for the convenience of the reader and should not be construed as representations that the Australian dollar amounts actually represent such U.S. dollar amounts or could be converted into U.S. dollars at the rate indicated.
- <sup>2</sup> The increase in ordinary shares in 2006 is primarily attributable to a U.S. public offering and a concurrent Australian share placement in which a total of 39,400,000 new ordinary shares were issued. In addition, 2,733,500 shares were issued in 2006 upon the exercising of stock options by management or employees under the Company's employee option plan. The increase in 2007 is primarily the full year effect of shares issued in 2006. In addition, 1,045,625 shares were issued in 2007 upon the exercising of stock options by management or employees under the Company's Employee Option Plan. The increase in 2008 is primarily attributable to an Australian share placement and share purchase plan in which a total of 15,819,587 ordinary shares were issued.

<b>As at 30 June 2008</b>	<b>2008 A\$</b>	<b>2007 A\$</b>	<b>2006 A\$</b>	<b>2005 A\$</b>	<b>2008 U.S.\$<sup>1</sup></b>
<i>In thousands</i>					
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	<b>111,842</b>	76,182	97,840	33,390	<b>106,943</b>
Total assets	<b>125,049</b>	82,648	104,267	37,937	<b>119,572</b>
Net assets	<b>119,121</b>	76,559	98,888	35,467	<b>113,904</b>
Contributed equity/capital stock	<b>194,680</b>	135,108	134,745	54,716	<b>186,153</b>

- <sup>1</sup> The amounts have been translated into U.S. dollars from Australian dollars based upon the noon buying rates in New York City as determined by the Federal Reserve Bank of New York on 30 June 2008, which was A\$1.00 to U.S.\$0.9562. These translations are merely for the convenience of the reader and should not be construed as representations that the Australian dollar amounts actually represent such U.S. dollar amounts or could be converted into U.S. dollars at the rate indicated.

<b>As at 30 June 2008</b>	<b>2008 A\$</b>	<b>2007 A\$</b>	<b>2006 A\$</b>	<b>2005 A\$</b>
<i>In thousands</i>				
Ordinary shares outstanding	<b>194,515</b>	177,949	176,904	134,770

No dividends have been paid in any of the years 2005 to 2008.

## 2.2 Operating and Financial Review and Prospects

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this report. This discussion and analysis contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under 'Risk Factors' and elsewhere in this report. Please also see the Section 1.1 Forward Looking Statements. Our financial year ends on 30 June. We designate our financial year by the year in which that financial year ends; e.g., in this section '2008' refers to our financial year ended 30 June 2008, unless noted otherwise.

### 2.2.1 Operating Results

#### *Overview*

We are a specialty pharmaceutical company focused on the development of new products for the diagnosis and treatment of chronic respiratory and immune disorders. We are most advanced in the development of products for asthma, cystic fibrosis and chronic obstructive pulmonary disease, or COPD, including bronchiectasis and chronic bronchitis.

We were incorporated in May 1998 and in October 1999 obtained a license to a series of patents in the autoimmune area owned by the Australian National University, or ANU. We issued 11.2 million ordinary shares valued at A\$1.4 million to acquire the license. Our area of focus remained the autoimmune diseases area until October 2001 when we licensed a series of patents from the Sydney South West Area Health Service, or SSWAHS, covering new treatments for chronic lung diseases and for the measurement of lung function. Our license with the ANU requires us to pay royalties based on sales revenue for products incorporating the licensed technology. Our current lead projects in the immune area are not dependent on the technology licensed from the ANU. Our license agreement with the SSWAHS requires us to pay royalties based on gross profit on product sales for products incorporating the licensed technology. Our products Aridol and Bronchitol are derived from the SSWAHS license.

We have closed recruitment in our Phase III clinical trial of Bronchitol in cystic fibrosis. We expect data from this trial in the first quarter of 2009 which, if successful will be the basis for a marketing application in Europe. We have recently commenced a Phase III clinical trial of Bronchitol in cystic fibrosis, the protocol design of which has been agreed with the U.S. FDA under its Special Protocol Assessment process.

We have completed one Phase III trial with Bronchitol in bronchiectasis on the basis of which we intend filing for marketing approval in Australia during 2008. We have agreed the clinical trial protocol design for an additional Phase III trial with both the U.S. FDA and the European Medicines Agency.

In June 2007 we successfully completed the E.U. mutual recognition procedure which permitted marketing approvals of Aridol by Germany, France, the United Kingdom, Italy, the Netherlands, Belgium, Denmark, Greece, Spain, Finland, Ireland, Norway, Sweden and Portugal. Individual country marketing certificates were issued from June 2007 to June 2008 at which time only Italy, France, Spain and Belgium were still being processed. We received marketing approval in Korea in January 2008. We intend filing a marketing application for Aridol in the U.S. during the third quarter of 2008.

We have one research project which has completed and one project about to commence pre-clinical evaluation (prior to being administered to volunteers or patients). Our development program has been designed to produce a series of products for large world markets over the coming years.

We have incurred losses since our inception. We recognized a loss of A\$20.4 million, A\$24.2 million and A\$17.7 million in the years ended 30 June 2008, 2007 and 2006, respectively. We expect to incur losses in the foreseeable future as we conduct clinical trials of our product candidates, expand our organization and commercially launch our products upon regulatory approval.

#### *Research and Development*

Our research and development expenses consist primarily of salaries and related employee benefits, costs associated with our clinical trials, non-clinical activities such as toxicology testing and scale-up synthesis, regulatory activities, the manufacture of material for clinical trials, development of manufacturing processes and research-related overhead expenses. Our most significant costs are for clinical trials, preclinical development and regulatory filings. These

expenses include regulatory consultants, clinical supplies and payments to external vendors such as hospitals and investigators. We expense all research and development costs as they are incurred. We expect our research and development expenses to increase significantly in the future as we continue to move our product candidates through the development pipeline.

We classify our research and development expenses into four components:

1. Our drug discovery unit based in Sydney. This unit is focused on immune disorders and respiratory drug discovery and in 2007 assumed the work previously carried out at the John Curtin School of Medical Research within the Australian National University.
2. Our preclinical development group which is managing the outsourced safety/toxicology studies of the Aridol and Bronchitol products and the preclinical development of lead compounds in the immune disorder area.
4. Our clinical trials group, which designs and monitors our clinical trials.
5. Our Australian Therapeutic Goods Administration, or TGA, registered manufacturing facility is primarily focused on producing material for clinical trials and developing enhanced manufacturing processes. It is therefore classified as a research and development expenditure.

We expect to continue to incur significant costs in the foreseeable future as we pursue these activities. We cannot accurately forecast or reasonably estimate the additional costs that will be required to complete all of these activities, or the exact timing for their completion due to the potential failure risks and other uncertainties inherent in the development of new drugs, such as unsuccessful clinical trials, unsuccessful development and/or commercialization and delayed regulatory approvals, amongst others. However, where the trial protocols have been finalized and negotiations with clinical research organizations and participating trial sites are sufficiently advanced, we are able to reasonably estimate the costs (as at 30 June 2008) and timeframes (stated in calendar years unless otherwise stated) of the next anticipated milestones described below:

- The cost to complete our Phase II dose-ranging study of Bronchitol for cystic fibrosis is currently estimated to be approximately A\$0.1 million. We completed dosing of subjects in this trial during the second quarter of 2008 and reported the topline results during the third quarter of 2008.
- The cost to complete our first Phase III trial of Bronchitol for cystic fibrosis is currently estimated to be approximately A\$5 million. This trial is being conducted in Europe and Australia. We completed recruitment for this trial in the third quarter of calendar 2008 and expect to complete dosing of subjects in the first half of 2009. This clinical trial is the first of two planned for this indication.
- The cost to complete our second Phase III trial of Bronchitol for cystic fibrosis is currently estimated to be approximately A\$10 million. This trial is being conducted in North America, Latin America and Europe. We commenced recruitment for this trial in the third quarter of calendar 2008 and expect to complete recruitment in the second quarter of 2009.
- The cost to complete our first Phase III trial of Bronchitol for bronchiectasis is currently estimated to be approximately A\$0.4 million. This trial was conducted in Europe and Australia. We completed dosing of subjects in the second quarter of 2008 and completed analysis of the trial data in the third quarter of 2008. This clinical trial is the first of two planned for this indication.
- The cost to complete our second Phase III trial of Bronchitol for bronchiectasis is currently estimated to be approximately A\$10 million. This trial is planned to be conducted in the U.S. and Europe. We expect to commence recruitment for this trial during the second half of 2008.

We do not expect to complete any of the Bronchitol research and development projects before the first half of 2009 and, therefore, we do not expect to receive any sales revenues prior to the completion of these projects. We anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct to each project on an on-going basis in response to the scientific and clinical success of each product candidate and available funds.

## 2.2.1 Operating Results (continued)

### *Administration*

Administration expenses consist primarily of salaries and related expenses and professional services fees and includes accounting, administration, office and public company costs. We anticipate that general and administrative expenses will increase as a result of the expected expansion of our operations, facilities and other activities associated with the planned expansion of our business. As an Australian listed company also listed in the U.S., we operate in an increasingly demanding regulatory environment which requires us to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, expanded disclosures, accelerated reporting requirements and complex accounting rules. Responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control.

### *Commercial*

Our commercial expenses consist of salaries and professional fees related to the commercial launch and ongoing sales and marketing of Aridol in Australia, Europe, the U.S. and Asia. We anticipate that commercial expenses will increase as we launch Aridol in additional jurisdictions, as we prepare to launch Bronchitol, and as we incur other selling and marketing costs.

## 2.2.2 Critical Accounting Policies and Estimates

Refer to Note 1 of the Annual Financial Report found in Section 3 of this Statutory Annual Report.

## 2.2.3 Review of 2008 Operations

### *Bronchitol*

We are developing Bronchitol for the management of chronic obstructive lung diseases including cystic fibrosis, bronchiectasis and other acute and chronic pulmonary conditions. 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:

- Our Phase III clinical trial of Bronchitol in CF being conducted in Europe and Australia reached its final recruitment target of 325 subjects. We expect all subjects to complete the efficacy arm of the trial and data to be available during the first half of 2009
- We concluded the Special Protocol Assessment process with the U.S. FDA in relation to a Phase III clinical trial with Bronchitol in adults and children with cystic fibrosis. This trial is to be conducted in North America, Latin America and Europe
- A three month clinical trial of Bronchitol in children with cystic fibrosis returned positive results
- Our Phase II CF dosing study completed
- We released positive headline clinical data on a 362 subject, 22 site international Phase III clinical trial of Bronchitol in bronchiectasis and subsequently the closure of the long term safety study extension arm of the study
- We reached agreement with the Australian TGA for us to file a marketing application for Bronchitol for bronchiectasis
- We concluded the Special Protocol Assessment process with the U.S. FDA, in relation to a twelve month Phase III clinical trial with Bronchitol in subjects with bronchiectasis. This trial protocol was also reviewed by the European Medicines Authority (EMA). This trial is to be conducted in the U.S. and Europe
- The Chinese FDA accepted for review our Bronchitol clinical trial application
- We established a global compassionate use program for Bronchitol

**Aridol**

Aridol is our 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:

- We commenced a major Aridol U.S. asthma management study in collaboration with the U.S. Asthma Clinical Research Network.
- Marketing authorizations for Aridol were issued by Germany, the United Kingdom, the Netherlands, Denmark, Greece, Finland, Ireland, Norway and Portugal.
- We received marketing approval for Aridol in Korea, our first Asian approval.

**Other milestones**

- Construction commenced on a new 7,000 square metre manufacturing and research facility at Frenchs Forest, NSW, Australia which is scheduled for completion in the first half of 2009.
- The preclinical studies with PXS25 were completed and it was shown to have an appropriate safety window to allow administration to human volunteers.
- PXS4159 was identified as a preclinical development candidate and entered formal preclinical development studies
- We opened a U.S. office in Exton, PA to strengthen our expanding U.S. clinical and regulatory program, and prepare for the commercialization of both Aridol and Bronchitol in the U.S.
- Senior Australian pharmaceutical executive Mr. Will Delaat joined our Board of Directors.
- We completed an Australian share placement and share purchase plan in which we issued 15.8 million shares and raised A\$59.2 million net of issue expenses.

**2.2.4 Results of Operations****Comparison of financial years ended 30 June 2008 and 30 June 2007**

Sales and gross profit. Sales were A\$0.5 million in 2008 compared to A\$0.2 million in 2006. Our first product Aridol was launched in Australia in June 2006 and following successful completion of the E.U. mutual recognition procedure in June 2007 we have during 2008 received marketing authorizations in Germany, the United Kingdom, the Netherlands, Denmark, Greece, Finland, Ireland, Norway and Portugal. Approximately 41 percent of sales for 2008 were in Australia, 26 percent in Europe and the remaining 33 percent of sales were to pharmaceutical companies for use in clinical trials. Gross profit was approximately 75 percent of sales in both 2008 and 2007.

Other revenue – interest. Interest and other income increased from A\$5.3 million in 2007 to A\$7.4 million in 2008.

The increase in interest income is mainly attributable to the greater level of funds invested during 2008. We started 2008 with \$76 million of cash and bank accepted commercial bills to which was added approximately \$60 million in October and November 2007 from a share placement on the ASX and a share purchase plan. By contrast we started 2007 with \$98 million of cash and bank accepted commercial bills. Interest rates on bank accepted commercial bills has also increased during 2008.

Other income. The predominant component of other income in both 2008 and 2007 is grant revenue. Grant revenue in 2008 includes A\$1.3 million claimed under an Australian Government Pharmaceuticals Partnerships Program grant ('P3 Grant') awarded to us in June 2004, and an Export Market Development Grant of A\$0.08 million. Grant revenue in 2007 includes A\$2.0 million claimed under the P3 Grant and an Export Market Development Grant of A\$0.2 million. Our claims under the P3 Grant are calculated at 30% of the increase of eligible R&D expenditure over a base amount (derived from average prior year expenditures). The P3 Grant has now concluded and no further amounts are claimable. In 2008 other income also includes amounts paid to us under a contract with a pharmaceutical company for services performed by our Australian sales force promoting a product of the pharmaceutical company to respiratory specialists.

Research and Development Expenses. Research and development expenses were \$20.0 million in 2008 compared to \$23.8 million in 2007.

## 2.2.4 Results of Operations (continued)

1. Our drug discovery group is based in leased laboratories in Sydney and also, until its closure during 2007, was based at the John Curtin School of Medical Research within the Australian National University. Our drug discovery group accounted for approximately 11 percent of our total research and development expenditure in the current year and increased by approximately 45 percent or A\$0.7 million compared to 2007. This group is focused on immune disorders and respiratory drug discovery. The increased level of expenditure reflects increased staffing during both 2008 and 2007 and increased levels of research activity associated with our SSAO/VAP-1 program.
2. Our preclinical development group accounted for approximately 3 percent of our total research and development expenditure in the current year and decreased by approximately 73 percent or A\$1.7 million compared to 2007. In 2007, approximately 90 percent of expenditure related to the outsourced Aridol and Bronchitol long term safety/toxicology studies. These were substantially completed in 2007. In 2008, the predominant expenditure was in relation to preclinical development of lead compounds in the immune disorder area (PXS25 and its pro-drug PXS64).
3. Our clinical group located at our Frenchs Forest facility accounted for approximately 56 percent of our total research and development expenditure in 2008 and decreased by approximately 19 percent or A\$2.6 million compared to 2007. The clinical group designs and monitors the clinical trials run by us. The majority of the expenditures of this group are directed at hospitals and other services related to the conduct and analysis of clinical trials. This significant decrease in expenditure reflects the number and size of clinical trials in the active dosing stage during 2008.
4. Our TGA registered manufacturing facility at Frenchs Forest is predominantly focused on producing material for clinical trials and developing enhanced manufacturing products and processes. Manufacturing expenses for the current year have therefore mainly been classified as a research and development expenditure. Costs associated with the Aridol product sold are classified as cost of sales. Manufacturing accounted for approximately 30 percent of our total research and development expenditure in 2008 and decreased by approximately 3 percent or A\$0.2 million compared to 2007.

*Commercial expenses.* Commercial expenses were A\$4.6 million in 2008 compared to A\$3.2 in 2007. Over half of this increased expenditure relates to higher (non cash) costs in relation to employee share options. Other increased expenditures include the launch of Aridol in Europe and the opening of an office in the U.S..

*Administration expenses.* Administration expenses were A\$5.2 million in 2008 and A\$4.7 million in 2007, an increase of 12 percent. Approximately half of this increased expenditure relates to higher (non cash) costs in relation to employee share options.

*Income tax expense.* Income tax expense was A\$0.03 million in 2008 and A\$0.02 million in 2007. The expense relates to income generated by our UK and US subsidiaries which are currently reimbursed for their expenditures on a cost plus basis upon which tax is payable.

*Loss.* Our loss decreased from A\$24.2 million in 2007 to A\$20.4 million in 2008. The significant increase in operating expenses discussed above was only partly offset by the increase in interest and other income.

*Basic and diluted net loss per share.* Basic and diluted net loss per share decreased from A\$0.136 in 2007 to A\$0.108 in 2008 predominantly because of the increase in research and development expenses in 2007, but also as a result of the share placement and share purchase plan in October and November 2007 in which we issued 15.8 million shares.

### **Comparison of financial years ended 30 June 2007 and 30 June 2006**

*Sales and gross profit.* Sales were A\$0.2 million in 2007 compared to A\$0.008 million in 2006. Our first product Aridol was launched in Australia in June 2006 and was approved for sale in Sweden in October 2006 and the E.U. mutual recognition procedure was successfully completed in June 2007 allowing for the issue of marketing authorizations in Germany, France, the United Kingdom, Italy, the Netherlands, Belgium, Denmark, Greece, Finland, Ireland, Norway and Portugal. Approximately 60 percent of sales for the 2007 were in Australia. The other 40 percent of sales were split approximately evenly between Sweden and a U.S. biopharmaceutical company which is using Aridol in clinical trials. Gross profit was approximately 75 percent of sales in both years.

*Other revenue – interest.* Interest and other income increased from A\$4.3 million in 2006 to A\$5.3 million in 2007. The increase in interest income is attributable to the greater level of funds invested during 2007. We started 2007 with \$98 million of cash and bank accepted commercial bills. By contrast we started 2006 with \$33 million of cash and bank accepted commercial bills, to which was added approximately \$80 million in November 2005 from the capital raising undertaken in Australia and the United States.

*Other income.* Other income consisted of grant revenue in both 2007 and 2006. Grant revenue in 2007 relates exclusively to an Australian Government Pharmaceuticals Partnerships Program grant ('P3 Grant') awarded to us in June 2004. Grant revenue in 2006 relates to an Australian Government R&D Start Grant ('Start Grant') awarded to us in June 2003 to develop new treatments for cystic fibrosis and the P3 Grant. The Start Grant was payable based on underlying expenditure on the research project, makes up approximately 35% of the total research grants received during 2006 and was completed on December 31, 2005. There are certain limited circumstances where we may be required to repay grant funding. The P3 Grant payable to us is 30% of the increase of eligible research and development expenditure over a base level of expenditure.

*Research and development expenses.* Research and development expenses were \$23.8 million in 2007 compared to \$17.0 million in 2006.

There are four components to the research and development expenses:

1. Our drug discovery group is based in leased laboratories in Sydney and also, until its closure during 2007, the John Curtin School of Medical Research within the Australian National University. Our drug discovery group accounted for approximately 7 percent of our total research and development expenditure in the current year and increased by approximately 44 percent or A\$0.5 million compared to 2006. This group is focused on immune disorders and respiratory drug discovery. This area of research accounted for approximately 7 percent of the increase in overall research and development expenditure during 2007.
2. Our preclinical development group accounted for approximately 10 percent of our total research and development expenditure in the current financial year and increased by approximately 4 percent or A\$0.1 million compared to 2006. This group is managing the outsourced safety/toxicology studies of the Aridol and Bronchitol products and the preclinical development of lead compounds in the immune disorder area (PXS25 and its pro-drug PXS64). Approximately 90 percent of expenditure in 2007 related to the Aridol and Bronchitol studies. This area of research accounted for approximately 1 percent of the increase in overall research and development expenditure during 2007.
3. Our clinical group located at our Frenchs Forest facility accounted for approximately 57 percent of our total research and development expenditure in 2007 and increased by approximately 34 percent or A\$3.5 million compared to 2006. The clinical group designs and monitors the clinical trials run by us. The majority of the expenditures of this group are directed at hospitals and other services related to the conduct and analysis of clinical trials. This significant increase in expenditure reflects the number and size of clinical trials ongoing during 2007. This area of research accounted for approximately 51 percent of the increase in overall research and development expenditure during 2007.
4. Our TGA registered manufacturing facility at Frenchs Forest is predominantly focused on producing material for clinical trials and developing enhanced manufacturing processes. Manufacturing expenses for the current year have therefore mainly been classified as a research and development expenditure. Manufacturing accounted for approximately 26 percent of our total research and development expenditure in 2007 and increased by approximately 83 percent or A\$2.8 million compared to 2006, reflecting manufacturing performance/yield innovation and product stability studies required to support registration applications. This area of expenditure accounted for approximately 41 percent of the increase in overall research and development expenditure during 2007.

*Commercial expenses.* Commercial expenses were A\$2.8 million in 2007 compared to A\$1.9 in 2006. The commercial launch of Aridol in Australia and preparation for the full commercial launch in Europe resulted in additional one-time expenses in addition to the first full year of costs associated with the hiring of a sales and marketing team in Australia and Europe late in 2006. In addition costs were incurred obtaining detailed global market information in relation to bronchiectasis.

## 2.2.4 Results of Operations (continued)

*Administration expenses.* Administration expenses were A\$4.7 million in 2007 and A\$4.4 million in 2006, an increase of 6 percent.

*Income tax expense.* We recorded an income tax expense for the first time in 2006 and again in 2007. The expense relates to income generated by our UK subsidiary which is currently reimbursed for its expenditures on a cost plus basis upon which tax is payable.

*Loss.* Our loss increased from A\$17.7 million in 2006 to A\$24.2 million in 2007. The significant increase in operating expenses discussed above was only partly offset by the increase in interest and other income.

*Basic and diluted net loss per share.* Basic and diluted net loss per share increased from A\$0.11 in the 2006 financial year to A\$0.14 in the 2007 financial year predominantly because of the increase in research and development expenses in 2007.

## 2.2.5 Liquidity and Capital Resources

Since our inception, our operations have mainly been financed through the issuance of equity securities and convertible redeemable preference shares. Additional funding has come through research grants, interest on investments and the exercise of options. With the commercial launch of our first product Aridol in Australia in June 2006 our operations also generated sales revenue. Through 30 June 2008, we had received net cash proceeds from the issue of ordinary and convertible redeemable preference shares of A\$194.7 million and approximately A\$9.0 million in research grants. We have incurred significant losses since our inception. We incurred losses of A\$17.7 million, A\$24.2 million and A\$20.4 million in the financial years ended 30 June 2006, 2007 and 2008 respectively. As of 30 June 2008 we had cash and cash equivalents of A\$111.8 million.

In 2008, we used net cash of A\$18.9 million for operating activities. This consisted of a net loss for the period of A\$20.4 million, which included A\$1.0 million of non-cash depreciation and amortization, and non-cash stock option expense of A\$3.4 million, and other working capital movements of A\$2.9 million. Net cash used in investing activities during 2008 was A\$5.1 million, which predominantly relates to the fit out of a facility being constructed for us and new manufacturing equipment to be housed in the facility. Net cash provided by financing activities during 2008 was A\$59.6 million primarily resulting from the issue and sale of our ordinary shares in an Australian share placement and share purchase plan.

In 2007, we used net cash of A\$20.7 million for operating activities. This consisted of a net loss for the period of A\$24.2 million, which included A\$0.9 million of non-cash depreciation and amortization, and non-cash stock option expense of A\$1.5 million, and other working capital movements of A\$1.1 million. Net cash used in investing activities during 2007 was A\$1.3 million, which included purchase of plant and equipment for quality control laboratory facilities and equipment. Net cash provided by financing activities during 2007 was A\$0.4 million resulting from the issue of shares upon the exercise of options granted under the Pharmaxis Employee Option Plan.

In 2006, we used net cash of A\$13.8 million for operating activities. This consisted of a net loss for the period of A\$17.7 million, which included A\$0.9 million of non-cash depreciation and amortization, and non-cash stock option expense of A\$1.1 million, and other working capital movements of A\$1.9 million. Net cash used in investing activities during 2006 was A\$1.8 million, which included purchase of plant and equipment for manufacturing expansion. Net cash provided by financing activities during 2006 was A\$80.0 million resulting from the issue and sale of our ordinary shares in a U.S. public offering and a concurrent Australian share placement.

At 30 June 2008, we had cash and cash equivalents of A\$111.8 million as compared to A\$76.2 million as of 30 June 2007. This overall increase was primarily due to our Australian share placement and share purchase plan in October and November 2007.



We believe that our cash and cash equivalents will be sufficient to meet our capital requirements for at least the next 12 months. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue one or more of our clinical trials or our operations.

We expect to continue to incur substantial losses. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the costs of expanding sales, marketing and distribution capabilities;
- the scope, results and timing of preclinical studies and clinical trials;
- the costs and timing of regulatory approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We anticipate that a substantial portion of our capital resources and efforts in the foreseeable future will be focused on funding the:

- clinical development of Bronchitol in patients with cystic fibrosis;
- clinical development of Bronchitol in patients with bronchiectasis and other acute and chronic pulmonary conditions;
- expansion of our manufacturing capabilities;
- continued commercial launch of Aridol for the management of asthma in the E.U. and the U.S.; and
- pre-clinical development of our product pipeline.

## **2.2.6 Quantitative and Qualitative Disclosures about Market Risk**

Our exposure to market risk is limited to interest income sensitivity, which is affected by changes in the general level of Australian interest rates, particularly because the majority of our investments are in cash and cash equivalents. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Our investment portfolio is subject to interest rate risk and will fall in value in the event market interest rates increase. Due to the short duration of our investment portfolio, we believe an immediate 10% change in interest rates would not be material to our financial condition or results of operations. We do not have derivative financial instruments.

## **2.2.7 Income Taxes**

As of 30 June 2008, we had net operating loss carry forwards of A\$102.3 million (A\$79.2 million as of 30 June 2007). While these losses do not expire, our utilization will depend upon our ability to derive future taxable income of a nature and of an amount sufficient to enable the deduction for the losses to be realized, our continued compliance with the conditions for deductibility imposed by tax legislation, and the absence of changes in tax legislation that adversely affect our ability to utilize the losses.

As of 30 June, 2007 and 2008, we did not record a benefit for the deferred tax assets because realization of the deferred tax assets was not more likely than not.

## **2.2.8 Recently Issued Accounting Announcements**

Refer to Note 1 of the Annual Financial Report found in Section 3 of this Statutory Annual Report.

## **2.2.9 Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

## 2.2.10 Contractual Obligations and Commitments

The following table summarizes financial data for our contractual obligations and other commercial commitments, including interest obligations, as of 30 June 2008 (in thousands):

Payments due by Period	Total A\$	Less than 1 year A\$	1 – 3 years A\$	3 – 5 years A\$	More than 5 years A\$
<b>Contractual Obligations</b>					
Long-Term Debt Obligations	–	–	–	–	–
Capital (Finance) Lease Obligations	–	–	–	–	–
Operating Lease Obligations	1,108	380	728	–	–
Purchase Obligations	9,314	9,314	–	–	–
Other Long-Term Liabilities	–	–	–	–	–
<b>Total</b>	<b>10,422</b>	<b>9,694</b>	<b>728</b>	<b>–</b>	<b>–</b>

In addition, we have entered into an agreement concerning the lease of a custom designed manufacturing, warehousing, research and office facility of approximately 75,000 square feet. The facility is being constructed to our specifications. Once the building is completed to specification according to the terms of the agreement, the lease commences. It will have a term of 15 years, with two options to renew of a further five years each and the option to break the lease at ten years but with financial penalties attached. The initial minimum annual rental under the agreement is \$1.46 million per annum, increasing each year for the term of the agreement by 3.25%. This minimum rental may increase as the result of variations to the building specifications required by us during its construction, or decrease as a result of the incentive owing to us under the agreement. The incentive may be used for building variations, building fit-out or rent reduction.

Purchase obligations in the above table relate to building fit-out and plant and equipment to be installed in the new custom designed facility.

The contractual summary above reflects only payment obligations that are fixed and determinable. We have additional contractual payment obligations that are contingent on future events. Our operating lease obligations primarily relate to the lease for our headquarters in Frenchs Forest. We also have agreements with clinical sites, and contract research organizations, for the conduct of our clinical trials and other research activities.

## 2.3 Controls and Procedures Required as a Result of Our U.S. Listing

### 2.3.1 Disclosure Controls and Procedures

Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Control Act of 1934, as amended (the Exchange Act)), as of 30 June 2008. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of such date. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

## **2.3.2 Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies may deteriorate.

Under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation, our management concluded that our internal control over financial reporting was effective as of 30 June 2008.

## **2.3.3 Changes in Internal Controls over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the year ended 30 June 2008 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## **2.3.4 Audit Committee Financial Expert**

Our Board of Directors adopted its Audit Committee charter on 4 December 2003 and reviews the charter annually. The last amendments to the charter were made on 9 August 2007. Our Board has determined that we do not have a financial expert serving on our Audit Committee as defined by Item 16A(b) of Form 20-F.

We believe that the combined knowledge, skills and experience of the members of our Audit Committee enables them, as a group, to act effectively in the fulfillment of their tasks and responsibilities, including those under the Sarbanes-Oxley Act of 2002, without appointing a member who would qualify as an Audit Committee financial expert.

## **2.3.5 Code of Ethics**

We have adopted a Code of Conduct that applies to the Chief Executive Officer and all senior financial officers, or persons performing similar functions, of the Company. The Code of Conduct is also posted on the Company's website at [www.pharmaxis.com.au](http://www.pharmaxis.com.au). Changes to the Code of Conduct will be posted on the Company's website within five business days of the change being effective.

## **2.3.6 Principal Accountant Fees and Services**

The Audit Committee of our Board of Directors chooses and engages our independent auditors to audit our financial statements. Our Board of Directors has adopted a policy requiring management to obtain the Audit Committee's approval before engaging our independent auditors to provide any other audit or permitted non-audit services to us. This policy, which is designed to assure that such engagements do not impair the independence of our auditors, requires the Audit Committee to pre-approve audit and non-audit services that may be performed by our auditors.

Refer to Note 19 to the Annual Financial Report in Section 3 of this Statutory Annual Report and Section 1.4.14 of this Statutory Annual Report for details of fees billed to the Company for financial years ended 30 June 2008 and 30 June 2007 by PricewaterhouseCoopers, the Company's principal accounting firm.

## 2.4 Risk Factors

Our regulatory filings in the U.S. require an extensive discussion of risk. The following risks relate specifically to the Company's business and should be considered carefully. Our business, financial condition and results of operations could be materially and adversely affected by any of the following risks. As a result, the trading price of our ordinary shares and our American Depositary Shares, or ADSs, could decline and the holders could lose part or all of their investment.

### *Risks Related to Our Business*

We are at an early stage of our development as a specialty pharmaceutical company. Our first product, Aridol, has commenced generating initial revenue. We may not be successful in deriving meaningful revenues from Aridol. We do not currently have, and we may never have, any other authorized products other than Aridol that generate revenues. Unless we are able to generate sufficient product revenue, we will continue to incur losses from operations and may not achieve or maintain profitability.

We are at an early stage of our development as a specialist integrated pharmaceutical company. We were incorporated in May 1998 and we have a limited operating history on which to evaluate our business and prospects. To date, we do not have, and we may never have, any products that generate significant revenues. We have generated a small amount of revenue from the sale of Aridol to date. To date, we have funded our operations and capital expenditures with proceeds from the sale of our securities, government grants and interest on investments.

We have incurred losses in each year since our inception and expect to continue to incur substantial losses. We incurred losses of approximately A\$17.7 million, A\$24.2 million and A\$20.4 million in the financial years ended 30 June 2006, 2007 and 2008, respectively. Our accumulated losses from inception to 30 June 2008 are A\$83.0 million. These losses, among other things, have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Unless we are able to generate sufficient product revenue, we will continue to incur losses from operations and may not achieve or maintain profitability.

We expect our expenses to increase significantly in the short term in connection with:

- the regulatory marketing authorization process to approve the sale of Aridol in the U.S. and other jurisdictions. Aridol was the first of our product candidates to complete Phase III trials in any jurisdiction and the first of our product candidates for which we have sought marketing authorization. We have to date received marketing authorization in Australia, a number of European countries and Korea. The work involved in seeking regulatory marketing authorization for Aridol in other jurisdictions, including the U.S., is extensive, time consuming and expensive;
- the development of our Aridol sales and marketing capability. Our existing sales and marketing capability is currently limited to a sales team for Australia and the U.K., distributors in Europe, a European and United States office to oversee regional activities and a distributor in Korea. Our sales and marketing capability must be increased further to enable the sales and marketing of Aridol in U.S. and to expand sales in Europe and Asia;
- the continuation of simultaneous Phase III clinical trials of Bronchitol for different chronic respiratory disorders. These clinical trials are carried out in a number of jurisdictions and with respect to a number of indications and are expensive;
- the commencement of new clinical trials and the continuation of existing clinical trials to more advanced phases and/ or additional sites. The more advanced clinical trials typically require more clinical trial participants, clinical trial sites and research investigators than earlier stage clinical trials and are consequently more expensive;
- the commencement of Phase I clinical trials of PXS25, which will represent a significant new expense for us;
- the commencement of new preclinical testing programs and the continuation of existing clinical testing programs with respect to a number of potential product candidates including PXS4159;
- the establishment and continuation of a number of early stage research and development projects being undertaken by or on behalf of the Company; and
- the fitting out of our purpose built manufacturing, warehousing and office facility which includes the acquisition of significant manufacturing plant and equipment.

We also expect to incur increased general and administrative expenses in support of our increased operations as well as the ongoing costs to operate as a company listed on the Australian Securities Exchange and on the Nasdaq Global Market.

Over the longer term, the costs referred to above will fluctuate, primarily dependant on regulatory marketing authorizations being sought, the extent of our sales and marketing operations, the number, type and size of clinical trials being undertaken by us at any one time, the preclinical development and research projects being undertaken and the timing and nature of the costs we will incur in fitting out our new purpose built manufacturing, warehousing and office facility. Costs will also increase if we are able to progress any further clinical trial candidates from preclinical testing to clinical trials or if we are able to complete clinical trials of any product candidates and seek regulatory marketing authorizations.

We may not become profitable if Bronchitol is unsuccessful in ongoing clinical trials or we are unable to obtain regulatory authorizations for Aridol and Bronchitol in key jurisdictions. Even though we have received regulatory authorization for Aridol in a number of jurisdictions, profitability will depend on our ability to obtain marketing authorizations for Aridol in other key jurisdictions and to likewise obtain marketing authorizations for Bronchitol in key jurisdictions. Even if we obtain these market authorizations, we cannot assure that we will be able to generate revenues from the sale of our products or the licensing of our technology.

We cannot be certain that our clinical development of Bronchitol or any of our other product candidates in preclinical testing or clinical development will be successful, that Aridol will receive regulatory authorizations in key markets such as the U.S, or that Bronchitol or any of our other product candidates will receive the regulatory authorizations required to commercialize them, or that any of our research and development programs will yield additional product candidates suitable for investigation through clinical trials.

We will undertake simultaneous clinical trials of Bronchitol for the treatment of cystic fibrosis and bronchiectasis. We have completed a Phase III study of Bronchitol for the treatment of people with bronchiectasis in Europe and Australia which met its two primary efficacy endpoints, being quality of life and mucus clearance. However, additional clinical trials are required to enable us to seek marketing authorization in Europe and the U.S. If Bronchitol is unsuccessful in these and other ongoing clinical trials, or we are unable to obtain marketing authorization of our products and product candidates in all key jurisdictions, we may not be profitable. Clinical trials of Bronchitol will continue for several years, but may take significantly longer to complete. There is a risk that these clinical trials of Bronchitol may not be successful or may not be successful with respect to a particular indication or that marketing authorization may not be granted in the future. If we are not able to successfully complete clinical trials of Bronchitol, and if we are unable to obtain marketing authorization of Bronchitol, we may not be profitable. If we are unable to obtain marketing authorization of Aridol in the U.S. and other key jurisdictions, we may not be profitable.

If we are unable to obtain marketing authorization of our products and product candidates in all key jurisdictions, we may not be profitable. We have completed the Phase III clinical trials of Aridol necessary for U.S. registration of Aridol. However, we cannot be certain that marketing authorizations will be granted in the U.S. There is a risk that these Phase III clinical trials in the U.S. may not be sufficient and that marketing authorization may not be granted in the U.S.

The process to develop, obtain regulatory authorizations for, and commercialize potential product candidates is long, complex and costly. Even if we receive regulatory authorizations for any product candidates, profitability will depend on our ability to generate revenues from the sale of our products or the licensing of our technology that will offset the significant and continuing expenditures required for us to advance our research, protect and extend our intellectual property rights and develop, manufacture, license, market, distribute and sell our technology and products successfully. Our ability to generate revenue depends on a number of factors, including our ability to:

- successfully conduct and complete clinical trials for Bronchitol and our other product candidates;
- develop and obtain all necessary regulatory marketing authorization, as well as approvals concerning pricing and reimbursement, which may be necessary in some E.U. member states and other jurisdictions, for Aridol and Bronchitol in our target markets where we do not currently have regulatory marketing authorization and, in the future, to develop and obtain regulatory marketing authorization for our other product candidates;
- manufacture or obtain commercial quantities of Aridol and Bronchitol or our other product candidates at acceptable cost levels; and
- successfully market and sell Aridol, Bronchitol and our other product candidates. In circumstances where we have licensed our technology to third parties, our ability to generate revenue will depend on the success of the licensee of the technology to successfully market and sell the licensed technology.

## 2.4 Risk Factors (continued)

Although we have a pipeline of potential product candidates, our business is currently substantially dependent on our ability to complete development, obtain regulatory approval for, and successfully commercialize Aridol and Bronchitol in a timely manner. If we are unable to successfully commercialize Aridol and/or Bronchitol or are unable to successfully commercialise them with respect to particular indications, we may not be able to earn sufficient revenues to continue our business. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, there would be a material adverse effect on our business and the holders of our ordinary shares and ADSs could lose all or part of their investment.

**Unsuccessful or delayed marketing authorization or approvals concerning pricing and reimbursement could increase our future development costs or impair our future revenue. Authorizations that may be given may not cover all the indications for which we seek approval or may contain significant limitations.**

To receive regulatory authorization for the commercial sale of any product or product candidate, we must complete preclinical development and extensive clinical trials to demonstrate safety and efficacy in humans and then apply to relevant regulatory authorities. This process of attempting to gain regulatory approval is expensive and can take many years, and failure can occur at any stage of the testing or approval process. We have received regulatory marketing authorization for Aridol in certain target markets including Australia, a number of European countries and Korea. Our failure to adequately demonstrate the safety and efficacy of Aridol in our other key markets and/or our failure to adequately demonstrate the safety and efficacy of Bronchitol for the treatment of various chronic respiratory disorders and/or any of our other product candidates or otherwise fail to satisfy regulatory requirements will prevent regulatory approval and commercialization of such product candidates. Our inability to successfully and effectively complete clinical trials for our product candidates, in particular clinical trials of Bronchitol, will severely harm our business and we may not be profitable.

Significant delays in clinical development could materially increase our product development costs, delay our receipt of revenue or allow our competitors to bring product candidates to market before we do, impairing our ability to effectively commercialize Aridol and Bronchitol or our other product candidates.

In addition, any authorization we may obtain may not cover all of the clinical indications for which we seek approval. Also, an authorization might contain significant limitations in the form of narrow indications, warnings, precautions or contraindications with respect to conditions of use.

Our inability to obtain satisfactory pricing and reimbursement approvals for Aridol, Bronchitol or other product candidates in certain jurisdictions may impair our ability to effectively commercialize Aridol and Bronchitol or our other product candidates in those jurisdictions.

**We will continue to need significant amounts of additional capital that may not be available to us on favorable terms or at all or which may be dilutive.**

To date, we have funded our operations and capital expenditures with proceeds from the sale of our securities, government grants and interest on investments.

In order to achieve our goal of being a fully integrated pharmaceutical company and to conduct the lengthy and expensive research, preclinical studies, clinical trials, regulatory approval process, manufacture, sales and marketing necessary to complete the full development of our product candidates, we may require substantial additional funds in addition to the funds received in connection with a share placement in 2007.

To meet these financing requirements, we may raise funds through the sale of our securities, debt financings, and through other means, including collaborations and license agreements. Raising additional funds by issuing equity or convertible debt securities may cause our shareholders to experience significant additional dilution in their ownership interests. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities. Additional funding may not be available to us on favorable terms, or at all. If we are unable to obtain additional funds, we may be forced to delay, reduce the scope or eliminate one or more of our clinical trials or research and development programs or future commercialization efforts. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights and control over our technologies, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

**If we fail to obtain additional financing, we may be unable to fund our operations and commercialize our product candidates.**

We expect that our cash expenditure will increase for the next several years, and that we will spend substantial amounts to complete the clinical development and commercialization of Aridol, Bronchitol, PXS25, PXS4159 and our other product candidates, and to license or acquire other product candidates. We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements for at least 12 months.

Our future funding requirements will depend on many factors, including the:

- scope, results, rate of progress, timing and costs of preclinical studies and clinical trials and other development activities;
- costs and timing of seeking and obtaining regulatory authorizations;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- costs of developing our sales and marketing capabilities and establishing distribution capabilities;
- costs of expanding our manufacturing capabilities to satisfy demand for our products;
- costs of additional management and scientific, manufacturing and sales and marketing personnel. We will be required to increase the number of our personnel over time;
- terms, timing and cash requirements of any future acquisitions, collaborative arrangements, licensing of product candidates or investing in businesses, product candidates and technologies;
- costs of securing coverage, payment and reimbursement of our product candidates which receive regulatory approval; and
- effects of competing clinical, technological and market developments.

If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or future commercialization efforts.

**We may be required to repay previously received grant revenue in certain circumstances which would have an adverse effect on our cash position.**

We have received substantial grant funding under a grant agreement with the Commonwealth of Australia. In certain circumstances where we fail to use our best endeavors to commercialize the project within a reasonable time of completion of the project or upon termination of a grant due to our breach of agreement or our insolvency, the Commonwealth of Australia may require us to repay some, or all, of the grant. If required to repay the grant amounts, we may be required to reallocate funds needed to continue the commercialization of our products and such repayment may have a material adverse effect on our cash position and us.

**Currency fluctuations may expose us to increased costs and revenue decreases.**

Our business may in the future be affected by fluctuations in foreign exchange rates. Currency fluctuations could, therefore, cause our costs to increase or revenues to decline. The majority of our expenses will continue to be denominated in Australian dollars although we will also be expending significant amounts of cash in other denominations, including the U.S. dollar, British pound, Swedish kroner, Danish kroner and the European euro. The exchange rates of the Australian dollar to the U.S. dollar, the British pound, the Swedish kroner and the European euro have fluctuated in recent years. In circumstances where the Australian dollar devalues against any or all of the U.S. dollar, the British pound, the Swedish kroner or the European euro, this may have an adverse effect on our costs incurred in either the U.S. or Europe (as applicable) but may have a positive effect on any revenues which we source from the U.S. or Europe (as applicable). The same principles apply in respect of our costs and revenues in other jurisdictions. In addition, we have offices in the United Kingdom and the United States and conduct clinical trials in many different countries and we have manufacturing of some of our product candidates undertaken outside of Australia, which exposes us to potential cost increases resulting from fluctuations in exchange rates. We do not currently have any plans to hedge the effect of currency fluctuations on our overseas expenditures. We manage our currency risks by settling foreign currency payables immediately upon recognition of a foreign currency liability and/or by holding foreign currency cash funds to match net foreign currency payables.

## 2.4 Risk Factors (continued)

### *Risks Related to Research and Development of Our Products*

Clinical trials are expensive, time consuming, subject to delay and their outcome is uncertain and may not be completed at all.

To receive regulatory authorization for the commercial sale of any product or product candidate, we must complete preclinical development and extensive clinical trials to demonstrate safety and efficacy in humans. Preclinical development and clinical trials are subject to extensive regulation by the regulatory authorities including the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMEA in Europe and other regulatory authorities elsewhere. In addition, clinical trials must be conducted with product candidates produced under applicable current Good Manufacturing Practices. Clinical trials are expensive and complex, can take many years, are often subject to delay and have uncertain outcomes. The FDA has accepted an Investigational New Drug Application, or IND, for inhaled dry powdered mannitol. We have completed the Phase III clinical trials of Aridol that we believe are necessary for U.S. marketing authorization of Aridol and are targeting filing our application in the second half of 2008. Our Phase III study of Bronchitol in Europe and Australia for the treatment of people with bronchiectasis met its two primary efficacy endpoints, being quality of life and mucus clearance. We have reached agreement with the FDA and the EMEA in relation to a protocol for a longer Phase III trial in subjects with bronchiectasis. We have recently closed recruitment in our Phase III clinical trial in Europe and Australia for the treatment of people with cystic fibrosis and have reached agreement with the FDA in relation to a protocol for a second U.S. Phase III trial for subjects with cystic fibrosis. Clinical trials of our product candidates, Bronchitol, PXS25 and PXS4159, will continue for several years, but may take significantly longer to complete.

There are numerous factors that could affect the timing of the commencement, continuation and completion of clinical trials which may delay the clinical trials or prevent us from completing these trials successfully, including but not limited to:

- delays in securing clinical investigators or trial sites for our clinical trials, scheduling conflicts with participating clinicians and clinical institutions, and delays in obtaining institutional review board, or IRB, and other regulatory approvals to commence a clinical trial. There are a limited number of clinical investigators and clinical trials sites worldwide able to conduct the clinical trials required by us. Clinical investigators and trial sites may have demands from a number of companies competing to use their resources;
- slower than anticipated recruitment and enrollment of patients who meet the trial eligibility criteria or the loss of patients during the course of the clinical trials;
- the requirement to repeat or undertake large clinical trials. Our Phase II and Phase III clinical trials involve a large number of patients and are typically carried out in different jurisdictions and may also need to be repeated if required by regulatory authorities;
- negative or inconclusive results from clinical trials, or deficiencies in the conduct of the clinical trials may require us to repeat clinical trials;
- unforeseen safety issues or unforeseen adverse side effects or fatalities or other adverse events arising during a clinical trial due to medical problems that may or may not be related to clinical trial treatments;
- the product candidate may not be competitive with current therapies;
- quality or stability of the product candidate may fall below acceptable standards;
- shortages of available product supply. We may be required to simultaneously provide product to patients in a range of jurisdictions which may have different packaging requirements and there may be shortages or delays in manufacturing and supplying the product in those jurisdictions;
- uncertain dosing issues; and
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols.

Due to the foregoing and other factors, the regulatory approval of Aridol in the U.S. or in other key markets where we do not currently have marketing approval of Aridol, as well as the regulatory approval of Bronchitol, PXS25, PXS4159 and any of our other future product candidates, could take a significantly longer time to gain regulatory authorizations than we expect or these products may never gain approval or may only gain approval in some but not all jurisdictions,



or may only gain approval in some but not all indications for which we seek marketing authorization, any of which could reduce or eliminate our revenue by delaying or terminating the potential commercialization of our products or product candidates. If we suffer any significant delays, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue the development of our products or product candidates or generate revenue and our business may be materially adversely affected.

**Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory authorizations.**

Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain regulatory approval for marketing. Phase I and Phase II clinical trials are not primarily designed to test the efficacy of a product candidate but rather to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate's side effects at various doses and administered according to varying schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. There is a risk that the final results of Phase III clinical trials may not show sufficient safety or efficacy to obtain regulatory marketing authorization in the U.S. or other key jurisdictions despite the completion of Phase III trials in other jurisdictions and the granting of marketing authorization in other jurisdictions. Likewise, clinical trials of product candidates may not show sufficient safety or efficacy to obtain regulatory approval for marketing.

We may conduct lengthy and expensive clinical trials of our product candidates, only to learn that the product candidate is not an effective treatment. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. In addition, clinical results are frequently susceptible to varying interpretations that may require trials to be redone or delay, limit or prevent regulatory authorizations.

Negative or inconclusive results or adverse medical events during a clinical trial could cause the clinical trial to be delayed, redone or terminated. In addition, failure to construct appropriate clinical trial protocols or other factors could require a clinical trial to be redone or terminated. The length of time necessary to complete clinical trials and to submit an application for marketing authorization for a final decision by applicable regulatory authorities may also vary significantly based on the type, complexity and novelty of the product candidate involved, as well as other factors.

**Due to our reliance on contract research organizations, hospitals and investigators to conduct clinical trials, we are unable to directly control the timing, conduct and expense of our clinical trials. We also use third parties to provide research and development services and do not have direct control of the timing, conduct and expense of certain of our research programs.**

We rely on third parties such as contract research organizations, hospitals and research investigators to provide services in connection with our clinical trials. Our clinical trials are conducted by a number of third parties at a number of sites in a range of jurisdictions.

We believe that the agreements that we enter into with these third parties are customary for agreements relating to the provision of clinical trial services. The agreements set out the parameters and protocols for the relevant clinical trials, set out the amount payable by us, as well as setting out the rights and obligations of the third parties and us.

To date, we have been able to manage the use of these third parties in order to effectively carry out our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory authorization for or successfully commercialize our products. Although there are a range of suitable institutions and investigators that would be able to conduct the clinical trials on our behalf, there is no guarantee that we will be able to enter into any such arrangement on acceptable terms, if at all.

## 2.4 Risk Factors (continued)

### ***Risks Related to the Manufacture of Our Products***

The failure to secure an adequate supply of the inhalers to be used in the administration of Aridol and Bronchitol could compromise the commercialization of Aridol and Bronchitol.

Both Aridol and Bronchitol are administered through a dry powder inhaler. If we are not able to enter into a supply agreement, or if there are delays in the supply of the necessary quantity or quality of inhalers, we would be subject to costly delays which may compromise the commercialization of Aridol and/or Bronchitol.

**Delays in the supply of the necessary quantity or quality of mannitol could compromise the commercialization of our products.**

Any delays in the supply of the necessary quantity or quality of mannitol for the manufacture of Aridol and Bronchitol could compromise the commercialization of our products.

**We currently have limited manufacturing capacity and outsource some manufacturing for the clinical development and commercial production of our products, all of which puts us at risk of lengthy and costly delays of bringing our products to market.**

We currently operate manufacturing facilities in Sydney, Australia. Our manufacturing facilities are licensed by the Australian Therapeutic Goods Administration, or TGA, to manufacture Good Manufacturing Practice grade material for commercial sale. We have outsourced the manufacturing of Good Manufacturing Practice grade PXS25 and PXS4159 for preclinical trials and clinical trials as our current manufacturing facilities are not suitable for the production of PXS25 or PXS4159.

We have entered into an agreement concerning the lease of a purpose built manufacturing, warehousing and office facility. Construction of the new facility is underway and is expected to complete in the first half of 2009. We will be subject to significant undetermined risks associated with the building of these new facilities, including delays in construction and disputes in connection with the construction, which may delay or severely compromise the commercialization of our products and our results and operations may be harmed. There is also a risk of delays to our research and clinical trial activities if we needed to change our existing outsourced manufacturers of PXS25 and PXS4159. Our new facility will need to be licensed by the TGA and, if we commence sales of product into the U.S. by the FDA.

We may fail to achieve and maintain required production yields or manufacturing standards which could result in patient injury or death, product recalls or withdrawals, product shortages, delays or failures in product testing or delivery or other problems that could seriously harm our business. In addition, we are subject to ongoing inspections and regulation of regulatory authorities, including by the TGA and the FDA.

**In circumstances where we seek to outsource the manufacture of certain products, there is no guarantee that we will be able to enter into any such arrangement on acceptable terms, if at all, and as a result we are at risk of lengthy and costly delays of bringing our products to market.**

In circumstances where we seek to outsource the manufacture of certain product candidates, such as PXS25 or PXS4159, there is no guarantee that we will be able to enter into any such arrangement on acceptable terms, if at all. We may be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties. To date, the agreements for the manufacture of preclinical quantities of PXS25 do not contain any such exclusivity provisions or termination penalties. In addition, contract manufacturers may have a limited number of facilities in which our products can be produced and any interruption of the operation of those facilities could result in the cancellation of shipments and loss of product, resulting in delays and additional costs.

We, and our contract manufacturers, are required to produce our clinical product and commercial product under FDA and E.U. current Good Manufacturing Practices in order to meet acceptable standards. If such standards change, our ability and the ability of contract manufacturers to produce our products when we require may be affected.

We will outsource the manufacturing of Good Manufacturing Practice grade PXS25 and PXS4159 for Phase I clinical trials as our manufacturing facilities are not currently suitable for the production of PXS25 or PXS4159. Our existing manufacturers of PXS25 and PXS4159 and any future contract manufacturers for PXS25 and PXS4159 or any of our other product candidates which we seek to contract manufacture may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products. We, or our contract manufacturers, may also fail to achieve and maintain required production yields or manufacturing standards which could result in patient injury or death, product recalls or withdrawals, product shortages, delays or failures in product testing or delivery or other problems that could seriously harm our business. In addition, we are, and our contract manufacturers are, subject to ongoing inspections and regulation of regulatory authorities, including by the TGA and the FDA.

The ability to find an acceptable manufacturer or to change manufacturers may be difficult for a number of reasons, including that the number of potential manufacturers is limited and we may not be able to negotiate agreements with manufacturers on commercially reasonable terms, the complex nature of the manufacturing process of certain of our product candidates, such as PXS25 and PXS4159, which may require a significant learning curve for the manufacturer, and the FDA must approve any replacement manufacturer prior to manufacturing, which requires new testing and compliance inspections.

If we were required and able to change manufacturers, the FDA would also require that we demonstrate structural and functional comparability between the same product manufactured by different organizations and may require comparability studies.

#### ***Risks Related to Marketing, Distribution and Sales***

**If we are unable to expand our sales and marketing force our business may be harmed.**

We currently have a limited number of sales and marketing staff and limited distribution capabilities including a sales force located in Australia, distributors in Europe, a European and United States office to oversee regional activities and a distributor in Korea. Our goal is to build an integrated pharmaceutical business undertaking research and development, clinical trials, sales and marketing for certain of our product candidates. We are proposing to develop our sales and marketing capability for products which address highly concentrated markets served by specialist physicians. We intend to contract or partner with third parties in respect of sales and marketing of products where the markets are larger, more diverse or less accessible. For our early stage products or any new products, we may form other strategic alliances with third parties, which have established distribution systems and sales forces, in order to commercialize our products. We market Aridol directly in Australia, the U.K. and Ireland, through distributors in the remainder of Europe and, assuming receipt of all necessary regulatory authorizations of Aridol for commercial sale, we intend to use a combination of direct marketing to pulmonary specialists and third parties in the U.S.

We will need to incur significant additional expenses and commit significant additional management resources to expand our existing sales and marketing force. Although we have already begun to develop our sales and marketing capability, we may not be able to successfully expand these capabilities despite additional expenditures. Even if we are successful in expanding our existing sales and marketing force, it may not be as effective as a third-party sales and marketing force. In circumstances where we elect to rely on third parties, we may receive less revenue than if we sold such products directly. In addition, we may have little or no control over the sales efforts of those third parties and they may not perform as agreed. In the event we are unable to sell sufficient quantities of Aridol, Bronchitol and other product candidates, either directly or through third parties, our business may be significantly harmed and we may be forced to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or future commercialization efforts.

**Our failure to implement and manage the distribution network for our products could result in the delay of supply of our products.**

We have recently established systems and processes necessary for distributing products to customers in Australia and to marketing/distribution partners in Europe. Failure to effectively implement and manage our expanding distribution arrangements could negatively impact the distribution of our products. Delays in supplying product arising from the failure to effectively manage our distribution process may harm the results of our operations.

## 2.4 Risk Factors (continued)

To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

Although our goal is to be a fully integrated pharmaceutical company, an important element of our strategy for developing, manufacturing and commercializing our product candidates is entering into partnerships and strategic alliances with other pharmaceutical companies or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. We may not be able to negotiate alliances on acceptable terms, if at all. Although we do not believe any of the marketing or distribution agreements we have are currently material, such arrangements may become material in the future to the extent any of them represents a significant source of our revenue. Although we are not currently party to any collaborative arrangement or strategic alliance that is material to our business, in the future we may rely on collaborative arrangements or strategic alliances to complete the development and commercialization of some of our product candidates. These arrangements may result in us receiving less revenue than if we sold such products directly, may place the development, sales and marketing of our products outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our strategic partner/collaborators may devote to the product candidates;
- our strategic partner/collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

### **We face costs associated with importing our products into markets outside of Australia.**

As much of our product is likely to be manufactured in Australia, we may face difficulties in importing our products into other jurisdictions as a result of, among other things, import licensing and approval requirements, import inspections, incomplete or inaccurate import documentation or defective packaging. There will be increased costs associated with importing/exporting our product.

### ***Risks Relating to Competition***

If our competitors are able to develop and market products that are preferred over Aridol, Bronchitol or our other product candidates our commercial opportunity may be significantly reduced or eliminated.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. We are seeking to develop and market products that will compete with other products and drugs that currently exist or are being developed or may be developed in the future. For Aridol, various products and treatments are currently marketed for monitoring lung hyper-responsiveness and the identification and assessment of asthma, including methacholine (Provocholine®) by Methapharm, Inc. as a direct bronchiol provocation agent. We believe Aridol is the only airway hyper-responsive test developed using dry powder inhalation technology. This test may not be well accepted in the market place or the medical community. Similarly, for Bronchitol, various products and treatments are currently marketed, including inhaled antibiotics, mucolytic agents and bronchodilators. Bronchitol may not work well in conjunction with existing marketed therapies. In addition, a number of companies are developing new approaches for the treatment of cystic fibrosis, including new antibiotic preparations by Gilead Sciences, Inc. and Novartis AG. and new agents to restore salt balance from Inspire Pharmaceuticals, Inc. and Gilead Sciences, Inc. In addition, many companies are interested in gene therapy. New antibiotic preparations are being tested in patients with bronchiectasis. For patients with chronic bronchitis, new anti-inflammatory agents and new bronchodilating agents are under development.

Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient, are less expensive, or that reach the market sooner than our products. Scientific, clinical or technical developments by our competitors may render Aridol and/or Bronchitol or our other product candidates obsolete or noncompetitive. Further, public announcements regarding the development of any such competing products could adversely affect the market price of our ordinary shares or ADSs. We anticipate that we will face increased competition in the future as new companies enter the markets and as scientific developments progress. If our products obtain regulatory authorizations, but do not compete effectively in the marketplace, our business will suffer.

Many of our competitors currently have significantly greater financial resources and expertise in conducting clinical trials, obtaining regulatory authorizations, undertaking and managing manufacturing and sales and marketing of products than we do. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements they may have with large and established companies. In addition, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring therapies and therapy licenses complementary to our programs.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully complete clinical trials and obtain all requisite regulatory authorizations in a cost-effective and timely manner;
- attract and retain key personnel;
- demonstrate the competitive advantages of our product candidates;
- build an adequate manufacturing, sales and marketing infrastructure to ensure that our infrastructure is adequate for the commercialization of our products;
- secure the support of key clinicians and physicians. The success of our products is dependent on the acceptance of our products by key clinicians and physicians and we face the risk that our products may not be well received or that a product will be released by a competitor which is preferred by key clinicians and physicians; and
- identify and obtain other product candidates on commercially reasonable terms which will provide us with a pipeline of potential product candidates which may reduce the risk if any of our existing product candidates or are adversely affected.

**Future sales of our products may suffer if they are not accepted in the marketplace by physicians, patients and the medical community.**

There is a risk that Aridol, Bronchitol or our other product candidates may not gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of Aridol and Bronchitol or our other product candidates will depend on a number of factors. For example, Aridol must prove to be convenient and effective as a test for airway hyper-responsiveness which assists with the identification and severity of asthma. Likewise, Bronchitol must improve the quality of life for people with chronic obstructive lung diseases such as bronchiectasis, cystic fibrosis and chronic bronchitis. The prevalence and severity of any side effects to Aridol or Bronchitol could negatively affect market acceptance of both Aridol and Bronchitol. Failure to achieve market acceptance of Aridol and Bronchitol would significantly harm our business.

The degree of market acceptance of any of our approved products will depend on a variety of factors, including:

- timing of market introduction and the number and clinical profile of competitive products. There are currently a range of existing alternative products to each of our products and we are aware that new products are being developed;
- our ability to provide acceptable evidence of safety and efficacy and our ability to secure the support of key clinicians and physicians for our products;
- relative convenience and ease of administration. In the case of Aridol and Bronchitol, there is a risk that using dry powder inhalation technology may not be well accepted in the market place;

## 2.4 Risk Factors (continued)

- cost-effectiveness compared to existing and new treatments;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-parties;
- prevalence and severity of adverse side effects; and
- other advantages over other treatment methods.

**If we are unable to obtain acceptable prices or adequate reimbursement from third-parties for Aridol and Bronchitol, or any other product candidates that we may seek to commercialize, our revenues and prospects for profitability will suffer.**

The commercial success of our product candidates is substantially dependent on whether third-party coverage and reimbursement is available from government bodies such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-parties.

Many patients will not be capable of paying for our products themselves and will rely on third-parties to pay for their medical needs. The U.S. Centers for Medicare and Medicaid Services, health maintenance organizations and other third-parties in the U.S., the E.U., Australia and other jurisdictions are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new products and, as a result, they may not cover or provide adequate payment for our products. Our products may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis.

Large private managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-parties, including Medicare, are challenging the prices charged for medical products and services, and many third-parties limit or delay reimbursement for newly approved health care products. In particular, third-parties may limit the reimbursed indications. Cost-control initiatives could decrease the price we establish for products, which could result in product revenues lower than anticipated. If the prices for our product candidates decrease or if governmental and other third-parties do not provide adequate coverage and reimbursement levels, our prospects for revenue and for profitability will suffer.

**If there are fewer individuals in our target markets than we estimate, we may not generate sufficient revenues to continue development of our other product candidates or to continue operations.**

It is difficult to determine the portion of the patient population that might use Aridol and/or Bronchitol, or our other product candidates. Our estimate of the patient population of our target markets is based on published studies as well as internal analyses and studies we have commissioned. If the results of these studies or our analysis do not accurately reflect the number of patients in our target markets, our assessment of the market may be wrong, making it difficult or impossible for us to meet our revenue goals.

**Our orphan drug exclusivity for Bronchitol may not provide us with a competitive advantage.**

The FDA has granted Orphan Drug designation to Bronchitol for the treatment of both bronchiectasis and CF for patients at risk of developing bronchiectasis. Orphan drug designation for Bronchitol for the treatment of both bronchiectasis and cystic fibrosis for patients at risk of developing bronchiectasis is an important element of our competitive strategy. Any company that obtains the first FDA approval for a designated orphan drug for a rare disease generally receives marketing exclusivity for use of that drug for the designated condition for a period of seven years from approval. However, the FDA may permit other companies to market a form of mannitol, the active ingredient in Bronchitol, not covered by our patent, to treat bronchiectasis and cystic fibrosis for patients at risk of developing bronchiectasis if any such product demonstrates clinical superiority, or if we are unable to provide sufficient drug supply to meet medical needs. More than one product may also be approved by the FDA for the same orphan indication or disease as long as the products are different drugs. Any of these FDA actions could create a more competitive market for us. Additionally, our orphan drug exclusivity for Bronchitol does not apply to other drugs to treat bronchiectasis or cystic fibrosis for patients at risk of developing bronchiectasis that do not contain mannitol, or to drugs containing mannitol that seek approval for uses other than bronchiectasis or cystic fibrosis for patients at risk of developing bronchiectasis.

The European Medicines Agency has likewise granted Orphan Drug designation for Bronchitol in the treatment of cystic fibrosis. European orphan drug designation provides comparable benefits to those granted in the U.S. but likewise, there are risks and limitations associated with orphan drug designation in Europe. Our orphan drug exclusivity may thus not ultimately provide us a true competitive advantage, and our business could suffer as a result.

### ***Risks Relating to Regulatory Issues***

**Our products are subject to extensive regulation, which can be costly and time-consuming, and we may not obtain authorizations for the commercialization of some or all of our products.**

The clinical development, manufacturing, sales and marketing of our products are subject to extensive regulation by regulatory authorities in the U.S., the E.U., Australia and elsewhere. These regulations vary in important, meaningful ways from country to country.

We are not permitted to market a potential drug in the U.S. until we receive approval of a New Drug Application, or NDA, from the FDA. We have not yet received an NDA approval from the FDA for any of our products. Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an investigational new drug application or IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In addition, failure to comply with FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions.

The FDA has accepted an IND for Aridol and for Bronchitol. We have completed two Phase III clinical trials of Aridol to support a U.S. registration of Aridol. Clinical trials of our other product candidates, including Bronchitol and PXS25/64, will continue for several years, but may take significantly longer to complete. We have completed a Phase II and a Phase III clinical trial of Bronchitol for the treatment of bronchiectasis outside of the U.S. and are preparing for an additional Phase III clinical trial of Bronchitol for bronchiectasis in the U.S. We have also completed a Phase II clinical trial of Bronchitol for the treatment of cystic fibrosis, have an additional Phase II dose ranging clinical trial and a Phase III clinical trial in progress outside of the U.S., and are preparing for an additional Phase III clinical trial of Bronchitol for cystic fibrosis in the U.S. Our other product candidates, including PXS25/64 are currently in varying stages of the research or preclinical phase of development.

Despite the substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions, regulatory approval is never guaranteed. The FDA and other regulatory authorities in the U.S., the E.U., Australia and elsewhere, exercise substantial discretion in the drug approval process. The number, size and design of preclinical studies and clinical trials that will be required will vary depending on the product, the disease or condition for which the product is intended to be used and the regulations and guidance documents applicable to any particular product. The FDA or other regulators can delay, limit or deny approval of a product for many reasons, including, but not limited to, the fact that regulators may not approve our, or our third-party, manufacturing processes or facilities or that new laws may be enacted or regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a product.

**Even if our product candidates receive regulatory authorization, we may still face development and regulatory difficulties that may delay or impair future sales of our products and we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our product candidates.**

Following regulatory authorization to sell our products, relevant regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses, manufacturing, labeling, packaging, storage, advertising, promotion and record keeping or impose ongoing requirements for post-approval studies and adverse event reporting. In addition,

## 2.4 Risk Factors (continued)

regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. If we discover previously unknown problems with a product or our manufacturing facilities or the manufacturing facilities of a contract manufacturer, a regulatory agency may impose restrictions on that product, on us or on our third-party contract manufacturers, including requiring us to withdraw the product from the market.

If we fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend our regulatory authorization;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities or terminating licenses to manufacture Good Manufacturing Practice grade material; or
- seize or detain products or require a product recall.

Any of the foregoing could seriously harm the commercialization of our products and our results and operations may be seriously harmed.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action. If we are not able to maintain regulatory compliance, we might not be permitted to market our products and our business could suffer.

### ***Risks Relating to Product Liability Claims***

If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and damage to our reputation and may be required to limit commercialization of Aridol and Bronchitol or other product candidates.

We face product liability exposure related to the testing of our product candidates in human clinical trials, with respect to commercial sale of Aridol and with respect to the supply of product on a named patient or other compassionate basis. Our potential exposure to product liability claims is likely to increase significantly as we increase commercial sales of Aridol and future products.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products and product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenues; and
- the inability to commercialize our products and product candidates.

With respect to our clinical trials, we enter into indemnity agreements in favor of the hospitals, institutions, authorities, clinicians and investigators who are involved in the clinical trials on our behalf. The majority of the indemnities are in a substantially similar form and where possible are based on industry standard indemnities in the countries in which we undertake clinical trials. Certain of the agreements have been negotiated on a case by case basis and vary from the standard. The standard indemnities typically provide that we will indemnify in respect of all claims and proceedings



made by any of the patients or non-patient volunteers participating in the relevant clinical trials for personal injury arising from the administration of the product under investigation or any clinical intervention or procedure required as a result of the administration of the product. We maintain liability insurance that covers our clinical trials in countries where we conduct clinical trials.

Our liability insurance cover also covers the commercial sale of Aridol and will expand insurance coverage in the future for any product candidates which are granted regulatory marketing authorization. Having regard to the good safety profile of Aridol and Bronchitol, the varied use of mannitol in humans, the number of clinical trials undertaken to date without a material claim being made against us, we consider that our liability insurance is reasonable for our current activities. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that we consider reasonable or that will be adequate to satisfy any liability that may arise and the claim for damages could be substantial. If we are not able to obtain adequate coverage at a reasonable cost, the commercialization of our products may be delayed or severely compromised.

If there is a claim made against us or some other problem that is attributable to our products or product candidates, our ordinary share and ADS prices may be negatively affected. Even if we were ultimately successful in product liability litigation, the litigation would consume substantial amounts of our financial and managerial resources and may create adverse publicity, all of which would impair our ability to generate sales of the product the subject of the litigation as well as our other potential products.

#### ***Risks Relating to Intellectual Property and License Arrangements***

Aridol and Bronchitol are based in part on intellectual property rights we license from others, and any termination of those licenses could seriously harm our business as the loss of any rights to market key products would seriously harm our operating results.

We have an exclusive worldwide license from Sydney South West Area Health Service to develop and commercialize certain intellectual property relating to the use of mannitol, the component part of both Aridol and Bronchitol, to induce sputum and promote airway clearance and also in the use as a test of airway function and susceptibility to asthma. This license agreement imposes payment and other material obligations on us. If our agreement with Sydney South West Area Health Service were terminated, then we would have no further rights to develop and commercialize Aridol and Bronchitol which would seriously harm our business.

**Third parties may own or control patents or patent applications that we may be required to license to commercialize our product candidates, that we may infringe, or that could result in litigation that would be costly and time consuming.**

Our ability to commercialize Aridol and Bronchitol and our other product candidates depends upon our ability to develop, manufacture, market and sell these products without infringing the proprietary rights of third parties. A number of pharmaceutical and biotechnology companies, universities and research institutions have or may be granted patents that cover technologies similar to the technologies owned by or licensed to us. We may choose to seek, or be required to seek, licenses under third-party patents, which would likely require the payment of license fees or royalties or both. A license may not be available to us on commercially reasonable terms, or at all. We may also be unaware of existing patents or other proprietary rights of third parties that may be infringed by Aridol and Bronchitol or our other product candidates. As patent applications can take many years to issue, there may be other currently pending applications which may later result in issued patents that are infringed by Aridol and Bronchitol or our other product candidates.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

As a result of intellectual property infringement claims, or to avoid potential claims, we might be:

## 2.4 Risk Factors (continued)

- prohibited from selling or licensing any product candidate that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- required to expend considerable amounts of money in defending the claim;
- required to pay substantial royalties or grant a cross license to our patents to another patent holder;
- required to pay substantial monetary damages; or
- required to redesign the formulation of a product so it does not infringe, which may not be possible or could require substantial funds and time.

We may also be forced to bring an infringement action if we believe that a third party is infringing our protected intellectual property. Any such litigation will be costly, time consuming and divert management's attention, and the outcome of any such litigation may not be favorable to us.

**Our intellectual property rights may not preclude competitors from developing competing products and our business may suffer.**

If we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our intellectual property to develop competing products. Our patents, including our licensed patents relating to the use and manufacture of Aridol and Bronchitol, may not be sufficient to prevent others from competing with us or using similar technologies. Most of our patents covering Aridol and Bronchitol expire in 2015. Therefore, we will not be able to depend on these patents past these relevant dates to exclude competitors from developing generic versions of Aridol and Bronchitol. Our issued patents and those that we may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the term of patent protection that we may have for our product candidates. The occurrence of any of the foregoing events could harm our competitive position and seriously harm our business.

Our trade secrets relating to our product candidates and the manufacture of our product candidates may become known or independently discovered or competitors may develop alternatives. We disclose confidential information and trade secrets from time to time provided that the recipient executes a non-disclosure agreement or otherwise owes us obligations of confidentiality. Confidentiality agreements may be breached and we may have no effective remedy for such a breach. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. Failure to obtain or maintain confidential information and trade secret protection could adversely affect our competitive business position.

**If we fail to enforce adequately or defend our intellectual property rights our business may be harmed.**

Our commercial success depends, to a large extent, on obtaining and maintaining patent and trade secret protection for our products, the methods used to manufacture those products and the methods for treating patients using those products. A key tool in protecting our products and our technologies from unauthorized use by third parties is the extent that valid and enforceable patents or trade secrets cover them. Our ability to obtain patents is uncertain and there is a risk that we may not be able to secure and maintain patents which we require to defend our intellectual property position. Patents provide only limited protections and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

Some countries in which we may sell our product candidates or license our intellectual property may fail to protect our intellectual property rights to the same extent as the protection that may be afforded in the U.S. or Australia. Some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the U.S., the E.U., Australia or elsewhere. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the U.S., the E.U. or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection.

Even if patents are issued, those patents can be challenged by our competitors who can argue such patents are invalid. Patents also will not protect our products if competitors devise ways of making these product candidates

without legally infringing our patents. The U.S. Federal Food, Drug and Cosmetic Act and FDA regulations and policies and equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, non-infringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes.

Proprietary trade secrets and unpatented know-how are also very important to our business. We rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position. To date, we are not aware of any unintentional or willful disclosure of any of our material confidential information or any unauthorized use of our confidential information and we have not been required to seek remedy for any such unauthorized disclosure or use.

### ***Risks Relating to Resources***

**If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.**

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel, manufacturing personnel, sales and marketing personnel and on our ability to develop and maintain important relationships with clinicians, scientists and leading academic and health institutions.

The loss of services of one or more of our members of key management could delay or compromise the successful completion of our clinical trials or the commercialization of Aridol and Bronchitol and our other product candidates. We enter into employment agreements with each of our employees, including each member of our key management. Each of our employees agree to a specific period of notice that they or we must give in order to terminate their employment. Employees can terminate their employment by giving between one to three months notice (as set out in the relevant employee's employment agreement).

In the near term we will need to continue to attract and retain manufacturing personnel and sales and marketing personnel and effectively integrate them into our organization to coincide with the expected growth of commercial sales of Aridol in Australia, Europe and in other jurisdictions. If we fail to attract or effectively integrate new personnel and consultants into our organization and create effective working relationships among them and other members of management, the future development and commercialization of Aridol and our other product candidates may suffer, harming future regulatory authorizations, sales of our products and our results of operations.

There is significant competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

The addition of new employees and the loss of key employees, particularly in key positions, can be disruptive and may also cause the future development and commercialization of our product candidates to suffer, harming future regulatory authorizations, sales of our products and our results of operations.

We do not currently carry 'key person' insurance on the lives of members of senior management. We consider that at this stage of our development it is reasonable not to carry any key person insurance.

**We will need to significantly increase the size of our organization, and we may experience difficulties in managing growth.**

In order to continue our clinical trials and commercialize our product candidates, manufacture commercial quantities of our products and market and sell products, we will need to increase our operations, including expanding our employee base. Our future financial performance and our ability to commercialize our products and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

## 2.4 Risk Factors (continued)

To that end, we must be able to:

- manage our preclinical studies and clinical trials effectively;
- undertake and manage the manufacturing of product effectively;
- undertake and manage sales and marketing effectively;
- integrate current and additional management, administrative, financial and sales and marketing personnel;
- develop our administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

**The acquisition or licensing of other products or product candidates may put a strain on our operations and will likely require us to seek additional financing.**

One of our strategies is to develop and license or acquire complementary products or product candidates. We have no present agreement regarding any new material product licensing or acquisitions. However, if we do undertake any such product licensing or acquisitions, the process of undertaking the licensing or acquisitions and integrating a licensed or acquired product or product candidate into our business may put a strain on our operations, including diversion of personnel and financial resources and diversion of management's attention. In addition, any acquisition would give rise to potentially significant additional operating costs which would likely require us to seek additional financing. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing shareholders and holders of our ADSs. Future acquisitions could also result in us incurring debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results.

### ***Risks Relating to Takeovers***

**Our constitution may discourage attempts by shareholders to make a proportional takeover for us and could restrict the ability for shareholders to obtain a premium from such a transaction.**

Our constitution contain a proportional takeover provision which provides that if a person makes a proportional takeover offer for less than all of the share capital in us, shareholders are entitled to vote to determine whether the proportional takeover offer may proceed. A person may wish to make a proportional takeover offer for a number of reasons, including, if they wish to increase their control of us and/or influence the composition of the Board of Directors. Arguably, the proportional takeover provisions in our constitution make it more difficult to achieve a proportional takeover and therefore may discourage proportional takeover offers and make it more difficult for a person to gain proportional control of us and could restrict the ability for shareholders to obtain a premium from such a transaction. The proportional takeover provisions in our constitution terminate and must be renewed every three years. At our annual general meeting of shareholders held on 26 October 2006, our shareholders approved the extension of the proportional takeover provision for a further three years.

**Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our shares.**

We are incorporated in Australia and are subject to the takeovers laws of Australia. Among other things, we are subject to the *Corporations Act 2001* (Commonwealth of Australia), or Corporations Act. Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares (including through the acquisition of ADSs) if the acquisition of that interest will lead to a person's or someone else's voting power in us increasing from 20% or below to more than 20%, or increasing from a starting point that is above 20% and below 90%. Exceptions to the general prohibition include circumstances where the person makes a formal takeover bid for us, if the person obtains shareholder approval for the acquisition or if the person acquires less than an additional 3% of the voting power of us in any rolling six month period. Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our shares. This may have the ancillary effect of entrenching our Board of Directors and may deprive or limit strategic opportunities of our shareholders and ADS holders to sell their shares and may restrict the ability of our shareholders and ADS holders to obtain a premium from such transactions.

## ***Risks Related to our ADSs or Ordinary Shares***

The price of our ordinary shares is highly volatile and could decline significantly.

The market price of our ordinary shares historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. These fluctuations may be due to factors specific to us, to changes in analysts' recommendations and earnings estimates, to arbitrage between our Australian quoted shares and our ADSs, to changes in exchange rates, or to factors affecting the biopharmaceutical industry or the securities markets in general. For example, from the initial quotation of our ordinary shares on the Australian Securities Exchange on 10 November 2003 until 15 August 2008, the closing price per share of our ordinary shares ranged from a low of A\$0.34 on 27 November 2003 to a high of A\$4.53 on 1 November 2007 and was A\$1.86 on 15 August 2008. We may experience a material decline in the market price of our shares, regardless of our operating performance. Therefore, a holder of our ordinary shares or ADSs may not be able to sell those ordinary shares or ADSs at or above the price paid by such holder for such shares or ADSs. Price declines in our ordinary shares or ADSs could result from a variety of factors, including many outside our control.

These factors include:

- adverse or inconclusive results or delays in our clinical trial programs;
- unforeseen safety issues or adverse side effects resulting from the clinical trials or the commercial use of any of our products;
- regulatory actions in respect of any of our products or the products of any of our competitors;
- failure or delay of any of our products obtaining regulatory authorizations in our key markets or limitations on the indications or other conditions on any regulatory authorizations given;
- failure to obtain satisfactory pricing and reimbursement approvals for Aridol, Bronchitol or other product candidates in key jurisdictions;
- failure of any of our products, such as Aridol, or any of our product candidates, such as Bronchitol (if approved), to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- market conditions, including market conditions in the pharmaceutical and biotechnology sectors;
- increases in our costs or decreases in our revenues due to unfavorable movements in foreign currency exchange rates;
- developments or litigation concerning patents, licenses and other intellectual property rights;
- litigation or public concern about the safety of our potential products;
- changes in recommendations or earnings estimates by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- rumors relating to us or our competitors;
- additions or departures of key personnel;
- changes in third-party reimbursement policies; and
- developments concerning current or future strategic alliances or acquisitions.

Class action litigation has been brought in the past against companies which have experienced volatility in the market price of their securities. We may become involved in this type of litigation in the future. Litigation of this type is often extremely expensive and diverts management's attention and Company's resources.

In addition, since the initial listing of our ADSs on Nasdaq Global Market trading volume in our ADSs has been limited and a significant portion of the ownership of our ADSs is concentrated with a small number of holders. The limited trading volume may adversely affect the prices at which the ADSs may be bought or sold. There can be no assurance that a more active trading market in our ADSs will develop in the U.S.

## 2.4 Risk Factors (continued)

Rights as a holder of ordinary shares are governed by Australian law and our Constitution. Holders of our ordinary shares or ADSs may have difficulty in effecting service of process in the U.S. or enforcing judgments obtained in the U.S.

We are a public company incorporated under the laws of Australia. Therefore, the rights of holders of our ordinary shares are governed by Australian law and our Constitution. These rights differ from the typical rights of shareholders in U.S. corporations. The rights of holders of ADSs are affected by Australian law and our Constitution but are governed by U.S. law. Circumstances that under U.S. law may entitle a shareholder in a U.S. company to claim damages may also give rise to a cause of action under Australian law entitling a shareholder in an Australian company to claim damages. However, this will not always be the case.

Holders of our ordinary shares or ADSs may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the U.S., liabilities under U.S. securities laws. In particular, if such a holder sought to bring proceedings in Australia based on U.S. securities laws, the Australian court might consider:

- that it did not have jurisdiction; and/or
- that it was not an appropriate forum for such proceedings; and/or
- that, applying Australian conflict of laws rule, U.S. law (including U.S. securities laws) did not apply to the relationship between holders of our ordinary shares or ADSs and us or our Directors and officers; and/or
- that the U.S. securities laws were of a public or penal nature and should not be enforced by the Australian court.

All but one of our Directors and executive officers are residents of countries other than the U.S. Furthermore, all or a substantial portion of their assets and our assets are located outside the U.S. As a result, it may be very difficult or may not be possible for a holder of our ordinary shares or ADSs to:

- effect service of process within the U.S. upon any of our Directors and executive officers or on us;
- enforce in U.S. courts judgments obtained against any of our Directors and executive officers or us in the U.S. courts in any action, including actions under the civil liability provisions of U.S. securities laws;
- enforce in U.S. courts judgments obtained against any of our Directors and senior management or us in courts of jurisdictions outside the United States in any action, including actions under the civil liability provisions of U.S. securities laws; or
- bring an original action in an Australian court to enforce liabilities against any of our Directors and executive officers or us based upon U.S. securities laws.

Holders of our ordinary shares and ADSs may also have difficulties enforcing in courts outside the U.S. judgments obtained in the U.S. courts against any of our Directors and executive officers or us, including actions under the civil liability provisions of the U.S. securities laws.

**Shares or ADSs eligible for public sale could adversely affect the price of our ordinary shares.**

The market price for our shares or ADSs could decline as a result of sales by our existing shareholders or management of ordinary shares or the perceptions that these sales could occur. These sales may also make it difficult for us to sell equity securities in the future at a time and at a price when we deem appropriate.

**Currency fluctuations may adversely affect the price of our ADSs relative to the price of our ordinary shares.**

The price of our ordinary shares is quoted in Australian dollars and the price of our ADSs is quoted in U.S. dollars. Movements in the Australian dollar/U.S. dollar exchange rate may adversely affect the U.S. dollar price of our ADSs and the U.S. dollar equivalent of the price of our ordinary shares. The exchange rates between the Australian dollar and the U.S. dollar have fluctuated. If the value of the Australian dollar appreciates against the U.S. dollar, this may positively affect the U.S. dollar price of our ADSs and the U.S. dollar equivalent of the price of our ordinary shares, even if the price of our ordinary shares in Australian dollars decreases or remains unchanged. However, if the Australian dollar weakens against the U.S. dollar, the U.S. dollar price of the ADSs could decline, even if the price of our ordinary shares in Australian dollars increases or remains unchanged. If dividends are payable, we will likely calculate and pay any cash dividends in Australian dollars and, as a result, exchange rate movements will affect the U.S. dollar amount of any dividends holders of our ADSs will receive from the depositary.

We may become a passive foreign investment company, or a PFIC, for U.S. federal income tax purposes, which could result in negative tax consequences to the holders of our ordinary shares or ADSs.

Based on an analysis of our assets and gross income, we believe that we may be a PFIC for our current tax year, that we have been a PFIC for our tax years ended 30 June 2008, 30 June 2006, 30 June 2005 and 30 June 2004 but that we have not been a PFIC for our tax year ended June 30 2007. We have not conducted a PFIC analysis for any tax year prior to our tax year ended June 30, 2004. The determination of whether we are, or at any time in the past have been, a PFIC is made annually on a taxable year basis and depends on factors such as the composition of our income and the value of our assets. If we are classified as a PFIC in any taxable year that a 'U.S. Holder' (as defined in the section entitled 'Taxation') owns our ordinary shares or ADSs, we generally will continue to be treated as a PFIC for that U.S. Holder in all succeeding years. Such U.S. Holder would be subject to additional taxes on any 'excess distributions' received from us and any gain realized from the sale or other disposition of our ordinary shares or ADSs. We urge U.S. investors to consult their own tax advisors about the application of the PFIC rules and certain elections that may help to minimize adverse U.S. federal income tax consequences in their particular circumstances. For a further discussion of the U.S. federal income tax consequences of investing in a PFIC, see the discussion under the Section 4.2.7 of this Statutory Annual Report.

**We have never paid a dividend and we do not intend to pay dividends in the foreseeable future which means that holders of shares and ADSs may not receive any return on their investment from dividends.**

To date, we have not declared or paid any cash dividends on our ordinary shares and currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. Dividends may only be paid out of our profits. Payment of cash dividends, if any, in the future will be at the discretion of our Board of Directors or, if our Directors do not exercise their power to issue dividends, our shareholders in a general meeting may. Our holders of shares and ADSs may not receive any return on their investment from dividends.

**Our ADR holders are not shareholders and do not have shareholder rights.**

The Bank of New York, as depositary, executes and delivers our American Depositary Receipts, or ADRs, on our behalf. Each ADR is a certificate evidencing a specific number of American Depositary Shares, also referred to as ADSs. Our ADR holders will not be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying our ADRs. Holders of our ADRs will have ADR holder rights. A deposit agreement among us, the depositary and our ADR holders, and the beneficial owners of ADRs, sets out ADR holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADRs.

Our ADR holders do not have the same voting rights as our shareholders. Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares. Our ADR holders may instruct the depositary to vote the ordinary shares underlying their ADRs, but only if we ask the depositary to ask for their instructions. If we do not ask the depositary to ask for the instructions, our ADR holders are not entitled to receive our notices of general meeting or instruct the depositary how to vote. Our ADR holders will not be entitled to attend and vote at a general meeting unless they withdraw the ordinary shares. However, our ADR holders may not know about the meeting enough in advance to withdraw the shares. If we ask for our ADR holders' instructions, the depositary will notify our ADR holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depositary will try, as far as practical, subject to Australian law and the provisions of the depositary agreement, to vote the shares as our ADR holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADR holders. We cannot assure our ADR holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their shares. In addition, there may be other circumstances in which our ADR holders may not be able to exercise voting rights.

## 2.4 Risk Factors (continued)

Our ADR holders do not have the same rights to receive dividends or other distributions as our shareholders. Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares will be paid to the depositary, which has agreed to pay to our ADR holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Our ADR holders will receive these distributions in proportion to the number of shares their ADSs represent. In addition, there may be certain circumstances in which the depositary may not pay to our ADR holders amounts distributed by us as a dividend or distribution.

**There are circumstances where it may be unlawful or impractical to make distributions to the holders of our ADRs.**

The deposit agreement with the depositary allows the depositary to distribute the foreign currency only to those ADR holders to whom it is possible to do so. If a distribution is payable by us in Australian dollars, the depositary will hold the foreign currency it cannot convert for the account of the ADR holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, our ADR holders may lose some of the value of the distribution.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADR holders. This means that our ADR holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us or the depositary to make them available to them.

**We are exposed to risks relating to evaluations of controls required by the Sarbanes-Oxley Act.**

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002 ('Sarbanes-Oxley Act') and related regulations implemented by the SEC, have substantially increased legal and financial compliance costs. We expect that our ongoing compliance with applicable laws and regulations, including the Sarbanes-Oxley Act, will involve potentially increasing costs. In particular, we must annually evaluate our internal controls systems to allow management to report on, and our independent auditors to attest to, our internal controls. We must perform the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and auditor attestation requirements of Sarbanes-Oxley Act. If we are not able to comply with the requirements of the Sarbanes-Oxley Act in a timely manner or adequately, we may be subject to sanctions or investigation by regulatory authorities, including the SEC. Any action of this type could adversely affect our financial results, investors' confidence in us and our ability to access capital markets, and could cause our share price and the price of our ADSs to decline.



# Section



## 3.1 Annual Financial Report

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

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

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

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

The financial report was authorised for issue by the directors on 12 August 2008. The company has the power to amend and reissue the financial report.

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

## Income Statements For the year ended 30 June 2008

	Notes	Consolidated			Parent Entity	
		2008 \$'000	2007 \$'000	2006 \$'000	2008 \$'000	2007 \$'000
<b>Revenue from continuing operations</b>						
Revenue from sale of goods	2	527	205	8	531	205
Cost of sales		(129)	(49)	(2)	(130)	(49)
<b>Gross profit</b>		<b>398</b>	156	6	<b>401</b>	156
Other revenue	2	7,402	5,278	4,282	7,398	5,278
Other income	3	1,576	2,152	1,299	1,576	2,152
Other expenses from ordinary activities	4					
Research & development expenses		(19,996)	(23,840)	(16,978)	(20,056)	(23,865)
Commercial expenses		(4,557)	(3,240)	(1,946)	(4,644)	(3,303)
Administration expenses		(5,231)	(4,666)	(4,391)	(5,231)	(4,672)
<b>Loss before income tax</b>		<b>(20,408)</b>	(24,160)	(17,728)	<b>(20,556)</b>	(24,254)
Income tax expense	5	(32)	(19)	(5)	-	-
<b>Loss for the year</b>		<b>(20,440)</b>	(24,179)	(17,733)	<b>(20,556)</b>	(24,254)
<b>Earnings per share:</b>						
		<b>Cents</b>	Cents	Cents	<b>Cents</b>	Cents
Basic earnings / (loss) per share	27	(10.8)	(13.6)	(11.1)	(10.9)	(13.7)
Diluted earnings / (loss) per share	27	(10.8)	(13.6)	(11.1)	(10.9)	(13.7)

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

## Balance Sheets As at 30 June 2008

	Notes	Consolidated		Parent Entity	
		2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
<b>ASSETS</b>					
<b>Current assets</b>					
Cash and cash equivalents	6	111,842	76,182	111,650	76,095
Trade and other receivables	7	6,651	1,026	6,617	1,020
Inventories	8	96	79	94	79
Total current assets		118,589	77,287	118,361	77,194
<b>Non current assets</b>					
Receivables	9	1,526	601	1,521	594
Other financial assets	10	39	–	39	–
Plant and equipment	11	3,668	3,521	3,611	3,504
Intangible assets	12	1,227	1,239	1,227	1,239
Total non current assets		6,460	5,361	6,398	5,337
<b>Total assets</b>		<b>125,049</b>	<b>82,648</b>	<b>124,759</b>	<b>82,531</b>
<b>LIABILITIES</b>					
<b>Current liabilities</b>					
Trade and other payables	13	5,709	5,944	5,656	5,945
Other liabilities	14	–	6	–	6
Current tax liabilities		31	24	–	–
Total current liabilities		5,740	5,974	5,656	5,951
<b>Non current liabilities</b>					
Provisions	15	188	115	188	115
Total non current liabilities		188	115	188	115
<b>Total liabilities</b>		<b>5,928</b>	<b>6,089</b>	<b>5,844</b>	<b>6,066</b>
<b>Net assets</b>		<b>119,121</b>	<b>76,559</b>	<b>118,915</b>	<b>76,465</b>
<b>EQUITY</b>					
Contributed equity	16	194,680	135,108	194,680	135,108
Reserves	17(a)	7,439	4,009	7,443	4,009
Accumulated losses	17(b)	(82,998)	(62,558)	(83,208)	(62,652)
<b>Total equity</b>		<b>119,121</b>	<b>76,559</b>	<b>118,915</b>	<b>76,465</b>

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

## Statements of Changes in Equity For the year ended 30 June 2008

	Notes	Consolidated			Parent Entity	
		2008 \$'000	2007 \$'000	2006 \$'000	2008 \$'000	2007 \$'000
<b>Total equity at the beginning of the financial year</b>		<b>76,559</b>	98,888	35,467	<b>76,465</b>	98,868
Exchange differences on translation of foreign operations	17(a)	(4)	(1)	1	-	-
<b>Net income recognised directly in equity</b>		<b>(4)</b>	(1)	1	-	-
<b>Loss for the year</b>		<b>(20,440)</b>	(24,179)	(17,733)	<b>(20,556)</b>	(24,254)
<b>Total recognised income and expense for the year</b>		<b>(20,444)</b>	(24,180)	(17,732)	<b>(20,556)</b>	(24,254)
Contributions of equity, net of transaction costs	16(a)	<b>59,572</b>	363	80,029	<b>59,572</b>	363
Employee share options	17(a)	<b>3,434</b>	1,488	1,124	<b>3,434</b>	1,488
<b>Total equity at the end of the financial year</b>		<b>119,121</b>	76,559	98,888	<b>118,915</b>	76,465

*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 2008

	Notes	Consolidated			Parent Entity	
		2008 \$'000	2007 \$'000	2006 \$'000	2008 \$'000	2007 \$'000
<b>Cash flows from operating activities</b>						
Receipts from customers (inclusive of goods and services tax)		601	191	1	617	191
Payments to suppliers and employees (inclusive of goods and services tax)		(28,299)	(28,458)	(18,960)	(28,511)	(28,559)
		(27,698)	(28,267)	(18,959)	(27,894)	(28,368)
Research grant receipts from government		1,542	2,292	902	1,542	2,292
Interest received		7,348	5,278	4,282	7,344	5,278
Income tax paid		(42)	-	-	-	-
<b>Net cash outflow from operating activities</b>	26	<b>(18,850)</b>	<b>(20,697)</b>	<b>(13,775)</b>	<b>(19,008)</b>	<b>(20,798)</b>
<b>Cash flows from investing activities</b>						
Payments for plant and equipment		(1,012)	(1,182)	(1,572)	(962)	(1,133)
Instalment payments to acquire plant and equipment		(2,396)	-	-	(2,396)	-
Payment of security deposits to acquire plant and equipment		(1,498)	-	-	(1,498)	-
Proceeds from disposal of plant and equipment		1	52	-	1	33
Payments for intangible assets		(154)	(192)	(232)	(154)	(192)
<b>Net cash outflow from investing activities</b>		<b>(5,059)</b>	<b>(1,322)</b>	<b>(1,804)</b>	<b>(5,009)</b>	<b>(1,292)</b>
<b>Cash flows from financing activities</b>						
Proceeds from issues of shares		62,093	363	87,080	62,093	363
Share issue transaction costs		(2,521)	-	(7,051)	(2,521)	-
<b>Net cash inflow from financing activities</b>		<b>59,572</b>	<b>363</b>	<b>80,029</b>	<b>59,572</b>	<b>363</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>						
		<b>35,663</b>	<b>(21,656)</b>	<b>64,450</b>	<b>35,555</b>	<b>(21,727)</b>
Cash and cash equivalents at the beginning of the financial year		76,182	97,840	33,390	76,095	97,822
Effects of exchange rate changes on cash and cash equivalents		(3)	(2)	-	-	-
<b>Cash and cash equivalents at the end of the financial year</b>	6	<b>111,842</b>	<b>76,182</b>	<b>97,840</b>	<b>111,650</b>	<b>76,095</b>

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

## Notes to the Financial Statements

### 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 subsidiaries.

#### (a) Basis of preparation

This general purpose financial report has been prepared in accordance with Australian Accounting Standards, other authoritative pronouncements of the Australian Accounting Standards Board, Urgent Issues Group Interpretations and the *Corporations Act 2001*.

##### *Compliance with IFRSs*

Australian Accounting Standards include Australian equivalents to International Financial Reporting Standards (AIFRS). The financial report also complies with International Financial Reporting Standards (IFRSs) as issued by the International Accounting Standards Board (IASB).

##### *Historical cost convention*

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

##### *Critical accounting estimates*

The preparation of financial statements 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.

##### *Comparatives*

When classification of items in the financial report is amended, comparative amounts have been reclassified to enhance comparability.

#### (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 2008 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.

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

### (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 risk and rewards passed to the customer.

#### (ii) Interest income

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

### (f) Government grants

Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received and the Company will comply with all attached conditions. When the company receives income in advance of incurring the relevant expenditure, it is treated as deferred income as the company 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 applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and unused tax losses.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the reporting date and are expected to apply when the related deferred income tax asset is realised or the deferred income tax liability is settled.

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 21). Payments made under operating leases (net of any incentives received from the lessor) are charged to the income statement on a straight line basis over the period of the lease.

## **(i) Impairment of assets**

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

## **(j) Cash and cash equivalents**

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

Bank accepted commercial bills are short-term deposits held with banks with maturities of three months or less, which are acquired at a discount to their face value. The bills are carried at cost plus a portion of the discount recognised as income on an effective yield basis. The discount brought to account each period is accounted for as interest received.

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

### (k) Trade receivables

Trade receivables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less provision for impairment. Trade receivables are due for settlement between 30 – 60 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 by reducing the carrying amount directly. An allowance account (provision for impairment of trade receivables) is used 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. Significant financial difficulties of the debtor, probability that the debtor will enter bankruptcy or financial reorganisation, and default or delinquency in payments (more than 30 days overdue) are considered indicators that the trade receivable is impaired. The amount of the impairment allowance 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 impairment loss is recognised in the income statement within administration expenses. When a trade receivable for which an impairment allowance had been recognised becomes uncollectible in a subsequent period, it is written off against the allowance account. Subsequent recoveries of amounts previously written off are credited against administration expenses in the income statement.

### (l) Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost and net realisable value. Cost comprises direct materials, direct labour and an appropriate proportion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity. Costs are assigned to individual items of inventory on 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.

### *(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 29. The fair value of options granted under the option plan is recognised as an employee benefit expense with a corresponding increase in equity. The fair value is measured at grant date and recognised over the period during which the employees become unconditionally entitled to the options.

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

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

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 recoverable from, or payable to, the taxation authority is included with other receivables or payables in the balance sheet.

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

### (t) **Rounding of amounts**

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

## (u) New accounting standards and interpretations

Certain new accounting standards and interpretations have been published that are not mandatory for the year ended 30 June 2008 reporting period. The Group's and the parent entity's assessment of the impact of these new standards and interpretations is set out below.

- (i) *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 is not expected to affect any of the amounts recognised in the financial statements.

- (ii) *Revised AASB 101 Presentation of Financial Statements and AASB 2007-8 Amendments to Australian Accounting Standards arising from AASB 101*

A revised AASB 101 was issued in September 2007 and is applicable for annual reporting periods beginning on or after 1 January 2009. It requires the presentation of a statement of comprehensive income and makes changes to the statement of changes in equity, but will not affect any of the amounts recognised in the financial statements. If an entity has made a prior period adjustment or has reclassified items in the financial statements, it will need to disclose a third balance sheet (statement of financial position), this one being as at the beginning of the comparative period. The Group intends to apply the revised standard from 1 July 2009.

- (iii) *AASB 2008-1 Amendments to Australian Accounting Standard – Share-based Payments: Vesting Conditions and Cancellations*

AASB 2008-1 was issued in February 2008 and will become applicable for annual reporting periods beginning on or after 1 January 2009. The revised standard clarifies that vesting conditions are service conditions and performance conditions only and that other features of a share-based payment are not vesting conditions. It also specifies that all cancellations, whether by the entity or by other parties, should receive the same accounting treatment. The Group will apply the revised standard from 1 July 2009, but it is not expected to affect the accounting for the Group's share-based payments.

- (iv) *Amendments to IFRS 1 and IAS 27 Cost of an Investment in a Subsidiary, Jointly Controlled Entity or Associate*

In May 2008, the IASB made amendments to IFRS 1 First-time Adoption of International Financial Reporting Standards and IAS 27 Consolidated and Separate Financial Statements. The new rules will apply to financial reporting periods commencing on or after 1 January 2009. Amendments to the corresponding Australian Accounting Standards are expected to be issued shortly. The Group will apply the revised rules from 1 July 2008. After that date, all dividends received from investments in subsidiaries, jointly controlled entities or associates will be recognised as revenue, even if they are paid out of pre-acquisition profits, but the investments may need to be tested for impairment as a result of the dividend payment. Furthermore, when a new intermediate parent entity is created in internal reorganisations it will measure its investment in subsidiaries at the carrying amounts of the net assets of the subsidiary rather than the subsidiary's fair value.

- (v) *Improvements to IFRSs*

In May 2008, the IASB issued a number of improvements to existing International Financial Reporting Standards. The amendments will generally apply to financial reporting periods commencing on or after 1 January 2009, except for some changes to IFRS 5 Non-current Assets Held for Sale and Discontinued Operations regarding the sale of the controlling interest in a subsidiary which will apply from 1 July 2009. We expect the AASB to make the same changes to Australian Accounting Standards shortly. The Group does not expect that any adjustments will be necessary as the result of applying the revised rules.

## 2. Revenue

	Consolidated			Parent Entity	
	2008 \$'000	2007 \$'000	2006 \$'000	2008 \$'000	2007 \$'000
Sales revenue					
Sale of goods	<b>527</b>	205	8	<b>531</b>	205
Other revenue					
Interest	<b>7,402</b>	5,278	4,282	<b>7,398</b>	5,278

## 3. Other income

	Consolidated			Parent Entity	
	2008 \$'000	2007 \$'000	2006 \$'000	2008 \$'000	2007 \$'000
Government grants	<b>1,358</b>	2,152	1,299	<b>1,358</b>	2,152
Other	<b>218</b>	–	–	<b>218</b>	–
	<b>1,576</b>	2,152	1,299	<b>1,576</b>	2,152

Government grants comprised the following:

- (i) R&D START program grants of \$5,584 (2007: \$47,862, 2006: \$444,313).
- (ii) Australian Government's Pharmaceuticals Partnerships Program ('P3') grants of \$1,263,018 (2007: \$1,954,592, 2006: \$848,476).
- (iii) Export Market Development grants of \$89,533 (2007: \$150,000, 2006: \$6,135 NSW DSRD).

Refer to Note 20 for information on the nature and extent of grants recognised and associated conditions.

## 4. Expenses

	Consolidated			Parent Entity	
	2008 \$'000	2007 \$'000	2006 \$'000	2008 \$'000	2007 \$'000
Loss before income tax includes the following specific expenses:					
Depreciation (note 11)					
Plant and equipment	610	631	592	608	629
Computer equipment	149	109	77	141	108
Leasehold improvements	99	51	26	99	51
Total depreciation	858	791	695	848	788
Impairment of plant & equipment	–	–	109	–	–
Amortisation (note 12)					
Patents	95	92	91	95	92
Trademarks	3	3	–	3	3
Software	68	53	6	68	53
Total amortisation	166	148	97	166	148
Impairment of intangible assets	–	–	46	–	–
Net loss on disposal of plant and equipment	6	24	40	6	14
Rental expense relating to operating leases	638	459	371	537	426
Net foreign exchange losses	96	47	5	98	49
Employee benefits expense					
Defined contribution superannuation	594	454	337	534	423
Other employee benefits expenses	12,592	9,007	5,498	11,304	8,400

## 5. Income tax expense

	Consolidated			Parent Entity	
	2008 \$'000	2007 \$'000	2006 \$'000	2008 \$'000	2007 \$'000
<b>(a) Numerical reconciliation of income tax expense to prima facie tax payable</b>					
Loss before income tax expense	<b>(20,408)</b>	(24,160)	(17,728)	<b>(20,556)</b>	(24,254)
Tax at the Australian tax rate of 30% (2007 30%)	<b>(6,122)</b>	(7,248)	(5,320)	<b>(6,167)</b>	(7,276)
Tax effect of amounts which are not deductible (taxable) in calculating taxable income:					
Share-based payments	<b>1,030</b>	446	337	<b>1,030</b>	446
Government research tax incentives	<b>(988)</b>	(1,900)	(1,556)	<b>(988)</b>	(1,900)
Sundry items	<b>6</b>	8	(9)	<b>6</b>	8
	<b>(6,074)</b>	(8,694)	(6,548)	<b>(6,119)</b>	(8,722)
Over/(under) provision in prior years	<b>18</b>	(251)	(370)	<b>18</b>	(251)
Difference in overseas tax rates	<b>(15)</b>	(9)	-	<b>-</b>	-
Total	<b>(6,071)</b>	(8,954)	(6,918)	<b>(6,101)</b>	(8,973)
Deferred tax benefits not recognised	<b>6,103</b>	8,973	6,923	<b>6,101</b>	8,973
Income tax expense	<b>32</b>	19	5	<b>-</b>	-
This represents current income tax expense.					
<b>(b) Deferred tax balances</b>					
Deferred tax asset comprises temporary differences attributable to the following:					
Interest and Grant receivables	<b>(363)</b>	(231)	-	<b>(363)</b>	(231)
Employee benefits	<b>303</b>	156	105	<b>260</b>	150
Share capital raising costs	<b>1,580</b>	1,637	2,313	<b>1,580</b>	1,637
Other	<b>17</b>	2	16	<b>17</b>	2
	<b>1,537</b>	1,564	2,434	<b>1,494</b>	1,558
Deferred tax assets attributable to temporary differences which are not recognised	<b>(1,537)</b>	(1,564)	(2,434)	<b>(1,494)</b>	(1,558)
	<b>-</b>	-	-	<b>-</b>	-
<b>(c) Tax losses</b>					
Unused tax losses for which no deferred tax asset has been recognised	<b>102,290</b>	79,219	47,880	<b>102,290</b>	79,219
Potential tax benefit @ 30%	<b>30,687</b>	23,766	14,364	<b>30,687</b>	23,766

All unused tax losses were incurred by the parent entity.



**6. Current assets – Cash and cash equivalents**

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Cash at bank and in hand	569	693	377	606
Deposits at call	1,533	1,994	1,533	1,994
Bank accepted commercial bills	109,740	73,495	109,740	73,495
	<b>111,842</b>	<b>76,182</b>	<b>111,650</b>	<b>76,095</b>

**(a) Interest rate risk exposure**

The Group's and the parent entity's exposure to interest rate risk is discussed in note 28. The maximum exposure to credit risk at the reporting date is the carrying amount of each class of cash and cash equivalents above.

**7. Current assets – Trade and other receivables**

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Trade receivables	222	34	210	34
Provision for impairment of receivables	–	–	–	–
	<b>222</b>	<b>34</b>	<b>210</b>	<b>34</b>
Government research grants receivable	350	407	350	407
Prepayments (note (b))	4,241	386	4,241	386
Other receivables (note (c))	1,544	–	1,544	–
Interest receivable	54	–	54	–
Tax related receivables	240	199	218	193
	<b>6,651</b>	<b>1,026</b>	<b>6,617</b>	<b>1,020</b>

**(a) Past due but not impaired**

As of 30 June 2008, trade receivables of \$144,244 (2007: \$17,904) were past due but not impaired. These relate to a number of independent customers for whom there is no recent history of default. The aging analysis of these trade receivables is as follows:

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Up to 1 month	24	10	24	10
1 to 2 months	97	–	97	–
Over 2 months	23	8	22	8
	<b>144</b>	<b>18</b>	<b>143</b>	<b>18</b>

The other classes within trade and other receivables do not contain impaired assets and are not past due. Based on the credit history of these other classes, it is expected that these amounts will be received when due. The group does not hold any collateral in relation to these receivables.

## 7. Current assets – Trade and other receivables (continued)

### (b) Prepayments

Prepayments primarily relate to advance payments for capital items.

### (c) Other receivables

Other receivables primarily represent cash held at bank to cover a letter of credit facility for the acquisition of plant and equipment.

### (d) Foreign exchange and interest rate risk

Information about the Group's and the parent entity's exposure to foreign currency risk and interest rate risk in relation to trade and other receivables is provided in note 28.

### (e) Fair value and credit risk

Due to the short-term nature of these receivables, their carrying amount is assumed to approximate their fair value. The maximum exposure to credit risk at the reporting date is the carrying amount of each class of receivables mentioned above. Refer to note 28 for more information on the risk management policy of the Group and the credit quality of the entity's trade receivables.

## 8. Current assets – Inventories

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Raw materials at cost	48	61	48	61
Work-in-progress at cost	10	15	10	15
Finished goods at cost	38	3	36	3
	<b>96</b>	<b>79</b>	<b>94</b>	<b>79</b>

## 9. Non-current assets – Receivables

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Other receivables (note (a))	1,377	385	1,372	378
Prepayments	149	216	149	216
	<b>1,526</b>	<b>601</b>	<b>1,521</b>	<b>594</b>

### (a) Other receivables

Other receivables primarily represent cash held at bank to cover bank guarantee facilities related to operating leases, corporate credit card and local payment clearing house facilities.

### (b) Fair value

The carrying amount of the non-current receivables approximates their fair value.

### (c) Risk exposure

Information about the Group's and the parent entity's exposure to credit risk, foreign exchange and interest rate risk is provided in note 28.

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

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Shares in subsidiaries (note 23)	-	-	-	-
Other	39	-	39	-
	<b>39</b>	<b>-</b>	<b>39</b>	<b>-</b>

The amount of the shares held in subsidiaries is \$13 which has been rounded to \$Nil for the purposes of disclosure. This is stated at cost.

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

Consolidated	Plant and equipment \$'000	Computer equipment \$'000	Leasehold improvements \$'000	Total \$'000
<b>At 1 July 2006</b>				
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
<b>Year ended 30 June 2007</b>				
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
<b>At 30 June 2007</b>				
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
<b>Year ended 30 June 2008</b>				
Opening net book amount	2,952	401	168	3,521
Additions	172	170	670	1,012
Disposals	-	(7)	-	(7)
Depreciation charge	(610)	(149)	(99)	(858)
Closing net book amount	2,514	415	739	3,668
<b>At 30 June 2008</b>				
Cost	5,395	768	1,024	7,187
Accumulated depreciation and impairment	(2,881)	(353)	(285)	(3,519)
Net book amount	2,514	415	739	3,668

## 11. Non-current assets – Plant and equipment (continued)

### (a) Assets in the course of construction

The carrying amount of the assets disclosed above include the following expenditure recognised in relation to plant and equipment which is in the course of construction:

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Leasehold improvements	632	–	632	–

## 12. Non-current assets – Intangible assets

Consolidated and parent	Patents \$'000	Trademarks \$'000	Software \$'000	Total \$'000
<b>At 1 July 2006</b>				
Cost	1,574	59	144	1,777
Accumulated amortisation and impairment	(576)	–	(6)	(582)
Net book amount	998	59	138	1,195
<b>Year ended 30 June 2007</b>				
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
<b>At 30 June 2007</b>				
Cost	1,608	65	296	1,969
Accumulated amortisation and impairment	(668)	(3)	(59)	(730)
Net book amount	940	62	237	1,239
<b>Year ended 30 June 2008</b>				
Opening net book amount	940	62	237	1,239
Additions	16	35	103	154
Amortisation charge	(95)	(3)	(68)	(166)
Closing net book amount	861	94	272	1,227
<b>At 30 June 2008</b>				
Cost	1,624	100	399	2,123
Accumulated amortisation and impairment	(763)	(6)	(127)	(896)
Net book amount	861	94	272	1,227

## 13. Current liabilities – Trade and other payables

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Trade payables	516	2,654	488	2,625
Other payables (note (a))	5,193	3,290	4,918	3,113
Trade payables to subsidiaries	–	–	250	207
	<b>5,709</b>	<b>5,944</b>	<b>5,656</b>	<b>5,945</b>

### (a) Other payables

Other payables include accruals for annual leave. The entire obligation is presented as current, since the Group does not have an unconditional right to defer settlement.

### (b) Risk exposure

Information about the Group's and the parent entity's exposure to foreign exchange risk is provided in note 28.

## 14. Current liabilities – Other liabilities

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Deferred government research grants	–	6	–	6

## 15. Non-current liabilities – Provisions

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Employee benefits long service leave	188	115	188	115

## 16. Contributed equity

	Notes	Parent Entity		Parent Entity	
		2008 Shares	2007 Shares	2008 \$'000	2007 \$'000
(a) Share capital					
Ordinary shares	(b),(c)				
Fully paid		194,514,762	177,949,217	194,680	135,108

## 16. Contributed equity (continued)

### Movements in ordinary share capital:

Date	Details	Number of shares	Issue price	\$'000
1 July 2006	Opening 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
1 July 2007	Opening balance	177,949,217		135,108
19 July 2007	Exercise of employee options	72,000	\$0.3125	22
19 July 2007	Exercise of employee options	5,000	\$1.7900	9
19 July 2007	Exercise of employee options	2,500	\$1.9170	5
28 September 2007	Exercise of employee options	3,750	\$1.7900	7
16 October 2007	Share Placement	12,820,513	\$3.9000	50,000
1 November 2007	Exercise of employee options	10,000	\$2.1940	22
1 November 2007	Exercise of employee options	2,500	\$1.9170	5
9 November 2007	Exercise of employee options	400,000	\$0.3125	125
9 November 2007	Exercise of employee options	160,000	\$0.3125	50
16 November 2007	Share Purchase Plan	2,999,074	\$3.9000	11,695
20 November 2007	Exercise of employee options	1,876	\$1.7900	3
20 November 2007	Exercise of employee options	875	\$1.9170	2
20 November 2007	Exercise of employee options	2,250	\$2.0340	4
20 December 2007	Exercise of employee options	10,000	\$1.7900	18
20 December 2007	Exercise of employee options	48,957	\$1.9170	94

## Movements in ordinary share capital:

Date	Details	Number of shares	Issue price	\$'000
8 February 2008	Exercise of employee options	15,000	\$1.1470	17
8 February 2008	Exercise of employee options	3,750	\$1.7900	7
8 February 2008	Exercise of employee options	1,250	\$1.9170	2
29 February 2008	Exercise of employee options	1,250	\$1.8918	2
4 March 2008	Exercise of employee options	5,000	\$0.8340	4
	Less: Transaction costs on share issues			(2,521)
		194,514,762		194,680

### (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 29.

### (d) Capital risk management

The Group's and the parent entity's objectives when managing capital are to safeguard their ability to continue as a going concern and to maintain an optimal capital structure to reduce the cost of capital.

The Group uses only equity to finance its projects. In order to maintain or adjust the capital structure, the Group may issue new shares.

## 17. Reserves and accumulated losses

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
<b>(a) Reserves</b>				
Share based payments reserve	7,443	4,009	7,443	4,009
Foreign currency translation reserve	(4)	-	-	-
	<b>7,439</b>	<b>4,009</b>	<b>7,443</b>	<b>4,009</b>
<i>Share based payments reserve</i>				
Balance 1 July	4,009	2,521	4,009	2,521
Option expense	3,434	1,488	3,434	1,488
Balance 30 June	<b>7,443</b>	<b>4,009</b>	<b>7,443</b>	<b>4,009</b>
<i>Foreign currency translation reserve</i>				
Balance 1 July	-	1	-	-
Currency translation differences arising during the year	(4)	(1)	-	-
Balance 30 June	<b>(4)</b>	<b>-</b>	<b>-</b>	<b>-</b>

## 17. Reserves and accumulated losses (continued)

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
<b>(b) Accumulated losses</b>				
Movements in accumulated losses were as follows:				
Balance 1 July	(62,558)	(38,379)	(62,652)	(38,398)
Net loss for the year	(20,440)	(24,179)	(20,556)	(24,254)
Balance 30 June	(82,998)	(62,558)	(83,208)	(62,652)

### (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 entities are taken to the foreign currency translation reserve, as described in note 1(d).

## 18. Key management personnel disclosures

### (a) Key management personnel compensation

	Consolidated		Parent Entity	
	2008 \$	2007 \$	2008 \$	2007 \$
Short term employee benefits	2,235,880	1,998,784	2,235,880	1,998,784
Post-employment benefits	156,613	143,680	156,613	143,680
Long-term benefits	70,445	30,311	70,445	30,311
Share based payments	1,997,655	1,032,982	1,997,655	1,032,982
	<b>4,460,593</b>	<b>3,205,757</b>	<b>4,460,593</b>	<b>3,205,757</b>

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.

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

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

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

(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.



# Section 3

2008						
Name	Balance at the start of the year	Granted during the year as compensation	Exercised during the year	Other changes during the year	Balance at the end of the year	Vested and exercisable at the end of the year
<b>Directors of Pharmaxis Ltd</b>						
DM Hanley	1,120,000	–	–	–	1,120,000	1,110,000
AD Robertson	2,380,000	300,000	–	–	2,680,000	2,342,500
CPH Kiefel <sup>(i)</sup>	68,957	–	(58,957)	(10,000)	–	–
MJ McComas	240,000	–	–	–	240,000	235,000
PC Farrell	220,000	–	–	–	220,000	120,000
J Villiger	–	200,000	–	–	200,000	100,000
<b>Other key management personnel of the Group</b>						
JF Crapper	560,000	250,000	–	–	810,000	547,500
IA McDonald	320,000	250,000	–	–	570,000	290,000
B Charlton	1,060,000	250,000	(400,000)	–	910,000	643,750
DM McGarvey	1,160,000	250,000	–	–	1,410,000	1,147,500
GJ Phillips	705,000	250,000	–	–	955,000	691,250

<sup>(i)</sup> CPH Kiefel resigned as a Director on 19th December 2007.

2007						
Name	Balance at the start of the year	Granted during the year as compensation	Exercised during the year	Other changes during the year	Balance at the end of the year	Vested and exercisable at the end of the year
<b>Directors of Pharmaxis Ltd</b>						
DM Hanley	1,080,000	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	–	–	–	–	–	–
<b>Other key management personnel of the Group</b>						
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

### (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).

## 18. Key management personnel disclosures (continued)

2008				
Name	Balance at the start of the year	Received during the year on the exercise of options	Other changes during the year	Balance at the end of the year
<b>Directors of Pharmaxis Ltd</b>				
<b>Ordinary shares</b>				
DM Hanley	784,661	–	5,126	789,787
AD Robertson	100,000	–	–	100,000
CPH Kiefel	200,000	58,957	(258,957)	–
MJ McComas	139,999	–	–	139,999
P Farrell	101,645	–	–	101,645
J Villiger	–	–	–	–
<b>Other key management personnel of the Group</b>				
<b>Ordinary shares</b>				
JF Crapper	2,000	–	–	2,000
IA McDonald	–	–	–	–
B Charlton	20,000	400,000	–	420,000
DM McGarvey	45,000	–	–	45,000
GJ Phillips	6,664	–	–	6,664
2007				
Name	Balance at the start of the year	Received during the year on the exercise of options	Other changes during the year	Balance at the end of the year
<b>Directors of Pharmaxis Ltd</b>				
<b>Ordinary shares</b>				
DM Hanley	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
P Farrell	101,645	–	–	101,645
J Villiger	–	–	–	–
<b>Other key management personnel of the Group</b>				
<b>Ordinary shares</b>				
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

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

There were no other transactions with key management personnel during the year ended 30 June 2008.

**19. Remuneration of auditors**

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

	Consolidated		Parent Entity	
	2008	2007	2008	2007
	\$	\$	\$	\$
<b>(a) Audit services</b>				
PricewaterhouseCoopers Australian firm				
Audit and review of financial reports	<b>313,420</b>	262,765	<b>313,420</b>	262,765
Non-PricewaterhouseCoopers audit firm for the audit of the financial report of Pharmaxis Pharmaceuticals Limited	<b>16,841</b>	20,104	-	-
Total remuneration for audit services	<b>330,261</b>	282,869	<b>313,420</b>	262,765
<b>(b) Audit-related services</b>				
PricewaterhouseCoopers Australian firm				
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
Sarbanes Oxley readiness and related reviews	-	61,592	-	61,592
Related practices of PricewaterhouseCoopers Australian firm				
Review of Shelf F-3 document	-	61,542	-	61,542
Total remuneration for audit-related services	-	145,309	-	145,309
<b>(c) Other services</b>				
Review of government research grant claims	<b>5,800</b>	6,500	<b>5,800</b>	6,500
IT Infrastructure review	<b>15,372</b>	-	<b>15,372</b>	-
Total remuneration for other services	<b>21,172</b>	6,500	<b>21,172</b>	6,500
<b>(d) Tax services</b>				
PricewaterhouseCoopers Australian firm				
International tax consulting and tax advice	<b>11,780</b>	9,986	<b>11,780</b>	9,986
Tax compliance services	<b>12,000</b>	12,000	<b>12,000</b>	12,000
Total remuneration for tax services	<b>23,780</b>	21,986	<b>23,780</b>	21,986

## 20. Contingent liabilities

The parent entity and Group had contingent liabilities at 30 June 2008 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 2008 was \$4,707,817 (2007: \$4,707,817).

The company received \$1,263,018 (2007: \$1,954,592) under the Australian Government's Pharmaceuticals Partnerships Program ('P3') during the financial year. The Government may require the company to repay all or some of the amount of the grant together with interest in any of the following circumstances:

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

### *Guarantees*

The company's bankers have issued bank guarantees of \$1,115,203 in relation to rental bond deposits for which no provision has been made in the accounts. These bank guarantees are secured by security deposits 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.

The company's bankers have issued a bank guarantee of USD100,000 in relation to corporate credit card and local payment clearing house facilities provided by an overseas affiliate of the banker to Pharmaxis, Inc. This bank guarantee is secured by a deposit held at the bank.

## 21. Commitments

### (a) Capital Commitments

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

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
<i>Building Fit-out</i>				
Payable: Within one year	7,188	–	7,188	–
<i>Plant and equipment</i>				
Payable: Within one year	2,126	85	2,126	85
<b>(b) Lease Commitments</b>				
<i>Commitments in relation to leases contracted for at the reporting date but not recognised as liabilities, payable:</i>				
Within one year	464	401	444	401
Later than one year but not later than five years	728	1,071	728	1,071
	<b>1,192</b>	<b>1,472</b>	<b>1,172</b>	<b>1,472</b>

(i) *Operating leases*

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

(ii) *Other commitments*

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

(iii) *New Facility*

The company has entered into an agreement concerning the lease of a custom designed manufacturing, warehousing, research and office facility of approximately 75,000 square feet. The facility is being constructed to our specifications. Once the building is completed to specification according to the terms of the agreement, the lease commences. It will have a term of 15 years, with two options to renew of a further five years each and the option to break the lease at ten years but with financial penalties attached. The initial minimum annual rental under the agreement is \$1.46 million, increasing each year for the term of the agreement by 3.25%. This minimum rental may increase as the result of variations to the building specifications required by us during its construction, or decrease as a result of the incentive owing to us under the agreement. The incentive may be used for building variations, building fitout or rent reduction.

## 22. 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 23.

**(c) Key management personnel**

Disclosures relating to key management personnel are set out in note 18.

**(d) Transactions with related parties**

The following transactions occurred with related parties:

	Consolidated		Parent Entity	
	2008	2007	2008	2007
	\$	\$	\$	\$
Marketing, clinical and administration services expenditure paid to subsidiaries	-	-	2,592,796	1,157,829

**(e) Outstanding balances arising from transactions**

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

*Current payables*

Subsidiaries	-	-	250,006	206,622
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**(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.

## 23. Subsidiaries

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

Name of entity	Country of incorporation	Class of shares	Equity holding	
			2008 %	2007 %
Pharmaxis Pharmaceuticals Limited	United Kingdom	Ordinary	100	100
Pharmaxis, Inc.	United States	Ordinary	100	–

Pharmaxis, Inc. was incorporated on 6th November 2007. Its results have been consolidated from this date.

## 24. Events occurring after the balance sheet date

No matter or circumstance has arisen since 30 June 2008 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.

## 25. 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 in a number of geographical areas. The operations in overseas jurisdictions are in the early days of establishment and currently do not have a material impact on the overall group operations.

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

	Consolidated			Parent Entity	
	2008 \$'000	2007 \$'000	2006 \$'000	2008 \$'000	2007 \$'000
Loss for the year	(20,440)	(24,179)	(17,733)	(20,556)	(24,254)
Depreciation and impairment of plant & equipment	858	791	804	848	788
Amortisation and impairment of intangibles	166	148	143	166	148
Non cash employee benefits expense share based payments	3,434	1,488	1,124	3,434	1,488
Net loss on disposal of non current assets	6	24	40	6	14
Change in operating assets and liabilities					
Increase in trade receivables	(188)	(27)	(7)	(176)	(27)
(Increase) / decrease in inventories	(17)	21	(100)	(15)	21
(Increase) / decrease in other operating assets	(2,508)	327	(956)	(2,493)	334
(Decrease) / increase in trade payables	(2,138)	1,841	56	(2,137)	1,812
Increase / (decrease) in other operating liabilities	1,904	(1,183)	2,817	1,842	(1,174)
Increase in other provisions	73	52	37	73	52
Net cash outflow from operating activities	(18,850)	(20,697)	(13,775)	(19,008)	(20,798)

## 27. Earnings per share

	Consolidated	
	2008 Cents	2007 Cents
<b>(a) Basic earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	(10.8)	(13.6)
<b>(b) Diluted earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	(10.8)	(13.6)
<b>(c) Weighted average number of shares used as the denominator</b>		
Weighted average number of ordinary shares used as the denominator in calculating basic and diluted earnings / (loss) per share	189,335,187	177,285,390

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

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 29.

## 28. Financial risk management

The Group's activities expose it to a variety of financial risks: market risk (including currency risk and interest rate risk), credit risk and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the financial performance of the Group.

The Group uses different methods to measure different types of risks to which it is exposed. These methods include sensitivity analysis in the case of interest rate, foreign exchange and other price risks and aging analysis for credit risk.

Risk management is carried out by the Chief Financial Officer under policies approved by the Board of Directors. The Board provides written principles of overall risk management, as well as policies covering specific areas, such as foreign exchange risk, interest rate risk, credit risk and investment of excess liquidity.

The Group and the parent entity hold the following financial instruments:

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
<b>Financial assets</b>				
Cash and cash equivalents	111,842	76,182	111,650	76,095
Trade and other receivables	6,651	1,026	6,617	1,020
Receivables	1,526	601	1,521	594
Other financial assets	39	–	39	–
	<b>120,058</b>	<b>77,809</b>	<b>119,827</b>	<b>77,709</b>
<b>Financial liabilities</b>				
Trade and other payables	5,709	5,944	5,656	5,945
Other liabilities	–	6	–	6
	<b>5,709</b>	<b>5,950</b>	<b>5,656</b>	<b>5,951</b>

## 28. Financial risk management (continued)

### (a) Market risk

#### (i) Foreign exchange risk

The Group and the parent entity operate internationally but are only exposed to minimal foreign exchange risk arising from various currency exposures.

Foreign exchange risk arises from future commercial transactions and recognised assets and liabilities denominated in a currency that is not the entity's functional currency. The risk is measured using sensitivity analysis and cash flow forecasting.

The Group's exposure to foreign currency risk at the reporting date was as follows:

	30 June 2008			30 June 2007		
	USD \$'000	GBP \$'000	EUR \$'000	USD \$'000	GBP \$'000	EUR \$'000
Cash and cash equivalents	9	9	83	71	157	16
Trade receivables	-	-	103	13	-	-
Prepayments	-	-	1,498	-	-	-
Other receivables	104	83	1,498	-	95	-
Trade payables	98	30	25	599	632	154
Other payables	288	736	1,591	501	254	134

The carrying amounts of the parent entity's financial assets and liabilities are denominated in Australian dollars except as set out below:

	30 June 2008			30 June 2007		
	USD \$'000	GBP \$'000	EUR \$'000	USD \$'000	GBP \$'000	EUR \$'000
Cash and cash equivalents	9	9	83	71	157	16
Trade receivables	-	-	103	13	-	-
Prepayments	-	-	1,498	-	-	-
Other receivables	104	83	1,498	-	95	-
Trade payables	98	30	25	599	632	154
Other payables	288	736	1,591	501	254	134
Trade payables to subsidiaries	10	240	-	-	207	-

#### Group sensitivity

Based on the financial instruments held at 30 June 2008, had the Australian dollar weakened/strengthened by 10% against the EUR with all other variables held constant, the Group's and parent entity post-tax loss for the year would have been \$142,000 higher/\$157,000 lower (2007 USD: \$96,000 higher/\$106,000 lower), mainly as a result of foreign exchange gains/losses on translation of EUR denominated financial assets/liabilities as detailed in the above table. The Group's and parent entity exposure to other foreign exchange movements is not material.

#### (ii) Cash flow and fair value interest rate risk

The Group's main interest exposure arises from bank accepted commercial bills held.



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As at the reporting date, the Group had the following cash profile:

	30 June 2008		30 June 2007	
	Weighted average interest rate %	Balance \$'000	Weighted average interest rate %	Balance \$'000
Cash and cash equivalents	6.0%	2,102	5.1%	2,687
Bank accepted commercial bills	7.7%	109,740	6.3%	73,495
Other receivables	5.3%	2,921	5.0%	385

#### Group sensitivity

The Group's and parent entity's main interest rate risk arises from cash and cash equivalents. At 30 June 2008, if interest rates had changed by +/- 80 basis points from the year-end rates with all other variables held constant, post-tax loss for the year would have been \$918,060 lower/higher (2007 – change of 60 bps: \$612,534 lower/higher), mainly as a result of higher/lower interest income from cash and cash equivalents.

#### (b) Credit risk

Credit risk is managed on a group basis. Credit risk arises from cash and cash equivalents and deposits with banks and financial institutions, as well as credit exposures to customers, including outstanding receivables and committed transactions. For banks and financial institutions, only independent rated parties with a minimum short term money market rating of 'A1+' and a long term credit rating of 'AA' are accepted. Credit risk on bank accepted bills is further managed by spreading these bills across three major Australian banks.

Customer credit risk is managed by the establishment of credit limits. The compliance with credit limits by customers is regularly monitored by management, as is the ageing analysis of receivable balances.

The maximum exposure to credit risk at the reporting date is the carrying amount of the financial assets as summarised in note 7 and note 9.

The credit quality of financial assets that are neither past due nor impaired can be assessed by reference to external credit ratings:

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
<b>Cash and cash equivalents</b>				
A1+	111,842	76,182	111,650	76,095
<b>Other receivables</b>				
AA+	290	279	290	279
AA	2,623	95	2,623	95
Not rated	8	11	3	4
	<b>2,921</b>	385	<b>2,916</b>	378

Other receivables primarily represent cash held at bank to cover a letter of credit facility for the acquisition of plant and equipment and bank guarantee facilities related to operating leases, corporate credit card and local payment clearing house facilities.

## 28. Financial risk management (continued)

### (c) Liquidity risk

Prudent liquidity risk management implies maintaining sufficient cash and cash equivalents. The Group manages liquidity risk by continuously monitoring forecast and actual cash flows and matching the maturity profiles of financial assets and liabilities. Surplus funds are generally only invested in instruments that are tradeable in highly liquid markets with short term maturity profiles.

#### *Maturities of financial liabilities*

The Group and parent entities financial liabilities are limited to non-derivative, non-interest bearing liabilities disclosed in note 13. These liabilities have less than 6 months maturity based on the remaining period at the reporting date to the contractual maturity date.

### (d) Fair value estimation

The fair value of financial assets and liabilities must be estimated for recognition and measurement or for disclosure purposes.

The carrying value less impairment provision of trade receivables and payables are assumed to approximate their fair values due to their short-term nature. The carrying value of financial liabilities are assumed to approximate their fair values due to their short-term nature.

## 29. Share-based payments

### (a) Employee Option Plan

The Pharmaxis Employee Option Plan ('EOP') was approved by shareholders in 1999 and amended by shareholders in June 2003. The maximum number of options available to be issued under the EOP is 15% of total issued shares including the EOP. All employees and directors are eligible to participate in the EOP, but do so at the invitation of the Board. The terms of option issues are determined by the Board. Options are generally granted for no consideration and vest equally over a four year period. 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 Securities 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 options.

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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 2008			Year ended 2007		
Exercise date	Fair value of shares at issue date	Number	Exercise date	Fair value of shares at issue date	Number
19 July 2007	\$3.55	72,000	19 July 2006	\$1.75	56,000
19 July 2007	\$3.55	5,000	19 July 2006	\$1.75	1,500
19 July 2007	\$3.55	2,500	4 September 2006	\$2.04	10,000
28 September 2007	\$4.05	3,750	19 October 2006	\$2.70	60,000
1 November 2007	\$4.44	10,000	19 October 2006	\$2.70	160,000
1 November 2007	\$4.44	2,500	19 October 2006	\$2.70	25,000
9 November 2007	\$4.39	400,000	6 November 2006	\$2.91	10,000
9 November 2007	\$4.39	160,000	27 November 2006	\$3.32	2,500
20 November 2007	\$4.28	1,876	27 November 2006	\$3.32	10,000
20 November 2007	\$4.28	875	27 November 2006	\$3.32	1,500
20 November 2007	\$4.28	2,250	7 December 2006	\$3.08	1,875
20 December 2007	\$4.12	10,000	7 December 2006	\$3.08	110,000
20 December 2007	\$4.12	48,957	7 December 2006	\$3.08	2,500
8 February 2008	\$3.20	15,000	7 December 2006	\$3.08	1,250
8 February 2008	\$3.20	3,750	16 January 2007	\$2.99	3,000
8 February 2008	\$3.20	1,250	23 January 2007	\$3.00	1,500
29 February 2008	\$2.60	1,250	26 February 2007	\$3.32	5,000
4 March 2008	\$2.47	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
		745,958			1,045,625

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 Securities Exchange on the day of the exercise of the options.

There were 8,413,250 vested options at 30 June 2008 (7,826,645 at 30 June 2007). There are no options under escrow (Nil at 30 June 2007). Set out below are summaries of options granted under the plan:

## 29. Share-based payments (continued)

Grant date	Expiry date	Exercise price	Balance at start of the year Number	Granted during the year Number	Exercised during the year Number	Forfeited during the year Number	Balance at end of the year Number	Vested at end of the year Number
<b>Consolidated and Parent Entity 2008</b>								
1 Dec 1999	30 Nov 2009	\$0.1250	1,120,000	–	–	–	1,120,000	1,120,000
1 Sept 2001	30 August 2011	\$0.3125	640,000	–	–	–	640,000	640,000
2 Dec 2001	30 Nov 2011	\$0.1250	100,000	–	–	–	100,000	100,000
12 May 2003	30 June 2012	\$0.3125	3,122,000	–	632,000	–	2,490,000	2,490,000
12 May 2003	30 Nov 2012	\$0.3125	480,000	–	–	–	480,000	480,000
12 May 2003	30 April 2013	\$0.3125	16,000	–	–	–	16,000	16,000
1 July 2003	30 June 2013	\$0.3125	360,000	–	–	–	360,000	360,000
4 July 2003	3 July 2013	\$0.3125	200,000	–	–	–	200,000	200,000
9 Dec 2003	30 Nov 2013	\$0.3760	500,000	–	–	–	500,000	500,000
25 April 2004	24 April 2014	\$0.5080	22,500	–	–	–	22,500	22,500
4 June 2004	3 June 2014	\$0.4260	15,000	–	–	–	15,000	15,000
2 Feb 2005	1 Feb 2015	\$0.8340	240,000	–	5,000	–	235,000	190,000
12 May 2005	11 May 2015	\$1.1470	320,000	–	15,000	15,000	290,000	230,000
5 Aug 2005	4 August 2015	\$1.7900	800,000	–	24,376	20,624	755,000	566,250
17 Oct 2005	16 Oct 2015	\$2.7720	70,000	–	–	–	70,000	52,500
13 Feb 2006	12 Feb 2016	\$2.1940	270,000	–	10,000	15,000	245,000	122,500
1 June 2006	31 May 2016	\$2.0340	96,500	–	2,250	6,750	87,500	43,750
15 Aug 2006	14 Aug 2016	\$1.9170	627,250	–	7,125	15,875	604,250	302,125
26 Oct 2006	14 Aug 2016	\$1.9170	278,957	–	48,957	–	230,000	155,000
20 Sept 2006	19 Sept 2016	\$1.8918	47,500	–	1,250	3,750	42,500	21,250
26 Oct 2006	15 Mar 2016	\$2.0680	200,000	–	–	–	200,000	100,000
14 Dec 2006	13 Dec 2016	\$3.0710	72,500	–	–	27,500	45,000	22,500
18 Jun 2007	17 Jun 2017	\$3.3155	237,500	–	–	45,000	192,500	48,125
10 Aug 2007	9 Aug 2017	\$3.3890	–	1,736,000	–	119,000	1,617,000	404,250
5 Nov 2007	9 Aug 2017	\$3.3890	–	150,000	–	–	150,000	37,500
5 Nov 2007	14 Nov 2016	\$3.2258	–	200,000	–	–	200,000	100,000
6 Nov 2007	5 Nov 2017	\$4.2900	–	527,000	–	10,000	517,000	73,000
14 Dec 2007	13 Dec 2017	\$4.1373	–	6,000	–	2,000	4,000	1,000
8 Feb 2008	7 Feb 2018	\$3.2666	–	18,500	–	–	18,500	–
11 Apr 2008	10 Apr 2018	\$2.1135	–	16,000	–	–	16,000	–
23 June 2008	22 June 2018	\$1.5990	–	73,500	–	–	73,500	–
<b>Total</b>			<b>9,835,707</b>	<b>2,727,000</b>	<b>745,958</b>	<b>280,499</b>	<b>11,536,250</b>	<b>8,413,250</b>
Weighted average exercise price			\$0.823	\$3.496	\$0.535	\$2.946	\$1.422	\$0.843

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Grant date	Expiry date	Exercise price	Balance at start of the year Number	Granted during the year Number	Exercised during the year Number	Forfeited during the year Number	Balance at end of the year Number	Vested at end of the year Number
<b>Consolidated and Parent Entity 2007</b>								
1 Dec 1999	30 Nov 2009	\$0.1250	1,120,000	–	–	–	1,120,000	1,120,000
1 July 2000	30 June 2010	\$0.1250	60,000	–	60,000	–	–	–
1 Sept 2001	30 August 2011	\$0.3125	640,000	–	–	–	640,000	640,000
2 Dec 2001	30 Nov 2011	\$0.1250	160,000	–	60,000	–	100,000	100,000
12 May 2003	30 June 2012	\$0.3125	3,502,000	–	380,000	–	3,122,000	3,122,000
12 May 2003	30 Nov 2012	\$0.3125	480,000	–	–	–	480,000	480,000
12 May 2003	30 April 2013	\$0.3125	216,000	–	200,000	–	16,000	16,000
1 July 2003	30 June 2013	\$0.3125	660,000	–	300,000	–	360,000	360,000
4 July 2003	3 July 2013	\$0.3125	200,000	–	–	–	200,000	200,000
9 Dec 2003	30 Nov 2013	\$0.3760	500,000	–	–	–	500,000	500,000
25 April 2004	24 April 2014	\$0.5080	22,500	–	–	–	22,500	15,000
4 June 2004	3 June 2014	\$0.4260	15,000	–	–	–	15,000	11,250
2 Feb 2005	1 Feb 2015	\$0.8340	255,000	–	7,500	7,500	240,000	147,500
12 May 2005	11 May 2015	\$1.1470	330,000	–	2,500	7,500	320,000	185,000
5 Aug 2005	4 August 2015	\$1.7900	954,500	–	35,625	118,875	800,000	400,000
17 Oct 2005	16 Oct 2015	\$2.7720	155,000	–	–	85,000	70,000	35,000
13 Feb 2006	12 Feb 2016	\$2.1940	310,000	–	–	40,000	270,000	67,500
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	–
<b>Total</b>			<b>9,691,500</b>	<b>1,518,457</b>	<b>1,045,625</b>	<b>328,625</b>	<b>9,835,707</b>	<b>7,826,645</b>
<b>Weighted average exercise price</b>			<b>\$0.597</b>	<b>\$2.215</b>	<b>\$0.347</b>	<b>\$2.113</b>	<b>\$0.823</b>	<b>\$0.512</b>

There were 280,499 options forfeited during 2008 (328,625 options during 2007).

The weighted average remaining contractual life of share options outstanding at the end of the period was 5.92 years (2007 – 6.01 years).

#### *Fair value of options granted*

The assessed fair value at grant date of options granted during the year ended 30 June 2008 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.

## 29. Share-based payments (continued)

The model inputs for options granted during the year ended 30 June 2008 are as follows:

Grant date	No. of options granted	Exercise Price	Share Price	Time to expiration (days)	Volatility (%)	Annual interest rate (%)	Option value
<b>Consolidated and Parent Entity 2008</b>							
10 Aug 2007	1,736,000	\$3.3890	\$3.3890	2,190	40.81	6.14	\$1.6678
5 Nov 2007	150,000	\$3.3890	\$3.3890	2,190	40.81	6.14	\$1.6932
5 Nov 2007	200,000	\$3.2258	\$3.2258	2,190	40.81	6.14	\$1.6117
6 Nov 2007	527,000	\$4.2900	\$4.2900	2,190	40.81	6.55	\$2.1434
14 Dec 2007	6,000	\$4.1373	\$4.1373	2,190	40.81	6.55	\$2.0671
8 Feb 2008	18,500	\$3.2666	\$3.2666	2,190	40.81	6.38	\$1.6404
11 Apr 2008	16,000	\$2.1135	\$2.1135	2,190	40.81	6.15	\$1.0523
23 June 2008	73,500	\$1.5990	\$1.5990	2,190	50.00	6.70	\$0.9045
	<u>2,727,000</u>						
<b>Consolidated and Parent Entity 2007</b>							
15 Aug 2006	649,500	\$1.9170	\$1.90	3,650	50.00	5.93%	\$1.3277
20 Sept 2006	72,500	\$1.8918	\$1.85	3,650	50.00	5.62%	\$1.2993
26 Oct 2006	278,957	\$1.9170	\$3.00	3,650	50.00	5.73%	\$1.3167
26 Oct 2006	200,000	\$2.0680	\$3.00	3,650	50.00	5.73%	\$1.4204
14 Dec 2006	80,000	\$3.0710	\$3.10	3,650	50.00	5.73%	\$2.1093
18 June 2007	237,500	\$3.3155	\$3.30	3,650	50.00	6.27%	\$2.3107
	<u>1,518,457</u>						

The options are issued for no consideration.

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

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

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

	Consolidated		Parent Entity	
	2008 \$'000	2007 \$'000	2008 \$'000	2007 \$'000
Options issued under employee option plan	<u>3,434</u>	1,488	<u>3,434</u>	1,488

## 3.2 Directors Declaration

In the directors' opinion:

- (a) the financial statements and notes set out on pages 96 to 132 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 2008 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.

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

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



**Alan D Robertson**  
Director

Sydney  
12th August 2008

## 3.3 Independent Auditors Report

### Independent auditor's report to the members of Pharmaxis Ltd

#### Report on the financial report

We have audited the accompanying financial report of Pharmaxis Ltd (the company), which comprises the balance sheet as at 30 June 2008, and the income statement, statement of changes in equity and cash flow statement for the year 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.

#### Directors' responsibility for the financial 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 controls 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 the financial report, comprising the financial statements and notes, complies with International Financial Reporting Standards as issued by the International Accounting Standards Board.

#### 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.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial 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 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.

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.

#### Independence

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

#### Auditor's opinion

In our opinion:

- (a) the financial report of Pharmaxis Ltd is in accordance with the *Corporations Act 2001*, including:
  - (i) giving a true and fair view of the company's and consolidated entity's financial position as at 30 June 2008 and 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 financial report also complies with International Financial Reporting Standards issued by the International Accounting Standards Board as disclosed in note 1(a).

## **Report on the Remuneration Report**

We have audited the Remuneration Report included in pages 40 to 57 of the directors' report for the year ended 30 June 2008. The directors of the company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

## **Auditor's opinion**

In our opinion, the Remuneration Report of Pharmaxis Ltd for the year ended 30 June 2008, complies with section 300A of the *Corporations Act 2001*.

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

This auditor's report relates to the financial report and remuneration report of Pharmaxis Ltd (the company) for the year ended 30 June 2008 included on Pharmaxis Ltd web site. The company's directors are responsible for the integrity of the Pharmaxis Ltd web site. We have not been engaged to report on the integrity of this web site. The auditor's report refers only to the financial report and remuneration report named above. It does not provide an opinion on any other information which may have been hyperlinked to/from these statements or the remuneration report. 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 report to confirm the information included in the audited financial report and remuneration report presented on this web site.



PricewaterhouseCoopers



**Mark Dow**

Partner

Sydney

12 August 2008

## 3.4 Adoption of IFRS for Inclusion in U.S. Filings (Form 20-F)

Following the publication of SEC Release 33-8879, Acceptance From Foreign Private Issuers of Financial Statements Prepared in Accordance With International Financial Reporting Standards Without Reconciliation to U.S. GAAP, we have included, for the first time in Form 20-F, consolidated financial statements prepared in accordance with Australian equivalents to IFRS (AIFRS). These financial statements also comply with IFRS as issued by the IASB. In previous years, our consolidated financial statements filed on Form 20-F were prepared in accordance with US GAAP.

An explanation of the significant differences between IFRS and U.S. GAAP that are relevant to our consolidated financial statements is presented below together with tabular reconciliations for the 2007 and 2006 financial years of our consolidated net income and consolidated shareholders' equity previously reported in accordance with U.S. GAAP to the equivalent measures restated in accordance with IFRS.

We adopted Australian equivalents to IFRS as our home country GAAP with a transition date of 1 July 2005. Previously our home country GAAP had been Australian GAAP. We applied Australian equivalents to IFRS retrospectively in accordance with IFRS 1 'First-time Adoption of IFRS'.

### 3.4.1 Exemptions from Retrospective Application of IFRS

We did not utilise any exemptions in retrospectively adopting IFRS.

### 3.4.2 Significant Differences between IFRS and U.S. GAAP

#### *Presentation difference*

Under IFRS grants received relating to costs are included in the income statement as a component of Other Income. 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. Under U.S. GAAP grants related to costs are recognized in the income statement against the related expenses. Grants related to the purchase of plant and equipment are recognized against the acquisition costs of the related plant and equipment as and when related assets are purchased.

There are no other differences between our consolidated financial statements prepared in accordance with IFRS and U.S. GAAP.

### 3.4.3 Tabular Reconciliation of U.S. GAAP to IFRS

<b>Year Ended 30 June</b>	<b>2007</b>	<b>2006</b>
Net loss under U.S. GAAP	(24,179)	(17,733)
Loss for the year under IFRS	(24,179)	(17,733)
<b>As at 30 June</b>	<b>2007</b>	<b>2006</b>
<b>Shareholders' Equity</b>		
Shareholders' equity under U.S. GAAP	76,559	98,888
Total equity under IFRS	76,559	98,888

# Section

# 4



## 4.1 Shareholder Information and Related Party Transactions

### 4.1.1 ASX Shareholder Disclosures

The shareholder information set out below was applicable as at 15 August 2008.

#### 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		964	3
1,001 – 5,000		2,200	18
5,001 – 10,000		1,059	20
10,001 – 100,000		1,461	35
100,001 and over		116	19
		5,800	95

There were 269 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
National Nominees Limited	30,740,214	15.8
ANZ Nominees Limited	25,275,348	13.0
HSBC Custody Nominees (Australia) Limited	13,356,401	6.9
J P Morgan Nominees Australia Limited	12,192,211	6.3
Citicorp Nominees Pty Limited	10,649,257	5.5
Australian Executor Trustees NSW Ltd	7,499,257	3.9
KFT Investments Pty Ltd	3,045,596	1.6
The Australian National University	2,810,000	1.4
CM Capital Investments Pty Ltd	2,491,042	1.3
Cogent Nominees Pty Limited	2,406,681	1.2
Credit Suisse Pty Limited	2,126,000	1.0
UBS Nominees Pty Ltd	1,441,519	0.7
Warnford Nominees Pty Limited	1,203,000	0.6
Citicorp Nominees Pty Ltd	1,142,466	0.6
Fleet Nominees Pty Limited	1,083,352	0.6
MLEQ Nominees Pty Limited	976,791	0.5
HSBC Custody Nominees (Australia) Limited-GSCO ECSA	970,000	0.5
Mr Andrew Reid	856,162	0.4
CIBC Australia VC Fund LLC	751,678	0.4
HSBC Custody Nominees (Australia) Limited – A/C 2	750,413	0.4

*Unquoted equity securities*

	Number Held	Number of Holders
Options issued under the Pharmaxis Ltd Employee Option Plan	12,970,750	89

**C. Substantial holders**

Substantial holders in the Company are set out below:

	Number	Percentage
Orbis Global Equity Fund Limited	36,761,762	18.9%
Fortis Investment Partners Pty Ltd	17,061,801	8.8%
Acorn Capital Limited	12,071,292	6.2%

**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.

**4.1.2 U.S. Shareholder Disclosures****Beneficial Ownership**

The following table presents certain information regarding the beneficial ownership of our ordinary shares as of 15 August 2008 by the following persons:

- each person known by us to be the beneficial owner of more than 5% of our ordinary shares;
- our Senior Executive Officers;
- our Directors; and
- our Senior Executive Officers and Directors as a group.

Beneficial ownership is determined according to the rules of the Securities and Exchange Commission and generally means that a person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security, and includes options that are exercisable within 60 days. Information with respect to beneficial ownership has been furnished to us by each Director, executive officer or 5% or more shareholder, as the case may be. Unless otherwise indicated, to our knowledge, each shareholder possesses sole voting and investment power over the shares listed, subject to community property laws where applicable. All holders of our ordinary shares have the same voting rights.

The table below lists applicable percentage ownership based on 194,537,262 ordinary shares outstanding as of 15 August 2008. Options to purchase our ordinary shares that are exercisable within 60 days of 15 August 2008 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage.

Unless otherwise indicated in the footnotes to the table below, the address for each of the persons listed in the table below is c/o Pharmaxis Ltd, Unit 2, 10 Rodborough Road, Frenchs Forest, NSW 2086, Australia.

#### 4.1.2 U.S. Shareholder Disclosures (Continued)

Individual/Group	Shares Beneficially Owned <sup>1</sup>	Options Exercisable within 60 Days	Beneficial Ownership	Percentage of Shares Outstanding
<i>5% Shareholders</i>				
Orbis Global Equity Fund Limited <sup>2</sup>	36,761,983	—	—	18.9%
Fortis Investment Partners Pty Ltd <sup>3</sup>	17,061,801	—	—	8.8%
Acorn Capital Limited <sup>8</sup>	12,071,292	—	—	6.2%
<i>Senior Executive Officers and Directors</i>				
Alan D. Robertson <sup>4</sup>	2,442,500	2,342,500	—	1.3%
Brett Charlton	1,025,860	643,750	—	*
John F. Crapper	549,000	547,000	—	*
Ian A. McDonald	290,000	290,000	—	*
David M. McGarvey <sup>5</sup>	1,192,500	1,147,500	—	*
Gary J. Phillips	697,914	691,250	—	*
Denis M. Hanley <sup>6</sup>	1,899,787	1,110,000	—	1.0%
William L. Delaat	—	—	—	—
Peter C. Farrell	221,645	120,000	—	*
Malcolm J. McComas <sup>7</sup>	374,999	235,000	—	*
John Villiger	100,000	100,000	—	*
All Senior Executive Officers and Directors as a group (11 persons)	8,832,095	7,227,000	—	4.5%

\* Represents beneficial ownership of less than one percent of our outstanding ordinary shares.

<sup>1</sup> Includes ordinary shares issuable pursuant to options exercisable within 60 days of 15 August 2008. The figures represent the amounts last notified to Pharmaxis unless otherwise stated. The relevant shareholders may have acquired or disposed of share since the last notification that are not reflected. However, any such transaction that resulted in a change of one percent or greater would require the notification of such to Pharmaxis.

<sup>2</sup> Consists of 20,261,983 ordinary shares and 1.1 million ADSs held by Orbis Global Equity Fund Limited and or companies associated with Orbis Global Equity Fund Limited.

<sup>3</sup> All of these shares are held of record by nominee and trustee companies on behalf of Fortis Investment Partners Pty Ltd. Fortis Investment Partners Pty Ltd has sole voting and dispositive power over these shares.

<sup>4</sup> Includes 100,000 ordinary shares held by Dr. Robertson's spouse.

<sup>5</sup> Includes 5,000 ordinary shares held by McGarvey Investments Pty Ltd., of which Mr. McGarvey's spouse is the sole director and shareholder. Mr. McGarvey disclaims beneficial ownership over the shares held by McGarvey Investments Pty Ltd.

<sup>6</sup> Includes 203,895 ordinary shares held partially by a trust and partially by a superannuation fund of which Mr. Hanley is a beneficiary. Also includes 17,946 ordinary shares held by Mr. Hanley's spouse.

<sup>7</sup> Includes (i) 100,000 ordinary shares held by Movilli Pty Ltd, and (ii) 26,666 ordinary shares held by Bunyula Super Pty Ltd. Mr. McComas has shared voting and dispositive power over the shares held by these two entities. Also includes 13,333 ordinary shares held by Mr. McComas' spouse.

<sup>8</sup> All of these shares are held of record by nominee and trustee companies on behalf of Acorn Capital Limited, in its capacity as discretionary investment manager to certain superannuation funds, pooled superannuation trusts, managed investment schemes and investment management agreements. Acorn Capital Limited has sole voting and dispositive power over these shares.

**Significant Changes to Percentage Ownership of Principal Shareholders**

The following table presents information with respect to certain significant changes in percentage ownership of our ordinary shares held by beneficial holders of more than five percent of our ordinary shares since 30 June 2003.

5% Shareholder	Date	% of Shares Beneficially Owned	Change in % of Shares Beneficially Owned
Fortis Investment Partners Pty Ltd	9 November 2007 <sup>1</sup>	8.2	8.2
	2 April 2008 <sup>13</sup>	8.8	0.6
Orbis Global Equity Fund Australia	11 November 2005 <sup>3</sup>	11.3	11.3
	31 October 2006 <sup>4</sup>	12.3	1.0
	20 November 2006 <sup>5</sup>	14.1	1.8
	9 November 2007 <sup>14</sup>	14.7	0.6
	27 May 2008 <sup>15</sup>	18.9	4.2
Acorn Capital Limited	10 November 2003 <sup>2</sup>	3.0	3.0
	27 February 2004 <sup>6</sup>	5.2	2.2
	24 June 2004 <sup>7</sup>	6.2	1.0
	13 September 2004 <sup>8</sup>	7.2	1.0
	11 November 2005 <sup>9</sup>	5.6	(1.6)
	31 October 2006 <sup>10</sup>	5.5	(0.1)
	26 February 2007 <sup>11</sup>	5.0	(0.5)
	31 October 2006 <sup>12</sup>	5.4	0.4
	14 April 2008 <sup>16</sup>	6.2	0.8

<sup>1</sup> After giving effect to the purchase of 15,656,831 shares in private transactions and an Australian private placement in October 2007

<sup>2</sup> After giving effect to shares purchased by the listed entity as part of the initial public offering of our ordinary shares on the Australian Securities Exchange in November 2003.

<sup>3</sup> After giving effect to shares issued by the listed entity as part of the US public offering of our ADS and Australian private placement of our ordinary shares in November 2005.

<sup>4</sup> After giving effect to the purchase of 2,094,341 ordinary shares in private transactions from 1 January 2006 to 3 November 2006.

<sup>5</sup> After giving effect to the purchase of 3,067,973 ordinary shares in private transactions on 29 November 2006.

<sup>6</sup> After giving effect to (i) 3,200,000 ordinary shares purchased by Acorn Capital Limited as part of the initial public offering of our ordinary shares on the Australian Stock Exchange in November 2003 and (ii) 2,377,359 ordinary shares purchased in private transactions from September 24, 2003 to February 27, 2004.

<sup>7</sup> After giving effect to the purchase of 1,109,441 ordinary shares in private transactions from 1 March 2004 to 24 June 2004.

<sup>8</sup> After giving effect to the purchase of 1,130,559 shares in private transactions from 28 June 2004 to 13 September 2004.

<sup>9</sup> After giving effect to the issue of shares by the Company in November 2005 in its US public offering and Australian private placement, and after giving effect to the purchase of 1,933,573 ordinary shares on 1 October 2004

<sup>10</sup> After giving effect to the issue of shares by the Company in the period 12 November 2005 to 31 October 2006 subsequent to the exercise of options granted under the Pharmaxis Employee Option Plan.

<sup>11</sup> After giving effect to the sale of 892,173 ordinary shares in private transactions from January 2006 to February 2007.

<sup>12</sup> After giving effect to the purchase of 1,411,737 shares in private transactions from February 2007 to November 2007 and an Australian private placement in October 2007.

<sup>13</sup> After giving effect to the purchase of 1,404,970 shares in private transactions from November 2007 to April 2008.

<sup>14</sup> After giving effect to the purchase of 3,169,470 shares in private transactions from February 2007 to November 2007 and an Australian private placement in October 2007.

<sup>15</sup> After giving effect to the purchase of 8,664,503 shares in private transactions from November 2007 to May 2008.

<sup>16</sup> After giving effect to the purchase of 1,800,796 shares in private transactions from October 2007 to April 2008.

#### 4.1.2 U.S. Shareholder Disclosures (Continued)

We are not aware of any other significant changes in percentage ownership with respect to our principal shareholders resulting from their respective purchases or sales of our ordinary shares.

Our major shareholders do not have different voting rights.

As of 15 August 2008, half a percent of our ordinary shares were held in the United States by eight holders of record, and 99% of our ordinary shares were held in Australia by 5,682 holders of record.

As of 15 August 2008 1,248,029 ADSs, representing 18,720,435 ordinary shares, were outstanding in the United States, and were held by four holders of record.

#### 4.1.3 Price History

##### Markets

Our ordinary shares are traded on the Australian Securities Exchange and our American Depository Shares are traded on the Nasdaq Global Market.

##### Ordinary Shares

The following tables present, for the periods indicated, the high and low market prices for our ordinary shares reported on the Australian Securities Exchange since November 10, 2003, the date on which our ordinary shares were initially quoted. Prior to the initial quotation of our ordinary shares on the Australian Securities Exchange on November 10, 2003, our ordinary shares were not regularly traded in any organized market and were not liquid.

		High A\$	Low A\$
Financial Year 2004	From 10 November 2003 to 30 June 2004	0.570	0.340
Financial Year 2005	Full Year	1.850	0.485
Financial Year 2006	Full Year		
Financial Year 2007	First Quarter	2.440	1.680
	Second Quarter	3.450	2.210
	Third Quarter	3.660	2.920
	Fourth Quarter	3.630	3.120
	Full Year	3.660	1.680
Financial Year 2008	First Quarter	4.300	3.050
	Second Quarter	4.530	3.780
	Third Quarter	4.220	2.040
	Fourth Quarter	2.770	1.400
	Full Year	4.530	1.400
Financial Year 2009 (through 15 August 2008)		2.090	1.310
Most Recent Six Months	February 2008	3.390	2.500
	March 2008	2.530	2.040
	April 2008	2.770	1.540
	May 2008	1.880	1.400
	June 2008	1.740	1.470
	July 2008	1.730	1.310



**American Depositary Shares (ADS)**

The following tables present, for the periods indicated, the high and low market prices for our ADSs as reported on the Nasdaq Global Market since August 29, 2005, the date on which our ADSs were initially quoted. Prior to the initial quotation of our ADSs on the Nasdaq Global Market on August 29, 2005, our ADSs were not regularly traded in any organized market and were not liquid.

		High A\$	Low A\$
Financial Year 2006	Full Year	35.980	19.440
Financial Year 2007	First Quarter (from 29 August 2005)	25.800	19.440
	Second Quarter	43.250	24.180
	Third Quarter	42.500	35.000
	Fourth Quarter	46.400	36.000
	Full Year	46.400	19.440
Financial Year 2008	First Quarter	54.700	35.510
	Second Quarter	62.500	50.000
	Third Quarter	58.500	30.000
	Fourth Quarter	33.750	13.120
	Full Year	62.500	13.120
Financial Year 2009 (to 15 August 2008)		25.22	10.000
Most Recent Six Months	February 2008	46.500	37.000
	March 2008	37.050	30.000
	April 2008	33.750	13.120
	May 2008	26.500	21.040
	June 2008	23.830	18.410
	July 2008	23.050	10.000

**4.1.4 Related Party Transactions****Transactions**

There are no related party transactions except as follows:

**Stock Options Granted to Executive Officers and Directors**

See Section 1.5 of this Statutory Annual Report.

**Employment Agreements**

We have entered into employment agreements with our Senior Executive Officers. For more information regarding these agreements, see Section 1.5.3 of this Statutory Annual Report.

**Director Indemnification**

We have on various dates entered into Deeds of Access to Documents and Indemnity with certain Senior Executive Officers and each of our Directors. See Section 1.4.3 of this Statutory Annual Report.

## 4.2 Additional Information

### 4.2.1 Constitution

Our primary constituent document is a Constitution. Our Constitution does not provide for or prescribe any specific objects or purposes of the Company. Our Constitution is subject to the terms of the Listing Rules of the Australian Securities Exchange and the *Corporations Act 2001*. Our Constitution may be amended or repealed and replaced by special resolution of shareholders, which is a resolution passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution.

#### **Board of Directors**

Our Board of Directors currently consists of six directors, including five non-executive directors, of which one is non-executive chairman. Under our Constitution, the number of Directors will not, unless otherwise determined by an ordinary resolution of Pharmaxis, be less than three nor more than nine. A Director need not be a shareholder of Pharmaxis. Only a person over the age of 18 may be appointed as a Director.

Our Directors are subject to periodic retirement and re-election by shareholders in accordance with our Constitution and the Listing Rules of the Australian Securities Exchange. At each annual general meeting, one-third of our Directors who are subject to retirement by rotation or, if their number is not a multiple of three, the nearest to one-third but not exceeding one-third, retire from office. Any Director appointed by the Directors since the last annual general meeting or for whom it would be their third annual general meeting must also retire from office. Any retiring Director is eligible for reappointment. Generally, the effect of the retirement by rotation provisions is that the Directors retire and are subject to re-election at staggered intervals.

The Directors may appoint one of themselves as a managing director, for any period and on any terms as the Directors decide. Dr. Alan Robertson is currently our managing director. The retirement by rotation provisions do not apply to the managing director.

A person ceases to be a Director if the *Corporations Act 2001* so provides, if the Director resigns by notice to Pharmaxis, if the shareholders in a general meeting remove the Director, if the Director is absent without the consent of the Board of Directors from all Directors' meetings during any six-month period, if the Director becomes mentally incapable and the Director's estate or property has had a personal representative or trustee appointed to administer it, or if the Director is an executive and he or she ceases to be an executive of Pharmaxis.

A Director may appoint an alternate for a specified period with the consent of the Directors. If the appointer of the alternate is not present, the alternate may attend the Directors' meeting, count in the quorum, speak, and vote in the place of the appointer and exercise any other powers (except the power to appoint an alternate) that the appointer may exercise. We may pay an alternate any remuneration the Directors decide, in reduction of the appointer's remuneration. We do not currently have any alternate Directors.

The Directors may meet, adjourn and otherwise regulate their meetings as they decide. Any Director may call a Directors' meeting. The quorum for a Directors' meeting is two Directors, unless the Board of Directors decides otherwise. If a person appointed as an alternate Director is already a Director, he or she must be counted as a Director and separately as an alternate for quorum purposes. If there are not enough Directors in office to form a quorum, the remaining Directors may only act to increase the number of Directors, to call a general meeting of shareholders or in an emergency.

Subject to the *Corporations Act 2001*, each Director has one vote. If a Director is also an alternate, the Director has one vote as a Director and one vote as an alternate. If a person is an alternate for more than one Director, the person has one vote for each appointment. A resolution of the Directors is passed by a majority of votes cast. Subject to the Listing Rules of the Australian Securities Exchange, the chairman has a deciding vote.

Our Board of Directors has all our powers to manage our business except for any powers that the *Corporations Act 2001*, the Listing Rules of Australian Securities Exchange or our Constitution requires Pharmaxis to exercise in a general meeting. The Directors may execute documents on behalf of Pharmaxis, execute negotiable instruments, delegate any of their powers to a committee of Directors or to one Director and may appoint any person to be our attorney and agent.

Subject to the Listing Rules of Australian Securities Exchange and the *Corporations Act 2001*, our Directors are not prohibited from entering into proposals, arrangements and contracts in which they are interested. A Director must declare to Pharmaxis the nature of their material personal interest unless the *Corporations Act 2001* provides otherwise. This notification may be a standing notification.

A Director who has a material personal interest in a proposal, arrangement or contract that is being considered at a Directors' meeting must not be present while the matter is being considered at the meeting or vote on the matter and may not be counted in a quorum unless the *Corporations Act 2001* provides otherwise. The Director may be present and vote at such a Directors' meeting if the Directors who do not have a material personal interest in the matter have passed a resolution that identifies the Director, the nature and extent of the Director's interest in the matter and its relation to our affairs and states that those Directors are satisfied that the interest should not disqualify the Director from being present or voting.

At a shareholders meeting, we will disregard any votes cast by a Director or any associate of a Director who is voting in his or her capacity as a shareholder on a resolution relating to a proposal, arrangement or contract in which the Director has a material personal interest if required to do so by the Listing Rules of the Australian Securities Exchange. The Listing Rules of the Australian Securities Exchange provide that the votes of certain shareholders must be disregarded in a number of circumstances. We may not be required to disregard the vote of the Director if the Director is voting as a proxy for a person who is entitled to vote.

We may remunerate each Director as the Board of Directors decides, but the total amount of the remuneration of non-executive Directors may not exceed the amount fixed by the shareholders in a general meeting. Other amounts may be payable by Pharmaxis to Directors, including the payment of reasonable costs and expenses incurred in the performance of their duties or amounts paid in respect of indemnity obligations. In addition, shareholder approval may also be required in relation to the remuneration of executive Directors unless the remuneration would be reasonable given our circumstances and the role of the executive director.

In order to loan money or give similar financial benefits to a Director, we must either obtain the approval of shareholders or the financial benefit must fall under an approved exception under the *Corporations Act 2001*.

### **Shareholders Meetings**

We must hold an annual general meeting within five months of the end of each financial year. Our financial year end is currently June 30 each year. At the annual general meeting, shareholders typically consider the annual financial report, directors' report and auditors' report and vote on matters, including the remuneration report and the election of directors. We may also hold other meetings of shareholders from time to time. The annual general meeting must be held in addition to any other meetings which we may hold.

A Director or the Board of Directors may call and arrange a meeting of shareholders, when and where they decide. The Directors must call a meeting of shareholders when requested by shareholders who hold at least 5% of the votes that may be cast at the meeting or at least 100 members who are entitled to vote at the meeting or as otherwise required by the *Corporations Act 2001*. Shareholders with at least 5% of the votes in us may also call a general meeting at their own cost.

At least 28 calendar days notice must be given of a meeting of shareholders. A meeting of shareholders may be called on shorter notice if, in respect of the annual general meeting, all of the shareholders agree beforehand, or in respect of any other meeting of shareholders, if 95% of the shareholders agree beforehand.

Directors, auditors, shareholders, proxies, and attorneys and representatives of shareholders are entitled to attend general meetings. We may refuse admission to the meeting to anyone (other than a Director) in accordance with our Constitution and applicable Australian law. For the purpose of determining who is a shareholder at a particular meeting, the Directors will determine that shareholders at a specified time (typically this will be 48 hours before the meeting) are taken to be shareholders at the meeting.

#### 4.2.1 Constitution (continued)

The necessary quorum for a meeting of shareholders is five shareholders entitled to vote. We believe this quorum requirement is consistent with common practice for many Australian public companies.

Unless applicable law or our Constitution requires a special resolution, a resolution of shareholders is passed if more than 50% of the votes cast by shareholders entitled to vote are cast in favor of the resolution. A special resolution is passed if the notice of meeting sets out the intention to propose the special resolution and states the resolution and it is passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution. A special resolution usually involves more important questions affecting us as a whole or the rights of some or all of our shareholders. Special resolutions are required in a variety of circumstances under our Constitution and the *Corporations Act 2001*, including without limitation:

- to change our name;
- to amend or repeal and replace our Constitution;
- to approve the terms of issue of preference shares;
- to approve the variation of class rights of any class of shareholders;
- to convert one class of shares into another class of shares;
- to approve certain buy backs of shares;
- to approve a selective capital reduction of our shares;
- to approve us financially assisting a person to acquire shares in us;
- to remove and replace our auditor;
- to approve the transfer of our place of registration to registration under a law of another state or territory of Australia;
- to change our company type;
- with the leave of an authorized Australian court, to approve our voluntary winding up;
- to confer on a liquidator of us either a general authority or a particular authority in respect of compensation arrangements of the liquidator; and
- to approve an arrangement entered into between a company about to be, or in the course of being, wound up.

#### **Shareholder Voting Rights**

At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares. In the case of an equality of votes on a resolution at a meeting (whether on a show of hands or on a poll), the chairman of the meeting has a deciding vote in addition to any vote that the chairman of the meeting has in respect of that resolution. A poll may be requested on any resolution by at least five shareholders entitled to vote on the resolution, by shareholders holding at least 5% of the votes that may be cast on the resolution or by the chairman. The Directors may, subject to the Corporations Act and the Listing Rules of the Australian Securities Exchange, determine that, at any general meeting or class meeting, a shareholder who is entitled to attend and vote at that meeting is entitled to give their vote by way of a direct vote by giving written notice of their voting intention. The Directors may specify the form, method and timing of giving a direct vote at a meeting in order for the vote to be valid and the manner in which the direct vote will be carried out. Subject to any other rights or restrictions which may be attached to any shares, where the Directors have approved the casting of votes by direct vote, every shareholder having the right to vote on the resolution has one vote for each fully paid share they hold and a fraction of a vote for each partly paid share they hold.

The Listing Rules of the Australian Securities Exchange provide that the votes of certain shareholders must be disregarded in certain circumstances. Generally, a shareholder's vote may be disregarded if the person may benefit from the transaction that is the subject of the resolution (subject to certain exceptions, such as where the benefit is received in their capacity as a shareholder in common with other shareholders).

ASX Limited may also identify a person who in their view should not be entitled to vote.

## ***Issue of Shares and Changes in Capital***

Subject to our Constitution, the *Corporations Act 2001*, the Listing Rules of the Australian Securities Exchange and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with preferred, deferred or other special rights and restrictions and for the consideration and other terms that the Directors determine. Our power to issue shares includes the power to issue bonus shares (for which no consideration is payable to us), preference shares (including redeemable preference shares) and partly paid shares. The Listing Rules of Australian Securities Exchange impose certain restrictions on the number of securities we are able to issue.

Subject to the requirements of our Constitution, the *Corporations Act 2001*, the Listing Rules of the Australian Securities Exchange and any other applicable law we may:

- consolidate or divide our share capital into a larger or smaller number by resolution passed by shareholders at a general meeting;
- may reduce our share capital by special resolution passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution provided that the reduction is fair and reasonable to our shareholders as a whole, and does not materially prejudice our ability to pay creditors;
- undertake an equal access buyback of our ordinary shares by ordinary resolution of shareholders (although if we have bought back less than 10% of our shares over the period of the previous 12 months, shareholder approval may not be required); and
- undertake a selective buyback of certain shareholders' shares by special resolution passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution, with no votes being cast in favor of the resolution by any person whose shares are proposed to be bought back or by their associates.

In certain circumstances, including the division of a class of shares into further classes of shares, the issue of additional shares or the issue of a new class of shares, we may require the approval of any class of shareholders whose rights are varied or are taken to be varied by special resolution of shareholders generally and by special resolution of the holder of shares in that class whose rights are varied or taken to be varied.

## ***Dividends***

Subject to any special rights or restrictions attached to a share, we may pay dividends on our shares as the Directors decide. Dividends may be only paid out of our profits.

Subject to any special rights or restrictions attached to a share, the Directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment. Dividends may be paid on shares of one class but not another and at different rates for different classes. If the Board of Directors does not exercise their power to issue dividends, the shareholders in a general meeting may. Under our Constitution, a shareholder or shareholders holding the requisite number of shares required to convene a general meeting would be able to convene a meeting or require the Directors to convene a meeting to consider whether we should pay a dividend. The proposed resolution to pay the dividend would need to be included in the notice of meeting and would be voted on by shareholders as an ordinary resolution. Any dividend payable would only be payable out of our profits.

## ***Liquidation Rights***

Subject to any special rights or restrictions attached to shares, on a winding up, all available assets must be repaid to the shareholders and any surplus must be distributed among the shareholders in proportion to the number of fully paid shares held by them. For this purpose a partly paid share is treated as a fraction of a share equal to the proportion which the amount paid bears to the total issue price of the share before the winding up began.

If we experience financial problems, the Directors may appoint an administrator to take over our operations to see if we can come to an arrangement with our creditors. If we cannot agree with our creditors, we may be wound up. A receiver, or receiver and manager, may be appointed by order of a court or under an agreement with a secured creditor to take over some or all of the assets of a company. A receiver may be appointed, for example, because an amount owed to a secured creditor is overdue. We may be wound up by order of a court, or voluntarily if our shareholders pass a special resolution to do so. A liquidator is appointed when a court orders a company to be wound up or the shareholders of a company pass a resolution to wind up the company. A liquidator is appointed to administer the winding up of a company.

#### 4.2.1 Constitution (continued)

##### *Calls, Lien and Forfeiture in Respect of Partly Paid Shares*

Subject to any special rights or restrictions attached to shares, the Board of Directors may make calls on the holder of a share for any unpaid portion of the issue price of that share at any time. The Directors may make a call payable by installments. If the amount called is not paid by the requisite time, the shareholder must pay us interest on the amount unpaid from the date the call becomes payable until and including the date of payment and our costs arising from the non-payment. Joint holders of a share and their respective personal representatives are all jointly and severally liable to pay all calls on the share. The Board of Directors may recover an amount presently payable as a result of a call by suing the shareholder for the debt, by enforcing the lien on the share or by declaring forfeit the share. The forfeiture of a share extinguishes the former shareholder's interest in the share. We have a first ranking lien on each share registered to a shareholder, dividends payable on a shares, proceeds on the sale of a share for an unpaid call or installment that is due but unpaid on the share, any amounts we are required by law to pay in respect of the shares of that shareholder, and in respect of any interest and costs presently payable to Pharmaxis by the shareholder. We may sell a share to enforce a lien in certain circumstances. We do not currently have any partly paid shares outstanding.

#### 4.2.2 Limitations on Rights to Own Shares and ADSs

The Foreign Acquisitions and Takeovers Act 1975 regulates acquisitions of shares by non-Australian persons giving rise to substantial interests or controlling interests in an Australian companies. Some of the relevant terms of the Foreign Acquisitions and Takeovers Act 1975 are summarized below.

In general terms, the Foreign Acquisitions and Takeovers Act 1975 prohibits a foreign interest from acquiring shares or entering into an agreement to acquire shares or interests in shares if, after the acquisition or agreement, such foreign interest would hold a substantial interest or controlling interest in an Australian corporation, without first applying for approval by the Treasurer of the Australian Government and such approval being granted or 40 days having elapsed after such application was made.

For foreign investors other than U.S. investors, the notification obligation arises in relation to proposals to acquire a substantial interest or controlling interest in an Australian business, the value of whose assets exceeds A\$100 million or whose business is valued at over A\$100 million. As of June 30, 2008, our business had a market valuation of greater than A\$100 million. In the case of U.S. investors, other than the U.S. government and other than when the investment proposal relates to investments in prescribed sensitive sectors, the requirement to notify the Australian Government of a proposal to acquire a substantial interest or a controlling interest in an Australian business arises when the value of the assets of the relevant Australian business exceeds A\$913 million or the value of the Australian business exceeds A\$913 million. A U.S. investor is defined as a national or permanent resident of the U.S., a U.S. enterprise, or a branch of an entity located in the U.S. and carrying on business activities in the U.S. As of June 30, 2008, we had assets and a market value less than A\$913 million and were not regarded as a business in a sensitive sector.

A 'foreign interest' is defined, in summary, as:

- a natural person not ordinarily resident in Australia;
- a company in which a natural person not ordinarily resident in Australia or a foreign company holds a substantial interest;
- a company in which two or more persons, each of whom is either a natural person not ordinarily resident in Australia or a foreign company, hold an aggregate substantial interest;
- the trustee of a trust estate in which a natural person not ordinarily resident in Australia or a foreign company holds a substantial interest; or
- the trustee of a trust estate in which two or more persons, each of whom is either a natural person not ordinarily resident in Australia or a foreign company, hold an aggregate substantial interest.

In summary, a person is taken to hold a substantial interest in a company if:

- the person, alone or together with any associate or associates of the person, is in a position to control not less than 15% of the voting power in the company or holds legal or equitable interests in not less than 15% of the issued shares in the company; or
- two or more persons are taken to hold an aggregate substantial interest in a company if they, together with any associate or associates of any of them, are in a position to control not less than 40% of the voting power in the company or hold legal or equitable interests in not less than 40% of the issued shares in the company.

Where a person holds a substantial interest in a company or two or more persons hold an aggregate substantial interest in a company, that person will be taken to hold a controlling interest in the company, or those persons will be taken to hold an aggregate controlling interest in the company, unless the Treasurer is satisfied that the person together with their associates (if any) are not in a position to determine the policy of the company.

The Treasurer may make an order prohibiting a proposed acquisition of shares or all or any of the proposed acquisitions. Where the Treasurer makes an order prohibiting a proposed acquisition of shares, it may also make an order in relation to a specified foreign person and their associates prohibiting those persons from acquiring additional interests or voting rights in the company.

Where a person has acquired shares in a company, and the Treasurer is satisfied that the acquisition has had the result that the company becomes controlled by foreign persons, or in the case of a company that was previously controlled by foreign persons, includes a person who is not one of the foreign persons forming part of the existing foreign interest, and that result is contrary to Australia's national interest, the Treasurer may make an order directing the person who acquired the shares to dispose of those shares within a specified time to any person or persons approved in writing by the Australian government.

If a person or persons acquires shares or enters into an agreement to acquire shares or interests which requires the approval of the Treasurer, but the person or persons fails to get approval, the person or persons are guilty of an offence and may be liable to penalties and imprisonment. Among other things, orders are able to be made restraining the exercise of any rights attached to shares held by the foreign person or corporation and directing the disposal of shares.

Shareholders, potential shareholders and holders of ADSs and potential holders of ADSs are urged to get their own independent legal advice in relation to the application of the Foreign Acquisitions and Takeovers Act 1975.

### 4.2.3 Change of Control

#### ***Corporations Act 2001***

Takeovers of listed Australian public companies, such as us, are regulated amongst other things by the *Corporations Act 2001* which prohibits the acquisition of a relevant interest in issued voting shares in a listed company if the acquisition will lead to the person's or someone else's voting power in the company increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%, subject to a range of exceptions.

A relevant interest is defined very broadly to capture most forms of interest in shares and would include interests in our ADSs. Generally, and without limitation, a person will have a relevant interest in securities if they:

- are the holder of the securities;
- have power to exercise, or control the exercise of, a right to vote attached to the securities; or
- have power to dispose of, or control the exercise of a power to dispose of, the securities (including any indirect or direct power or control).

It does not matter how remote the relevant interest is or how it arises. If two or more people can jointly exercise one of these powers, each of them is taken to have that power.

#### 4.2.3 Change of Control (cont'd)

If at a particular time a person has a relevant interest in issued securities and the person:

- has entered or enters into an agreement with another person with respect to the securities;
- has given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities; or
- has granted or grants an option to, or has been or is granted an option by, another person with respect to the securities, and the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised, the other person is taken to already have a relevant interest in the securities.

A person will also be regarded as having a relevant interest in voting shares in a company if the non-voting securities in which the person already had a relevant interest become voting shares in the company or there is an increase in the number of votes that may be cast on a poll attached to voting shares that the person already had a relevant interest in. In these circumstances, the acquisition of the relevant interest will occur when the securities become voting shares or the number of votes increases. There are a number of exceptions to the prohibition on acquiring a relevant interest in issued voting shares in a listed company if the acquisition will lead to the person's or someone else's voting power in the company increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%. Some of the more significant exceptions include in summary terms:

- when the acquisition results from the acceptance of an offer under a formal takeover bid;
- when the acquisition is conducted on market by or on behalf of the bidder under a takeover bid and the acquisition occurs during the bid period;
- when shareholders of the company approve the takeover by resolution passed at general meeting;
- an acquisition by a person if, throughout the 6 months before the acquisition, that person, or any other person, has had voting power in the company of at least 19% and as a result of the acquisition, none of the relevant persons would have voting power in the company more than 3 percentage points higher than they had 6 months before the acquisition;
- as a result of a pro-rata rights issue;
- as a result of dividend reinvestment schemes;
- as a result of underwriting arrangements;
- through operation of law;
- an acquisition which arises through the acquisition of a relevant interest in another listed company;
- arising from an auction of forfeited shares; or
- arising through a compromise, arrangement, liquidation or buyback.

Breaches of the takeovers provisions of the *Corporations Act 2001* are criminal offences. The Australian Securities and Investments Commission and the Australian Takeover Panel have a wide range of powers relating to breaches of takeover provisions including the ability to make orders canceling contracts, freezing transfers of, and rights attached to, securities, and forcing a party to dispose of securities. There are certain defenses to breaches to the takeovers provisions provided in the *Corporations Act 2001*.

##### **Proportional Takeover**

Our Constitution contains what is known as a proportional takeover provision which provides that the registration of transfers giving effect to a takeover for only a specified proportion of us is prohibited until a resolution to approve the bid is passed by shareholders of the bid class of securities. The resolution is passed if the proportion of bid class shareholders accepting the resolution is greater than 50%. The proportional takeover provision in our Constitution expires every three years. At our annual general meeting on October 26, 2006 shareholders approved the renewal of the proportional takeover provision in our Constitution until October 26, 2009. Shareholders may prior to or after that time again renew the applicability of the proportional takeover provision at a general meeting.



#### 4.2.4 Disclosure of Interests

The *Corporations Act 2001* requires that a person must give notice to us in the prescribed form within two business days (or in some cases by the next business day) if:

- the person begins to have, or ceases to have, a substantial holding in us. A substantial holding will arise if a person and their associates have a relevant interest in 5% or more of the votes in us or the person has made a takeover bid for the voting shares in us;
- if the person has a substantial holding in us and there is a movement of 1% in their holding; or
- if the person makes a takeover bid for us.

For the purposes of the notification obligation, a 'relevant interest' in the voting shares is defined very broadly to capture most forms of interests in shares and would include interests in our ADSs. Generally, a person will have a relevant interest in securities if such person is the holder of the securities, has power to exercise, or control the exercise of, a right to vote attached to the securities or has power to dispose of, or control the exercise of a power to dispose of, the securities (including any indirect or direct control or power). Likewise, 'associates' are defined broadly and include:

- corporate entities owned or controlled by the person;
- corporate entities that control the person;
- corporate entities that are controlled by an entity which controls the person;
- persons with whom the person has or proposes to enter into agreements with which relate to the composition of our Board; and
- persons with whom the person is acting or is proposing to act in concert.

The rights attaching to our shares for non-compliance with the disclosure of interest requirements may result in disenfranchisement, loss of entitlement to dividends and other payments and restrictions on transfer. A person who contravenes these obligations is liable to compensate a person for any loss or damage the person suffers because of the contravention.

#### 4.2.5 Material Contracts

Following is a summary of our material contracts, other than contracts entered into in the ordinary course of business, to which we are a party, for the two years immediately preceding the filing of this document.

##### ***License Agreement with the Sydney South West Area Health Service***

On October 10, 2001, we entered into a license agreement with Sydney South West Area Health Service. Pursuant to the license agreement, Sydney South West Area Health Service grants us an exclusive, worldwide license, which is able to be sublicensed, to exploit certain key intellectual property and patents relating to the use of respirable dry powders for the assessment of bronchial hyper-responsiveness, a condition consistent with active asthma, for monitoring steroid use in asthma patients, and for the management of diseases such as cystic fibrosis, bronchiectasis and chronic bronchitis.

There is no fixed expiry date for the license agreement. The term of the license in each relevant country is for the longer of 10 years from the first commercial sale of products which exploits the Sydney South West Area Health Service intellectual property in that country or until the expiry of the last registered patent in that country. The license may be terminated earlier by either party if there is a breach of the agreement by a party and that party fails to remedy the breach within 30 days after receiving notice to do so, or if any party becomes insolvent or if we determine in our commercial judgment that it is not prudent to continue the license. If we decide not to obtain product approval in any country, we will not unreasonably refuse to convert the license into a non-exclusive license for that country.

We must bear the cost of maintaining the relevant registered Sydney South West Area Health Service intellectual property and must use our reasonable commercial endeavors to exploit and undertake research and development of the intellectual property.

#### 4.2.5 Material Contracts (continued)

We may at our own cost prosecute applications for any new patentable inventions arising in the course of exploiting the Sydney South West Area Health Service intellectual property, in our name. If we do not seek patent protection for the new patentable invention in any country, Sydney South West Area Health Service may at its own cost file patent applications.

For the term of the license, we are liable to pay the royalties described below to Sydney South West Area Health Service on the net sales of products and services which exploit the Sydney South West Area Health Service intellectual property.

In respect of the upper and lower airway function test application of the intellectual property:

- no royalties until aggregate net sales of products and services from all countries of A\$500,000 have been achieved;
- a royalty of 4% of the gross margin if the net sales of the products or services by us achieve a gross margin of 20% or less;
- a royalty of 8% of the gross margin if the net sales of the products or services by us achieve a gross margin between 20% and 40%;
- a royalty of 10% of the gross margin if the net sales of the products or services by us achieve a gross margin greater than 40%; and
- 20% of any royalty received from any sub-licensee.

In respect of the mucociliary clearance and sputum induction applications of the intellectual property:

- no royalties are payable until sales representing a gross margin of A\$1 million have been achieved then, when the gross margin achieved by the product sales is between A\$1 million and A\$25 million a royalty equal to 3% of the gross margin will apply, when it is between A\$25 million and A\$75 million a royalty equal to 2.5% of the gross margin will apply and when it is greater than A\$75 million a royalty equal to 2% of the gross margin will apply; and
- 20% of any royalty received from a sub-licensee.

To date, we have only made limited royalty payments to Sydney South West Area Health Service. We are not able to accurately estimate the aggregate amount of potential payments that may be due to Sydney South West Area Health Service as this amount will be a function of the future sales of our applicable products and the percentage royalty set out above.

We have agreed to indemnify Sydney South West Area Health Service against all loss and damage that Sydney South West Area Health Service may sustain or incur as a result of any actions, claims, suits, proceedings or demands arising directly or indirectly out of the breach of the license by us. Both parties have agreed to indemnify the other party against all loss and damage that the other party may sustain or incur as a result of any damage to the other party's property or injury to or death of any of the other party's personnel arising out of the agreement.

Subject to a policy being available on commercially reasonable terms, we must maintain a product liability insurance policy naming Sydney South West Area Health Service, both during the term of the agreement and for a period of six years after the termination of the agreement.

#### ***AusIndustry P3 Pharmaceuticals Partnerships Program Funding Deed***

On August 12, 2004, we entered into a funding deed with the Commonwealth of Australia under the AusIndustry P3 Pharmaceuticals Partnerships Program. The term of the funding deed ended on June 30, 2008 and we expect to receive our final payment in relation to our 2008 financial year expenditure in the third quarter of 2008.

The Commonwealth of Australia does not assert any ownership of, or any right to, any of the intellectual property created under the funding deed. We have granted to the Commonwealth of Australia a permanent, irrevocable, royalty free, worldwide, non-exclusive license to use, reproduce, publish, transmit, adapt and modify any documents and associated materials brought into existence for the purpose of us reporting on the performance of our obligations under the deed or otherwise used in connection with the grant program. This licensed material may only be used for the purposes of the Commonwealth of Australia's dissemination, reporting and accountability requirements, but not to commercially exploit such material.

We must continue to provide a range of reports following the termination of the funding deed.

### ***Research and Development Start Program Grant Agreement***

On 17 June 2003, we entered into a grant agreement with the Commonwealth of Australia under the research and development Start Grant Program pursuant to which we have been paid A\$3.0 million. Notwithstanding that the relevant grant funding ceased on 31 December 2005 in accordance with the payment schedule, we have ongoing reporting obligations beyond the project completion date until the formal termination of the grant agreement which occurs on 31 December 2010.

We must provide reports to the Commonwealth of Australia in the first, third and fifth years after the completion of the grant funding which occurred in December 2005. In certain limited circumstances where we fail to use our best endeavors to commercialize the project within a reasonable time of completion of the project or upon termination of a grant due to our breach of agreement or our insolvency, the Commonwealth of Australia may require us to repay some or all of the grant. We consider that the likelihood of being required to repay grant funding is remote while we continue to act in good faith with respect to this grant. To date, we have not been required to repay any amounts paid to us under our current two grant agreements and we are not aware of any current circumstances that would require us to repay any such amounts.

### ***Put and Call Option Deed***

On 31 October 2007, we entered into a put and call option deed with GE Real Estate Investments Australia Pty Limited ('GE') and Goodman Property Services (Aust) Pty Limited ('Goodman'). Pursuant to the put and call option deed, Goodman has agreed to construct a custom designed facility on land which is owned by GE and located in Frenchs Forest, Sydney Australia. Under the put and call option deed we had the right to exercise a call option to require GE and us to enter into a lease with respect to the new facility. We exercised the option on 22 April 2008.

The put and call option deed sets out the obligations of Goodman and us with respect to the construction of the new facility, including the standards to which the works must be undertaken, the specifications for the works and the process for varying those specifications and the schedule of works and the manner in which the schedule of works may be varied. A project control group with representatives of GE, Goodman and us has been established to oversee the project.

We have agreed to release GE and Goodman from liability for injury, death or loss arising in connection with the deed except to the extent such claims were caused by GE or Goodman. We have indemnified GE and Goodman against all claims for which GE or Goodman suffer which are caused or contributed to by any willful or negligent act or omission by us, any default by us under the deed, the carrying out of work by us or the use of the land by us, except to the extent such claims were caused by the negligence of GE or Goodman.

A party may terminate the deed if there is an event of default by one of the other party's to the agreement and the defaulting party fails to remedy the breach within 7 days after receiving notice requiring it to do so. A party is taken to have committed an event of default if they are insolvent or default under the deed and fail to remedy the breach within 30 days of receipt of written notice from another party requiring it to do so. We have agreed that if Goodman breaches any of its obligations under the deed, other than any breach caused or contributed to by delay or timeliness, our only claim will be in damages against Goodman and we will not be entitled to terminate the deed, except that we may terminate the deed by notice in writing to the other parties and after consultation with the other parties if practical completion of the construction of the new facility is not achieved on or before a specified sunset date. If the deed is validly terminated by GE arising from a breach by us, in addition to any other causes of action against us, we must pay damages as a result, including compensation for lost rent and outgoings due to the lease not proceeding. If we validly terminate the deed, as a result of a breach by Goodman, then in addition to any other causes of action we may have, Goodman must pay damages as a result, including compensation for consequential loss due to the lease not proceeding.

The lease which forms an annexure to the put and call option deed contains customary representations, warranties, conditions and indemnifications of the parties. Under the lease we have a lease to the facility for a term of 15 years with two options exercisable by us to extend the term of the lease by five years per option. We will be in default under the lease if any part of the rent or other amounts owing remain unpaid for 28 days after it is due, if we fail to perform or observe any of our other obligations under the lease and have not rectified that failure within a reasonable time after receipt of written notice from GE, we become insolvent or we fail to comply with any of certain essential terms of the lease. If an event of default occurs, GE may take possession of the facility and by notice terminate the lease.

#### 4.2.6 Exchange Controls

For a description of any governmental laws, decrees, regulations or other legislation of Australia which may affect (1) the import or export of capital, including the availability of cash and cash equivalents for use by us, or (2) the remittance of dividends, interest or other payments to nonresident holders of our securities, see Section 4.2.1 of this Statutory Annual report.

#### 4.2.7 Taxation Summary Applicable to U.S. Holders

The following is a summary of certain material Australian income tax and U.S. federal income tax considerations related to the ownership and disposition of our ordinary shares or ADSs that may be relevant to you if you are a U.S. Holder (as defined below). This summary is based on the Australian and U.S. tax laws currently in effect. The term 'U.S. Holder' means a beneficial owner of our ordinary shares or ADSs that is, for U.S. federal income tax purposes, a citizen or individual resident of the United States, a domestic corporation, an estate whose income is subject to U.S. federal income tax regardless of its source, or a trust if a U.S. court can exercise primary supervision over the administration of the trust and one or more U.S. persons are authorized to control all substantial decisions of the trust, or a trust that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

U.S. Holders of our ordinary shares or ADSs should consult their own tax advisors regarding the application of the Australian and U.S. federal income tax laws to their particular situations as well as any tax considerations under other tax laws (such as estate and gift tax laws), or the laws of any province, state or local jurisdiction.

If an entity is treated as a partnership, the tax treatment of a partner will generally depend on the status of the partner and upon the activity of the partnership. If you are a partner of a partnership that will hold our ordinary shares or ADSs, we suggest you consult your own tax advisor.

##### ***Australian Taxation***

The following summary of the Australian taxation implications is based on the provisions of the Income Tax Assessment Act 1936, the Income Tax Assessment Act 1997, the International Tax Agreements Act 1953, or IntTAA with the United States Convention as amended by the United States Protocol, or USDTA, public taxation rulings and available case law current as at the date of this Statutory Annual Report, or collectively referred to in this section as Australian Taxation Laws. The Australian Taxation Laws and their interpretation are subject to change at any time.

##### *General Principle of Taxation in Australia*

This summary discusses only two items of income that may arise from an investment in our ordinary shares or ADSs, namely:

- gains realized from the sale of our ordinary shares or ADSs; and
- dividends that may be paid by us with respect to those shares and ADSs. Please note that we have not paid any dividends to date and do not expect to pay any in the near to medium term.

##### *Gains on Sale of Shares or ADSs by U.S. Holders*

Under Australian law, tax is typically not payable on the gain made on the disposal of ordinary shares or ADSs by U.S. Holders.

However, a U.S. Holder is liable to tax on the gain made on the disposal of ordinary shares or ADSs where the U.S. Holder is carrying on a business in Australia through a permanent establishment or that are providing personal services in Australia through a fixed place of business. The gain made by the U.S. Holder in these circumstances will be treated as either income or capital, depending on whether or not the U.S. Holder is carrying on a business of share trading in Australia. If the U.S. Holder is carrying on a business of share trading in Australia, then the gain made on the sale of our ordinary shares or ADSs is regarded as ordinary income and the U.S. Holder will be taxed accordingly. If the U.S. Holder is not carrying on a business of share trading in Australia, the gain made on the sale of our ordinary shares or ADSs is a capital gain. If the U.S. Holder is an individual, a complying superannuation entity, a trust or a life insurance company, the U.S. Holder may be entitled to the CGT discount upon the disposal of our ordinary shares or ADSs held for at least 12 months. The CGT discount reduces the capital gain otherwise liable to tax by 50% in the case of an individual or by 33% in the case of a complying superannuation entity or life insurance company. The capital gain (net of a CGT discount if applicable) must then be included in the assessable income of the relevant U.S. Holder and taxed accordingly.

## *Dividends Paid to U.S. Holders*

Dividends paid to U.S. Holders will be subject to the withholding tax provisions of the Australian Taxation Laws.

The general withholding tax rate in Australia for dividends is 30% but under the USDTA this is reduced to 5% of the gross amount of the dividend if the person beneficially entitled to the dividend is a company which holds at least 10% of the voting power in the company or otherwise is reduced to 15%. If the U.S. Holder has held shares which hold a voting power of at least 80% for at least a 12 month period then there may be no withholding tax if the holder is a certain type of person such as a listed company.

However certain dividends paid to non-residents are exempt from withholding tax. The exemption from withholding tax is explained below.

Australia has an imputation system which allows a company which distributes profits to its members to pass on to its members a credit for the tax already paid by the company to its members. This is known as a franking credit. To the extent that the dividend is franked, the dividend is not subject to withholding tax. This means that a fully franked dividend is not subject to any withholding tax. To the extent that the dividend is not franked (i.e. unfranked dividends), then that part of the dividend will be subject to withholding tax but at the reduced rate referred to above.

A dividend which is unfranked is also exempt from withholding tax to the extent it is referable to certain categories of foreign income of the payer which are treated on a conduit basis in Australia.

If a US Holder holds shares in us through a permanent establishment in Australia, then dividends paid on those shares will not be subject to withholding tax but will be assessed as taxable income in Australia and taxed at the marginal tax rates. Such a US Holder may be entitled to a tax offset for any franking credit attached to such dividends.

There are also additional exemptions depending on the nature of the shareholder which are designed to ensure that an entity that is otherwise exempt from tax is not subject to withholding tax, e.g., charitable institutions.

## ***U.S. Taxation for U.S Holders***

The following is a summary of certain material U.S. federal income tax considerations related to the ownership and disposition of our ordinary shares and ADSs that may be relevant to you if you are a U.S. Holder. This summary is based on the Internal Revenue Code of 1986, as amended (the 'Code'), existing and proposed Treasury regulations promulgated under the Code and administrative and judicial interpretations of the Code, all as of the date of this Statutory Annual Report and all of which are subject to change, possibly with retroactive effect.

This summary is also based in part upon the representations of the depositary and the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms. In general, and taking into account such assumptions, a U.S. Holder of ADSs will be treated as an owner of the ordinary shares represented by those ADSs. Therefore, exchanges of ordinary shares for ADSs, and ADSs for ordinary shares, will not have U.S. federal income tax consequences.

This summary deals only with ordinary shares and ADSs held as capital assets within the meaning of Section 1221 of the Code. It does not discuss all of the U.S. federal income tax considerations that may be relevant to U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special rules, such as dealers in securities or currencies, traders in securities that elect to mark-to-market their securities, expatriates, partnerships and other pass through entities, tax-exempt organizations, insurance companies, U.S. Holders subject to the alternative minimum tax, U.S. Holders that actually or constructively own 10% or more of our ordinary shares, U.S. Holders holding our ordinary shares or ADSs as part of a hedging or constructive sale transaction, 'straddle,' conversion transaction, or other integrated transaction, or U.S. Holders whose functional currency is not the U.S. dollar.

#### 4.2.7 Taxation Summary Applicable to U.S. Holders (continued)

##### *Ownership of Ordinary Shares and ADSs by U.S. Holders*

The gross amount of any distribution received by a U.S. Holder with respect to our ordinary shares or ADSs generally will be included in the U.S. Holder's gross income as a dividend to the extent attributable to our current and accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder's pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but no below zero) the adjusted tax basis of the U.S. Holder's shares. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder's shares, the remainder will be taxed as capital gain (the taxation of capital gain is discussed under the heading 'Sale of Ordinary Shares and ADSs' below).

For taxable years beginning after December 31, 2002 and before January 1, 2009, dividends received by non-corporate U.S. holders from a qualified foreign corporation are taxed at the same preferential rates that apply to net long-term capital gains. A foreign corporation is a 'qualified foreign corporation' if it is eligible for the benefits of a comprehensive income tax treaty with the United States (the income tax treaty between Australia and the United States is such a treaty) or its shares or ADSs with respect to which such dividend is paid are readily tradable on an established securities market in the United States (such as the Nasdaq National Market on which our ADSs are traded). Notwithstanding satisfaction of one or both of these conditions, a foreign corporation is not a qualified foreign corporation if it is a passive foreign investment company ('PFIC') for the taxable year of the corporation in which the dividend is paid or the preceding taxable year. A foreign corporation will also not be a qualified foreign corporation with respect to a particular holder (subject to certain limited exceptions) if it was a PFIC for any taxable year in that holder's holding period. Dividends received from a foreign corporation that is not a qualified foreign corporation will be taxed at ordinary income tax rates. As discussed in more detail below, under the section entitled 'Taxation—Passive Foreign Investment Companies,' there is a risk that we will continue to be a PFIC in the future.

If a distribution is paid in Australian dollars, the U.S. dollar value of such distribution on the date of receipt is used to determine the amount of the distribution received by a U.S. Holder (and the amount of Australian tax withheld, if any). A U.S. Holder who continues to hold such Australian dollars after the date on which they are received, may recognize gain or loss upon their disposition due to exchange rate fluctuations. Generally such gains and losses will be ordinary income or loss from U.S. sources.

U.S. Holders may deduct Australian tax withheld from distributions they receive from us for the purpose of computing their U.S. federal taxable income or alternatively elect to claim a foreign tax credit against their U.S. federal income tax liability for such taxes. The foreign tax credit is subject to a number of limitations and the rules governing its determination are very complex. Prospective U.S. Holders should consult their own tax advisors to determine whether and to what extent they would be entitled to claim a foreign tax credit.

Corporate U.S. Holders generally will not be allowed a dividends received deduction with respect to dividends they receive from us.

##### *Sale of Ordinary Shares and ADSs by U.S. Holders*

Subject to the PFIC rules discussed below, a U.S. Holder that sells or otherwise disposes of ordinary shares or ADSs will recognize capital gain or loss equal to the difference between the U.S. dollar value of the amount realized and its adjusted tax basis in those ordinary shares or ADSs. This gain or loss generally will be capital gain or loss from U.S. sources, and will be long-term capital gain or loss if the U.S. Holder held its shares for more than 12 months. Generally, the net long-term capital gain of a non-corporate U.S. Holder recognized before January 1, 2009 is subject to tax at a top marginal rate of 15%. Capital gain that is not long-term capital gain is taxed at ordinary income tax rates.

## *Passive Foreign Investment Companies*

We will be a PFIC if in any taxable year either: (a) 75% or more of our gross income consists of passive income; or (b) 50% or more of the value of our assets is attributable to assets that produce, or are held for the production of, passive income. Subject to certain limited exceptions, if we meet the gross income test or the asset test for a particular taxable year, ordinary shares or ADSs held by a U.S. Holder in that year will be treated as shares of a PFIC ("Pharmaxis PFIC Shares") for that year and all subsequent years in the U.S. Holder's holding period, even if we fail to meet either test in a subsequent year.

Gain realized from the sale of Pharmaxis PFIC Shares will be subject to tax under the excess distribution regime, unless the U.S. Holder makes one of the elections discussed below. Under the excess distribution regime, federal income tax on a U.S. Holder's gain from the sale of Pharmaxis PFIC Shares would be calculated by allocating the gain ratably to each day the U.S. Holder held its ordinary shares or ADSs. Gain allocated to years preceding the first year in which we were a PFIC in the U.S. Holder's holding period, if any, and gain allocated to the year of disposition would be treated as gain arising in the year of disposition and taxed as ordinary income. Gain allocated to all other years (the "Pharmaxis PFIC Years") would be taxed at the highest tax rate in effect for each of those years. Interest for the late payment of tax would be calculated and added to the tax due for each of the Pharmaxis PFIC Years, as if the tax was due and payable with the tax return filed for that year. A distribution that exceeds 125% of the average distributions received on Pharmaxis PFIC Shares by a U.S. Holder during the 3 preceding taxable years (or, if shorter, the portion of the U.S. Holder's holding period before the taxable year) would be taxed in a similar manner.

A U.S. Holder may avoid taxation under the excess distribution regime by making a qualified electing fund ("QEF") election. For each year that we would meet the PFIC gross income test or asset test, an electing U.S. Holder would be required to include in gross income, its pro rata share of our net ordinary income and net capital gains, if any. The U.S. Holder's adjusted tax basis in our shares would be increased by the amount of such income inclusions. An actual distribution to the U.S. Holder out of such income inclusions would not be treated as a dividend and would decrease the U.S. Holder's adjusted tax basis in our shares. Gain realized from the sale of our ordinary shares or ADSs covered by a QEF election would be taxed as a capital gain. A U.S. Holder may make a QEF election, only if we agree in advance to provide the U.S. Holder the information necessary to allow the U.S. Holder to comply with the QEF rules. Due to the administrative burden associated with our providing this information to each U.S. Holder, we will not agree to provide this information to U.S. Holders. Accordingly, a U.S. Holder will not be eligible to make a QEF election.

A U.S. Holder may also avoid taxation under the excess distribution regime by timely making a mark-to-market election. An electing U.S. Holder would include in gross income the increase in the value of its Pharmaxis PFIC Shares during each of its taxable years and deduct from gross income the decrease in the value of its Pharmaxis PFIC Shares during each of its taxable years. Amounts included in gross income or deducted from gross income by an electing U.S. Holder are treated as ordinary income and ordinary deductions from U.S. sources. Deductions for any year are limited to the amount by which the income inclusions of prior years exceed the income deductions of prior years. Gain from the sale of Pharmaxis PFIC Shares covered by an election is treated as ordinary income from U.S. sources while a loss is treated as an ordinary deduction from U.S. sources only to the extent of prior income inclusions. Losses in excess of such prior income inclusions are treated as capital losses from U.S. sources. A mark-to-market election is timely if it is made by the due date of the U.S. Holder's tax return for the first taxable year in which the U.S. Holder held our ordinary shares or ADSs that includes the close of our taxable year for which we met the PFIC gross income test or asset test. A mark-to-market election is made on IRS Form 8621.

As noted above (under the heading titled 'Ownership of Ordinary Shares and ADSs'), a PFIC is not a qualified foreign corporation and hence dividends received from a PFIC are not eligible for taxation at preferential net long-term capital gain tax rates. Similarly, ordinary income included in the gross income of a U.S. Holder as a result of the holder having made a QEF election or a mark-to-market election, and dividends received from corporations subject to such election, are not eligible for taxation at preferential net long-term capital gain rates.

Based on an analysis of our gross income and the value of our assets, we believe that, we were a PFIC for our taxable years ended 30 June, 2008, 30 June 2006, 30 June 2005 and 30 June 2004, but we were not a PFIC for our taxable year ended 30 June 2007.

#### **4.2.7 Taxation Summary Applicable to U.S. Holders (continued)**

##### *U.S. Information Reporting and Backup Withholding*

United States information reporting and backup withholding requirements may apply with respect to distributions to U.S. Holders, or the payment of proceeds from the sale of shares, unless the U.S. Holder: (a) is an exempt recipient (including a corporation); (b) complies with certain requirements, including applicable certification requirements; or (c) is described in certain other categories of persons. The backup withholding tax rate is currently 28%. Any amounts withheld from a payment to a U.S. Holder under the backup withholding rules may be credited against any U.S. federal income tax liability of the U.S. Holder and may entitle the U.S. Holder to a refund.

#### **4.2.8 Documents on Display**

We file annual reports and other information with the Australian Securities Exchange and certain information with the Australian Securities and Investments Commission. Information filed with the Australian Securities Exchange is available from [www.asx.com.au](http://www.asx.com.au) or from our website [www.pharmaxis.com.au](http://www.pharmaxis.com.au). Information filed with the Australian Securities and Investments Commission is available through [www.asic.gov.au](http://www.asic.gov.au).

We also file annual reports and other information with the U.S. Securities and Exchange Commission. We will file annual reports on Form 20-F and submit other information under cover of Form 6-K. As we are considered a foreign private issuer by the U.S. Securities Exchange Commission, we are exempt from the proxy requirements of Section 14 of the Exchange Act and our officers, Directors and principal shareholders will be exempt from the insider short-swing disclosure and profit recovery rules of Section 16 of the Exchange Act. Annual reports and other information we file with the U.S. Securities Exchange Commission may be inspected at the public reference facilities maintained by the Commission at Room 1024, Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549, and at its regional offices located at 233 Broadway, New York, New York 10279 and 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and copies of all or any part thereof may be obtained from such offices upon payment of the prescribed fees. You may call the U.S. Securities Exchange Commission from the U.S. by dialing 1-800-SEC-0330 for further information on the operation of the public reference rooms and you can request copies of the documents upon payment of a duplicating fee, by writing to the U.S. Securities Exchange Commission. In addition, the U.S. Securities Exchange Commission maintains a web site that contains reports and other information regarding registrants (including us) that file electronically with the Commission which can be accessed at [www.sec.gov](http://www.sec.gov).

#### **4.2.9 Enforceability of Civil Liabilities by U.S. Shareholders**

We are a public company incorporated and domiciled under the laws of Australia. A majority of our Directors and executive officers are residents of countries other than the United States. Furthermore, all or a substantial portion of their assets and our assets are located outside the United States. As a result, it may not be possible for our U.S. shareholders to:

- effect service of process within the United States upon any of our Directors and executive officers or on us; or
- enforce in U.S. courts judgments obtained against any of our Directors and executive officers or us in the U.S. courts in any action, including actions under the civil liability provisions of U.S. securities laws;
- enforce in U.S. courts judgments obtained against any of our Directors and senior management or us in courts of jurisdictions outside the United States in any action, including actions under the civil liability provisions of U.S. securities laws; or
- to bring an original action in an Australian court to enforce liabilities against any of our Directors and executive officers or us based upon U.S. securities laws.

You may also have difficulties enforcing in courts outside the United States judgments obtained in the U.S. courts against any of our Directors and executive officers or us, including actions under the civil liability provisions of the U.S. securities laws.



#### 4.2.10 Exchange Rate Information

The following table presents exchange rates of the Australian dollar into the U.S. dollars for the periods indicated. Annual averages are calculated using the average of month-end rates of the relevant year. Monthly averages are calculated using the average of the daily rates during the relevant period.

Period	Average U.S.\$	High U.S.\$	Low U.S.\$
<i>Five most recent financial years</i>			
2004	0.7155	0.7979	0.6390
2005	0.7568	0.7974	0.6880
2006	0.7472	0.7781	0.7056
2007	0.7925	0.8491	0.7407
2008	0.8969	0.9610	0.7860
<i>Six most recent months</i>			
February 2008	0.9133	0.9370	0.9035
March 2008	0.9221	0.9132	0.9409
April 2008	0.9309	0.9419	0.9067
May 2008	0.9492	0.9551	0.9338
June 2008	0.9511	0.9610	0.9342
July 2008	0.9620	0.9797	0.9415
On 15 August the exchange rate was \$0.8676			

## 4.3 Glossary

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

<b>ciliated cell</b>	An epithelial cell which has cilia on its external surface. Found in the lungs and other airway passages such as bronchi and nose.
<b>clinical trial</b>	Refer to explanation/diagram later in this section
<b>Cooperative Research Centre</b>	The CRCAA (formerly the Cooperative Research Centre for Asthma) is an Australian for Asthma and Airways (CRCAA) research cooperative that was expanded in 2006 to include all airways diseases. It focuses on three core areas of airways research: diagnosis and monitoring, new treatments, and assessing the consequences of air quality.
<b>COPD</b>	Chronic obstructive pulmonary disease. Refer to disease information earlier in this section
<b>corticosteroids</b>	Any of the steroid hormones produced by the adrenal cortex or their synthetic equivalents. Corticosteroids are used clinically for hormonal replacement therapy, for suppression of glands such as the anterior pituitary, as anti-cancer and anti-allergic and anti-inflammatory agents, and to suppress the immune response. They may be injected, taken as pills, inhaled via a puffer or rubbed on to the skin.
<b>cystic fibrosis (CF)</b>	Refer to disease information earlier in this section
<b>direct challenge test</b>	The process of directly stimulating receptors in the lung walls and inducing a constriction or narrowing of the airways by administering a substance to the airways that acts directly on the airway wall and testing the response by spirometry. Examples include methacholine and histamine.
<b>dose response curve</b>	A dose response curve illustrates the relation between the amount of a drug or other chemical administered to a person or an animal and the degree of response it produces.
<b>dosing phase</b>	Refer to explanation/diagram later in this section
<b>endothelial</b>	An endothelial cell layer refers to the layer of cells that lines the blood vessels and airways
<b>epithelial mast cells</b>	Mast cells are a variety of leukocytes or white blood cells containing granules that store a variety of inflammatory chemicals including histamine and serotonin. Mast cells play a central role in inflammatory and immediate allergic reactions. The release of mediators from the cell is known as degranulation and may be induced by the presence of a specific antigen (allergen). Epithelial mast cells are those found in the epithelium (the membranous tissue composed of one or more layers of cells separated by very little intercellular substance and forming the covering of most internal and external surfaces of the body and its organs. Skin and the lung linings are two examples of epithelium.)
<b>eucapnic hyperpnoea</b>	Eucapnic (adjective) is defined as a normal healthy level of carbon dioxide (CO <sub>2</sub> ). Hyperpnoea is abnormally fast breathing.
<b>European Medicines Agency (EMA)</b>	The EMA is an agency that coordinates the evaluation and supervision of medicinal products throughout the European Union.
<b>exercise challenge test</b>	A test in which patients undertake a physical activity, such as exercise, running or bike riding, and the body's response to the activity is measured. It can be used to determine if a patient is asthmatic by measuring the degree of bronchial constriction that is induced during a period of exercise.
<b>exocrine glands</b>	Glands that produced mucus, saliva, sweat and tears
<b>FDA</b>	United States of America's Food and Drug Administration
<b>flare or flare-up</b>	A period of worsening symptoms
<b>GMP</b>	Good Manufacturing Practice – set of principles and procedures which, when followed by manufacturers of therapeutic goods, helps ensure that the products manufactured will have the required quality goblet cell A mucus-secreting epithelial cell that is distended with secretion, so called because of its histological shape.
<b>head-to-head trial</b>	A clinical trial in which a test compound is evaluated against another compound
<b>hypertonic saline</b>	A solution with a higher salt concentration than in normal cells of the body and the blood. A salt solution containing more than 0.9% salt is hypertonic.
<b>indirect challenge test</b>	The process of indirectly inducing a constriction or narrowing of the airways by causing cells in the airways to release molecules that subsequently act on the airway, and testing the response by spirometry. Mannitol mimics an allergen challenge or asthma attack. The attack can be controlled by administering increasing doses and the response at each dose is measured. Other examples include exercise and hypertonic saline.

#### 4.3 Glossary (Continued)

<b>International Committee on Harmonisation (ICH)</b>	An international body that provides test guidelines that cover the manufacture of drug substances, the manufacture of the dosage form, and the safety testing that must be conducted before evaluation in humans can proceed
<b>in vitro</b>	In an artificial environment, outside the living body e.g. in a test tube
<b>in vivo</b>	In the living body of a plant or animal, or in real life
<b>leukocytes</b>	Immune cells; white blood cells
<b>ligand</b>	A molecule that binds to cell receptors
<b>lung function</b>	Ability of a person to move air in and out of their lungs. A measure often used is termed FEV <sub>1</sub> , which is the volume of air that can be forcibly expelled from the lungs in one second
<b>lymphocyte</b>	A type of white blood cell found in the body's lymph, a clear fluid that flows through the body and has an important function in defending the body against disease
<b>mannitol</b>	Mannitol is a naturally occurring sugar alcohol used variously as a food additive, a therapeutic product, and a sweetener.
<b>marketing authorisation</b>	The legal authority granted to an individual or company to sell a product
<b>meta-analysis</b>	Pooling and examining data from a number of studies
<b>methacholine inhalation test</b>	A test used in the diagnosis of asthma. Methacholine is inhaled as a vapour and causes bronchial constriction in asthmatic patients.
<b>mucociliary clearance</b>	A constant, natural process where the cilia lining the lungs move continuously and propel the overlying blanket of salt, water and mucus up to the throat, where secretions are swallowed or expelled as sputum. This helps keep the airways clean, allows the passage of clean, warm air through the lungs, and removes any foreign bodies from the airways, preventing infection.
<b>mucosal hydration</b>	The natural process of keeping mucus hydrated to prevent it becoming thick and sticky i.e. maintaining the correct balance of water mucus Thin, slippery substance secreted by the lungs (and other organs in the body) to defend against germs, dust particles and other foreign bodies
<b>multi-centre study</b>	Study conducted simultaneously in a number of clinics, hospitals, etc
<b>multiple sclerosis (MS)</b>	Refer to disease information earlier in this section
<b>myelin</b>	The protective protein sheath that insulates the nerve cells and helps speed the conduction of nerve signals to the brain and spinal cord
<b>NASDAQ</b>	National Association of Securities Dealers Automated Quotation system (US)
<b>nebulised medication</b>	Medication delivered to the lungs of patients in fine spray by aerosol or face mask
<b>oral medication</b>	Medication taken by mouth e.g. tablets, liquids
<b>orphan drug</b>	A product intended for the diagnosis, prevention and treatment of a rare disease (orphan disease) or condition where current therapy would be improved or no therapy exists.
<b>osmotic balance</b>	Osmosis is the passage of water from a region of high water concentration through a semi-permeable membrane, such as a cell, lung or intestinal wall, to a region of low water concentration. Osmotic balance is when there is no tendency for water to flow across the membrane.
<b>P3</b>	Pharmaceuticals Partnerships Program (Australian Federal government grant program)
<b>pathogen</b>	Disease-causing microorganism
<b>PBS</b>	Pharmaceutical Benefits Scheme (Australian government program that reduces the cost of some drugs to patients)
<b>PCT</b>	Patent Cooperation Treaty
<b>PEP mask</b>	A mask worn over the nose and mouth, which pumps air into the lungs (positive expiratory pressure)
<b>pharmaco-economic evaluation</b>	Evaluation of the potential of a new pharmaceutical product to produce cost savings to a national economy
<b>pharmacokinetic profile</b>	How a drug interacts in the body in terms of its absorption, distribution, metabolism, and excretion

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

## 4.4 Corporate Directory

### Directors

Denis Hanley – Chairman  
Alan Robertson – Chief Executive Officer  
William Delaat  
Peter Farrell  
Malcolm McComas  
John Villiger

### Company Secretary and Chief Financial Officer

David McGarvey

### General Counsel

Cameron Billingsley

### Corporate Affairs

Virginia Nicholls

### Registered Office

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### Web Site

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Australia

### Venable LLP

575 7th Street, NW  
Washington, DC 20004  
United States of America

### Auditor

PricewaterhouseCoopers  
Darling Park Tower 2  
201 Sussex Street  
Sydney NSW 2000  
Australia

### Bankers

HSBC Bank Australia Ltd  
Westpac Banking Corporation

### Securities 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

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Telephone: +61 3 9415 4000  
(within Australia: 1300 855 080)  
Fax: +61 3 9473 2500  
www.computershare.com

### American Depositary Receipts

#### Registrar and Transfer Agent:

BNY Mellon Shareowner Services  
480 Washington Blvd., 27th floor  
Jersey City, NJ 07310  
United States of America  
Telephone within the U.S.: (201) 680-4000  
Telephone outside the U.S.: +1 201 680 6825

### U.S. Agent for Service of Notice

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### Incorporation Information

Incorporated in Australia  
Australian Company Number 082 811 630  
Australian Business Number 75 082 811 630



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