



pharmaxis

# New Therapies for Respiratory Diseases

2009 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)

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 thereby forming part of the report. All other references in this report to websites are inactive textual references and the information contained therein is not incorporated by reference into this 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. 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.

## 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') on which we listed in November 2003. Our American Depositary Shares ('ADS') are traded in the over-the-counter market in the U.S. Each ADS represents 15 ordinary shares.

We have completed share and ADS issues which are described in Section 2.2.5 – Liquidity and Capital Resources.

Our principal place of business is 20 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 (CF), chronic obstructive pulmonary disease (COPD) and bronchiectasis; and for the treatment of other acute and chronic pulmonary conditions. Bronchitol has not yet been approved for any indication in any market.

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

- In May 2009 we reported the headline results of a Phase III clinical trial of Bronchitol in patients with CF in Europe and Australia, conducted according to a clinical trial protocol agreed with the European Medicines Agency, or EMEA. The clinical trial demonstrated a statistically significant early and sustained improvement in lung function relative to control over a twenty six week treatment period. The study also demonstrated a statistically significant improvement in lung function in patients already being treated with the most commonly used CF therapeutic, rhDNase.

- In June 2009 we agreed with the European Medicines Agency a timetable for submission of a marketing authorization application for Bronchitol for the treatment of cystic fibrosis for the second half of 2009.
- In 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.
- In 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 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 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.
- 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 and a significant change in mucus clearance on patients receiving Bronchitol versus those patients receiving placebo.
- In 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 applied for marketing approval of Bronchitol for the treatment of bronchiectasis in Australia in September 2008.
- In 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 COPD and patients within hospital intensive care units.

### **Aridol**

We have developed Aridol (mannitol bronchial challenge test), as a novel tool for the detection of airway hyperresponsiveness and to assist in the diagnosis and management of asthma. 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 2009 at which time Belgium was still being processed.
- We received marketing approval in South Korea in January 2008 and await pricing approval before a full commercial launch.

### 1.2.2 Business Overview (continued)

- In March 2009 we submitted a new drug application to the U.S. Food and Drug Administration (FDA) for Aridol. In May 2009 the FDA accepted the submission for review and advised that its response will be received on 27 December 2009.
- In 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.
- 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 fibrotic and inflammatory diseases, including asthma and other pulmonary conditions. PXS25 has been identified as an antifibrotic agent and PXS4159 has been identified as an anti-inflammatory agent. Preclinical trials have been completed with PXS25 and during the next twelve months PXS25 is scheduled to commence Phase I clinical trials. Preclinical trials are in progress with PXS4159 to determine its suitability for Phase I human clinical trials. 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 other chronic and acute pulmonary conditions including COPD and bronchiectasis. 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 mechanisms of 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 2008 was 37.4 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 are also usually required to treat secondary infections, and to prevent infection.

rhDNase 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 rhDNase were approximately U.S.\$275million in 2008. Based on our clinical trials we estimate that rhDNase has a market penetration in the U.S. of about 60% and in the major European pharmaceutical markets of Germany, France, United Kingdom, Italy and Spain of about 50%. Although rhDNase demonstrates lung function improvement in CF patients, similar benefit was not shown in other respiratory conditions, including bronchiectasis.

### ***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, 210 million people suffer from COPD and the disease was responsible for 3 million deaths 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.

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 can lead 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

## 1.2.2 Business Overview (continued)

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 may cause 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 is 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.

### **(iii) Bronchitol Development**

We are developing Bronchitol, our proprietary inhaled mannitol formulation, for the treatment of chronic respiratory diseases, including cystic fibrosis, COPD, bronchiectasis 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 26 week Phase III clinical trial involving 324 cystic fibrosis patients sponsored by us, Bronchitol demonstrated a statistically significant, early and sustained improvement in lung function relative to control, determined by the change in Forced Expiratory Volume in 1 second, known as FEV<sub>1</sub>. The improvement in FEV<sub>1</sub> at 26 weeks was 6.5%. The study also demonstrated a statistically significant improvement in lung function in patients irrespective of treatment with the most commonly used CF therapeutic, rhDNase.

In June 2009 we agreed with the European Medicines Agency a timetable for submission of a marketing authorization application for Bronchitol for the treatment of cystic fibrosis for the second half of 2009.

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 measured by 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%.

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.

### 1.2.2 Business Overview (continued)

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.

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. It has been 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 May 2009, we announced results from a Company sponsored Phase III clinical trial involving 324 patients with cystic fibrosis. The trial was a multi-centre, randomised, double blind, placebo controlled, 26 week study, with an optional further 6 month open label uncontrolled period. It was conducted in 40 centres in the United Kingdom, Ireland, Australia and New Zealand. The primary endpoint of the trial was to assess whether Bronchitol improves lung function as measured by a change in FEV<sub>1</sub> when administered twice per day for six months. FEV<sub>1</sub> 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 key secondary endpoint of the trial was to assess whether Bronchitol further improves lung function in patients already being treated with the most commonly used CF therapeutic, rhDNase. Additional endpoints included changes in the Forced Vital Capacity (FVC) of the lung, pulmonary exacerbations and antibiotic use. Safety evaluation included the incidence of adverse events and the microbiology of sputum samples. The study was designed in consultation with the European Medicines Agency (EMA).

For the 324 subjects randomized, the treatment groups were balanced with respect to key demographic and background characteristics: the average age was approximately 23 years old, the mean lung function on entry to the trial was 62% of the predicted normal FEV<sub>1</sub>, and 55% of the population were using rhDNase. The ages ranged from 6 years to 56 years and the lung function ranges were from 26% to 94% of the predicted FEV<sub>1</sub>.

In this trial, Bronchitol had a positive impact on lung function. There was a clinically meaningful change from baseline (119mL) and placebo (93mL) at week 26 with Bronchitol for FEV<sub>1</sub> ( $p < 0.001$ ). Importantly, treatment with Bronchitol showed an early and sustained improvement in lung function (FEV<sub>1</sub>) over the 26 weeks ( $p < 0.001$ ). For the subgroup of patients on concomitant rhDNase there was also a significant improvement in FEV<sub>1</sub> from baseline (88mL) and from placebo (109mL) at week 26 with Bronchitol ( $p = 0.002$ ). Again, there was an early and sustained improvement in FEV<sub>1</sub> over the 26 week period of the study ( $p = 0.008$ ). While the study was not powered to show a reduction in the secondary endpoint of exacerbation, the rate of a protocol defined pulmonary exacerbation (PDPE) per subject for the 26 weeks was lower for Bronchitol versus control: overall reduction in rate of 25% ( $p = 0.2$ ). There was a non significant increase in time to first PDPE ( $p = 0.1$ ) for the intention to treat group, however, for the per protocol population, i.e. those who were mostly compliant with therapy and stayed in the study, there was a significant increase in time to first PDPE ( $p = 0.026$ ). There was a clinically meaningful change from baseline (129mL) and control (113mL) at week 26 with Bronchitol for FVC of the lung ( $p = 0.002$ ). Additionally, treatment with Bronchitol showed an early and sustained improvement in lung capacity (FVC) over the 26 week treatment period ( $p < 0.001$ ).

In relation to safety, there was a similar number of adverse events and serious adverse events per treatment group, with no deaths in the study. Respiratory adverse events that were more common with Bronchitol compared with placebo, included cough (25.4% versus 20.3%), haemoptysis (11.9% versus 8.5%) and pharyngolaryngeal pain (13.6% versus 4.2%). There were similar rates between the groups for adverse events of particular interest including: wheezing, asthma and bronchospasm (Bronchitol 4.5% versus 5.9%). At screening 7% of patients were ineligible to participate due to suspected undiagnosed hyperreactive airway disease. Overall infections were lower in the Bronchitol group (39% versus 47.5%). There was no difference in microbial growth for specific microorganisms between treatment groups, confirming that Bronchitol does not contribute to the bacterial load in the lung.

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 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 rhDNase 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. 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 patients at risk of developing bronchiectasis. 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 rhDNase in children. Both Bronchitol and rhDNase 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	8.8%*	8.1%*
240 mg treatment group	3.9%	3.1%
120 mg treatment group	3.6%	1.7%
40 mg treatment group	(1.6%)	(0.9%)

\*p<0.0005 relative to 40 mg dose



### 1.2.2 Business Overview (continued)

No serious adverse events emerged during treatment periods and the adverse event profile was similar across all doses.

In September 2008 we commenced a second Phase III trial with Bronchitol in cystic fibrosis, having agreed the clinical trial protocol with the U.S. FDA under its Special Protocol Assessment procedure. This trial is the second of two required by the FDA before a New Drug Application (NDA) can be submitted for Bronchitol to treat cystic fibrosis and is a multi-centre, randomised, double blind, placebo controlled, 26 week study being conducted in 300 subjects with cystic fibrosis at 65 sites in the U.S., Canada, Argentina, France, Germany, Belgium and the Netherlands. The clinical trial is studying 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> over 26 weeks. Additional endpoints of the trial included a reduction in exacerbation frequency, quality of life and other lung function measurements. The trial is due to complete recruitment during the third quarter of 2009 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.

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

In 2007 we completed a Phase III clinical trial of Bronchitol in 362 bronchiectasis subjects. This placebo-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. 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 placebo 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 placebo ( $p < 0.05$ ). 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.

In 2004 we completed a proof of concept Phase II clinical trial of Bronchitol in 60 bronchiectasis subjects. We began this placebo-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 placebo, twice a day for 14 days. 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 placebo, there was a statistically significant improvement in the Epworth sleep score ( $p<0.02$  versus placebo). 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 placebo ( $p<0.05$ ). 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 placebo 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 placebo 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 ( $p=0.055$ ).

No therapies to enhance mucus clearance in bronchiectasis patients have been approved in over 20 years in the U.S. In 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. We expect to commence dosing in this trial during the third quarter of 2009.

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 clinical trials in patients with chronic bronchitis. The objective of these trials will be to determine if Bronchitol assists in clearing mucus and improving the clinical outcome after an exacerbation requiring hospitalization.

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 2009 at which time Belgium was still being processed. We received marketing approval in Korea in January 2008. In 2009 we received marketing approval in Switzerland, Singapore and Malaysia.

In October 2006 we completed a 509 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 submitted a New Drug Application (NDA) with the FDA in March 2009. In May 2009 the FDA accepted the submission for review and advised that its response will be received on 27 December 2009.

Aridol is the subject of 54 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 aid in assessment of disease severity, with a high correlation to in-depth patient assessment by a pulmonary specialist physician;
- help monitor the effectiveness of treatment, with a positive test indicating active airway inflammation and the need to consider 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 60%, 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, Sweden, France, Italy, Spain, Switzerland, Singapore and Malaysia. We have also filed for marketing approval in the U.S..

We utilised our own sales force in Australia to launch Aridol. 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 oversee 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 the 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 509 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 59% of cases (sensitivity). In comparison methacholine, an approved lung function test in the U.S., identified 56% of cases. The difference between the two tests was not statistically significant. Aridol also had similar specificity to methacholine, (65% versus 69% 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 ( $p < 0.05$ ).

### 1.2.2 Business Overview (continued)

Based on this study and the earlier Phase III clinical trial that was the basis of marketing approval in Australia and Europe, we filed a New Drug Application (NDA) with the FDA in March 2009. 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 risk sub-optimal control of this disease, falling 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 ( $p=0.001$ ).

#### **(v) Drug Development**

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

##### **PXS25**

PXS25 is in development for the treatment of pulmonary fibrosis (IPF). According to the U.S. National Heart Lung and Blood Institute, there are about 200,000 Americans with pulmonary fibrosis and about 50,000 new cases are diagnosed each year. IPF mostly affects people who are 50 to 75 years of age. IPF varies from person to person. In some people, the lung tissue quickly becomes thick and stiff. In others, the process is much slower. In some people, the condition stays the same for years. IPF has no cure yet. Many people live only about 3 to 5 years after diagnosis. The most common cause of death related to IPF is respiratory failure.

We believe there are over 500,000 people in the major pharmaceutical markets with pulmonary fibrosis.

PXS25 has been developed as an antifibrotic agent and has shown promising activity in a number of biochemical and cellular assays. Its activity is believed to be due to its ability to interfere with the function of tissue growth factor – a protein partially responsible for wound repair.

PXS25 is an effective antifibrotic agent in multiple cell lines and has potential utility outside of the lung – for example in kidney fibrosis. PXS25 works by inhibiting the function of TGF $\beta$ .

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. Following approval from the ethics committee and the regulatory agencies, we plan to begin the Phase I trial during the second half of 2009.



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.

PXS25 has demonstrated antifibrotic activity in the eye and in the kidney and the skin and may find additional clinical utility in fibrotic disorders outside of the lung.

## **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 form 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. PXS4159, is effectively absorbed following oral administration and is well tolerated. On this basis, we selected PXS4159 as our preferred development candidate and commenced scale up manufacture and the pre-clinical safety studies necessary to evaluate the compound in humans. The preclinical safety studies are in progress.

## **(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 first Phase III clinical trial, commenced recruitment of our second Phase III clinical trial (in Europe, the U.S., Canada and Argentina) and agreed a European marketing authorization application submission timetable with the EMEA. 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 are about to commence dosing, and have filed 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 and supply of clinical trial material. We have just taken possession of a purpose built manufacturing, research and office facility in which additional manufacturing capacity is currently being installed, commissioned and validated 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 parts of Europe, Australia and parts of Asia, filed 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 and suitable partners identified and appointed.
- *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. We have commenced detailed planning for the commercial launch of Bronchitol in Europe and the U.S.

## 1.2.2 Business Overview (Continued)

- *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.

### (vii) Sales and Marketing

We have a sales and marketing group in Australia and the United Kingdom 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 regional 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 currently manufacture both Aridol and Bronchitol in our TGA licensed production facility located at Unit 2, 10 Rodborough Road Frenchs Forest, Sydney, Australia, under conditions of current Good Manufacturing Practice, known as cGMP. The 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 an exclusive basis through a supply agreement.

We believe that our manufacturing facility at Unit 2, 10 Rodborough Road 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.

In May 2009 we took possession of a 7,200 square metre purpose built manufacturing, warehousing, research and office facility, located at 20 Rodborough Road Frenchs Forest, Sydney Australia. We lease our facility at 20 Rodborough Road under a 15 year agreement, with the option of two lease extensions of five years each. Within this new facility we are in the process of installing, commissioning and validating various pieces of equipment so as to provide us with increased capacity sufficient for a commercial launch of Bronchitol. We are currently scheduled for the new facility to be fully operational, inspected and licensed by the middle of 2010.

Our cGMP facilities at Unit 2, 10 Rodborough Road 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 2009, 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 PXS25 and PXS64 and a further application relates to PXS4159 and this is at the PCT stage. 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 Enterprise 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.

## 1.2.2 Business Overview (Continued)

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., the E.U. 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 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 8 – Novel inhibitors of SSAO/VAP-1 (PXS4159)	PCT			
Patent Family 9 – Novel pyrans for the treatment of fibrotic disorders	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; 23 Feb 1995).

***Patent Family 2 – Phosphosugar-Based Anti-Inflammatory and/or Immunosuppressive Drugs***

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

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

This family of patents is owned by The Australian National University (‘ANU’) and claims priority to Australian Provisional application P19942/88 filed on 19 August 1988. Subsequently, complete applications were based on a PCT application (PCT/AU89/00350) filed 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 autoimmune encephalomyelitis in the rat (a model of multiple sclerosis) and two different types of delayed-type hypersensitivity responses in mice. Issued claims in the U.S. patent cover some of these novel phosphosugar compositions and methods of treating cell-mediated inflammation in a human or non-human mammalian patient by administering these compositions.

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

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

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

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

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

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

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

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

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

#### **Patent Family 9 – Novel pyrans for the treatment of fibrotic disorders**

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. 61/173,416	Provisional Application	20 years from filing date

The U.S. provisional application was filed in the name of Pharmaxis Ltd on 28 April 2009 and the non-provisional and/or the international application must be filed by no later than 28 April 2010 in order to claim priority from this provisional application.

#### **(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.

## 1.2.2 Business Overview (continued)

### ***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 Authorization 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, either in the United States or abroad.

## **(xii) Employees**

The table below presents certain information regarding our employees and full time contractors as of 30 June 2007, 2008 and 2009, respectively.

<b>As at June</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>
Research and development	38	35	27
Manufacturing	37	35	26
Commercial	8	11	9
Administration	10	5	6
	<b>93</b>	<b>86</b>	<b>68</b>

Our main office facility is at Frenchs Forest, Sydney. We also have an office in the United Kingdom where we base a commercial team and a clinical research team; an office in the United States where we have a commercial team, a clinical research team and a regulatory team; and a representative office of two in China.

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. 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 law. The notice periods in our contracts of employment are equal to or exceed the minimum requirements.

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

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.

## 1.2.2 Business Overview (continued)

### (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 no current grants that assist us in funding any of our research programs.

Our most recent grant that concluded at 30 June 2008 was under the AusIndustry P3 Pharmaceuticals Partnerships Program under which 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.

## 1.2.3 Organizational 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 2009 we lease the following facilities:

- Approximately 7,200 square metres of purpose built manufacturing, warehousing, research and office facility, located at 20 Rodborough Road Frenchs Forest, Sydney Australia. We commenced the lease of 20 Rodborough Road under a 15 year agreement, 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. As of 30 June 2009 we had spent approximately A\$18 million on the fitout of this facility and manufacturing equipment.
- Approximately 1,800 square metres of manufacturing, warehouse and office space at Unit 2, 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.
- Approximately 110 square metres of office space located at Basepoint Business & Innovation Centre 110 Butterfield Grey Luton, Bedfordshire, UK. Our UK office is located at these premises. Our lease is terminable at a minimum of two weeks notice to the end on the last day of a calendar month.
- Approximately 300 square metres of office space located at 403 Gordon Drive Exton, PA 19341, U.S.. Our U.S. office is located at these premises. Our lease is terminable at 180 days notice.

Until May 2009 we licensed approximately 20 square metres of research laboratory and office space at Building 34, 1 Rivett Road, Riverside Corporate Park, North Ryde, Sydney, Australia. We terminated this license when our research staff based at this site relocated to our new facility at Frenchs Forest in May 2009.

## 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.

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 13 August 2009. 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 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.



### 1.3.2 ASX Disclosures (continued)

#### ***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 seven directors, including six 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 six non-executive Directors, Messrs. Delaat, Farrell, Hanley, McComas, van den Broek and Villiger 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.

#### ***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 2009. 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 2009 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.

Review of individual director performance is considered and assessed by the relevant Board or Committee chair.

## **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.

### 1.3.2 ASX Disclosures (continued)

#### *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*
- *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 names of the members of the Audit Committee, their qualifications, the number of meetings held in the financial year ended 30 June 2009 and the number of meetings attended by each member is detailed in Section 1.4.2 of this Statutory Annual Report.

#### *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. 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.

Our Remuneration and Nomination Committee consists exclusively of 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.

## 1.4 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 2009.

### 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 53)*, 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 62)*, 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 67)*, 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 was a member of our Remuneration and Nomination Committee until 18 June 2009.

*Malcolm J. McComas (age 55)*, 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 Ocean Capital Limited and is deputy chairman of Finsia, the Financial Services Institute of Australasia. Mr. McComas was previously non-executive chairman of Sunshine Heart Inc. until December 2008. Mr. McComas holds a Bachelor of Economics and a Bachelor of Laws from Monash University. Mr McComas is chairman of our Audit Committee.

*Richard A. van den Broek (age 43)*, was appointed a member of our Board of Directors on 7 April 2009. Mr. van den Broek is a life science investment manager with over 18 years experience in the biotech industry. Mr van den Broek is founder and managing partner of HSMR Advisors LLC, a U.S. based fund manager with an investment emphasis on small and mid-cap biotech public companies. Prior to this Mr. van den Broek was a Partner at Cooper Hill Partners, LLC, an investment fund focused on the healthcare sector and earlier in his career worked as a biotech analyst, at Oppenheimer & Co., then Merrill Lynch, and finally at Hambrecht & Quist. Mr van den Broek is a Chartered Financial Analyst, and is a graduate of Harvard University. Mr. van den Broek is a member of our Remuneration and Nomination Committee.

*John Villiger, Ph.D. (age 57)*, has been a member of our Board of Directors since November 2006. Dr. Villiger is executive chairman of Proacta Inc. 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.

*William L. Delaat (age 59)*, has been a member of our Board of Directors since June 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.

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 2009, and the number of meetings attended by each Director was:

	Board		Meetings of Committees			
	Meetings		Audit		Remuneration & Nomination	
	A	B	A	B	A	B
DM Hanley	10	10	3	3	4	4
AD Robertson	10	10				
WL Delaat	10	10	3	3		
MJ McComas	10	10	3	3		
PC Farrell	10	4			4	1
RA van den Broek	6	6			1	1
J Villiger	10	9			4	3

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 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.

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 \$168,000 to insure the directors and officers of the Group for the policy year ended 25 September 2009. 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 respiratory diseases.

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

A review of the operations of the Group for the financial year ended 30 June 2009 is set out in Section 2.2 of this Statutory Annual Report.

#### **1.4.7 Remuneration Report, Shares Under Option and Shares Issued on the Exercise of Options**

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.

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

The share placement and share purchase plan conducted in June 2009 increased cash funds by A\$51.2 million after deducting associated expenses. Together with pre-existing funds the Group ended the year with A\$125.0 million in cash and bank accepted commercial bills. Capital expenditure for the 2009 financial year of A\$11.5 million compares

to A\$5.1 million in 2008. Expenditure was predominantly related to the fit out of the new facility which has been constructed for us and additional manufacturing equipment housed in the new facility. During the year we entered into a 15 year lease of our new facility as a result of which we have recognized a leased building and a financial lease obligation of approximately \$13.9 million. Refer also to Section 2.2.5 of this Statutory Annual Report.

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

On 23 July 2009 the Group voluntarily de-listed from the Nasdaq Global Market, based on a review of the demand from existing and potential international investors for the secondary listing of its American Depositary Shares ('ADS's') on Nasdaq and the volume of Pharmaxis ADS trading in the secondary Nasdaq market. The Group is also withdrawing its registration with the U.S. Securities and Exchange Commission ('SEC') which is expected to be effective on 21 October 2009. SEC reporting requirements were suspended from 3 August 2009.

No other matter or circumstance has arisen since 30 June 2009 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 is applying 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 22 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 2009, 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

13 August 2009

#### 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

13 August 2009

## 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 Pharmaxis Ltd Employee option plan.

#### **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 2009 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 Executive Officers 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.

During the year the Group initiated a review of its equity-based remuneration policies as a consequence of growth, increasing employee numbers, the change in the Group's shareholder base and the upcoming transformation of the Group into an operating business. The announcement of significant changes to the Australian taxation of equity-based remuneration resulted in this review being suspended until these changes are enacted and further clarified. The Board did however proceed with changes to equity based remuneration of Non Executive Directors, as discussed below. In addition, the Group brought forward the annual option grant to employees from August to June 2009 in order to fall within the former Australian taxation regime. Certain of the following disclosures therefore include options grants in August 2008 with respect to employee performance in the 2008 financial year and option grants in June 2009 with respect to employee performance in the 2009 financial year.

### ***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;
- the chairman is also paid an office allowance of \$2,400.
- Non-Executive Directors are permitted to package their remuneration to include superannuation and, until 30 June 2007, options in the Group granted under our Employee Option Plan.

Historically Independent Directors were issued 200,000 options on becoming a Director of the Company, subject to shareholder approval. The options vested over four years.

The current year review of equity-based remuneration discussed above assessed the ongoing value of equity grants in attracting Independent Directors and reviewed current Australian and international perspectives on forms of equity grant. The Board has now adopted the policy of granting newly appointed directors 30,000 fully paid shares in the Group, subject to shareholder approval in each instance. The shares are to be restricted from sale by the director for three years from the date of grant, except in the case of a takeover offer being made for the Group in which case the shares are available for sale.

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 Australia 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. Between 2003 and 2005 the group also granted founder options and sign-on options which vested over shorter periods.

Base pay for 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 33 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
Howard George Fox	Chief Medical Officer	Pharmaxis Ltd
Ian Alexander McDonald	Chief Scientific 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.



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

Name	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>	117,079	–	–	10,321	–	4,298	131,698
WL Delaat	65,000	–	–	–	–	78,885	143,885
MJ McComas	70,000	–	–	–	–	2,149	72,149
PC Farrell	65,000	–	–	–	–	45,807	110,807
J Villiger	64,996	–	–	–	–	79,165	144,161
R van den Broek <sup>2</sup>	14,151	–	–	–	–	–	14,151
<b>Sub-total Non-Executive Directors</b>	<b>396,226</b>	<b>–</b>	<b>–</b>	<b>10,321</b>	<b>–</b>	<b>210,304</b>	<b>616,851</b>
<i>Executive Director</i>							
AD Robertson	353,903	88,000	–	32,441	983	288,166	763,493
<i>Senior Executive Officers</i>							
B Charlton	270,113	40,000	–	24,310	751	228,096	563,270
JF Crapper	253,575	40,000	–	22,822	175	223,590	540,162
HG Fox <sup>3</sup>	102,388	13,500	–	7,595	190	30,737	154,410
IA McDonald	204,000	40,000	–	18,360	257	223,010	485,627
DM McGarvey	281,138	40,000	–	25,302	(220)	223,590	569,810
GJ Phillips	275,625	40,000	–	24,807	(255)	223,979	564,156
<b>Totals</b>	<b>2,136,968</b>	<b>301,500</b>	<b>–</b>	<b>165,958</b>	<b>1,881</b>	<b>1,651,472</b>	<b>4,257,779</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 van den Broek was appointed as a Director on 7th April 2009.

<sup>3</sup> Dr Fox commenced employment on 16th February 2009.

# 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

#### *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 Committee.

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 2009 <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
Howard G. Fox, MB, BS <i>Chief Medical Officer</i>	30 June 2012	A\$225,000	A\$20,250
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.

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

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.
23 October 2008	22 June 2018	\$1.5990	\$0.8537	200,000	1	25% at each of 30 June 2009, 2010, 2011 and 2012, subject to Remuneration and Nomination Committee annual approval.
12 August 2008	11 August 2018	\$1.8170	\$1.0064	750,000	5	25% at each of 30 June 2009, 2010, 2011 and 2012, subject to Remuneration and Nomination Committee annual approval.
23 October 2008	11 August 2018	\$1.8170	\$0.9701	200,000	1	25% at each of 30 June 2009, 2010, 2011 and 2012, 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
5 February 2009	4 February 2019	\$1.3380	\$0.6949	250,000	1	25% at each of 30 June 2010, 2011, 2012 and 2013, subject to Remuneration and Nomination Committee annual approval.
23 June 2009	22 June 2019	\$2.5498	\$1.3873	900,000	6	25% at each of 30 June 2010, 2011, 2012 and 2013, 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.*

**Option Grants in 2009 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 33 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		
	2009		2008	2009	2008	
	Expiration Date	Exercise Price	Number	Number		
<b>Directors of Pharmaxis Ltd</b>						
DM Hanley <i>Chairman</i>	-	-	-	-	<b>10,000</b>	10,000
AD Robertson <i>Chief Executive Officer</i>	<b>11 Aug 2018</b>	<b>\$1.8170</b>	<b>200,000</b>	300,000	<b>200,000</b>	150,000
MJ McComas	-	-	-	-	<b>5,000</b>	5,000
PC Farrell	-	-	-	-	<b>50,000</b>	50,000
J Villiger	-	-	-	200,000	<b>50,000</b>	50,000
WL Delaat	<b>22 Jun 2018</b>	<b>\$1.5990</b>	<b>200,000</b>	-	<b>50,000</b>	-
R van den Broek	-	-	-	-	-	-
CPH Kiefel	-	-	-	-	-	5,000
<b>Senior Executive Officers</b>						
B Charlton	<b>11 Aug 2018</b>	<b>\$1.8170</b>	<b>150,000</b>	250,000	<b>152,500</b>	115,000
	<b>22 Jun 2019</b>	<b>\$2.5498</b>	<b>150,000</b>			
JF Crapper	<b>11 Aug 2018</b>	<b>\$1.8170</b>	<b>150,000</b>	250,000	<b>150,000</b>	112,500
	<b>22 Jun 2019</b>	<b>\$2.5498</b>	<b>150,000</b>			
HG Fox	<b>4 Feb 2019</b>	<b>\$1.3380</b>	<b>250,000</b>	-	-	-
	<b>22 Jun 2019</b>	<b>\$2.5498</b>	<b>150,000</b>			
IA McDonald	<b>11 Aug 2018</b>	<b>\$1.8170</b>	<b>150,000</b>	250,000	<b>167,500</b>	130,000
	<b>22 Jun 2019</b>	<b>\$2.5498</b>	<b>150,000</b>			
DM McGarvey	<b>11 Aug 2018</b>	<b>\$1.8170</b>	<b>150,000</b>	250,000	<b>150,000</b>	112,500
	<b>22 Jun 2019</b>	<b>\$2.5498</b>	<b>150,000</b>			
GJ Phillips	<b>11 Aug 2018</b>	<b>\$1.8170</b>	<b>150,000</b>	250,000	<b>151,250</b>	113,750
	<b>22 Jun 2019</b>	<b>\$2.5498</b>	<b>150,000</b>		-	

The second grant of options during 2009 with an expiry of 22 June 2019 represent the annual option grant made earlier than in prior years subsequent to changes in the Australian taxation of employee options effective 30 June 2009.

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.

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Vesting	Grant date	Expiry date	Exercise price	Share price at grant date	Expected price volatility of the Company's shares	Risk free interest rate
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The model inputs for options granted to Directors and Senior Executive Officers during the year ended 30 June 2009

25% at each of 30 June 2009, 2010, 2011 and 2012	23 October 2008	22 June 2018	\$1.5990	\$1.58	50%	4.69%
25% at each of 30 June 2009, 2010, 2011 and 2012	12 August 2008	11 August 2018	\$1.8170	\$1.93	50%	5.78%
25% at each of 30 June 2009, 2010, 2011 and 2012	23 October 2008	11 August 2018	\$1.8170	\$1.58	50%	4.69%
25% at each of 30 June 2010, 2011, 2012 and 2013	5 February 2009	4 February 2019	\$1.3380	\$1.13	50%	3.60%
25% at each of 30 June 2010, 2011, 2012 and 2013	23 June 2009	22 June 2019	\$2.5498	\$2.33	50%	5.33%

The model inputs for options granted to Directors and Senior Executive Officers during the year ended 30 June 2008

25% at each of 30 June 2008, 2009, 2010 and 2011	10 August 2007	9 August 2017	\$3.3890	\$3.389	40.81%	6.14%
25% at each of 30 June 2008, 2009, 2010 and 2011	5 November 2007	14 November 2016	\$3.2258	\$4.200	40.81%	6.55%

Note: Vesting is subject to Remuneration and Nomination Committee annual approval.

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

##### *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. Further information on Directors' shareholdings can be found in Note 21 to the Annual Financial Report in Section 3 of this Statutory Annual Report.

Name	Date of exercise of options	Number of ordinary shares issued on exercise of options during the year	
		2009	2008
<b>Directors of Pharmaxis Ltd</b>			
CPH Kiefel	20 December 2007	–	58,957
<b>Senior Executive Officers of the Group</b>			
B Charlton	9 November 2007	–	400,000

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

Exercise date	Amount paid per share
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 and Shares Granted to Directors and Senior Executive Officers under the Employee Option Plan since 30 June 2009***

On 23 June 2009 the Board of Directors resolved to grant under the Pharmaxis Employee Option Plan 200,000 options to the Chief Executive Officer (Executive Director). The options will have an exercise price of \$2.5498 and will expire 22 June 2019. The grant of options to the Executive Director requires shareholder approval and such approval will be sought at the 2009 annual meeting.

In August 2009 the Board of Directors resolved to grant 30,000 restricted ordinary fully paid shares to Mr Richard van den Broek subsequent to his joining the Board earlier in the year. The shares will not be available for sale before 12 August 2012, unless a takeover offer is made for the Group in which case the shares are available for sale. The granting of shares to a Non Executive Director requires shareholder approval and such approval will be sought at the 2009 annual meeting.

## Details of Option Values

The numbers of options to purchase our ordinary shares held at 13 August 2009 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	7,500 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>
	200,000	1.8170	11 August 2018	50,000 at each of 30 June 2009, 2010, 2011 and 2012 <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

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

Name	Number of Securities	Exercise Price A\$	Expiration Date	Vesting
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
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	200,000	1.599	22 June 2018	50,000 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</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 2018	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>
	150,000	2.5498	22 June 2019	37,500 at each of 30 June 2010, 2011, 2012 and 2013 <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 2018	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>
	150,000	2.5498	22 June 2019	37,500 at each of 30 June 2010, 2011, 2012 and 2013 <sup>1</sup>
HG Fox	250,000	1.338	4 February 2019	62,500 at each of 30 June 2010, 2011, 2012 and 2013 <sup>1</sup>
	150,000	2.5498	22 June 2019	37,500 at each of 30 June 2010, 2011, 2012 and 2013 <sup>1</sup>

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Name	Number of Securities	Exercise Price A\$	Expiration Date	Vesting
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 2018	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>
	150,000	2.5498	22 June 2019	37,500 at each of 30 June 2010, 2011, 2012 and 2013 <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 2018	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>
	150,000	2.5498	22 June 2019	37,500 at each of 30 June 2010, 2011, 2012 and 2013 <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 2018	37,500 at each of 30 June 2009, 2010, 2011 and 2012 <sup>1</sup>
	150,000	2.5498	22 June 2019	37,500 at each of 30 June 2010, 2011, 2012 and 2013 <sup>1</sup>

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

<sup>2</sup> On 23 June 2009 the Board resolved to issue 200,000 options to Dr Alan Robertson under the Employee Option. The option grant is subject to shareholder approval which will be sought at the 2009 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 2009.

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	–	–	–	–
AD Robertson	80	20	2009	25	–	2010 to 2012	–	104,379
			2008	25	–	2010 to 2011	–	112,504
			2007	25	–	2010	–	13,419
MJ McComas	–	–	2006	25	–	–	–	–
PC Farrell	–	–	2007	25	–	2010	–	19,302
J Villiger	–	–	2008	25	–	2010	–	30,386
WL Delaat	–	–	2009	25	–	2010 to 2012	–	91,855
B Charlton	80	20	2009	–	–	2010 to 2013	–	205,961
			2009	25	–	2010 to 2012	–	75,383
			2008	25	–	2010 to 2011	–	89,650
			2007	25	–	2010	–	8,990
JF Crapper	80	20	2009	–	–	2010 to 2013	–	205,961
			2009	25	–	2010 to 2012	–	75,383
			2008	25	–	2010 to 2011	–	89,650
			2007	25	–	2010	–	8,562
HG Fox	80	20	2009	–	–	2010 to 2013	–	205,961
			2009	–	–	2010 to 2013	–	145,122
IA McDonald	80	20	2009	–	–	2010 to 2013	–	205,961
			2009	25	–	2010 to 2012	–	75,383
			2008	25	–	2010 to 2011	–	89,650
			2007	25	–	2010	–	8,562
DM McGarvey	80	20	2009	–	–	2010 to 2013	–	205,961
			2009	25	–	2010 to 2012	–	75,383
			2008	25	–	2010 to 2011	–	89,650
			2007	25	–	2010	–	8,562
GJ Phillips	80	20	2009	–	–	2010 to 2013	–	205,961
			2009	25	–	2010 to 2012	–	75,383
			2008	25	–	2010 to 2011	–	89,650
			2007	25	–	2010	–	8,562



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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 2009 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	29%	194,020	–	–
MJ McComas	–	–	–	–
PC Farrell	–	–	–	–
WL Delaat	72%	170,740	–	–
J Villiger	–	–	–	–
R van den Broek	–	–	–	–
B Charlton	52%	359,055	–	–
JF Crapper	53%	359,055	–	–
HG Fox	76%	381,820	–	–
IA McDonald	58%	359,055	–	–
DM McGarvey	51%	359,055	–	–
GJ Phillips	51%	359,055	–	–

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 1 January 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 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 1 September 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.

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.

# Section 1

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 2008 and 2009 are provided in Note 33 to the Annual Financial Report included in Section 3 of this Statutory Annual Report.

During the year the Group initiated a review of its equity-based remuneration policies as a consequence of growth, increasing employee numbers, the change in the Group's shareholder base and the upcoming transformation of the Group into an operating business. The announcement of significant changes to the Australian taxation of equity-based remuneration resulted in this review being suspended until these changes are enacted and further clarified.

## 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 2009 – refer Note 32 to the Annual Financial Report included in Section 3 of this Statutory Annual Report			15,075,000
Options granted during the period from 1 July 2009 to 13 August 2009:			Nil
Options exercised (shares issued) during the period from 1 July 2009 to 13 August 2009:			
13 February 2006	12 February 2016	\$2.194	(25,000)
15 August 2006	14 August 2016	\$1.917	(1,250)
12 August 2008	11 August 2018	\$1.817	(18,750)
Options lapsed during the period from 1 July 2009 to 13 August 2009:			
17 October 2005	16 October 2015	\$2.772	(22,500)
13 February 2006	12 February 2016	\$2.194	(35,000)
15 August 2006	14 August 2016	\$1.917	(2,500)
14 December 2006	13 December 2016	\$3.071	(3,125)
10 August 2007	9 August 2017	\$3.389	(3,000)
12 August 2008	11 August 2018	\$1.817	(4,000)
6 November 2007	5 November 2017	\$4.290	(56,250)
23 June 2008	22 June 2018	\$1.599	(5,625)
23 April 2009	22 April 2019	\$1.9574	(2,500)
			14,895,500

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

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

#### *Shares issued on the exercise of options*

The following of our ordinary shares were issued during the year ended 30 June 2009 on the exercise of options granted under our Employee Option Plan. No amounts are unpaid on any of the shares.

Date options granted	Issue price of shares	Number of shares issued
25 April 2004	\$ 0.5080	22,500
13 February 2006	\$ 2.1940	50,000
15 August 2006	\$ 1.9170	2,500
		75,000

## 1.6 Senior Management 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 13 August 2009.

Name	Age	Position
Alan D. Robertson, Ph.D.	53	Chief Executive Officer and Managing Director
Brett Charlton, Ph.D.	54	Medical Director
John F. Crapper	57	Chief Operations Officer
Howard G. Fox	47	Chief Medical Officer
Ian A. McDonald, Ph.D.	62	Chief Scientific Officer
David M. McGarvey.	53	Chief Financial Officer and Company Secretary
Gary J. Phillips	49	Commercial Director

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

*Alan D. Robertson, Ph.D.*, Refer to Directors' 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.

*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.

*Howard G. Fox* joined Pharmaxis as Chief Medical Officer on 16th February 2009. Dr Fox assumed responsibility for regulatory affairs, pharmacovigilance and medical affairs. Dr Fox has more than 15 years experience in the international pharmaceutical industry, the last ten of which have been in respiratory product development. He was most recently with Novartis as a Global Brand Medical Director and previously held the positions of Senior Clinical Research Physician and Principle Medical Expert for Novartis.

*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 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.





# Section



## 2.1 Five 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 2007, 2008 and 2009, and the balance sheet data as at 30 June 2008 and 2009, 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 2006, 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 2009 refers to our financial year ended 30 June 2009.

Year Ended 30 June	2009 A\$	2008 A\$	2007 A\$	2006 A\$	2005 A\$
<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	595	527	205	8	–
Cost of sales	(153)	(129)	(49)	(2)	–
<b>Gross profit</b>	442	398	156	6	–
Other revenue – interest income	5,347	7,402	5,278	4,282	1,702
Other income	523	1,576	2,152	1,299	1,219
<b>Other expenses from ordinary activities:</b>					
Research and development	(29,308)	(19,996)	(23,840)	(16,978)	(9,269)
Commercial expenses	(6,202)	(4,557)	(3,240)	(1,946)	(963)
Administration expenses	(5,800)	(5,231)	(4,666)	(4,391)	(3,134)
Finance expense	(122)	–	–	–	–
<b>Loss before income tax</b>	(35,120)	(20,408)	(24,160)	(17,728)	(10,445)
Income tax expense	(51)	(32)	(19)	(5)	–
<b>Loss for the year</b>	(35,171)	(20,440)	(24,179)	(17,733)	(10,445)
	<b>Cents</b>	<b>Cents</b>	<b>Cents</b>	<b>Cents</b>	<b>Cents</b>
Basic and diluted loss per share	(18.0)	(10.8)	(13.6)	(11.1)	(8.4)
Weighted average number of ordinary shares used in calculating basic and diluted net loss per share <sup>1</sup>	195,588	189,340	177,285	160,349	123,933

- <sup>1</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. The increase in 2009 is primarily attributable to a share placement and share purchase plan in which a total of 23,069,347 ordinary shares were issued.

<b>As at 30 June</b>	<b>2009 A\$</b>	<b>2008 A\$</b>	<b>2007 A\$</b>	<b>2006 A\$</b>	<b>2005 A\$</b>
<i>In thousands</i>					
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	<b>124,993</b>	111,842	76,182	97,840	33,390
Total assets	<b>163,997</b>	125,049	82,648	104,267	37,937
Net assets	<b>137,691</b>	119,121	76,559	98,888	35,467
Contributed equity/capital stock	<b>245,958</b>	194,680	135,108	134,745	54,716

<b>As at 30 June</b>	<b>2009 A\$</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>217,659</b>	194,515	177,949	176,904	134,770

No dividends have been paid in any of the years 2005 to 2009.

## 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 entitled 'Special Note Regarding 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 '2009' refers to our financial year ended 30 June 2009, 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 do not fall within the scope of the license with 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 fall within the scope of the SSWAHS license.

We reported positive results from our first Phase III clinical trial of Bronchitol in cystic fibrosis in May 2009 and expect to file a marketing application in Europe in the second half of 2009. We are actively recruiting a second 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 expect to close recruitment in the third calendar quarter of 2009.

We have completed one Phase III trial with Bronchitol in bronchiectasis on the basis of which we filed for marketing approval in Australia in September 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 and expect to commence recruiting patients during the third quarter of 2009.

We have received marketing approval of Aridol in Australia, South Korea, Switzerland, Germany, France, the United Kingdom, Italy, the Netherlands, Belgium, Denmark, Greece, Spain, Finland, Ireland, Norway, Sweden and Portugal. We submitted a marketing application for Aridol in the U.S. in March 2009. The U.S. FDA advised us they will provide a complete response on 27 December 2009. We expect to commence sales in the larger markets of Germany, South Korea and the U.S. during the 2010 financial year.

We have one early stage research project which has completed preclinical evaluation 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\$35.2 million, A\$20.4 million and A\$24.2 million in the years ended 30 June 2009, 2008 and 2007, 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 respiratory drug discovery and immune disorders 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, producing and analyzing material in support of regulatory filings 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 30 2009) and timeframes (stated in calendar years unless otherwise stated) of the next anticipated milestones described below:

- The cost to complete the safety extension of our first Phase III trial of Bronchitol for cystic fibrosis is currently estimated to be approximately A\$1.5 million. This trial is being conducted in Europe and Australia. We reported positive headline results from this trial in May 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 third quarter of 2009.
- The cost to complete our second Phase III trial of Bronchitol for bronchiectasis is currently estimated to be approximately A\$13 million. This trial is planned to be conducted in the U.S., Argentina, Australia, New Zealand and Europe. We expect to commence recruitment for this trial during the second half of 2009.
- The cost to complete a Phase IA safety study of PXS25 is currently estimated to be approximately A\$0.5 million. This trial is being conducted in Australia and we expect to commence recruitment in the second half of 2009.

We expect to file a marketing application for Bronchitol in Europe in the second half of 2009 and, therefore, we do not expect to receive any sales revenues prior to the second half of calendar 2010. 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.

### ***General and Administrative***

General and administrative 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.

### ***Commercial***

Our commercial expenses consist of salaries and professional fees related to developing and delivering the commercial strategy and capability to sell Aridol and Bronchitol. We anticipate that commercial expenses will increase as we prepare to launch Bronchitol, as we launch Aridol in additional jurisdictions, and as we incur other selling and marketing costs.

## 2.2.1 Operating Results (continued)

### *Finance Costs*

Finance costs represent the ongoing finance charge associated with the capitalized finance lease of our new facility at Frenchs Forest.

## 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 2009 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 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:

- We reported positive top line results of our first Phase III clinical trial of Bronchitol in CF. The trial which involved 325 patients with CF and was conducted across 40 sites in Europe and Australia. Based on this trial we expect to file a marketing application in Europe in the second half of 2009.
- We reported successful clinical data from our Phase II dosing trial in patients with cystic fibrosis.
- We commenced dosing our second Phase III clinical trial in patients with CF. The trial is being conducted across 65 sites in the U.S., Canada, Argentina, France, Germany, Belgium and the Netherlands. This trial is required in order for us to submit a marketing application in the U.S.
- We reported positive long-term safety data from our first Phase III clinical trial of Bronchitol in people living with bronchiectasis
- We filed a marketing application with the Australian regulatory agency for Bronchitol for bronchiectasis.

### *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 filed a new drug application with the U.S. FDA in March 2009.
- We received marketing approval in Switzerland, Malaysia and Singapore.

### *Other milestones*

- Construction was completed on our new 7,200 square metre manufacturing and research facility at Frenchs Forest, NSW, Australia and we took possession in May 2009. Installation, commissioning and validation of our expanded manufacturing capacity commenced during the year and is scheduled to be complete in the first half of 2010.
- The preclinical studies with PXS25 were completed and it was shown to have an appropriate safety window to allow administration to human volunteers.
- Dr Howard Fox joined our senior executive team.
- U.S. life science investment manager Mr. Richard van den Broek joined our Board of Directors.
- We completed a share placement and share purchase plan in which we issued 23.1 million shares and raised A\$51.2 million net of issue expenses.

## 2.2.4 Results of Operations

### Comparison of financial years ended 30 June 2009 and 30 June 2008

*Sales and Gross Profit.* Sales were A\$0.6 million in 2009 compared to A\$0.5 million in 2008 and relate to sales of our first product, Aridol. Aridol has been approved and launched in Australia, various European countries and Korea. In addition we sell Aridol to pharmaceutical companies for use in clinical trials. Sales by region are made up as follows:

Year ended 30 June	2009 A\$	2008 A\$
<i>In thousands</i>		
Australia	232	216
Europe	267	137
Korea	32	–
Clinical trials	64	174
	595	527

Gross profit was approximately 74 percent and 75 percent of sales in 2009 and 2008 respectively.

*Other revenue – interest.* Interest and other income decreased from A\$7.4 million in 2008 to A\$5.3 million in 2009. The decrease in interest income is attributable to both the lower level of funds invested during 2009 and lower prevailing interest rates. We started 2009 with cash and bank accepted commercial bills of \$111.8 million to which was added approximately \$51.2 million in the second half of June 2009. By contrast 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. Average interest rates on bank accepted commercial bills during 2009 were significantly less than during 2008.

*Other income.* The main component of other income in 2009 is amounts paid to us under a contract with pharmaceutical companies for services performed by our sales representatives promoting products of the pharmaceutical companies to respiratory specialists. In 2009 we also received an Export Market Development Grant from the Australian government of A\$0.15 million. In 2008 the main component of other income was grant revenue, including A\$1.3 million claimed under an Australian Government Pharmaceuticals Partnerships Program grant ('P3 Grant') awarded to us in June 2004, and an Australian Export Market Development Grant of A\$0.08 million. Our claims under the P3 Grant were calculated at 30% of the increase of eligible R&D expenditure over a base amount (derived from average prior year expenditures). The P3 Grant concluded at 30 June 2008 and no further amounts are claimable.

*Research and Development Expenses.* Research and development expenses were \$29.3 million in 2009 compared to \$20.0 million in 2008.

1. Our drug discovery group, now based in our new facility at Frenchs Forest accounted for approximately 7 percent of our total research and development expenditure in the current year and decreased by approximately 10 percent or A\$0.2 million compared to 2008. This group is focused on respiratory and immune disorders drug discovery. The decreased level of expenditure reflects reduced contract research required during the year.
2. Our preclinical development group accounted for approximately 6 percent of our total research and development expenditure in the current year and increased by approximately 175 percent or A\$1.1 million compared to 2008. The increased level of expenditure relates to toxicology studies in PXS4159 and PXS25 and additional efficacy data in PXS25.
3. Our clinical group accounted for approximately 64 percent of our total research and development expenditure in 2009 and increased by approximately 70 percent or A\$7.7 million compared to 2008. 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 in the active dosing stage during 2009, including two Phase III clinical trial in CF.

## 2.2.4 Results of Operations (continued)

4. Our TGA registered manufacturing facility at Frenchs Forest is predominantly focused on producing material for clinical trials, producing and analyzing material in support of regulatory filings 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 21 percent of our total research and development expenditure in 2009 and increased by approximately 4 percent or A\$0.2 million compared to 2008.

*Commercial expenses.* Commercial expenses were A\$6.2 million in 2009 compared to A\$4.6 in 2008. During 2009 we incurred expenditure in preparation for the commercial launch of Bronchitol for CF in Europe and the U.S. and in preparation for the commercial launch of Aridol in the U.S.. In 2009 we increased our sales representatives in the UK as Aridol was launched. This expenditure was in part offset by other income received from other pharmaceutical companies. The costs of our U.S. operations established part way through 2008 were incurred for the whole of 2009.

*General and Administrative Expenses.* General and administrative expenses were A\$5.8 million in 2009 and A\$5.2 million in 2008, an increase of 13 percent. In 2009 administration expenses include costs associated with expanding internationally, costs related to our larger facility at Frenchs Forest, costs to support our expanded clinical program, and impairment of trade receivables and other assets.

*Finance Costs.* Finance costs represent the ongoing finance charge associated with the capitalized finance lease of our new facility at Frenchs Forest. These costs commenced in May 2009.

*Income Tax Expense.* Income tax expense was A\$0.05 million in 2009 and A\$0.03 million in 2008. 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 increased from A\$20.4 million in 2008 to A\$35.2 million in 2009 due to the significant increase in operating expenses discussed, together with a decrease in interest income.

*Basic and diluted net loss per share.* Basic and diluted net loss per share increased from A\$0.108 in 2008 to A\$0.180 in 2009 predominantly because of the increase in research and development expenses in 2009, but also partially offset by the share placement and share purchase plan in June 2009 in which we issued 23.1 million shares.

### **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 2007. 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.

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 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 2008 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 55 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..

*General and Administrative Expenses.* General and administrative 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.

## 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 2009, we had received net cash proceeds from the issue of ordinary and convertible redeemable preference shares of A\$249.0 million and approximately A\$9.5 million in research grants. We have incurred significant losses since our inception. We incurred losses of A\$24.2 million, A\$20.4 million and A\$35.2 million in the financial years ended 30 June 2007, 2008 and 2009 respectively. As of 30 June 2009 we had cash and cash equivalents of A\$125.0 million.

In 2009, we used net cash of A\$26.5 million for operating activities. This consisted of a net loss for the period of A\$35.2 million, which included A\$1.3 million of non-cash depreciation and amortization, and non-cash stock option expense of A\$2.4 million, and positive other working capital movements of A\$4.7 million. Net cash used in investing activities during 2009 was A\$11.5 million, which predominantly relates to the fit out of the facility constructed for us and new manufacturing equipment being installed in the facility. Net cash provided by financing activities during 2009 was A\$51.1 million primarily resulting from the issue and sale of our ordinary shares in a share placement and share purchase plan.

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.

At 30 June 2009, we had cash and cash equivalents of A\$125.0 million as compared to A\$111.8 million as of 30 June 2008. This overall increase was primarily due to our share placement and share purchase plan in June 2009.

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

## 2.3 Risk Factors

*The following summary of 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 securities, 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, is 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, 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\$24.2 million, A\$20.4 million and A\$35.2 million in the financial years ended 30 June 2007, 2008, and 2009 respectively. Our accumulated losses from inception to 30 June 2009 are A\$118.2million. 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 and Bronchitol 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. We have not yet sought marketing authorization for Bronchitol in any jurisdiction outside of Australia and the process for seeking approval of Bronchitol will likewise be extensive, time consuming and expensive;
- the development of our sales and marketing capability for Aridol and, if successful in obtaining regulatory approval, for Bronchitol. Our existing sales and marketing capability is currently limited to a sales team for Australia and the U.K., distributors in Europe and Korea, and a European and United States office to oversee regional activities. 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; and
- the establishment and continuation of a number of early stage research and development projects being undertaken by or on behalf of the Company.

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.

### 2.3 Risk Factors (continued)

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 and the preclinical development and research projects being undertaken. 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 an international Phase III trial of Bronchitol in people with cystic fibrosis which met its primary efficacy endpoint. We have also 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. 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. Notwithstanding earlier successes, 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, and have submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) 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 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

- to significantly expand our sales and marketing capability 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.

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 commercialize 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 securities 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 and have submitted an NDA with the FDA. 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 or delay regulatory approval and commercialization of such product candidates, which will severely harm our business and result in us not being profitable.

Significant delays in regulatory authorization could materially increase our 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 or delays in achieving satisfactory pricing and reimbursement approvals for Aridol, Bronchitol or other product candidates in certain jurisdictions may impair or delay our ability to effectively commercialize Aridol and Bronchitol or our other product candidates in those jurisdictions.

**We may 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 and commercial launch of our product candidates, we may require substantial funds in addition to the funds we have at 30 June 2009.

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

- costs and timing of seeking and obtaining regulatory approval;
- costs and timing of securing coverage, payment and reimbursement of our product candidates which receive regulatory approval;
- costs and timing of developing our sales and marketing capabilities and establishing distribution capabilities and conducting sale and marketing;

### 2.3 Risk Factors (continued)

- 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 in particular, we will need to significantly expand our sales and marketing personnel;
- scope, results, rate of progress, timing and costs of preclinical studies and clinical trials and other development activities;
- costs of manufacturing to satisfy demand for our products;
- 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 filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- effects of competing clinical, technological and market developments.

We believe that our existing cash and cash equivalents will be sufficient to meet our projected operating requirements for at least 12 months.

We believe that our existing cash funds will be sufficient to finance the regulatory review and commercial launch of Bronchitol for cystic fibrosis in Europe. Significant delays in regulatory authorization or delays in achieving satisfactory pricing and reimbursement approvals for Bronchitol in Europe could delay our receipt of revenue and impair our ability to meet our funding requirements.

To meet these funding requirements, we may therefore be required to 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 require but fail to obtain additional financing, we may be unable to fund our operations and commercialize our product candidates.**

If we require but are not able to secure additional funding when needed, amongst other things, 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.

**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.



## ***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. We have submitted a New Drug Application, or NDA, with the U.S. FDA. Our Phase III study of Bronchitol in Europe and Australia for the treatment of people with bronchiectasis met its two primary efficacy endpoints. 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 completed an international Phase III trial of Bronchitol in people with cystic fibrosis which met its primary efficacy endpoint and have commenced recruitment for a second U.S. Phase III trial for subjects with cystic fibrosis. Clinical trials of our product candidates, Bronchitol, PXS25 and PXS4159, if successful, 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;
- 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 key markets where we do not currently have marketing approval, 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 the relevant 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.



## 2.3 Risk Factors (continued)

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 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 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.

### ***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 are in the process of finalizing the scale up and approval of our new manufacturing facility, We have retained our original manufacturing facilities which are licensed by the Australian Therapeutic Goods Administration, or TGA, to manufacture Good Manufacturing Practice grade material for commercial sale. We outsource 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.

There is also a risk of delays as we seek to finalise the scale up and obtain a license by the TGA of our new manufacturing facility and 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. 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.

### 2.3 Risk Factors (continued)

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 small sales force located in Australia, distributors in Europe and South Korea, and a European and United States office to oversee regional activities. 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 other part of Europe and Asia 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.

**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. Provocholine is delivered as a solution to the lungs. We believe a dry powder version of Provocholine is under development that may be well accepted in the market place. Although, Aridol is currently the only approved airway hyper-responsive test developed using dry powder inhalation technology, this situation may change. Aridol 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. 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 AOP Orphan, Pharmaceuticals AG, 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 securities. 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.

### 2.3 Risk Factors (continued)

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:

- 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 cystic fibrosis, bronchiectasis, or 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;
- 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 products and 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. Regulatory health organizations and other third-parties around the world 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, 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.

## 2.3 Risk Factors (continued)

### *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 until we have received the relevant regulatory approvals. Although we have approvals in Australia, some parts of Europe and Korea, we have not yet received approval in a number of other key jurisdictions, including the U.S.. Approval processes are an expensive, complex, lengthy and uncertain process and can only be made following completion of clinical results. 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.

Despite the substantial time and expense invested in preparation and submission of an application for regulatory approval, regulatory approval is never guaranteed. Regulatory authorities 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 jurisdiction and 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. Regulatory authorities 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, 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 commence sale of Bronchitol and other 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 the price and value of our securities 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.

## 2.3 Risk Factors (continued)

### *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:

- 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., E.U. 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.

## 2.3 Risk Factors (continued)

### *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 and the future anticipated launch of Bronchitol. 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 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, 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.

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 security holders. 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 contains 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 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 securityholders to sell their securities and may restrict the ability of our securityholders to obtain a premium from such transactions.

### ***Risks Related to our Securityholders***

**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 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 14 August 2009, 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\$2.39 on 14 August 2009. We may experience a material decline in the market price of our shares, regardless of our operating performance. Therefore, a holder of our securities may not be able to sell those securities at or above the price paid by such holder for such securities. Price declines in our securities could result from a variety of factors, including many outside our control.

## 2.3 Risk Factors (continued)

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, of any of our product candidates, such as Bronchitol (if approved), to achieve commercial success in a timely fashion or at all;
- 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.

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





# 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  
20 Rodborough Road  
Frenchs Forest, NSW 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 13th August 2009. 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 2009

	Notes	Consolidated			Parent Entity	
		2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
<b>Revenue from continuing operations</b>						
Revenue from sale of goods	2	595	527	205	563	531
Cost of sales		(153)	(129)	(49)	(153)	(130)
<b>Gross profit</b>		<b>442</b>	<b>398</b>	<b>156</b>	<b>410</b>	<b>401</b>
Other revenue	2	5,347	7,402	5,278	5,345	7,398
Other income	3	523	1,576	2,152	320	1,576
Other expenses from ordinary activities	4					
Research & development expenses		(29,308)	(19,996)	(23,840)	(29,406)	(20,056)
Commercial expenses		(6,202)	(4,557)	(3,240)	(5,985)	(4,644)
Administration expenses		(5,800)	(5,231)	(4,666)	(5,791)	(5,231)
Finance expenses		(122)	–	–	(122)	–
<b>Loss before income tax</b>		<b>(35,120)</b>	<b>(20,408)</b>	<b>(24,160)</b>	<b>(35,229)</b>	<b>(20,556)</b>
Income tax expense	5	(51)	(32)	(19)	–	–
<b>Loss for the year</b>		<b>(35,171)</b>	<b>(20,440)</b>	<b>(24,179)</b>	<b>(35,229)</b>	<b>(20,556)</b>
Earnings per share:		<b>Cents</b>	Cents	Cents	<b>Cents</b>	Cents
Basic earnings / (loss) per share	31	(18.0)	(10.8)	(13.6)	(18.0)	(10.9)
Diluted earnings / (loss) per share	31	(18.0)	(10.8)	(13.6)	(18.0)	(10.9)

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

## Balance Sheets As at 30 June 2009

	Notes	Consolidated		Parent Entity	
		2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
<b>ASSETS</b>					
<b>Current assets</b>					
Cash and cash equivalents	6	124,993	111,842	124,797	111,650
Trade and other receivables	7	1,219	6,651	1,113	6,617
Inventories	8	254	96	247	94
<b>Total current assets</b>		<b>126,466</b>	118,589	<b>126,157</b>	118,361
<b>Non current assets</b>					
Receivables	9	3,392	1,526	3,384	1,521
Other financial assets	10	248	39	248	39
Property, plant and equipment	11	32,698	3,668	32,625	3,611
Intangible assets	12	1,193	1,227	1,193	1,227
<b>Total non current assets</b>		<b>37,531</b>	6,460	<b>37,450</b>	6,398
<b>Total assets</b>		<b>163,997</b>	125,049	<b>163,607</b>	124,759
<b>LIABILITIES</b>					
<b>Current liabilities</b>					
Trade and other payables	13	8,587	5,709	8,547	5,656
Borrowings	14	316	–	316	–
Other liabilities	15	239	–	239	–
Current tax liabilities		55	31	–	–
<b>Total current liabilities</b>		<b>9,197</b>	5,740	<b>9,102</b>	5,656
<b>Non current liabilities</b>					
Borrowings	16	13,559	–	13,559	–
Other liabilities	17	3,307	–	3,307	–
Provisions	18	243	188	243	188
<b>Total non current liabilities</b>		<b>17,109</b>	188	<b>17,109</b>	188
<b>Total liabilities</b>		<b>26,306</b>	5,928	<b>26,211</b>	5,844
<b>Net assets</b>		<b>137,691</b>	119,121	<b>137,396</b>	118,915
<b>EQUITY</b>					
Contributed equity	19	245,958	194,680	245,958	194,680
Reserves	20(a)	9,902	7,439	9,875	7,443
Accumulated losses	20(b)	(118,169)	(82,998)	(118,437)	(83,208)
<b>Total equity</b>		<b>137,691</b>	119,121	<b>137,396</b>	118,915

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

## Statements of Changes in Equity For the year ended 30 June 2009

	Notes	Consolidated			Parent Entity	
		2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
<b>Total equity at the beginning of the financial year</b>		<b>119,121</b>	76,559	98,888	<b>118,915</b>	76,465
Exchange differences on translation of foreign operations	20(a)	31	(4)	(1)	-	-
<b>Net income recognised directly in equity</b>		<b>31</b>	(4)	(1)	-	-
<b>Loss for the year</b>		<b>(35,171)</b>	(20,440)	(24,179)	<b>(35,229)</b>	(20,556)
<b>Total recognised income and expense for the year</b>		<b>(35,140)</b>	(20,444)	(24,180)	<b>(35,229)</b>	(20,556)
Contributions of equity, net of transaction costs	19(a)	51,278	59,572	363	51,278	59,572
Employee share options	20(a)	2,432	3,434	1,488	2,432	3,434
<b>Total equity at the end of the financial year</b>		<b>137,691</b>	119,121	76,559	<b>137,396</b>	118,915

*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 2009

	Notes	Consolidated			Parent Entity	
		2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
<b>Cash flows from operating activities</b>						
Receipts from customers (inclusive of goods and services tax)		963	601	191	790	617
Payments to suppliers and employees (inclusive of goods and services tax)		(36,747)	(28,299)	(28,458)	(36,587)	(28,511)
		<b>(35,784)</b>	(27,698)	(28,267)	<b>(35,797)</b>	(27,894)
Lease incentive receipt		3,578	–	–	3,578	–
Grant receipts from government		443	1,542	2,292	443	1,542
Interest received		5,321	7,348	5,278	5,319	7,344
Income tax paid		(27)	(42)	–	–	–
<b>Net cash outflow from operating activities</b>	29	<b>(26,469)</b>	(18,850)	(20,697)	<b>(26,457)</b>	(19,008)
<b>Cash flows from investing activities</b>						
Payments for property, plant and equipment		(12,516)	(1,012)	(1,182)	(12,485)	(962)
Instalment payments to acquire plant and equipment		(362)	(2,396)	–	(362)	(2,396)
Release/(payment) of security deposits to acquire plant and equipment		1,498	(1,498)	–	1,498	(1,498)
Proceeds from disposal of plant and equipment		7	1	52	7	1
Payments for intangible assets		(169)	(154)	(192)	(169)	(154)
<b>Net cash outflow from investing activities</b>		<b>(11,542)</b>	(5,059)	(1,322)	<b>(11,511)</b>	(5,009)
<b>Cash flows from financing activities</b>						
Net proceeds from issues of shares		51,278	59,572	363	51,278	59,572
Finance lease payments		(163)	–	–	(163)	–
<b>Net cash inflow from financing activities</b>		<b>51,115</b>	59,572	363	<b>51,115</b>	59,572
<b>Net increase / (decrease) in cash and cash equivalents</b>						
		<b>13,104</b>	35,663	(21,656)	<b>13,147</b>	35,555
Cash and cash equivalents at the beginning of the financial year		111,842	76,182	97,840	111,650	76,095
Effects of exchange rate changes on cash and cash equivalents		47	(3)	(2)	–	–
<b>Cash and cash equivalents at the end of the financial year</b>	6	<b>124,993</b>	111,842	76,182	<b>124,797</b>	111,650
Non-cash investing and financing activities	30					

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*

The financial report of Pharmaxis Ltd also complies with International Financial Reporting Standards (IFRS) 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 2009 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.

### (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) Service income

Service income relates to revenue received from other pharmaceutical companies for use of the Groups sales force to promote their products. Service income is recognised in the period the service is performed.

#### (iii) 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 of property where the Group, as lessee, has substantially all the risks and rewards of ownership are classified as finance leases (note 24). Finance leases are capitalised at the lease's inception at the fair value of the leased property or, if lower, the present value of the minimum lease payments. The corresponding rental obligations, net of finance charges, are included in other short-term and long-term payables. Each lease payment is allocated between the principal repayment and the finance cost. The finance cost is charged to the income statement over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The property acquired under the finance lease is depreciated over the asset's useful life or over the shorter of the asset's useful life and the lease term if there is no reasonable certainty that the Group will obtain ownership at the end of the lease term. Any lease incentive received is recognised in the income statement on a straight-line basis over the lease term.

Leases of plant and equipment in which a significant portion of the risks and rewards of ownership are not transferred to the Group as lessee are classified as operating leases (note 24). 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.

Lease income from operating leases where the Group is a lessor is recognised in income on a straight-line basis over the lease term.

## **(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.

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

### (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.

### (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) Property, plant and equipment

Property, 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 – 15 years
Computer equipment	4 years
Leased building and improvements	15 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 as a 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 33. 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) **Other liabilities**

Other liabilities comprises a deferred lease incentive which relates to a cash incentive received pursuant to the 'Put and Call Option to Lease' agreement. The deferred incentive is amortised to the income statement over the lease term of 15 years.

### (r) **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.

### (s) **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.

### (t) **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.

## **(u) 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.

## **(v) New accounting standards and interpretations**

Certain new accounting standards and interpretations have been published that are not mandatory for the year ended 30 June 2009 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 (effective from 1 January 2009)*

AASB 8 may result in a significant change in the approach to segment reporting, as it requires adoption of a 'management approach' to reporting on 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 will adopt AASB 8 from 1 July 2009. The segments will be reported in a manner that is consistent with the internal reporting provided to the chief operating decision-maker, however at present it is unlikely that the other segments will meet the reportable thresholds.

*(ii) Revised AASB 101 Presentation of Financial Statements and AASB 2007-8 Amendments to Australian Accounting Standards arising from AASB 101 (effective from 1 January 2009)*

The September 2007 revised AASB 101 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 will apply the revised standard from 1 July 2009.

*(iii) AASB 2008-1 Amendments to Australian Accounting Standard – Share-based Payments: Vesting Conditions and Cancellations (effective from 1 January 2009)*

AASB 2008-1 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) AASB 2009-4 Amendments to Australian Accounting Standards arising from the Annual Improvements Project (effective for annual periods beginning on or after 1 July 2009)*

The AASB has made amendments to AASB 2 Share-based payment, AASB 138 Intangible Assets and AASB Interpretations 9 Reassessment of Embedded Derivatives and 16 Hedges of a Net Investment in a Foreign Operation as a result to the IASB's annual improvements project. The Group will apply the amendments from 1 July 2009. The Group does not expect that any adjustments will be necessary as a result of applying the revised rules.

*(v) AASB 2009-5 Further Amendments to Australian Accounting Standards arising from the Annual Improvements Project (effective for annual periods beginning on or after 1 January 2010)*

In May 2009, the AASB issued a number of improvements to existing Australian Accounting Standards. The Group will apply the revised standards from 1 July 2010. The Group does not expect that any adjustments will be necessary as the result of applying the revised rules.

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

(vi) *Group Cash-settled Share-based Payment Transactions – Amendments to IFRS 2 (effective for annual periods commencing on or after 1 January 2010)*

The amendments made by the IASB to IFRS 2 confirm that an entity receiving goods or services in a group share-based payment arrangement must recognise an expense for those goods or services regardless of which entity in the group settles the transaction or whether the transaction is settled in shares or cash. They also clarify how the group share-based payment arrangement should be measured, that is, whether it is measured as an equity- or a cash-settled transaction. The AASB is expected to make equivalent amendments to AASB 2 shortly. The Group will apply these amendments retrospectively for the financial reporting period commencing on 1 July 2009. However, as the amendments only affect the accounting in the individual entities there will be no impact on the financial statements of the Group.

(vii) *Revised AASB 123 Borrowing Costs and AASB 2007-6 Amendments to Australian Accounting Standards arising from AASB 123 (effective from 1 January 2009)*

The revised AASB 123 has removed the option to expense all borrowing costs and – when adopted – will require the capitalisation of all borrowing costs directly attributable to the acquisition, construction or production of a qualifying asset. There will be no impact on the financial report of the Group, as the Group already capitalises borrowing costs relating to qualifying assets.

## 2. Revenue

	Consolidated			Parent Entity	
	2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
Sales revenue					
Sale of goods	595	527	205	563	531
Other revenue					
Interest	5,347	7,402	5,278	5,345	7,398

## 3. Other income

	Consolidated			Parent Entity	
	2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
Government grants	93	1,358	2,152	93	1,358
Service income	430	218	–	227	218
	523	1,576	2,152	320	1,576

Service income comprised revenue received from other pharmaceutical companies for use of the Groups sales force to promote their products.

## 4. Expenses

	Consolidated			Parent Entity	
	2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
<b>Loss before income tax includes the following specific expenses:</b>					
Depreciation (note 11)					
Plant and equipment	566	610	631	564	608
Computer equipment	196	149	109	175	141
Leased building and improvements	300	99	51	300	99
Total depreciation	1,062	858	791	1,039	848
Amortisation (note 12)					
Patents	96	95	92	96	95
Trademarks	5	3	3	5	3
Software	102	68	53	102	68
Total amortisation	203	166	148	203	166
<i>Impairment losses – financial assets</i>					
Trade receivables	150	–	–	150	–
Other financial assets	39	–	–	39	–
Net loss on disposal of plant and equipment	–	6	24	–	6
Rental expense relating to operating leases	774	638	459	619	537
Net foreign exchange losses	12	96	47	12	98
Employee benefits expense					
Defined contribution superannuation	761	594	454	662	534
Other employee benefits expenses	14,272	12,592	9,007	11,560	11,304



## 5. Income tax expense

	Consolidated			Parent Entity	
	2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
<b>(a) Numerical reconciliation of income tax expense to prima facie tax payable</b>					
Loss before income tax expense	<b>(35,120)</b>	(20,408)	(24,160)	<b>(35,229)</b>	(20,556)
Tax at the Australian tax rate 30% (2008:30%)	<b>(10,536)</b>	(6,122)	(7,248)	<b>(10,569)</b>	(6,167)
Tax effect of amounts which are not deductible (taxable) in calculating taxable income:					
Share-based payments	<b>730</b>	1,030	446	<b>730</b>	1,030
Government research tax incentives	<b>(2,331)</b>	(988)	(1,900)	<b>(2,331)</b>	(988)
Sundry items	<b>8</b>	6	8	<b>8</b>	6
	<b>(12,129)</b>	(6,074)	(8,694)	<b>(12,162)</b>	(6,119)
Over/(under) provision in prior years	<b>563</b>	18	(251)	<b>533</b>	18
Difference in overseas tax rates	<b>(12)</b>	(15)	(9)	<b>-</b>	-
Total	<b>(11,578)</b>	(6,071)	(8,954)	<b>(11,629)</b>	(6,101)
Deferred tax benefits not recognised	<b>11,629</b>	6,103	8,973	<b>11,629</b>	6,101
Income tax expense	<b>51</b>	32	19	<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>(56)</b>	(363)	(231)	<b>(56)</b>	(363)
Lease balances	<b>26</b>	-	-	<b>26</b>	-
Deferred lease incentive	<b>1,064</b>	-	-	<b>1,064</b>	-
Employee benefits	<b>323</b>	303	156	<b>283</b>	260
Share capital raising costs	<b>1,625</b>	1,580	1,637	<b>1,625</b>	1,580
Other	<b>101</b>	17	2	<b>101</b>	17
	<b>3,083</b>	1,537	1,564	<b>3,043</b>	1,494
Deferred tax assets attributable to temporary differences which are not recognised	<b>(3,083)</b>	(1,537)	(1,564)	<b>(3,043)</b>	(1,494)
	<b>-</b>	-	-	<b>-</b>	-
<b>(c) Tax losses</b>					
Unused tax losses for which no deferred tax asset has been recognised	<b>139,200</b>	102,290	79,219	<b>139,200</b>	102,290
Potential tax benefit @ 30%	<b>41,760</b>	30,687	23,766	<b>41,760</b>	30,687

All unused tax losses were incurred by the parent entity.

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

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Cash at bank and in hand	627	569	431	377
Deposits at call	9,773	1,533	9,773	1,533
Bank accepted commercial bills	114,593	109,740	114,593	109,740
	<b>124,993</b>	<b>111,842</b>	<b>124,797</b>	<b>111,650</b>

**Interest rate risk exposure**

The Group's and the parent entity's exposure to interest rate risk is discussed in note 32. 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	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Trade receivables	408	222	295	210
Provision for impairment of receivables (note (b))	(150)	–	(150)	–
	<b>258</b>	<b>222</b>	<b>145</b>	<b>210</b>
Government research grants receivable	–	350	–	350
Prepayments (note (c))	519	4,241	519	4,241
Other receivables (note (d))	52	1,598	52	1,598
Tax related receivables	390	240	397	218
	<b>1,219</b>	<b>6,651</b>	<b>1,113</b>	<b>6,617</b>

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

As of 30 June 2009, trade receivables of \$60,366 (2008: \$144,244) 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	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Up to 1 month	54	24	53	24
1 to 2 months	3	97	–	97
Over 2 months	3	23	1	22
	<b>60</b>	<b>144</b>	<b>54</b>	<b>143</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) Impaired trade receivables

As of 30 June 2009, trade receivables of \$149,645 (2008: \$Nil) over 6 months were impaired. These relate to one distributor which is having difficulty repaying due to limited financial resources given current economic conditions.

### (c) Prepayments

Prepayments primarily relate to advance payments for items of plant and equipment.

### (d) Other receivables

Other receivables primarily represent cash held at bank to cover bank guarantee facilities related to short term operating leases. The balance at 30 June 2008 represented cash held at bank to cover a letter of credit facility for the acquisition of plant and equipment.

### (e) 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 32.

### (f) 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 32 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	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Raw materials at cost	122	48	122	48
Work-in-progress at cost	70	10	70	10
Finished goods at cost	62	38	55	36
	<b>254</b>	96	<b>247</b>	94

## 9. Non-current assets – Receivables

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Other receivables (note (a))	3,307	1,377	3,302	1,372
Prepayments	85	149	82	149
	<b>3,392</b>	1,526	<b>3,384</b>	1,521

### (a) Other receivables

Other receivables primarily represents cash held at bank to cover bank guarantee facilities related to finance and operating lease commitments, 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 32.

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

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Shares in subsidiaries (note 26)	–	–	–	–
Other	248	39	248	39
	<b>248</b>	<b>39</b>	<b>248</b>	<b>39</b>

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

**11. Non-current assets – Property, plant and equipment**

Consolidated	Plant and equipment \$'000	Computer equipment \$'000	Leased buildings & improvements \$'000	Total \$'000
<b>At 1 July 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
<b>Year ended 30 June 2009</b>				
Opening net book amount	2,514	415	739	3,668
Exchange differences	–	8	–	8
Additions	7,903	317	21,871	30,091
Disposals	(6)	(1)	–	(7)
Depreciation charge	(566)	(196)	(300)	(1,062)
Closing net book amount	9,845	543	22,310	32,698

## 11. Non-current assets – Property, plant and equipment (continued)

Consolidated	Plant and equipment \$'000	Computer equipment \$'000	Leased buildings & improvements \$'000	Total \$'000
<b>At 30 June 2009</b>				
Cost	13,276	1,089	22,895	37,260
Accumulated depreciation and impairment	(3,431)	(546)	(585)	(4,562)
Net book amount	9,845	543	22,310	32,698

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

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

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Leased building and improvements	–	632	–	632
Plant and equipment	6,599	–	6,599	–
	6,599	632	6,599	632

### (b) Leased assets

Leased building and improvements includes the following amounts where the Group is a lessee under a finance lease:

	Consolidated	Parent Entity	Consolidated	Parent Entity
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Cost	13,916	–	13,916	–
Accumulated amortisation	(126)	–	(126)	–
Net book amount	13,790	–	13,790	–

## 12. Non-current assets – Intangible assets

Consolidated and parent entity	Patents \$'000	Trademarks \$'000	Software \$'000	Total \$'000
<b>At 1 July 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

**12. Non-current assets – Intangible assets (continued)**

Consolidated and parent entity	Patents	Trademarks	Software	Total
	\$'000	\$'000	\$'000	\$'000
<b>Year ended 30 June 2009</b>				
Opening net book amount	861	94	272	1,227
Additions	43	13	113	169
Amortisation charge	(96)	(5)	(102)	(203)
Closing net book amount	808	102	283	1,193
<b>At 30 June 2009</b>				
Cost	1,667	113	512	2,292
Accumulated amortisation and impairment	(859)	(11)	(229)	(1,099)
Net book amount	808	102	283	1,193

**13. Current liabilities – Trade and other payables**

	Consolidated		Parent Entity	
	2009	2008	2009	2008
	\$'000	\$'000	\$'000	\$'000
Trade payables	1,582	516	1,522	488
Other payables (note (a))	7,005	5,193	6,418	4,918
Trade payables to subsidiaries	–	–	607	250
	<b>8,587</b>	<b>5,709</b>	<b>8,547</b>	<b>5,656</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 32.

**14. Current liabilities – Borrowings**

	Consolidated		Parent Entity	
	2009	2008	2009	2008
	\$'000	\$'000	\$'000	\$'000
Secured				
Lease liabilities (note 24)	316	–	316	–

**(a) Security and fair value disclosures**

Information about the security relating to each of the secured liabilities and the fair value of each of the borrowings is provided in note 16.

**(b) Risk exposure**

Information about the Group's and the parent entity's exposure to risks arising from current and non-current borrowings is provided in note 32.

## 15. Current liabilities – Other liabilities

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Deferred lease incentive	239	–	239	–

Information about the deferred lease incentive is provided in note 17.

## 16. Non-current liabilities – Borrowings

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Secured Lease liabilities (note 24)	13,559	–	13,559	–

### Secured liabilities and assets pledged as security

Lease liabilities are effectively secured, as the rights to the leased assets recognised in the financial statements revert to the lessor in the event of default.

## 17. Non-current liabilities – Other liabilities

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Deferred lease incentive	3,307	–	3,307	–

The deferred lease incentive relates to a cash incentive received pursuant to the 'Put and Call Option to Lease' agreement. The deferred incentive is amortised over the 15 year lease term on a straight-line basis.

## 18. Non-current liabilities – Provisions

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Employee benefits long service leave	243	188	243	188



## 19. Contributed equity

	Notes	Consolidated and Parent Entity		Consolidated and Parent Entity	
		2009 Shares	2008 Shares	2009 \$'000	2008 \$'000
<b>(a) Share capital</b>					
Ordinary shares	(b),(c)				
Fully paid		<b>217,659,109</b>	194,514,762	<b>245,958</b>	194,680

## Movements in ordinary share capital:

Date	Details	Number of shares	Issue price	\$'000
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
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)
1 July 2008	Opening balance	194,514,762		194,680
7 August 2008	Exercise of employee options	22,500	\$ 0.5080	11
4 June 2009	Share Placement (initial settlement)	500,000	\$ 2.3500	1,175
10 June 2009	Exercise of employee options	50,000	\$ 2.1940	109
10 June 2009	Exercise of employee options	2,500	\$ 1.9170	5
11 June 2009	Share Placement (main settlement)	19,500,000	\$ 2.3500	45,825
30 June 2009	Share Purchase Plan	3,069,347	\$ 2.3500	7,213
	Less: Transaction costs on share issues			(3,060)
		<b>217,659,109</b>		<b>245,958</b>

## 19. Contributed equity (continued)

### (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 33.

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

## 20. Reserves and accumulated losses

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
<b>(a) Reserves</b>				
Share based payments reserve	9,875	7,443	9,875	7,443
Foreign currency translation reserve	27	(4)	-	-
	<b>9,902</b>	<b>7,439</b>	<b>9,875</b>	<b>7,443</b>
<i>Share based payments reserve</i>				
Balance 1 July	7,443	4,009	7,443	4,009
Option expense	2,432	3,434	2,432	3,434
Balance 30 June	<b>9,875</b>	<b>7,443</b>	<b>9,875</b>	<b>7,443</b>
<i>Foreign currency translation reserve</i>				
Balance 1 July	(4)	-	-	-
Currency translation differences arising during the year	31	(4)	-	-
Balance 30 June	<b>27</b>	<b>(4)</b>	<b>-</b>	<b>-</b>
<b>(b) Accumulated losses</b>				
Movements in accumulated losses were as follows:				
Balance 1 July	(82,998)	(62,558)	(83,208)	(62,652)
Net loss for the year	(35,171)	(20,440)	(35,229)	(20,556)
Balance 30 June	<b>(118,169)</b>	<b>(82,998)</b>	<b>(118,437)</b>	<b>(83,208)</b>

**20. Reserves and accumulated losses (continued)****(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).

**21. Key management personnel disclosures****(a) Key management personnel compensation**

	Consolidated		Parent Entity	
	2009	2008	2009	2008
	\$	\$	\$	\$
Short term employee benefits	<b>2,438,468</b>	2,235,880	<b>2,438,468</b>	2,235,880
Post-employment benefits	<b>165,958</b>	156,613	<b>165,958</b>	156,613
Long-term benefits	<b>1,881</b>	70,445	<b>1,881</b>	70,445
Share based payments	<b>1,651,472</b>	1,997,655	<b>1,651,472</b>	1,997,655
	<b>4,257,779</b>	4,460,593	<b>4,257,779</b>	4,460,593

Detailed remuneration disclosures are provided in the remuneration report under section 1.5.

**(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 over.

## 21. Key management personnel disclosures (continued)

2009						
Name	Balance at the start of the year	Granted during the year as compensation <sup>(i)</sup>	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	1,120,000
AD Robertson	2,680,000	200,000	–	–	2,880,000	2,542,500
MJ McComas	240,000	–	–	–	240,000	240,000
PC Farrell	220,000	–	–	–	220,000	170,000
J Villiger	200,000	–	–	–	200,000	150,000
W Delaat	–	200,000	–	–	200,000	50,000
R van den Broek	–	–	–	–	–	–
<b>Other key management personnel of the Group</b>						
B Charlton	910,000	300,000	–	–	1,210,000	796,250
JF Crapper	810,000	300,000	–	–	1,110,000	697,500
HG Fox	–	400,000	–	–	400,000	–
IA McDonald	570,000	300,000	–	–	870,000	457,500
DM McGarvey	1,410,000	300,000	–	–	1,710,000	1,297,500
GJ Phillips	955,000	300,000	–	–	1,255,000	842,500

<sup>(i)</sup> Options granted during the year covers two grant issues. The first issue in August 2008 for the financial year ended 30 June 2009 and the second issue in June 2009 for the year ended 30 June 2010.

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	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>						
B Charlton	1,060,000	250,000	(400,000)	–	910,000	643,750
JF Crapper	560,000	250,000	–	–	810,000	547,500
IA McDonald	320,000	250,000	–	–	570,000	290,000
DM McGarvey	1,160,000	250,000	–	–	1,410,000	1,147,500
GJ Phillips	705,000	250,000	–	–	955,000	691,250

### (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).

**21. Key management personnel disclosures (continued)**

2009				
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	789,787	–	8,508	798,295
AD Robertson	100,000	–	–	100,000
MJ McComas	139,999	–	–	139,999
P Farrell	101,645	–	–	101,645
J Villiger	–	–	–	–
W. Delaat	–	–	25,000	25,000
R van den Broek <sup>(1)</sup>	–	–	45,000	45,000
<b>Other key management personnel of the Group</b>				
<b>Ordinary shares</b>				
B Charlton	420,000	–	(419,954)	46
JF Crapper	2,000	–	–	2,000
HG Fox	–	–	–	–
IA McDonald	–	–	–	–
DM McGarvey	45,000	–	2,127	47,127
GJ Phillips	6,664	–	–	6,664

<sup>(1)</sup> R van den Broek is associated with HSMR Advisors (QP) L.P, HSMR Advisors (QP) L.P, held 830,000 shares as at 30 June 2009. R van den Broek was not a director as at 30 June 2008.

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>				
B Charlton	20,000	400,000	–	420,000
JF Crapper	2,000	–	–	2,000
IA McDonald	–	–	–	–
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 2009.

## 22. 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	
	2009	2008	2009	2008
	\$	\$	\$	\$
<b>(a) Audit services</b>				
PricewaterhouseCoopers Australian firm				
Audit and review of financial reports	<b>274,421</b>	313,420	<b>274,421</b>	313,420
Non-PricewaterhouseCoopers audit firm for the audit of the financial report of Pharmaxis Pharmaceuticals Limited	<b>20,467</b>	16,841	-	-
Total remuneration for audit services	<b>294,888</b>	330,261	<b>274,421</b>	313,420
<b>(b) Other services</b>				
PricewaterhouseCoopers Australian firm				
Review of government research grant claims	-	5,800	-	5,800
IT Infrastructure review	-	15,372	-	15,372
	-	21,172	-	21,172
PricewaterhouseCoopers China firm				
Accounting review services	<b>23,304</b>	-	<b>23,304</b>	-
Total remuneration for other services	<b>23,304</b>	21,172	<b>23,304</b>	21,172
<b>(c) Tax services</b>				
PricewaterhouseCoopers Australian firm				
International tax consulting and tax advice	<b>8,700</b>	11,780	<b>8,700</b>	11,780
Tax compliance services	<b>12,900</b>	12,000	<b>12,900</b>	12,000
	<b>21,600</b>	23,780	<b>21,600</b>	23,780
PricewaterhouseCoopers China firm				
Tax compliance services	<b>13,580</b>	-	<b>13,580</b>	-
Total remuneration for tax services	<b>35,180</b>	23,780	<b>35,180</b>	23,780

## 23. Contingent liabilities

The parent entity and Group had contingent liabilities at 30 June 2009 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 2009 was \$4,707,817 (2008: \$4,707,817).

The company completed the Australian Government's Pharmaceuticals Partnerships Program ('P3') at 30 June 2008 and received cash proceeds of \$297,871 (2008: \$1,320,584) as the final payment 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 \$2,891,097 in relation to rental bond deposits for which no provision has been made in the accounts. The rental bond deposits cover the leased building which has been accounted for as a finance lease and other leased premises accounted for as operating leases. These bank guarantees are secured by security deposits held at the bank.

The company's bankers have provided a corporate credit card facility which is secured by a deposit held at the bank totalling \$72,141.

The company's bankers have issued a bank guarantee of GBP70,000 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.

## 24. Commitments

### (a) Capital Commitments

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

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
<i>Building Fit-out</i>				
Payable: Within one year	<b>135</b>	7,188	<b>135</b>	7,188
<i>Plant and equipment</i>				
Payable: Within one year	<b>1,357</b>	2,126	<b>1,357</b>	2,126



## 24. Commitments (continued)

### (b) Lease Commitments

#### (i) Non-cancellable operating leases

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

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
<i>Commitments for minimum lease payments in relation to non-cancellable operating leases are payable as follows:</i>				
Within one year	868	464	838	444
Later than one year but not later than five years	2,338	728	2,338	728
Later than 5 years	5,089	–	5,089	–
	<b>8,295</b>	1,192	<b>8,265</b>	1,172

#### (ii) Finance leases

The company has entered into an agreement concerning the lease of a custom designed manufacturing, warehousing, research and office facility of approximately 7,200 square metres, constructed to our specifications. The lease has 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 for the finance lease component is \$1.2 million. The operating lease component (disclosed in note 24 (b) (i)) is \$0.4 million. Both components increase each year for the term of the agreement by 3.25%.

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
<i>Commitments in relation to finance leases are payable as follows:</i>				
Within one year	1,198	–	1,198	–
Later than one year but not later than five years	5,193	–	5,193	–
Later than five years	15,984	–	15,984	–
Minimum lease payments	22,375	–	22,375	–
Future finance charges	(8,500)	–	(8,500)	–
Total lease liabilities	<b>13,875</b>	–	<b>13,875</b>	–
Representing lease liabilities:				
Current (note 14)	316	–	316	–
Non-current (note 16)	13,559	–	13,559	–
	<b>13,875</b>	–	<b>13,875</b>	–

#### (iii) 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.

## 25. 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 26.

### (c) Key management personnel

Disclosures relating to key management personnel are set out in note 21.

### (d) Transactions with related parties

The following transactions occurred with related parties:

	Consolidated		Parent Entity	
	2009 \$	2008 \$	2009 \$	2008 \$
Marketing, clinical, regulatory and administration services expenditure paid to subsidiaries	-	-	4,961,884	2,592,796

### (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	-	-	607,108	250,006
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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.

## 26. 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	
			2009 %	2008 %
Pharmaxis Pharmaceuticals Limited	United Kingdom	Ordinary	100	100
Pharmaxis, Inc.	United States	Ordinary	100	100

## 27. Events occurring after the balance sheet date

No matter or circumstance has arisen since 30 June 2009 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.

## 28. 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.

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

	Consolidated			Parent Entity	
	2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
Loss for the year	<b>(35,171)</b>	(20,440)	(24,179)	<b>(35,229)</b>	(20,556)
Depreciation of property, plant & equipment	<b>1,062</b>	858	791	<b>1,039</b>	848
Amortisation of intangibles	<b>203</b>	166	148	<b>203</b>	166
Amortisation of lease incentive	<b>(32)</b>	–	–	<b>(32)</b>	–
Impairment losses – financial assets					
Trade receivables	<b>150</b>	–	–	<b>150</b>	–
Other financial assets	<b>39</b>	–	–	<b>39</b>	–
Finance charges	<b>122</b>	–	–	<b>122</b>	–
Non cash employee benefits expense					
share based payments	<b>2,432</b>	3,434	1,488	<b>2,432</b>	3,434
Net loss on disposal of non current assets	–	6	24	–	6
Change in operating assets and liabilities					
(Increase) in trade receivables	<b>(186)</b>	(188)	(27)	<b>(85)</b>	(176)
(Increase) / decrease in inventories	<b>(158)</b>	(17)	21	<b>(153)</b>	(15)
(Increase) / decrease in other operating assets	<b>(178)</b>	(2,508)	327	<b>(204)</b>	(2,493)
Increase / (decrease) in trade payables	<b>1,066</b>	(2,138)	1,841	<b>1,034</b>	(2,137)
Increase / (decrease) in other operating liabilities	<b>4,127</b>	1,904	(1,183)	<b>4,172</b>	1,842
Increase in other provisions	<b>55</b>	73	52	<b>55</b>	73
Net cash outflow from operating activities	<b>(26,469)</b>	(18,850)	(20,697)	<b>(26,457)</b>	(19,008)

**30. Non-cash investing and financing activities**

	Consolidated			Parent Entity	
	2009 \$'000	2008 \$'000	2007 \$'000	2009 \$'000	2008 \$'000
Acquisition of leased building and improvements by means of finance leases	13,916	-	-	13,916	-

**31. Earnings per share**

	Consolidated	
	2009 Cents	2008 Cents
<b>(a) Basic earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	(18.0)	(10.8)
<b>(b) Diluted earnings per share</b>		
Loss attributable to the ordinary equity holders of the company	(18.0)	(10.8)
<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	195,588,481	189,335,187

**(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 33.

## 32. 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	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
<b>Financial assets</b>				
Cash and cash equivalents	124,993	111,842	124,797	111,650
Trade and other receivables	1,219	6,651	1,113	6,617
Receivables	3,392	1,526	3,384	1,521
Other financial assets	248	39	248	39
	<b>129,852</b>	120,058	<b>129,542</b>	119,827

	Consolidated		Parent Entity	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
<b>Financial liabilities</b>				
Trade and other payables	8,587	5,709	8,547	5,656
Borrowings	13,875	–	13,875	–
Other liabilities	3,546	–	3,546	–
	<b>26,008</b>	5,709	<b>25,968</b>	5,656

### (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.

# Section 3

The Group's exposure to foreign currency risk at the reporting date was as follows:

	30 June 2009			30 June 2008		
	USD	GBP	EUR	USD	GBP	EUR
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
Cash and cash equivalents	3	6	20	9	9	83
Trade receivables	-	-	198	-	-	103
Prepayments	-	-	362	-	-	1,498
Other receivables	127	149	-	104	83	1,498
Trade payables	700	159	75	98	30	25
Other payables	530	925	649	288	736	1,591

The carrying amounts of the parent entity's financial assets and liabilities are denominated in Australian dollars except as set out below:

	30 June 2009			30 June 2008		
	USD	GBP	EUR	USD	GBP	EUR
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
Cash and cash equivalents	3	6	20	9	9	83
Trade receivables	-	-	198	-	-	103
Prepayments	-	-	362	-	-	1,498
Other receivables	127	149	-	104	83	1,498
Trade payables	700	159	75	98	30	25
Other payables	530	925	649	288	736	1,591
Trade payables to subsidiaries	486	121	-	10	240	-

#### Group sensitivity

Based on the financial instruments held at 30 June 2009, had the Australian dollar weakened/strengthened by 10% against the GBP with all other variables held constant, the Group's and parent entity post-tax loss for the year would have been \$103,000 higher/\$84,000 lower (2008 EUR: \$142,000 higher/\$157,000 lower), mainly as a result of foreign exchange gains/losses on translation of GBP (2008: EUR) denominated financial assets/liabilities as detailed in the above table. Profit/Loss is more sensitive to movements in the Australian dollar/GBP exchange rates in 2009 than 2008 because of the increased amount of other liabilities in GBP. 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.

As at the reporting date, the Group had the following cash profile:

	30 June 2009		30 June 2008	
	Weighted average	Balance	Weighted average	Balance
	interest rate %	\$'000	interest rate %	\$'000
Cash and cash equivalents	2.47%	10,400	6.0%	2,102
Bank accepted commercial bills	3.18%	114,593	7.7%	109,740
Other receivables	2.97%	3,359	5.3%	2,921

#### Group sensitivity

The Group's and parent entity's main interest rate risk arises from cash and cash equivalents. At 30 June 2009, 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 \$1,026,819 lower/higher (2008 - change of 80 bps: \$918,060 lower/higher), mainly as a result of higher/lower interest income from cash and cash equivalents.

## 32. Financial risk management (continued)

### (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 four 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	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
<b>Cash and cash equivalents</b>				
A1+	<b>124,993</b>	111,842	<b>124,797</b>	111,650
<b>Other receivables</b>				
AA+	–	290	–	290
AA	<b>3,324</b>	2,623	<b>3,324</b>	2,623
Not rated	<b>35</b>	8	<b>30</b>	3
	<b>3,359</b>	2,921	<b>3,354</b>	2,916

Other receivables primarily represent bank guarantee facilities related to operating leases, corporate credit card and local payment clearing house facilities. Other receivables at 30 June 2008 also included cash held at bank to cover a letter of credit facility for the acquisition of plant and equipment.



**(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 tables below analyse the Group's financial liabilities, into relevant maturity groupings based on the remaining period at the reporting date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

	Less than 1 year \$'000	Between 1 and 2 years \$'000	Between 2 and 5 years \$'000	Over 5 years \$'0000	Total contractual cash flows \$'000	Carrying Amount (assets)/ liabilities \$'000
<b>Group at – 30 June 2009</b>						
Non-interest bearing	8,826	239	716	2,352	12,133	12,133
Fixed rate	310	371	1,533	11,661	13,875	13,875
<b>Total non-derivatives</b>	<b>9,136</b>	<b>610</b>	<b>2,249</b>	<b>14,013</b>	<b>26,008</b>	<b>26,008</b>
<b>Group at – 30 June 2008</b>						
Non-interest bearing	5,709	–	–	–	5,709	5,709
Fixed rate	–	–	–	–	–	–
<b>Total non-derivatives</b>	<b>5,709</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>5,709</b>	<b>5,709</b>
<b>Parent entity at – 30 June 2009</b>						
Non-interest bearing	8,786	239	716	2,352	12,093	12,093
Fixed rate	310	371	1,533	11,661	13,875	13,875
<b>Total non-derivatives</b>	<b>9,096</b>	<b>610</b>	<b>2,249</b>	<b>14,013</b>	<b>25,968</b>	<b>25,968</b>
<b>Parent entity at – 30 June 2008</b>						
Non-interest bearing	5,656	–	–	–	5,656	5,656
Fixed rate	–	–	–	–	–	–
<b>Total non-derivatives</b>	<b>5,656</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>5,656</b>	<b>5,656</b>

**(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 for disclosure purposes is estimated by discounting future contractual cash flows at the current market interest rate that is available to the Group for similar financial instruments.

### 33. 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.

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 2009			Year ended 2008		
Exercise date	Fair value of shares at issue date	Number	Exercise date	Fair value of shares at issue date	Number
7 August 2008	\$ 1.80	22,500	19 July 2007	\$ 3.55	72,000
10 June 2009	\$ 2.50	50,000	19 July 2007	\$ 3.55	5,000
10 June 2009	\$ 2.50	2,500	19 July 2007	\$ 3.55	2,500
			28 September 2007	\$ 4.05	3,750
			1 November 2007	\$ 4.44	10,000
			1 November 2007	\$ 4.44	2,500
			9 November 2007	\$ 4.39	400,000
			9 November 2007	\$ 4.39	160,000
			20 November 2007	\$ 4.28	1,876
			20 November 2007	\$ 4.28	875
			20 November 2007	\$ 4.28	2,250
			20 December 2007	\$ 4.12	10,000
			20 December 2007	\$ 4.12	48,957
			8 February 2008	\$ 3.20	15,000
			8 February 2008	\$ 3.20	3,750
			8 February 2008	\$ 3.20	1,250
			29 February 2008	\$ 2.60	1,250
			4 March 2008	\$ 2.47	5,000
		75,000			745,958

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 10,186,188 vested options at 30 June 2009 (8,413,250 at 30 June 2008). There are no options under escrow (Nil at 30 June 2008). Set out below are summaries of options granted under the plan:

# Section 3

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 2009</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	2,490,000	–	–	–	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	–	–	–
4 June 2004	3 June 2014	\$0.4260	15,000	–	–	–	15,000	15,000
2 Feb 2005	1 Feb 2015	\$0.8340	235,000	–	–	–	235,000	235,000
12 May 2005	11 May 2015	\$1.1470	290,000	–	–	–	290,000	290,000
5 Aug 2005	4 August 2015	\$1.7900	755,000	–	–	7,500	747,500	747,500
17 Oct 2005	16 Oct 2015	\$2.7720	70,000	–	–	17,500	52,500	52,500
13 Feb 2006	12 Feb 2016	\$2.1940	245,000	–	50,000	100,000	95,000	58,750
1 June 2006	31 May 2016	\$2.0340	87,500	–	–	–	87,500	65,625
15 Aug 2006	14 Aug 2016	\$1.9170	604,250	–	2,500	14,500	587,250	439,813
26 Oct 2006	14 Aug 2016	\$1.9170	230,000	–	–	–	230,000	192,500
20 Sept 2006	19 Sept 2016	\$1.8918	42,500	–	–	–	42,500	31,875
26 Oct 2006	15 Mar 2016	\$2.0680	200,000	–	–	–	200,000	150,000
14 Dec 2006	13 Dec 2016	\$3.0710	45,000	–	–	–	45,000	33,750
18 Jun 2007	17 Jun 2017	\$3.3155	192,500	–	–	35,000	157,500	78,750
10 Aug 2007	9 Aug 2017	\$3.3890	1,617,000	–	–	60,750	1,556,250	778,125
5 Nov 2007	9 Aug 2017	\$3.3890	150,000	–	–	–	150,000	75,000
5 Nov 2007	14 Nov 2016	\$3.2258	200,000	–	–	–	200,000	150,000
6 Nov 2007	5 Nov 2017	\$4.2900	517,000	–	–	10,000	507,000	366,000
14 Dec 2007	13 Dec 2017	\$4.1373	4,000	–	–	2,000	2,000	1,000
8 Feb 2008	7 Feb 2018	\$3.2666	18,500	–	–	–	18,500	4,625
11 Apr 2008	10 Apr 2018	\$2.1135	16,000	–	–	2,000	14,000	3,500
23 June 2008	22 June 2018	\$1.5990	73,500	–	–	12,500	61,000	15,250
23 Oct 2008	22 June 2018	\$1.5990	–	200,000	–	–	200,000	50,000
12 Aug 2008	11 Aug 2018	\$1.8170	–	1,479,500	–	104,500	1,375,000	343,750
23 Oct 2008	11 Aug 2018	\$1.8170	–	200,000	–	–	200,000	50,000
23 Oct 2008	22 Oct 2018	\$1.6060	–	162,500	–	5,000	157,500	39,375
11 Dec 2008	10 Dec 2018	\$1.1607	–	50,000	–	–	50,000	12,500
5 Feb 2009	4 Feb 2019	\$1.3380	–	276,000	–	–	276,000	–
23 Apr 2009	22 Apr 2019	\$1.9574	–	7,500	–	–	7,500	–
23 Jun 2009	22 Jun 2019	\$2.5498	–	1,609,500	–	–	1,609,500	–
<b>Total</b>			<b>11,536,250</b>	<b>3,985,000</b>	<b>75,000</b>	<b>371,250</b>	<b>15,075,000</b>	<b>10,186,188</b>
<b>Weighted average exercise price</b>			<b>\$ 1.422</b>	<b>\$ 2.052</b>	<b>\$ 1.679</b>	<b>\$ 2.436</b>	<b>\$ 1.562</b>	<b>\$ 1.153</b>

### 33. 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

There were 371,250 options forfeited during 2009 (280,499 options during 2008).

The weighted average remaining contractual life of share options outstanding at the end of the period was 6.06 years (2008 – 5.92 years).

# Section 3

## Fair value of options granted

The assessed fair value at grant date of options granted during the year ended 30 June 2009 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.

The model inputs for options granted during the year ended 30 June 2009 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 2009</b>							
23 Oct 2008	200,000	\$1.5990	\$1.58	2,190	50.00	4.69	\$0.8537
12 Aug 2008	1,479,500	\$1.8170	\$1.93	2,190	50.00	5.78	\$1.0064
23 Oct 2008	200,000	\$1.8170	\$1.58	2,190	50.00	4.69	\$0.9701
23 Oct 2008	162,500	\$1.6060	\$1.58	2,190	50.00	4.69	\$0.8574
11 Dec 2008	50,000	\$1.1607	\$1.05	2,190	50.00	3.75	\$0.6056
5 Feb 2009	276,000	\$1.3380	\$1.13	2,190	50.00	3.60	\$0.6949
23 Apr 2009	7,500	\$1.9574	\$2.14	2,190	50.00	4.05	\$1.0250
23 Jun 2009	1,609,500	\$2.5498	\$2.33	2,190	50.00	5.33	\$1.3873
	<u>3,985,000</u>						
<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>						

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	
	2009 \$'000	2008 \$'000	2009 \$'000	2008 \$'000
Options issued under employee option plan	<u>2,432</u>	3,434	<u>2,432</u>	3,434

### 3.2 Directors Declaration

In the directors' opinion:

- (a) the financial statements and notes set out on pages 88 to 127 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 2009 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

13th August 2009

## 3.3 Independent Auditors Report



**PricewaterhouseCoopers**  
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### **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 2009, 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.

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*.

**Independent auditor's report to the members of  
Pharmaxis Ltd (continued)**

*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 2009 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 under section 1.5 of the directors' report for the year ended 30 June 2009. 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 2009, 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 2009 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  
13 August 2009

Liability limited by a scheme approved under Professional Standards Legislation





# Section

# 4

## 4.1 Shareholder Information

### 4.1.1 ASX Shareholder Disclosures

The shareholder information set out below was applicable as at 14 August 2009.

#### 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	1,106	0
1,001 – 5,000	2,403	18
5,001 – 10,000	1,156	20
10,001 – 100,000	1,508	41
100,001 and over	117	21
	6,290	100

There were 210 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	45,881,382	21.1
Citicorp Nominees Pty Limited	29,988,742	13.8
HSBC Custody Nominees (Australia) Limited	19,352,678	8.9
J P Morgan Nominees Australia Limited	18,195,825	8.4
Australian Executor Trustees NSW Ltd	8,269,291	3.8
ANZ Nominees Limited	5,669,487	2.6
Cogent Nominees Pty Limited	5,121,820	2.4
KFT Investments Pty Ltd	3,520,732	1.6
The Australian National University	2,610,000	1.2
Citicorp Nominees Pty Ltd	1,456,413	0.7
RBC Dexia Investor Services Australia Nominees Pty Limited (BKCust a/c)	1,161,344	0.5
Bond Street Custodians Limited	928,804	0.4
UBS Wealth Management Australia Nominees Pty Ltd	885,022	0.4
Alexander Capital Investment Pty Ltd	604,795	0.3
RBC Dexia Investor Services Australia Nominees Pty Limited (MLCI a/c)	603,882	0.3
Citicorp Nominees Pty Limited (CFSIL CFS WS Small Comp a/c)	602,225	0.3
Litster & Associates Pty Ltd	600,000	0.3
Denis Michael Hanley	570,073	0.3
National Australia Trustees Limited	507,545	0.2
Megreg Holdings Pty Ltd	466,293	0.2

*Unquoted equity securities*

	<b>Number Held</b>	<b>Number of Holders</b>
Options issued under the Pharmaxis Ltd Employee Option Plan	14,695,750	100

**C. Substantial holders**

Substantial holders in the Company are set out below:

	<b>Number</b>	<b>Percentage</b>
Orbis Global Equity Fund Limited	39,153,234	18.0%
Fortis Investment Partners Pty Ltd	20,970,994	9.6%
Acorn Capital Limited	15,283,351	7.0%

**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 Price History

##### Markets

Our ordinary shares are traded on the Australian Securities Exchange. Our American Depositary Shares were traded on the Nasdaq Global Market until 23 July 2009 after which they have traded on the U.S. over-the-counter 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 November 10, 2003 to June 30, 2004	0.570	0.340
Financial Year 2005	Full Year	1.850	0.485
Financial Year 2006	Full Year	3.280	1.530
Financial Year 2007	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	First Quarter	2.450	1.310
	Second Quarter	2.400	0.940
	Third Quarter	1.800	1.120
	Fourth Quarter	2.830	1.700
	Full Year	2.830	1.310
Financial Year 2010 (through 14 August 2009)		2.600	2.260
Most Recent Six Months	February 2009	1.370	1.120
	March 2009	1.800	1.150
	April 2009	2.200	1.700
	May 2009	2.830	2.150
	June 2009	2.690	2.300
	July 2009	2.600	2.260

## 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.

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.

#### **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.

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.

#### 4.2.1 Constitution (continued)

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 in accordance with the requirements of the *Corporations Act 2001*. 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.

##### **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.

#### 4.2.2 Limitations on Rights to Securities

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 certain foreign interests 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.

Securityholders, and potential securityholders 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. 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).

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%.

Securityholders, and potential securityholders are urged to get their own independent legal advice in relation to the application Australian takeovers laws and regulations.

## ***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 Securityholder 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 broadly. 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).



## 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</b>	When a person's bronchial tubes (tubes that lead to the left and right lung) are abnormally
<b>or over-sensitivity</b>	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 for Asthma and Airways (CRCAA)</b>	The CRCAA is an Australian research cooperative that 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.)

#### 4.3 Glossary (continued)

<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
<b>goblet cell</b>	A mucus-secreting epithelial cell that is distended with secretion, so called because of its histological shape.
<b>head-to-head trial</b>	A clinical trial in which a test compound is evaluated against another compound
<b>hypertonic saline</b>	A solution with a higher salt concentration than in normal cells of the body and the blood. A salt solution containing more than 0.9% salt is hypertonic.
<b>indirect challenge test</b>	The process of indirectly inducing a constriction or narrowing of the airways by causing cells in the airways to release molecules that subsequently act on the airway, and testing the response by spirometry. Mannitol mimics an allergen challenge or asthma attack. The attack can be controlled by administering increasing doses and the response at each dose is measured. Other examples include exercise and hypertonic saline.
<b>International Committee on Harmonisation (ICH)</b>	An international body that provides test guidelines that cover the manufacture of drug substances, the manufacture of the dosage form, and the safety testing that must be conducted before evaluation in humans can proceed
<b>in vitro</b>	In an artificial environment, outside the living body e.g. in a test tube in vivo in the living body of a plant or animal, or in real life
<b>leukocytes</b>	Immune cells; white blood cells
<b>lung function</b>	A molecule that binds to cell receptors 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 authorization</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
<b>mucus</b>	Thin, slippery substance secreted by the lungs (and other organs in the body) to defend against germs, dust particles and other foreign bodies
<b>multi-centre study</b>	Study conducted simultaneously in a number of clinics, hospitals, etc
<b>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
<b>water concentration</b>	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 section 1.2.2 phase II clinical trial Refer to section 1.2.2
<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

#### 4.3 Glossary (continued)

<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>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  
Richard van den Broek  
John Villiger

### Company Secretary and Chief Financial Officer

David McGarvey

### General Counsel

Cameron Billingsley

### Corporate Affairs

Virginia Nicholls

### Registered Office

20 Rodborough Road  
Locked Bag 5015  
Frenchs Forest NSW 2086  
Australia  
Telephone: +61 2 9454 7200  
Fax: +61 2 9451 3622  
Email: [info@pharmaxis.com.au](mailto:info@pharmaxis.com.au)

### Web Site

[www.pharmaxis.com.au](http://www.pharmaxis.com.au)

### Legal Advisors

PFM Legal Pty Ltd  
Level 12, 117 York Street  
Sydney NSW 2000  
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 traded on the U.S. over-the-counter market (Code: PXSPLY)

### Share Registry

Computershare Investor Services Pty Ltd  
Level 3, 60 Carrington Street  
Sydney NSW 2000  
Australia  
Telephone: +61 3 9415 4000  
(within Australia: 1300 855 080)  
Fax: +61 3 9473 2500  
[www.computershare.com](http://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

### Incorporation Information

Incorporated in Australia  
Australian Company Number 082 811 630  
Australian Business Number 75 082 811 630

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pharmaxis

**Pharmaxis Ltd**

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