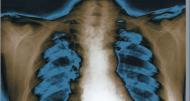
### Pharmaxis Ltd ACN 082 811 630

A fully underwritten Offer of 42 million Shares at an issue price of \$0.50 to raise \$21 million with an ability to accept oversubscriptions of up to 8 million Shares to raise up to \$4 million

# Prospectus







# pharmaxis

# pharmaxis

Pharmaxis is an emerging pharmaceutical company devoted to the research, development and commercial application of new treatment options for autoimmune and respiratory diseases.

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#### IMPORTANT INFORMATION

This Prospectus is dated 26 September 2003.

A copy of this Prospectus was lodged with ASIC on 26 September 2003. Neither ASIC nor ASX, or any of their officers, take any responsibility for the contents of this Prospectus.

No applications for Shares will be accepted nor will Shares be issued on the basis of this Prospectus:

- (a) earlier than seven days after lodgement of this Prospectus with ASIC or any longer period required by ASIC under section 727(3) of the Corporations Act 2001; or
- (b) later than 13 months after the date of this Prospectus (i.e. 25 October 2004).

The Prospectus has not been, nor will it be, lodged, filed or registered with any regulatory authority under the securities laws of any other country. The Shares the subject of this Prospectus have not been, nor will they be, approved by or registered with any regulatory authority of any other country.

This Prospectus does not constitute an offer or issue in any place in which, or to any person to whom, it would not be lawful to make such an offer or issue. If this is an electronic Prospectus, the offer of Shares under the electronic Prospectus is only made to persons receiving the electronic Prospectus within Australia who reside in Australia.

No person is authorised to give any information or make any representation in connection with the Offer other than as contained in this Prospectus. Any information or representation in connection with the Offer not contained in this Prospectus is not, and may not be relied on as having been, authorised by the Company (or any of its officers).

The Company will place this Prospectus on the Company's website at www.pharmaxis.com.au. Persons who receive a copy of this Prospectus in electronic form are entitled to obtain a paper copy of the Prospectus free of charge by contacting the Company.

Investors can only apply for Shares on the Application Form accompanying a complete paper copy of this Prospectus or a completed downloaded copy of the electronic Prospectus and on the terms and conditions set out in this Prospectus.

This document is important and it should be read in its entirety. The research, development, manufacturing, marketing and sales of pharmaceutical products involve a number of risks. The Shares offered under this Prospectus should be viewed as a speculative investment. You should consult your professional advisor about the contents of this Prospectus.

# :Summary of the Offer

#### Section



The Company is seeking to raise approximately \$21 million through the fully underwritten Offer of 42 million new Shares at an issue price of \$0.50 each with an ability to accept oversubscriptions of up to 8 million new Shares to raise up to a further \$4 million. All Shares to be issued are new fully paid ordinary Shares in the capital of the Company.

# Summary of the Offer

| Amount to be raised  | \$21 million (with an ability to accept<br>oversubscriptions up to a further \$4 million) |
|--|---|
| Offer price per Share  | \$0.50  |
| Number of new Shares being offered under this Prospectus                                     | 42 million (with an ability to accept oversubscriptions of up to 8 million Shares)        |
| Number of existing Shares (at the time of issue and allotment of new Shares under the Offer) | 58 million  |
| Total number of Shares at the time of issue and allotment of Shares under the Offer          | 100 million (plus any oversubscriptions)  |
| Indicative market capitalisation on quotation of the Company at the Offer Price              | \$50 million (plus any oversubscriptions)   |

#### Notes:

- (i) Table excludes the 10,184,000 existing unlisted options currently granted (of which 5,360,000 are vested).
- (ii) Figures rounded.

# Indicative Key Dates

| Prospectus lodged with ASIC                                    | 26 September 2003 |
|--|-------------------|
| Expected Opening Date  | 7 October 2003    |
| Expected Closing Date  | 31 October 2003   |
| Expected date for dispatch of holding statements               | 12 November 2003  |
| Expected date of quotation for the Company's Shares on the ASX | 14 November 2003  |

The Directors expressly reserve the right to vary the Offer dates. The Directors also reserve the right not to proceed with the Offer. In that case Application Money will be returned without interest. In any event, no Application Form for Shares will be accepted nor will Shares be issued until the expiry of a minimum period of seven days or any longer period required by ASIC under section 727(3) of the Corporations Act, after lodgement of this Prospectus with ASIC.

1

# 2

# :Chairman's Letter

#### Section





#### Dear Investor

On behalf of the board of Directors, it is with great pleasure that I invite you to become a shareholder of Pharmaxis Ltd.

Pharmaxis is a specialist pharmaceutical company committed to the research, development and commercialisation of human therapeutic products for chronic respiratory and autoimmune diseases.

Pharmaxis' key strength lies in its diversified portfolio of products at various stages of development which target highly attractive international markets across a range of diseases. Pharmaxis is supported by an experienced board of Directors and led by a management team with a proven track record in developing and commercialising breakthrough products.

Pharmaxis' portfolio of products capitalises on an internationally recognised base of Australian research in respiratory diseases and immunology. Pharmaxis' projects include new treatments for multiple sclerosis, cystic fibrosis, rheumatoid arthritis, chronic bronchitis and bronchiectasis, as well as a lung function test for people with airway diseases, including asthma, which is already in the final stage of clinical trials.

Pharmaxis' main projects in later stage development address respiratory diseases. In the 12 months to June 2003 the respiratory therapeutic market represented the fourth largest therapeutic category with worldwide sales of US\$27 billion.

Pharmaxis' strategy is to build a fully integrated specialist pharmaceutical company with activities spanning research and development, through to the manufacture and marketing of its products to clinicians across major international markets. In selected situations, Pharmaxis may secure value for its products by developing collaborative relationships with market leaders.

Pharmaxis is well advanced in many of its development programs, it has the use of research and development facilities at the Australian National University and has established a modern manufacturing plant in Sydney. The manufacturing plant has been licensed by the Therapeutics Goods Administration and is currently manufacturing product for clinical trials.

Pharmaxis' board and management have significant medical research, development and manufacturing expertise. To date, Pharmaxis has secured the benefit of five government research and development grants and has obtained equity funding from reputable and knowledgeable investors and a prestigious Australian research institute. Existing shareholders, Directors and management have committed to purchase \$6 million worth of new Shares under this Prospectus. All independent Directors and senior management have indicated their intention to subscribe to this Offer.

Pharmaxis is seeking to raise \$21 million under this Offer which will be used predominantly for the further development of its products and technologies.

An investment in Pharmaxis involves a number of risks but also provides an excellent opportunity to participate in the building of an internationally competitive pharmaceutical company. On behalf of the board of Directors, I commend this Offer to you and recommend that you read this Prospectus in full. I look forward to welcoming you as a shareholder of Pharmaxis.

Yours faithfully

Denis Hanley AM

Chairman

# Investment Overview

#### Section



# 3.1 The Company

Pharmaxis is a specialist pharmaceutical company committed to the research, development and commercialisation of human therapeutic products for chronic respiratory and autoimmune diseases and the development of an improved lung function test.

# 3.2 Product Pipeline and Portfolio

Pharmaxis is focused on the development of its two leading technologies. The first technology includes Bronchitol and Aridol™, inhaled non-ionic osmolytes. Bronchitol is being developed for the treatment of respiratory diseases – in particular, cystic fibrosis, bronchiectasis and chronic bronchitis. Aridol™ is an improved lung function test. The second technology focuses on new immune response modifiers represented by PXS25 and PXS2000 for the treatment of multiple sclerosis and rheumatoid arthritis.

Bronchitol and Aridol™ represent the culmination of 10 years research at the Royal Prince Alfred Hospital in Sydney. PXS25, discovered in the Company's research laboratories, represents the outcome of 10 years research at the John Curtin School of Medical Research in Canberra. PXS2000 has been discovered most recently in the Company's research laboratories.

The Company's product development pipeline and the indicative timeframe for the development of those products is illustrated below.

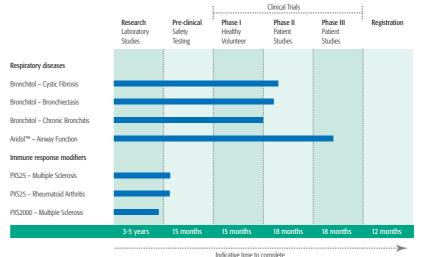
For further information on the development pipeline, refer to section 6 of this Prospectus.

#### 3.2.1 Respiratory diseases

Bronchitol and Aridol™ are both inhaled non-ionic osmolytes targeting the following inflammatory lung diseases:

Bronchitol for the treatment of cystic fibrosis - Pilot clinical trials undertaken by scientists at the Royal Prince Alfred Hospital in Sydney have shown that the use of Bronchitol helps the lungs of people with cystic fibrosis clear mucus more effectively. Bronchitol is a proprietary formulation of mannitol taken in a dry powder inhaler system (mannitol is readily available and is used variously as a food additive, a therapeutic product and a sweetener). The Company has commenced additional clinical trials with a view to demonstrating that Bronchitol improves lung function and quality of life. These phase II trials are expected to complete mid 2004. The Company expects that ongoing use of Bronchitol will reduce the number of infectious episodes and consequently reduce the need for patients to use antibiotics.





- Bronchitol for the treatment of bronchiectasis and chronic bronchitis - Clinical studies undertaken by scientists at the Royal Prince Alfred Hospital have shown that Bronchitol can bring about a dramatic improvement in mucus clearance and significantly improve the quality of life for people suffering from bronchiectasis. The Company has commenced more extensive clinical trials which are expected to complete in 2004 ahead of the important pre-registration phase III studies. Additional pilot studies have also shown a benefit for people suffering from chronic bronchitis.
- *Aridol*<sup>™</sup> *for lung function testing* Aridol<sup>™</sup> is in the final clinical development phase prior to registration. These phase III trials are expected to complete in mid 2004. Aridol™ (also a proprietary respirable form of mannitol) is an innovative lung function test. The Aridol™ test is a simple, accurate and rapid test that allows more accurate monitoring of lung function in people with diseases such as asthma.

#### 3.2.2 Autoimmune diseases

PXS25 and PXS2000 are both immune response modifiers targeting the following autoimmune diseases:

- PXS25 targeting multiple sclerosis This new compound invented in the Company's research laboratories interferes with the inappropriate migration of the immune cells implicated in the progression of multiple sclerosis without compromising the normal function of the immune system. Laboratory studies indicate that PXS25 has the potential to reduce the severity of the disease and shorten the disability period. PXS25 is in an early pre-clinical development phase.
- PXS25 targeting rheumatoid arthritis The Company's research studies have shown that PXS25 has a positive effect in retarding the progression of rheumatoid arthritis.

PXS2000 targeting multiple sclerosis – This new compound, also invented in the Company's research laboratories, operates through activation of receptors on immune cells and has shown benefit in models of multiple sclerosis. The potential of this compound in other autoimmune diseases is also being evaluated. This compound is potentially complementary with PXS25 to alleviate the symptoms of multiple sclerosis.

For more information on the Company's projects and the market for these projects, refer to section 6 of this Prospectus.

## 3.3 Strategy

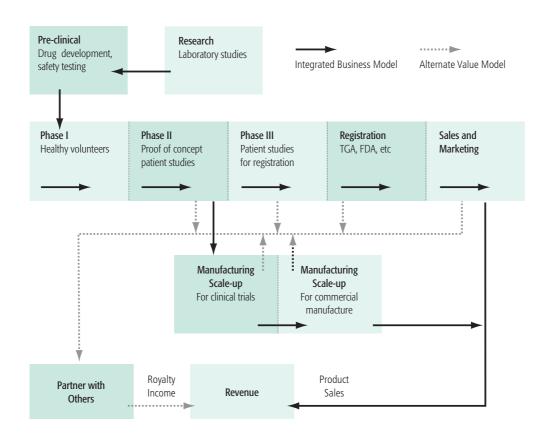
The Company's goal is to build a fully integrated specialist pharmaceutical company which develops and commercialises specialist therapeutic products both independently and through collaborative relationships with selected market leaders. Key aspects of its strategy comprise:

- focusing on highly attractive product development and commercialisation opportunities;
- participating in the complete product development and commercialisation value chain;
- focusing on its core therapeutic markets and maintaining a diversified product pipeline; and
- expanding the Company's research and development pipeline.

The Company's commercialisation value chain is highlighted on the next page and the details of the strategy are in section 6.3 of this Prospectus.







# 3.4 Board and Management

The Company has a highly experienced board of Directors and management with extensive experience in technology development including drug development and commercialisation, research, clinical trials, manufacturing, business development and corporate finance. The Company will capitalise on this experience and expertise in building a valuable business, recognised internationally for its approach to therapeutic discovery, development and commercialisation. For further details of the Company's Directors and management, refer to section 7 of this Prospectus.



# 3.5 Financial Prospects, Dividend Policy and Risk Factors

The Company is in a development stage. Revenue, profits and cash flows for the Company are dependent on a number of factors including the level of sales achieved after the registration of the Company's products, a process only complete after extensive product research and development. In light of these factors, the Directors consider that at this stage of the Company's development, they are unable to provide potential investors with reliable revenue, profit or cash flow projections or forecasts.

The primary focus of the Company is to complete the development and commercialisation of its existing projects. During this phase, the Company is unlikely to pay a dividend. The ability for the Company to pay a dividend in the future and the timing of any dividend is dependent on a number of factors including deriving sufficient cash flows from future operations.

An investment in the Company should be regarded as being speculative and involving a number of risks. These risks are set out throughout this Prospectus and in particular in section 11 of this Prospectus.

# 4

# :Details of the Offer

Section



#### 4.1 The Offer

The Company is offering 42 million new Shares at an issue price of \$0.50 under this Prospectus to raise \$21 million. The Company may accept oversubscriptions up to a further 8 million Shares to raise up to \$4 million.

### 4.2 Offer Price

The Offer Price of the Shares is \$0.50 per Share. The Offer Price is payable in full on application.

# 4.3 Number of Shares Offered

The Company is offering 42 million new Shares under this Prospectus.

In the event that the Offer is oversubscribed, the Directors in consultation with the Underwriter may at their discretion determine the amount and the basis of allocation (giving priority in the manner described below) of oversubscriptions up to 8 million Shares.

Certain existing shareholders, Directors and management of the Company have committed in advance to subscribe for 12,000,000 new Shares at the Offer Price under the Offer. For details of the commitments and certain fees payable to these Applicants by Wilson HTM in respect of these commitments, refer to section 12 of this Prospectus.

Applications for Shares must be for a minimum of 5,000 Shares and thereafter in multiples of 1,000.

### 4.4 Allocation of Shares

Priority allocation will be given to those existing shareholders, Directors and management of the Company that have given a firm commitment to Wilson HTM to apply for Shares. Priority allocation will then be given to Applicants who receive a firm offer over Applicants under the general offer.

The firm offer is open to Australian resident investors and institutional investors who are offered a firm allocation of Shares from the Underwriter or other brokers participating in the Offer which indicate that it is a firm offer.

The general offer is open to members of the general public who are resident in Australia and institutions who have not been offered an allocation of Shares under the firm offer.

The Directors, in consultation with the Underwriter reserve the right to allocate to any Applicant a lesser number of Shares than that Applicant applied for, or to reject any Application without being obliged to provide any reason. Pending the allocation of Shares under the Offer, all Application Money will be deposited into a separate bank account to be held in trust for so long as the money is liable to be repaid under the Corporations Act. Surplus Application Money will be returned to the relevant Applicants within 45 days after the Closing Date. No interest will be paid on returned Application Money.

Successful Applicants will be notified in writing of the number of Shares allotted to them as soon as practicable after the Closing Date. It is the responsibility of Applicants to confirm the number of Shares allotted to them prior to trading in the Shares.

### 4.5 Terms of Shares

The Shares are to be issued as new fully paid ordinary Shares in the capital of the Company. These Shares will rank equally with all other existing issued Shares. For a summary of the terms of the Shares, refer to section 12 of this Prospectus.

# 4.6 Summary Capital Structure

On the issue and allotment of Shares under this Prospectus, the Company will have 100,016,000 Shares on issue and 10,184,000 unlisted options (of which 5,360,000 are vested) and any further Shares issued as a result of acceptance of oversubscriptions.

| S                         | hares on issue and allotment under this Prospectus | % of Shares on issue and allotment | Issued unlisted options |
|---------------------------|--|------------------------------------|-------------------------|
| Existing Shares           | 58,016,000   | 58%                                | 10,184,000              |
| New Shares                | 42,000,000   | 42%                                | Nil                     |
| Total securities on issue | 100,016,000  | 100%                               | 10,184,000              |

For details of the capital structure and control of the Company, refer to section 12 of this Prospectus. The table does not include the impact of the acceptance of any oversubscriptions.

## 4.7 Underwriting

The Offer of 42 million new Shares is fully underwritten by Wilson HTM Corporate Finance Ltd. For a summary of the Underwriting Agreement, refer to section 12 of this Prospectus.

#### 4.8 Allotment

The Company will proceed to allotment of Shares once the Offer closes. The Closing Date of the Offer may vary.

# 4.9 Source and Use of Funds

The amount raised under the Offer and the cash reserves that the Company currently has available to it and the R&D Start Grant and miscellaneous income, will be applied to the clinical and pre-clinical development and commercialisation of its projects, scale-up of its manufacturing capability, general corporate purposes and expenses of the Offer.

The sources of funds available to the Company are summarised in the table below:

| Source of funds                                | \$'000                |
|--|-----------------------|
| Proceeds of the Offer                          | 21,000 <sup>®</sup>   |
| Cash on hand                                   | 7,000                 |
| R&D Start Grant and other miscellaneous income | 3,700 <sup>(ii)</sup> |
| Total  | \$31,700              |

The money raised pursuant to this Offer will be used by the Company as follows:

| Use of Funds  | \$'000                      |
|---|-----------------------------|
| For the further development of its existing technologies and products including the cost of:  • clinical trials and related manufacture of Bronchitol for cystic fibrosis and bronchiectasis;  • clinical trials, related manufacture and registration of Aridol™;  • clinical trials and related manufacture of PXS25 and PXS2000; and  • additional development associated with the Company's technology. | 20,100 <sup>©</sup>         |
| Commercial scale-up for the manufacture of Bronchitol and Aridol™   | 1,700                       |
| General corporate purposes including staff costs and administrative overheads   | 8,200                       |
| The costs of this Offer   | 1,700                       |
| Total   | \$31,700 <sup>(1)(ii)</sup> |

#### Notes to tables:

- (i) The Company may accept oversubscriptions of up to 8 million Shares to raise up to \$4 million. If the Company accepts oversubscriptions, the Company will increase the level of funds it provides for the further development of its existing technologies and products. The costs of the Offer will also increase by 6% of the value of the oversubscriptions accepted being the fee payable to the Underwriter under the Underwriting Agreement.
- (ii) Assumes receipt in full of that amount of the R&D Start Grant that has yet to be received and that the Company continues to satisfy the conditions associated with the receipt of the R&D Start Grant so it is not required to be repaid. The R&D Start Grant funds are paid in tranches and are not all available at the date of this Prospectus. For a summary of the terms of the R&D Start Grant, refer to section 12 of this Prospectus.

The final allocation of funds may vary depending upon the circumstances in which the business develops and operates.

In accordance with the use of funds table above and the objectives set out in section 6 of this Prospectus, on the successful completion of the Offer, the Directors believe that the Company will have sufficient working capital to carry out those stated objectives.

The funds raised from the Offer will not enable the Company to progress all of the Company's projects to the point where sales revenue can be derived from products. To continue the development of the Company's projects, additional sources of funding will be required within the next three years. This funding may be obtained by the issue of additional equity, debt finance or other appropriate means determined by the Directors at that time.

# 4.10 Stock Exchange Listing

The Company intends to apply within seven days after the date of this Prospectus to be admitted to the official list of the ASX and for the Shares to be granted official quotation on the ASX.

If the Company is not admitted to the official list of the ASX and the Shares offered under this Prospectus are not granted official quotation within three months after the date of this Prospectus, none of the Shares offered under this Prospectus will be issued and allotted and all Application Monies will be refunded without interest to Applicants within the time prescribed by the Corporations Act.

The ASX takes no responsibility for the contents of this Prospectus. The fact that the ASX may admit the Company to the official list is not to be taken in any way as an indication of the merits of the Offer, the Company or the Shares offered pursuant to this Prospectus.

### **4.11 CHESS**

The Company will participate in the Clearing House Electronic Sub-register System, known as CHESS, in accordance with the Listing Rules and the SCH Business Rules, and will maintain an electronic issuer sponsored sub-register and an electronic CHESS sub-register.

Following the allotment of the Shares to successful Applicants, shareholders will receive an initial statement of holding that sets out the number of Shares which they have been allocated in the Offer and details of the shareholder's holder identification number or sponsoring issuer number. Shareholders will receive subsequent statements at the end of any month in which there has been a change in their

holding on the register and as otherwise required under the Listing Rules and SCH Business Rules. The shareholder may require the Company to provide a statement at other times subject to payment of an administration fee for these additional statements.

# 4.12 Application Form and Monies

Applicants who receive a firm offer (as described in section 4.4 of this Prospectus) should return their completed Application Forms with the necessary Application Monies to the Underwriter or broker from whom they received their firm allocation of Shares (unless instructed otherwise).

Applicants who receive a general offer should return their completed Application Forms and cheques payable to the 'Pharmaxis Ltd Trust Account' and crossed 'Not Negotiable':

By mail to:

The Pharmaxis Share Offer Computershare Investor Services Pty Ltd GPO Box 7115 Sydney NSW 1115

By hand to: Computershare Investor Services Pty Ltd Level 3, 60 Carrington Street Sydney NSW 2000

Applications must be received by 5.00pm Australian Eastern Standard Time on the Closing Date. As previously stated, the Offer may be closed early or may be extended beyond this date. Accordingly, Applicants are encouraged to submit their Application as early as possible.

### 4.13 Stamping Fee

A stamping fee of 1.0% of the value of Shares issued in respect of Applications lodged and accepted under the general offer bearing their stamp will be paid by the Underwriter to participating organisations of the ASX, dealers in securities and licensed investment advisors.

### 4.14 Questions

If you have any questions as to how to subscribe for Shares under this Offer, consult your professional advisor.

# 5 : Corporate History

#### Section



The Company was incorporated on 29 May 1998 as a proprietary limited company. Until October 1999, the Company was a wholly owned subsidiary of Praxis Pharmaceuticals Inc., a public company incorporated and listed in the U.S.

The Australian Bioscience Trust managed by Rothschild Bioscience Managers Limited (now known as GBS Venture Partners Ltd), invested in the Company in October 1999 and the funds raised were used for the development of autoimmune disease research licensed from Anutech Pty Ltd (the development arm of the ANU).

In October 2001, the Company secured a further licence to a patent family owned by the CSAHS covering new treatments for chronic lung diseases and for the measurement of lung function.

The CSAHS Licence and the Anutech Licence are summarised in section 12 of this Prospectus.

In August 2002, a group of investors invested in the Company in order to fund further development of its product portfolio. The investors who took a beneficial interest in the Company include:

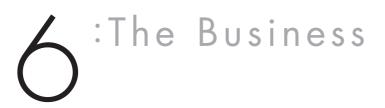
- The Australian Bioscience Trust;
- Bioscience Ventures II;
- CM Capital Venture Trust No 3;
- Australia Venture Capital Fund L.P.;
- Mooroolbark Technology Ltd; and
- Australian National University.

To date, the Company has secured approximately \$13 million in equity funding. The Company has also secured the benefit of five research grants totalling approximately \$4.8 million. The most recent grant of \$3 million was awarded in June 2003 by the Commonwealth of Australia R&D Start Grant Program for the development of new treatments for cystic fibrosis.

In November 2002, the Company established an office and clean room manufacturing facility in Frenchs Forest, a suburb of Sydney, Australia. In May 2003, the TGA accredited the Company's facilities for the manufacture of Bronchitol and Aridol™ for clinical trials.







Section



# 6.1 The Company

Pharmaxis is a specialist pharmaceutical company committed to the research, development and commercialisation of human therapeutic products for chronic respiratory and autoimmune diseases and the development of an improved lung function test.

The mission of the Company is to build a valuable business, recognised internationally for its approach to therapeutic discovery, development and commercialisation in the fields of respiratory and autoimmune diseases.

## 6.2 Industry Overview

The pharmaceutical industry is a global industry that supplies medicinal products for human or veterinary health. The global human pharmaceutical market, measured by the 13 leading countries, had sales of US\$293 billion in the 12 months to June 2003. According to the IMS Health Drug Monitor, drugs for cardiovascular disease were the largest single therapeutic category in those territories, with sales of US\$56 billion in the 12 months to June 2003. Respiratory disease (including cystic fibrosis, asthma and chronic obstructive lung disease) was the fourth largest therapeutic category, with sales of US\$27 billion at a growth rate of 3% in the 12 months to June 2003. The musculoskeletal therapeutic category, which includes rheumatoid arthritis and multiple sclerosis, had sales of US\$18 billion at a growth rate of 7% in the 12 months to June 2003.

## 6.3 Strategy

The goal of the Company is to build a fully integrated pharmaceutical company developing and commercialising specialist therapeutic products both independently and in collaborative relationships with selected market leaders. Key aspects of the Company's strategy comprise:

- Focusing on highly attractive product development and commercialisation opportunities. The Company is developing products that address selected categories of chronic respiratory and autoimmune disease markets. These markets represent highly attractive opportunities for Pharmaxis due to:
  - the limited number of effective and convenient alternative therapeutic options. By way of example there are few effective therapies for cystic fibrosis patients and no product comparable to Aridol™ is currently available;
  - current treatments represent a significant cost to the healthcare system and represent potential high value product opportunities;





- current treatment alternatives suffer from patient dissatisfaction. As an example, for chronic obstructive lung disease, current treatment alternatives are sometimes ineffective and sometimes use inconvenient nebuliser systems. Bronchitol, however, offers the potential of both a safe and effective therapy and the convenience of a hand-held portable dry powder inhalation device; and
- the markets in which some of the Company's projects will operate are highly concentrated and primarily served by specialist physicians. As such, they are accessible and can be addressed effectively with a relatively modest commercialisation infrastructure. In many cases key opinion leaders in these physician groups are participants in Pharmaxis' late stage clinical development programs. As such these highly regarded physicians become fully aware of the product's potential.
- Participating in the complete product development and commercialisation value chain. Pharmaxis intends to build a fully integrated specialist pharmaceutical company. It has focused strategically on attractive product development opportunities where it can undertake the complete product development, registration and commercialisation activities. Pharmaxis has assembled a high calibre pharmaceutical product research, development and commercialisation management team and has advanced its products in certain cases through to late stage clinical development with the associated completion of manufacturing infrastructure.

- In situations where its products address markets that are larger, more diverse or in some way less accessible, Pharmaxis will establish selective collaborative relationships with market leaders, to capture the maximum value from its investment in product related research and development.
- Focusing on its core therapeutic markets and maintaining a diversified product pipeline. To mitigate the risk of any one product's delay or failure, Pharmaxis has established a portfolio with a diversified product development pipeline in its selected therapeutic categories. This product pipeline is diversified both from the perspective of the differentiated approach to multiple disease categories and in terms of its variety of stages of pre-clinical and clinical development. Pharmaxis will seek to maintain a diversified product pipeline consistent with its core competencies in its selected therapeutic markets.
- Expanding the Company's research and development pipeline. The Company will build selectively by strengthening its existing technology, and may also 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 in a manner determined by the board of Directors at that time. In addition, the Company will evaluate opportunities to acquire other businesses that complement its existing business, and either add to the product development pipeline or enhance the Company's ability to execute its strategy.



| Product    | Target Application   | Targeted Product Features  | Approximate Patient Population World (ii) |
|------------|--|--|---|
| Bronchitol | Cystic fibrosis  | Quantitative improvement in lung function, more effective clearance of mucus, reduced infection rate, improved quality of life | 75,000                                    |
| Bronchitol | Chronic obstructive<br>pulmonary disease –<br>Bronchiectasis     | Improved mucus clearance,<br>improved quality of life, reduction<br>in infection rate  | 580,000                                   |
| Bronchitol | Chronic obstructive<br>pulmonary disease –<br>Chronic bronchitis | Improved mucus clearance,<br>improved quality of life  | 30,000,000                                |
| Aridol™    | Lung function test —<br>Management of asthma<br>treatment        | Monitoring of asthma severity allowing improved management of asthma medications   | Data not available <sup>(1)</sup>         |
| PXS25      | Multiple sclerosis   | Reduce severity of disease,<br>shorten disability periods  | 1,100,000                                 |
| PXS2000    | Multiple sclerosis   | Alleviate symptoms   | 1,100,000                                 |
| PXS25      | Rheumatoid arthritis   | Retard progression of disease  | 5,500,000                                 |

- (i) The Aridol™ test is currently being developed for sufferers of asthma with moderate to severe forms of the disease. For illustrative purposes only, the world population of asthma sufferers is approximately 30 million and the market size of treatments for asthma is A\$5,069 million. The Company has no reliable figures of how much of this market the Company can target and there are currently no reliable figures available as to the potential patient population size and existing market size for a lung function test.

  (ii) References to "World" in this table only includes the eight largest pharmaceutical markets.



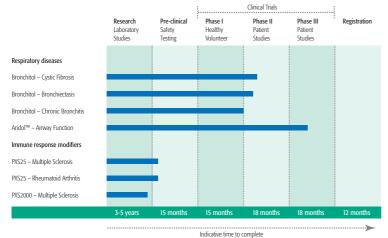
| Approximate Market Size (sale of existing treatments)   | Development Status  |  |  |  |
|---|---|--|--|--|
| World A\$ <sup>®</sup>  | Development status as at September 2003   | Plans for 2004 and 2005  |  |  |
| 575 million   | Commenced multicentre phase II<br>clinical study in Australia   | Complete phase II dose ranging study;<br>commence phase II/III clinical trials in Australia,<br>UK and U.S.; and commence major phase III clinical<br>trials in Australia and U.S. |  |  |
| Data not available.  Market data not segregated from chronic obstructive pulmonary disease/chronic bronchitis described below | Commenced phase II proof of<br>efficacy in Australia and New Zealand  | Complete phase II proof of efficacy; commence<br>and substantially complete international phase III<br>clinical trial  |  |  |
| 3,840 million   | Pilot proof of concept study completed  | Wait for completion of the bronchiectasis trials   |  |  |
| Data not available <sup>(1)</sup>   | Commenced phase III clinical trial for Australian and European registration; commenced long-term toxicology studies | Complete phase III clinical trials; prepare and lodge marketing authorisation applications in Australia and Europe; commence marketing and sales in Australia and Europe           |  |  |
| 3,533 million   | Commenced scale-up synthesis and toxicology studies   | Initiate and complete phase I safety studies in humans.<br>Commence phase II proof of efficacy clinical trials   |  |  |
| 3,533 million   | Candidate identified  | Complete scale-up synthesis and toxicology studies, commence phase I clinical trial – safety in humans   |  |  |
| 3,600 million   | Commenced scale-up synthesis and toxicology studies   | Complete phase I safety studies in humans, commence phase II proof of efficacy clinical trials   |  |  |



# 6.4 Product Pipeline and Portfolio

The table below illustrates the Company's pipeline of products and gives an indicative timeframe for the research and development of those products. The Company currently has four projects at clinical study stage (in patients), two projects in pre-clinical evaluation (prior to being administered to volunteers or patients) and one research project to identify a compound for development.

The Company has a suite of products that are being developed simultaneously for large world markets, each in various stages of development. The Company's development program has been designed to produce a series of marketed products over the coming years.



Indicative time to complete

## 6.5.1 Bronchitol for respiratory diseases

**6.5** Respiratory Diseases

Pharmaxis is developing Bronchitol for the management of various chronic obstructive lung diseases, in particular cystic fibrosis, bronchiectasis and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol in a dry powder inhaler system. Mannitol is readily available and is used variously as a food additive, a therapeutic product and a sweetener. Bronchitol is formulated as a dry powder of a specific particle size to allow effective respiration of the mannitol into the lungs. Bronchitol has been licensed from CSAHS.

The lungs (and other mucosal surfaces of the body) have a natural mechanism for cleansing and protecting the mucosal surface. Mucus is secreted by cells lining the lung. Specialised surface cells projecting cilia beat continuously and propel the overlying blanket of salt, water and mucus to the throat where secretions are swallowed or expelled (this process is called mucociliary clearance).

Many people who suffer from various chronic obstructive lung diseases such as bronchiectasis, chronic bronchitis and cystic fibrosis are generally affected by a breakdown in the natural process of mucosal hydration and mucociliary clearance. Sufferers face the constant challenge of clearing excessive and thickened lung secretions. A key therapeutic goal for clinicians treating these patients is to assist in the resumption of the natural process of mucosal hydration and mucociliary clearance.

In a number of trials in diseased patients and healthy volunteers, inhaled mannitol has been shown to be safe and well tolerated and to effectively assist in the hydration of mucus and promote mucociliary clearance. The results to date have been published in prominent respiratory journals including American Journal of Respiratory and Critical Care



Bronchitol is prepared as a powder of a specific particle size and a measured dose incorporated into a capsule. The device delivers the measured dose to the patient's lungs.

Medicine, Paediatric Pulmonology, European Respiratory Journal and Chest. These findings have been well received by leaders in the field of lung disease at international meetings of Thoracic Societies in Europe, Canada and the U.S.

#### Bronchitol for cystic fibrosis

Pharmaxis is developing Bronchitol as a therapy for the management of cystic fibrosis.

#### The disease

Cystic fibrosis is a life-threatening disease involving a genetic mutation that disrupts the cystic fibrosis transmembrane regulator protein. This protein acts as an ion-specific channel that modulates salt and water transport. A disruption to the balance of salt and water leads to poorly hydrated and thick mucus secretions in the airways and lungs and a severely impaired ability to clear excessive mucus through the natural process of mucociliary clearance. Impairments in these vital lung defence mechanisms typically begin in early childhood and often result in chronic secondary infections, resulting in progressive lung dysfunction and deterioration.

Respiratory failure accounts for about 90% of deaths in patients with cystic fibrosis. According to the U.S. Cystic Fibrosis Foundation, the median life expectancy today for patients with cystic fibrosis is 31 years.

There are 33,000 diagnosed cystic fibrosis patients in the United States and a total of 75,000 in the eight major pharmaceutical markets. In Australia, 2,500 people suffer from the disease. The problem of mucus clearance and resulting progressive deterioration in lung function is common to all sufferers and is a chronic lifelong disability.

A clinical trial participant undergoing treatment with Bronchitol for the management of her chronic lung complaint.



#### **Treatment options**

Currently there is no cure for cystic fibrosis. The goal for clinicians treating sufferers of cystic fibrosis is to hydrate, breakdown and mobilise the viscous, excessive mucus secretions and thus improve lung function and reduce the number and severity of secondary lung infections. Doctors typically prescribe various nebulised agents and recommend physical therapy, but treatment options are limited and of these, few are effective. In cases where secondary infections have occurred, clinicians may prescribe an antibiotic. In addition most treatment options suffer from the inconvenience of nebuliser delivery requiring a time consuming, at-home procedure.

#### **Expected product advantages**

Pharmaxis expects Bronchitol to meet the key clinical goals in the management of cystic fibrosis, that of stimulating mucociliary clearance, reducing the viscosity of mucus and enhancing cough clearance. In addition to helping patients clear mucus more effectively and improving quality of life, the Company expects that the use of Bronchitol will improve lung function and reduce the number of infectious episodes and the need for antibiotics.

In addition, the Company believes an important advantage of Bronchitol is that it is formulated as a respirable powder and administered by a convenient, hand-held, pocket-sized device making it significantly more user friendly and portable than nebulised aerosols.

#### Development program

Studies performed by clinicians at Royal Prince Alfred Hospital in Sydney evaluated inhaled Bronchitol's impact on mucociliary clearance in cystic fibrosis patients. In these studies a single intervention with Bronchitol increased mucociliary clearance over 24 hours. These proof-of-concept studies for the acute benefit of Bronchitol on mucociliary clearance have been published in various well-respected medical journals. This is a significant advance for patients with cystic fibrosis and the Company is undertaking further studies aimed at assessing the benefit of long-term daily use.

It is expected that the use of Bronchitol will improve mucus clearance and thereby reduce infectious episodes and antibiotic use. The Company has commenced longer-term clinical studies to determine the optimum dose and frequency of administration to maximise clinical benefit for the patient. Key trial sites have been identified and 60 patients are being recruited for a two-week trial of daily Bronchitol inhalation. The data generated from this trial is scheduled to be available in the second quarter of 2004 and will be used to support phase III studies in Australia, the U.S. and the U.K.

As a prerequisite to longer-term (three-month) chronic studies, a comprehensive rodent safety study of chronic Bronchitol inhalation is in progress. The Company is aiming to have all studies completed to enable submission of a general marketing approval with Australian, U.S. and European regulatory authorities before the end of 2007.

#### Bronchitol for bronchiectasis and chronic bronchitis

# A new treatment for the management of chronic obstructive pulmonary disease

This application of the Bronchitol technology has been investigated in patients suffering from chronic obstructive pulmonary disease. The phase II clinical studies have been undertaken in a condition known as bronchiectasis and pilot studies have also been completed in patients with chronic bronchitis. These studies have been positive and the Company is currently undertaking more extensive studies.

#### The diseases

Chronic bronchitis is defined as the presence of chronic productive cough for at least three months in each of two consecutive years, without other specific causes of cough. These symptoms result from inflammation and scarring of the lining of the bronchial tubes.

Symptoms of chronic bronchitis include the presence of yellow/green mucus, shortness of breath, and acute exacerbations consisting of worsening cough and mucus production and shortness of breath. Patients with chronic bronchitis experience persistent airway inflammation and airflow obstruction, with recurrent exacerbations often induced by bacterial pathogens contributing to the progressive decline in pulmonary function. Infectious exacerbations not only cause direct damage to the bronchial epithelium, but also contribute to the maintenance of chronic inflammation and immune-mediated cell damage.

Bronchiectasis is a disease characterised by irreversible dilation and destruction of bronchial walls. Bronchiectasis results in impaired mucociliary clearance, excessive mucus secretions throughout the bronchial tree and consequential secondary infections.

Worldwide, there is an estimated 30 million people affected with chronic bronchitis. Mortality is significant in this condition. In the U.S. and most western European countries, chronic obstructive pulmonary disease represents the fourth leading cause of death following heart disease, cancer and stroke. Many of the deaths associated with chronic bronchitis are included in the chronic obstructive pulmonary disease figure that now accounts for over 100,000 deaths a year.

#### Treatment options

Conventional treatment of chronic bronchitis consists of various general supportive measures, as well as pharmacologic management. Supportive measures include giving up smoking, limiting exposure to dust and chemicals, avoiding sudden temperature changes, chest physiotherapy, deep-breathing exercises and increased fluid intake to keep bronchial secretions thin. The mainstays of conventional pharmacologic management of chronic bronchitis and bronchiectasis target:

- · dilation of the airways;
- reduction of airway inflammation; and
- mobilisation and clearance of mucus secretions.

While there are a number of pharmaceutical options to dilate the airway and reduce airway inflammation, there are few therapeutic products available to effectively clear excess mucus secretions.

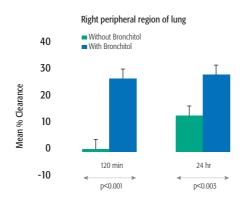
#### **Expected product advantages**

The Company expects Bronchitol to address the need for an effective agent for the clearance of excess mucus secretions. The Company believes that the use of Bronchitol potentially in combination with other agents will improve lung function and improve the quality of life for chronic bronchitis and bronchiectasis sufferers.

#### Development program

A patient study undertaken by clinicians at the Royal Prince Alfred Hospital has shown that inhaled Bronchitol can bring about an improvement in mucus clearance for patients suffering from bronchiectasis. Analogous to the results that are being obtained in patients with cystic fibrosis, the Company believes there is a role for Bronchitol in treating patients suffering chronic obstructive pulmonary diseases such as chronic bronchitis, bronchiectasis and smoking-related diseases. Longer-term chronic studies are in progress.

Percentage fluid clearance from lungs of bronchiectasis patients with and without Bronchitol



This data was taken from an acute study in patients suffering from bronchiectasis and having difficulty with mucus clearance. The data shows that the effect of Bronchitol is rapid and durable.

Clinical studies are in progress and the ultimate goal is to demonstrate an improved quality of life for the patient through:

- reducing the number of bacterial infections;
- improving the oxygen delivery from the lungs;
- · reducing the need for physiotherapy;
- · reducing the need for hospitalisation;
- improving exercise capacity;
- · improving sleep quality; and
- improving lung function.



The phase II clinical trials are due to be completed in 2004 and the Company is aiming to have all studies completed to enable submission of a general marketing approval for bronchiectasis with the Australian regulatory authorities by 2006. Clinical trials for the use of Bronchitol for the treatment of chronic bronchitis will be scheduled following completion of the above bronchiectasis studies.

#### *Aridol*™ *for monitoring lung function*

The Company is developing a simple, rapid and inexpensive to manufacture test that will diagnose not only the presence but, most importantly, the severity of bronchial hyperresponsiveness consistent with various respiratory diseases such as asthma.

#### The disease

Asthma is a condition which affects the small airways of the lungs. People with asthma have sensitive airways, which, when exposed to certain 'triggers' can cause the airways to narrow, leading to difficulty in breathing. The narrowing of the airways is caused by inflammation and swelling of the airway lining, the tightening of the muscles around the airways and the production of excess mucus. The result is a reduction of air flow in and out of the lungs.

Asthma is a major public health problem. Approximately 2 million Australians have reported asthma as either a recent or a long-term condition. There are about 15 million asthmatics in the U.S. Recent studies have shown that asthma incidence in Australian children is increasing. Asthma remains a major cause of mortality and morbidity with over 500 deaths from asthma in Australia in 2001.

#### Treatment options

Although there are multiple therapeutic options for asthmatics, a key challenge is effective diagnosis and monitoring. Underdiagnosis and misdiagnosis of asthma is a serious unmet medical need causing extensive morbidity and mortality. Much of the deterioration in the quality of life of the asthma sufferer could be prevented through correct early diagnosis of the disease, appropriate treatment and effective ongoing monitoring.

A diagnosis of asthma is currently achieved using hypertonic saline or methacholine as a provocative agent. At present there is no accepted product for the monitoring of asthma severity and therefore no method of regulating medication levels.

#### **Expected product advantages**

The Company considers the Aridol™ test will be:

- simple, rapid and inexpensive;
- specific for the presence and severity of bronchial hyper-responsiveness and asthma;
- convenient and not restricted to specialist centres.

#### Development program

Studies using the Aridol™ test have been performed in 500 adults and children with asthma and in healthy subjects. Over 1,000 tests in total have been carried out and these have established the efficacy, safety, repeatability and patient acceptability of the test. No untoward side effects have been experienced and no medical intervention has been required during testing. The median time to complete a positive test is 13 minutes and the median time to complete a negative test is 21 minutes.

The ability of Aridol™ to confirm a diagnosis of asthma represents a modest market opportunity. However, a more significant market opportunity exists for its ability to determine the severity of disease progression and the effectiveness of therapeutic intervention.

The development of Aridol™ is now in its final clinical stages, with the 12-month pivotal phase III registration study having commenced. The data collected from this study will be used to file a marketing authorisation application in Europe and Australia. Additional data will be collected prior to submitting a marketing authorisation application in the U.S.

The Company is aiming to have all studies completed to enable submission of a general marketing approval application with the Australian and European regulatory authorities by the end of 2004.

# **6.5.2** Immune response modifiers for autoimmune disease

The Company is developing new immune response modifiers for the treatment of autoimmune disease, in particular, multiple sclerosis and rheumatoid arthritis. The lead candidates are PXS25 and PXS2000.

If functioning normally, the immune system reacts against foreign antigens and provides essential protection against infectious agents. In autoimmune diseases the immune system reacts to proteins or other molecules that are natural constituents of the body that normally do not illicit an immune response giving rise to diseases such as multiple sclerosis, rheumatoid arthritis, psoriasis and irritable bowel disease.

#### PXS25 for multiple sclerosis

The Company is developing PXS25 as a therapy for the management of multiple sclerosis.

#### The disease

Multiple sclerosis is a progressive debilitating disease of the central nervous system which is thought to be caused by an autoimmune reaction. The immune system attacks the protective protein sheath (known as myelin) that coats the axons (elongated extensions of nerve cells, or neurones, that send information to target cells in the brain and spinal cord). Myelin helps speed the conduction of nerve signals around the body. Damage to the myelin is eventually replaced by scar-like tissue, which further interferes with nerve signalling.

There are about 1.1 million people affected by multiple sclerosis in the developed world. There is no cure for multiple sclerosis although treatments aimed at delaying the progression of the disease do exist.

The average annual economic cost of multiple sclerosis in the U.K. has been estimated at more than £1.2 billion, or about £18,000 per patient. About 40% of this cost results from medical treatments and most of the balance from indirect costs, including lost earnings.

#### Treatment options

There are currently five drugs available for the treatment of multiple sclerosis, of which three are beta interferons.

The mechanism of action of the interferons in the treatment of multiple sclerosis is not well understood. To date, the major treatments concentrate on relieving the symptoms rather than addressing the underlying cause. Many of the current treatments have limited effectiveness, a poor side effect profile and suffer from low level of patient acceptability.

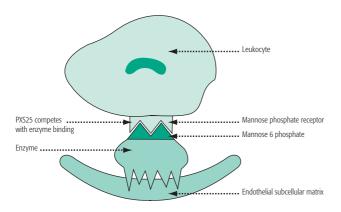
#### **Expected product profile**

The Company is developing PXS25 to target the underlying disease process. The market for a safe and effective agent with low side effects in the major forms of multiple sclerosis will be large, the total worldwide market in 2002 was more than US\$2.3 billion.

The Company has an active research program designed to identify compounds that prevent inappropriate migration of immune cells (leukocyte) from the blood compartment to the surrounding tissue. PXS25 has been identified as such a compound and has demonstrated therapeutic efficacy in rodent models of autoimmune diseases such as multiple sclerosis and rheumatoid arthritis. The Company believes PXS25 stops enzyme expression and therefore prevents leukocyte migration to sites of inflammation.

Unlike existing approaches to the management of multiple sclerosis, PXS25 has the potential to be delivered orally.

#### Pharmaxis inhibitors prevent leukocytes reaching nerve cells

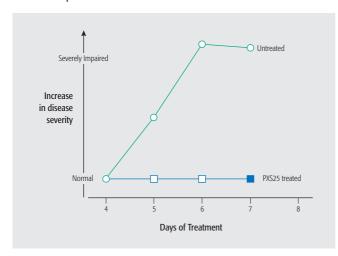


#### Development program

PXS has been studied in widely accepted rodent models of experimentally induced multiple sclerosis.

Overall, treatment with PXS25 has resulted in a marked reduction in peak severity of disease signs, with complete abrogation of disease in some experiments.

# Treatment of rodents with PXS25 following experimentally induced multiple sclerosis



In pre-clinical trials, rodents treated with PXS25 did not develop the symptoms of the disease and remained normal throughout the course of the study. This important result highlights the potential of this class of compound and is superior to published results obtained in this model with the current clinical treatments.

The Company has commenced toxicology studies and initial clinical trials are scheduled for 2004.

#### PXS25 for rheumatoid arthritis

The same technology that gave rise to PXS25 has a number of other potential applications. The Company is studying new compounds from this family for their potential application in other autoimmune diseases such as rheumatoid arthritis

#### The disease

Rheumatoid arthritis is a form of arthritis that leads to inflammation in the lining of the joints. Although its exact cause is unknown, it is thought to result from an autoimmune condition. Rheumatoid arthritis varies a great deal from person to person. For some sufferers, it can last for up to a couple of years, then goes away without causing any noticeable damage. Other patients have mild or moderate disease, with periods of worsening symptoms, called flares, and periods in which they feel better, called remissions. Still others have severe disease that is active most of the time, lasts for many years, and leads to serious joint damage and disability.

Rheumatoid arthritis affects 1-3% of the population in the U.S. and Europe, 70% of the sufferers are women, with a usual age of onset of 30-40 years.

#### Treatment options

The disease modifying anti-rheumatic drugs are reserved for moderate to severe forms of the disease. They have demonstrated an ability to alter the course of the disease but are associated with increased safety risks.

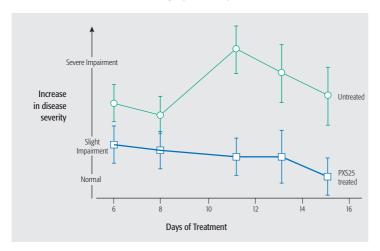
#### Expected product profile

The Company has discovered that immune cell inhibitors such as PXS25 can also have a positive impact on the progression of rheumatoid arthritis in rodent models of the disease. The Company believes that PXS25 will inhibit inflammatory cells from migrating to the joint and halt the progression of the disease. Unlike the more recent innovations in this market, PXS25 has the potential to be delivered orally.

#### Development program

PXS25 has been studied in rodent models of experimentally induced arthritis. In these studies PXS25 had a marked effect on disease progression. Those rodents treated with PXS25 did not progress to the more severe form of the disease, and by the end of the experiment were returning to normal. In contrast, those rodents that did not receive the drug developed extensive symptoms of experimentally-induced arthritis. This result highlights the excellent potential for this class of compound in rheumatoid arthritis.

Treatment of rodents with PXS25 following experimentally induced arthritis



PXS25 has commenced pre-clinical safety studies and the Company is scheduling initial clinical trials for 2004.

PXS25 technology is potentially applicable to other autoimmune diseases. A research initiative of the Company is to examine the effects of the compounds on other diseases such as inflammatory bowel disease and psoriasis.

#### PXS2000 for the treatment of multiple sclerosis

PXS2000 is a new synthetic compound which was discovered by the Company's research scientists and exploits the positive clinical benefits that can be obtained from the administration of cannabis. PXS2000 is a selective cannabinoid ligand, and is anticipated to provide relief of symptoms for people with autoimmune diseases such as multiple sclerosis.

#### The approach

Cannabinoids are compounds derived from the cannabis sativa plant, commonly known as marijuana. The most active constituent of the naturally occurring cannabinoids is tetrahydrocannabinol. This compound was isolated and identified in the 1960's and since that time there has been scientific interest in the effects and pharmacology of the cannabinoids. However, prior to the discovery of tetrahydrocannabinol, the effects and benefits of marijuana use have been known for several thousand years. Marijuana-based medications have been a mainstay of many herbal and folk medicines for many centuries. Among the beneficial pharmacological properties attributed to marijuana are analgesia, lowering blood and intraocular pressure and anti-emetic activity in both animals and man. Indeed, in NSW, it is proposed that marijuana use be permitted in certain limited situations, such as its use

in cancer patients for ameliorating the nausea induced by chemotherapy, for treating pain or for reducing the side effects associated with multiple sclerosis.

As marijuana's beneficial effects have long been known, so have its negative effects. Notably psychological distortions of perception, loss of short-term memory, loss of motor coordination, sedation and euphoria.

The Company has been working on developing new treatments based on the findings that the administration of cannabis can be of therapeutic effect. The Company has now developed a new series of compounds, typified by PXS2000, that retain the beneficial properties associated with cannabis but remove the undesirable psychotropic effects. These new compounds have shown positive effects in rodent models of multiple sclerosis.

#### Development program

PXS2000 represents the lead compound for the Company in this area and is undergoing tests to determine its suitability for clinical use. It will be developed to assist with the management of the side effects associated with multiple sclerosis. PXS2000 is also being investigated for its potential in treating other autoimmune diseases such as asthma.

The Company is scheduling pre-clinical toxicology studies for 2004.

# 6.6 Manufacturing

#### 6.6.1 Bronchitol and Aridol™

Mannitol (the major raw material of Bronchitol and Aridol™) is readily available and there are a number of suppliers of Good Manufacturing Practice grade material suitable for Bronchitol and Aridol™ production. The Company has established a GMP accredited facility in Sydney, NSW that is producing Bronchitol and Aridol™ for clinical trials. The TGA inspected the Company's facilities and issued a licence to manufacture therapeutic goods in May 2003 for the manufacture of clinical trial material (licence number 170995). The Company expects to require additional facilities as commercial demand for the product increases.

#### 6.6.2 PXS25

The scale-up manufacture of PXS25 has been developed by the Company's scientists. The manufacture of the material is through a totally synthetic process using readily available starting materials. Sufficient drug substance has been prepared by the Company's scientists to undertake pre-clinical development. GMP grade material is not required for the pre-clinical and early clinical evaluation.

# 6.7 Regulation and Approval Process

The development of human therapeutic products is a highly regulated process. Evaluation and testing for safety and efficacy proceed through laboratory (research), animal (pre-clinical) and human (clinical) phases of development. Guidelines have been prepared by the International Committee on Harmonisation which have provided a consistent set of test guidelines applicable to the major pharmaceutical territories of the world before evaluation in humans can proceed. These guidelines cover the manufacture of the drug substance, the manufacture of the dosage form and the safety testing. The Company conducts its pre-clinical safety evaluation in accordance with these guidelines.

Clinical testing involves a three-phase process.

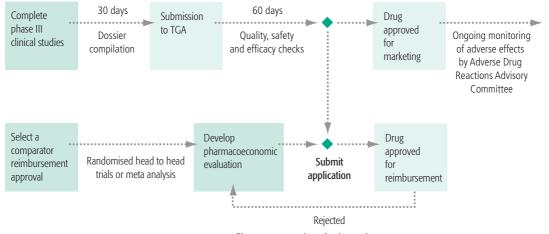
- In phase I, clinical trials are conducted with a small number (typically 10-50) of healthy subjects to determine the early safety profile and pharmacokinetic profile (pattern of drug distribution and metabolism).
- In phase II, clinical trials are conducted with groups
  of patients with a specified disease (typically 100-200)
  to determine preliminary effectiveness, optimal dosages
  and expanded evidence of safety. This is intended to
  show that the drug is effective in different patient
  populations under a variety of doses.

- In phase III, large-scale (typically >1,000), multicentre, comparative clinical trials are conducted with patients with the target disease to provide sufficient data to statistically evaluate the effectiveness and safety of the product. During these clinical studies, the manufacture of the drug will be refined and an optimal formulation will be selected. Additional safety studies will be required, including long-term toxicology studies (possibly of 12 months duration) and carcinogenicity studies.
   The Company will also undertake a detailed study of the pharmacology of the drug as well as identify any breakdown products and the routes of excretion.
- The Company's therapeutic and diagnostic products require regulatory approval by governmental agencies before the Company can start testing in humans and marketing.

For a summary of the risks associated with the regulation and approval process, refer to section 11 of this Prospectus.

Drug registration and reimbursement process in Australia

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



- Pharmacoeconomic evaluation against comparator
- Estimate implications for pharmaceutical benefit scheme
- Estimate usage over two years

## 6.8 Intellectual Property

#### 6.8.1 Patents

The Company has the benefit of a portfolio of four core patent families.

These are based on:

- a licensed patent family of a new formulation of mannitol facilitating mucociliary clearance in diseases such as cystic fibrosis and chronic obstructive pulmonary disease and for a lung function test for the management of asthma; and
- two licensed patent families and one of the Company's own patent families based on the use of carbohydratebased drugs as anti-inflammatory agents.

The Company also has two provisional patent families based on the use of carbohydrate-based drugs as anti-inflammatory agents.

The Company's portfolio of patent families and provisional patent families is set out in the Report on Intellectual Property in section 10 of this Prospectus.

In respect of the intellectual property that is referred to in the Report on Intellectual Property which the Company does not own, the Company has entered into licence arrangements to secure the intellectual property.

#### 6.8.2 Licences

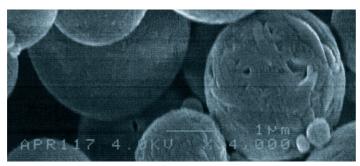
#### **CSAHS Licence**

The Company has secured a licence to intellectual property relating to the use of respirable dry powders for assessment of bronchial hyper-responsiveness, a condition consistent with active asthma, for monitoring steroid use in asthma patients, and for the management of diseases such as cystic fibrosis, bronchiectasis and chronic bronchitis. The test was developed in the Department of Respiratory Medicine at the Royal Prince Alfred Hospital, Sydney, NSW, which collaborates with the Company on the development of this technology.

#### **Anutech Licence**

The Company has entered into an agreement with Anutech (as agent for and on behalf of the ANU) to exclusively licence intellectual property possessed by the ANU in the area of phosphosugars and their analogues as anti-inflammatory agents. The Company's ongoing research and development has led to filing of further patents in this area that are owned exclusively by the Company.

For a summary of the CSAHS Licence and the Anutech Licence, refer to section 12 of this Prospectus. Refer to the Report on Intellectual Property in section 10 of this Prospectus for details of the licensed patents.





# Board, Management and Employees

Section





L – R Charles Kiefel Carrie Hillyard Denis Hanley David McGarvey Alan Robertson Brigitte Smith Brett Charlton Malcolm McComas

### 7.1 Board of Directors

# **Denis M Hanley** MBA Independent Chairman

Denis is recognised as a leading expert in developing and commercialising new Australian technology. He also has extensive experience in growing Australian corporations to become successful global entities. He is a fellow of the Australian Institute of Company Directors and a Fellow of CPA Australia.

In 1994, Denis was awarded membership in the Order of Australia and the Clunies Ross Medal for his work in helping Australian technology businesses commercialise their assets. He is a foundation member of the Principals group of companies, which focuses on helping Australian technology businesses commercialise their technologies.

For 14 years Denis led Memtec Limited, first as Managing Director and later as Chairman and CEO. During this time Memtec grew from a small start-up company with four employees, to become a successful NASDAQ and later NYSE-listed global business with 1,800 employees, multiple technology platforms and a market capitalisation of approximately \$900 million.

Memtec grew organically but also internationally through the acquisition of related businesses and their successful integration into the overall global business.

Prior to his Memtec experience, Denis spent more than a decade at the international medical company Baxter Labs, both in the U.S. and also as their Australian Managing Director. Denis has also served as a Board member and then Chairman of the IR&D Board, a Member of the Prime Minister's Science and Engineering Council, a Member of the Industry & Higher Education round table, a Member of the Australian Council for the Development of Environmental Opportunity and as Chairman of Judges at the Australian Technology Awards.

In 1976, Denis was awarded an MBA with High Distinction and was named a Baker School at the Harvard Graduate School of Business Administration.

### Alan D Robertson BSc, PhD

Chief Executive Officer

Alan has more than 20 years' experience in drug discovery and development with leading pharmaceutical companies. He has also assisted early-stage pharmaceutical companies in their start-up and development.

Alan is the co-inventor of 18 patents and author of more than 35 scientific papers. He has a PhD in synthetic organic chemistry from the University of Glasgow and undertook a three-year post-doctoral appointment with Nobel Laureate, Professor Sir John Cornforth, at the University of Sussex.

Alan joined the pharmaceutical company Wellcome plc in 1984 as a medicinal chemist working on the design and synthesis of new prostaglandin compounds. During this period a number of innovative discoveries were made and two compounds progressed to clinical study. Alan then led a large team of medicinal chemists targeting new treatments for migraine and cardiovascular disease from which a number of important scientific discoveries were made.

Three compounds progressed to clinical study and one to market. This compound, now known as Zomig, is distributed and marketed worldwide by Astra Zeneca.

He joined the Faulding group in 1992 as New Product Development Manager with specific responsibilities for the global development of generic injectable drugs. He introduced a number of new formulations and helped expand the company from an imitator of marketed drugs to inventor. He was actively involved in introducing improved formulations, many of which were developed for worldwide sale and continue to contribute to Fauldings' growth.

In 1994, Alan joined Amrad Pty Ltd as Head of Drug Development and assisted in preparing Amrad for listing on the ASX. Alan was also responsible for a large number of drug discovery/development projects, three of which have now reached the stage of clinical trials in patients.

Since leaving Amrad Pty Ltd in 1999, Alan has assisted in the establishment of two start-up companies, Promics Pty Ltd and Pharmaxis, as well as providing expert drug discovery and development advice to Kinacia Pty Ltd.

#### Brett Charlton MBBS, PhD

Medical Director

Brett is a medical researcher and specialist, particularly in the areas of autoimmune disease. Brett co-founded Pharmaxis in 1998 and has negotiated licence and research arrangements with the ANU for intellectual property and research facilities. He helped to successfully attract funding from Rothschild Bioscience, Auslndustry Start, the ACT Government and the Biotechnology Innovation Fund.

He has an MBBS with Honours from the University of NSW. He completed a PhD at the Centre for Biomedical Engineering in 1985. He has written more than 60 scientific papers, attracted significant research grants, and served on several professional society committees.

After completing his PhD, Brett was an NH&MRC postdoctoral fellow at the Walter and Eliza Hall Institute, and visiting clinician at Royal Melbourne Hospital working on diabetes and autoimmunity. Brett was recruited to the Baxter Centre for Medical Research in 1988 and was a part of Baxter Healthcare's technology and business assessment team. He produced corporate strategy reports for the Baxter Healthcare board in the fields of diabetes and transplantation and was responsible for establishing and managing a multi-centre clinical trial in renal dialysis.

In 1992, Brett took a Research Associate position in Immunology at Stanford University working on autoimmune disease. He also consulted to Sciclone Pharmaceuticals and the Polymer Technology Group.

In 1995, he was awarded the Aza/Lilly Diabetes Fellowship of Diabetes Australia and returned to a faculty position at the John Curtin School of Medical Research, which he still holds. He was founding Medical Director of the National Health Sciences Centre in Canberra and established the Clinical Trials Unit where he was responsible for the conduct of clinical trials arising from research at the ANU. He has managed research programs in autoimmunity including successfully attracting research grants of more than \$3 million and has been involved in the management of clinical trials for 15 years.

# Brigitte H Smith B.Chem Eng, MBA, MALD Non-executive Director

Brigitte is a venture capital investor, with more than 10 years' experience in strategy and working with early stage technology businesses. A former Fulbright Scholar, in 1995 Brigitte was awarded an MBA with Honours from the Harvard Business School, and a Master of Arts from the Fletcher School of Law and Diplomacy. She also holds a Bachelor of Chemical Engineering with Honours from the University of Melbourne and is a Member of the Australian Institute of Company Directors.

Brigitte worked as a strategic management consultant for Bain & Company between 1989 and 1992. After working for Motorola to develop an international customisation strategy for a \$3 billion product group, she commenced a business and corporate development role for Molten Metal Technology, a spin-out company from the Massachusetts Institute of Technology. During her time at Molten Metal Technology, the company grew from 150 to 650 employees, and to a market capitalisation of US\$1 billion.

On returning to Australia, Brigitte consulted to a variety of early stage technology-based businesses before joining Rothschild Bioscience in 1998. In 2002, Brigitte and her business partner completed a management buy-out of Rothschild Bioscience's \$150 million specialist life science venture capital business and formed GBS Venture Partners, of which she is Managing Director. Brigitte sits on the board of four of GBS Venture Partners' portfolio companies.

Brigitte is an Adjunct Senior Lecturer at Melbourne Business School where she teaches Entrepreneurial Finance. She has published eight case studies and five academic papers.

#### Charles PH Kiefel BCom

Non-executive Director

Charles has more than 17 years' experience in the financial and investment banking sector having advised clients in a broad range of industry sectors including information technology and data communications, pharmaceutical,

telecommunications, financial services, environmental and water management, resources and mining, utilities and transport. Charles has relevant experience with technology growth companies including serving as an original investment banker in the initial public offerings and equity raisings for Memtec Ltd and Datacraft Limited. Charles has wide experience and access to equity investors including high net worth individuals, institutions and fund managers.

Charles was formerly Managing Director of Corporate Finance at ANZ Investment Bank and worked in the ANZ Banking Group for 10 years. Prior to joining the ANZ Banking Group, Charles worked as a chartered accountant with Coopers&Lybrand in Sydney and London, served as Director of Corporate Finance at Ord Minnett, and also worked with Lazard Brothers & Co. Ltd (London) and Lazard Frere (New York).

Charles is current Chairman of the Military Superannuation and Benefits Board of Trustees and serves on a number of company boards including Lochard Limited, Universal Biosensors Pty Ltd, Wilson HTM Asset Management Limited (non-executive Chairman), Wilson HTM Capital Management Limited (non-executive Chairman), The Principals Funds Management Pty Ltd and The Principals Cornerstone Fund Pty Ltd. He is also retained as a consultant U.S. money manager.

Charles is a Fellow of the Institute of Chartered Accountants in Australia and a Fellow of the Australian Institute of Company Directors. He has a Bachelor of Commerce from the University of NSW.

### Malcolm J McComas BEc, LLB

Non-executive Director

Malcolm McComas has 18 years' investment banking experience and five years' legal experience. He has experience in equity and debt finance, acquisitions and divestments, and the structuring and implementation of major equity issues and privatisations. He has advised on more than 50 equity issues for corporations, institutions and governments in various sectors including financial institutions, consumer products, media and telecommunications, manufacturing and healthcare.

Since 1999, he has been a director of Grant Samuel, the corporate advisory, property services and funds management group. In the 10 years from 1988, he established and developed County NatWest's Corporate Finance business which in 1998 became, through a merger, the Investment Banking division of Salomon Smith Barney in Australia (a subsidiary of Citigroup, Inc). Malcolm was a Managing Director and Co-Head of Investment Banking at Salomon Smith Barney. He was Managing Director of Investment Banking at County NatWest. He has also

had executive roles with Morgan Grenfell (now a subsidiary of Deutsche Bank AG) in Australia and London. He was formerly a lawyer in Melbourne, where he specialised in tax and corporate reorganisations.

Malcolm has a Bachelor of Economics and a Bachelor of Laws from Monash University. He is a director of ION Limited, a Fellow of the Securities Institute of Australia and a member of Markets Policy Group.

# Carrie Hillyard BSc (Hons), PhD, FTSE Non-executive Director

Carrie has more than 20 years' experience in medical research and commercialisation, including eight as the Director of Research and Development for AGEN Biomedical Ltd. in Brisbane, where she led a staff of 25 scientists in the development of new diagnostic tests and technologies for human and veterinary medicine.

She is the inventor of six patent families and has been responsible for the development of new products from initial research to commercialisation and clinical trials. Her roles have also involved liaison with pharmaceutical companies and institutions, licensing of technology, managing collaborations, assisting entrepreneurs and early stage life science companies.

Carrie was a member of the Federal Industry Research and Development Board from 1995-1998, involving advice to government to promote the use of science and technology and in commercialising Australian research and development programs. She chaired the Tax Concession Committee from 1996-1997, was a member of the Start Grants and Biological Committees and a member of biotechnology, venture capital and pharmaceutical advisory boards to the Federal and Queensland Governments. Carrie is the Partner at CM Capital Investments responsible for the Life Sciences practice, a director of three other portfolio companies and a member of the board of the Australian Nuclear Science and Technology Organisation.

Carrie holds an honours degree from the University of London and a PhD for her early research in cancer and endocrinology of the menopause at the Royal Postgraduate Medical School (London). She has been a regular international speaker and has published more than 100 scientific papers. She was elected as a fellow of the Academy of Technological Sciences and Engineering in 1997 and awarded a Centenary medal in 2003.

#### David M McGarvey BA, CA

Company Secretary and Chief Financial Officer

For career synopsis, see summary under the heading 'Senior Management Team' in section 7.3 of this Prospectus.

# 7.2 Scientific Advisory Board

Sandra Anderson BSc Syd, PhD London, DSc London, FANZSRS Sandra's major work has been in the field of asthma, particularly the application of measurement to its diagnosis and treatment. She has developed a variety of tests for identifying asthma and is a world authority in the measurement, management and mechanisms of exercise-induced asthma.

Sandra works in the Department of Respiratory Medicine of the Royal Prince Alfred Hospital, Sydney, where she holds the position of Principal Hospital Scientist. She is an Honorary Associate of the Department of Pharmacology at the University of Sydney and a Visiting Fellow of the University of New South Wales. She is a Vice President of Asthma NSW and is the Co-Chairman of their Research Advisory Committee. She has served as a member of the European Respiratory Society Task Force on Indirect Challenges and the Bronchial Provocation Committee of the American Academy of Allergy, Asthma and Immunology. She currently serves on an independent panel of the International Olympic Committee Medical Commission.

In 1990, she was awarded a Doctor of Science in Medicine from the University of London for her published research in clinical respiratory physiology. She has received the Fisons' Medal for Research from the Thoracic Society of Australia and New Zealand, the RPA Achievement Award, and later the RPA Foundation Medal for Research. In 2000, Sandra became the first Fellow of the Australian and New Zealand Society of Respiratory Science.

Sandra graduated as a Bachelor of Science in Physiology from the University of Sydney. She completed post-graduate training at the Universities of California (Cardiovascular Research Institute, San Francisco) and London (Institute of Diseases of the Chest, The Brompton Hospital) and received her Doctor of Philosophy in Medicine from the University of London for studies on 'Exercise-induced Bronchoconstriction'. She has more than 130 papers in peer-reviewed journals and 100 invited publications and book chapters.

#### Norbert Berend MBBS, MD, FRACP

Norbert is Director of the Woolcock Institute of Medical Research, Royal Prince Alfred Hospital, Sydney and is internationally recognised for work on the structurefunctional relationships in chronic obstructive pulmonary disease. Norbert has previously held positions on the NHMRC Grants Committee, the Asthma Foundation of NSW Research Advisory Committee and is currently Chairman of the Lincoln Centre for Bone and Joint Disease Research Advisory Committee. Norbert is active in national and international peer groups, is a member of the chronic obstructive pulmonary disease guidelines working party and serves on the Respiratory Clinical Expert Reference Committee, NSW Department of Health.

He is author of more than 95 publications, including 50 related to airways disease and emphysema and 10 related to infection in chronic obstructive pulmonary disease. Norbert is a Senior Investigator for the CRC for Asthma and a Director of the CRC for Chronic Inflammatory Diseases.

#### Malcolm Fisher MBChB, MD

Professor Malcolm Fisher has been recognised for his work in critical care medicine. He has received a number of awards including the Thomas J. Iberti Memorial Award, the Christer Grenvik Award for international services to critical care medicine, the Alan Gilston Medal, the Inaugural ANZICS Medal and he is an officer in the Order of Australia.

He is a Staff Specialist in Intensive Care Unit of Royal North Shore Hospital, Area Director of Intensive Care and Clinical Professor in Intensive Care Medicine, Departments of Medicine and Anaesthesia, University of Sydney. He is a past President of the World Federation of Intensive and Critical Care Medicine Societies, and ANZICS.

He is the author of two books and more than 130 scientific articles.

#### Richard JI Morgan CBiol MIBiol, DRCPath

Richard has more than 25 years experience in pharmaceutical research and development. He has held various senior management positions within Pre-clinical Safety including Head of Toxicology at Wellcome plc and International Head of Toxicology and Pre-clinical Outsourcing for GlaxoWellcome plc.

With GlaxoWellcome (later GlaxoSmithKline) he was responsible for the Pre-clinical Safety Evaluation of more than 100 new chemical entities, covering areas as diverse as CNS, CVS, respiratory, metabolic, anti-infectives, anti-parasitics, neuromuscular blockers, oncology, monoclonals, and vaccines. He has been involved in the development of a large number of successful, marketed pharmaceutical products.

After leaving GlaxoSmithKline and after a period as Interim Head of Pre-clinical for PowderJect Pharmaceuticals, Richard established his own consultancy company (R&B HealthCare Ltd), providing advice on Toxicology and Pre-clinical Discovery and Development to client companies in the UK and Australia.

Richard holds CBiol MIBiol (Laboratory Animal Pathology) and is a Diplomate of the Royal College of Pathologists in Toxicology.

# 7.3 Senior Management

The Company has an experienced team of pharmaceutical/ technology industry professionals with extensive experience both in Australia and internationally. The group has a demonstrable track record in innovation management and commercialisation, combining its complementary skills to facilitate the smooth running of the business.

The senior management team has extensive combined experience in discovery, intellectual property protection and management, drug development, commercialisation and business. The team's complementary skills allow rapid evaluation of new project opportunities and have been responsible for the negotiation and successful execution of a large number of agreements.

#### Alan D Robertson BSc, PhD Chief Executive Officer

For career synopsis, refer to previous summary under the heading 'Board of Directors' in section 7.1 of this Prospectus.

# **Brett Charlton** MBBS, PhD Medical Director

For career synopsis, refer to previous summary under the heading 'Board of Directors' in section 7.1 of this Prospectus.



#### William B Cowden BS, PhD Chief Scientific Officer

Bill is Chief Scientific Officer of Pharmaxis, which he co-founded in 1998 to commercialise a promising group of patented compounds with the potential to treat inflammatory diseases and other immune-mediated diseases.

Bill has spent 20 years developing new therapeutic compounds for the treatments of cancer, infectious disease, and inflammatory diseases, including multiple sclerosis, and has developed patented compounds that are licensed to Johnson & Johnson Medical and to Cypros Pharmaceuticals (currently in phase III clinical trials).

He has extensive experience in research, including positions with the Department of Medical Chemistry at the John Curtin School of Medical Research (Australian National University), a Research Fellowship in the same institution, funded by the World Health Organisation in the Department of Experimental Pathology, and with Peptide Technology Ltd (Peptech) as Senior Scientist. Work carried out during Bill's time at Peptech led to the development of compounds that are also in human clinical trials, several of which are licensed to major pharmaceutical companies. One aspect of Bill's research, carried out in collaboration with Professor Ian Ramshaw, has been sold to Auragen/Agracetis and this forms a substantive basis of that company's international patent on DNA vaccine technology.

He was appointed at the John Curtin School as a Senior Research Fellow, in the Department of Cell Biology and Virology. He was consulting scientist to Anutech on a project conducted in collaboration with Progen Industries Ltd and maintains a fractional appointment at the John Curtin School where he is Head of the Immunopathology Research Group. Bill has been a specialist advisor to the TGA and has been an assessor for several prescription drugs currently registered for use in Australia.

Bill received a PhD in Medical Chemistry from the University of Queensland in 1979. He is the co-inventor of 12 patents and author of over 130 scientific papers, and has raised more than \$9 million in grants and stipends to support work under his direction.

L – R John Crapper William Cowden David McGarvey Alan Robertson Brett Charlton

### 7:Board, Management and Employees CONTINUED

#### David M McGarvey BA, CA

Company Secretary and Chief Financial Officer

David has 18 years' experience as Chief Financial Officer of successful Australian-based international technology businesses.

After 10 years with PricewaterhouseCoopers, David joined high technology start-up Memtec Limited as Chief Financial Officer. At that time the company had sales of A\$40,000 with 22 employees and a focus on R&D, manufacturing scale-up and application marketing. The next 12 years saw Memtec grow to become a NYSE-listed company with sales of US\$243 million and 1,800 employees. As a global business, Memtec's operations and revenues were predominantly based outside of Australia with subsidiaries in North America, Germany, France, the U.K., Italy, Japan and South East Asia. Memtec's growth was attributable to a focused development of the core Australian technology business and more than 10 successful international acquisitions of mature, established filtration businesses.

Following the acquisition of Memtec by US Filter Corporation in late 1997, David remained with the restructured and renamed US Filter Filtration & Separations Group, a business that continued the Memtec growth strategy, achieving global sales to US\$415 million and employing 3,150 people by the end of 2001.

David headed the financial and due diligence aspects of US Filter's divestment of FSG, across three separate transactions. Subsequently David worked with the successful bidder to facilitate smooth integration.

David has a Bachelor of Arts (Accounting Major) from Macquarie University. He was admitted to the Institute of Chartered Accountants in Australia in 1981, and the Australian Society of CPAs in 1993.

#### John F Crapper BSc, MBA Chief Operations Officer

John has 32 years of manufacturing and operations experience, 17 years of which has been in the pharmaceutical industry. He is formerly Senior Vice-President and General Manager of Memcor International and Managing Director Memcor Australia Pty Ltd (formerly a subsidiary of Memtec Limited).

Memcor Australia houses the international membrane manufacturing operation and the major research and development group for the global organisation. John's role was to manage these operations and a small technical sales and engineering group for the Asian region, including full profit and loss, balance sheet and cash flow management, as well as Board responsibilities for the local legal entity.

During his time at Memcor, John was responsible for establishing the membrane manufacturing operation, including managing the scale-up of new manufacturing equipment and processes from the R&D group, creating full scale production operations and managing the establishment of the QA (Quality Assurance) and ERP systems. Over the 15 years of John's tenure he managed the development and growth of the operations from start-up to a global manufacturing operation with more than 200 people at a large facility producing membranes and filtration modules, 95% of which were exported to the U.S., Europe and Asia.

Prior to this John was Technical Director at Syntex Pharmaceutical's Animal Health division in Australia. John was originally at VR Laboratories, an Australian start-up veterinary pharmaceutical company which after 10 years continuous growth was acquired by Syntex in the early 1980's. John was responsible for formulation development, as well as all manufacturing operations. During this time he was also responsible for construction of a new manufacturing facility including sterile products, tablets, capsules, creams and liquid processes and obtaining TGA/FDA licences.

John has a Bachelor of Science in Applied Chemistry from the University of Technology, Sydney and an MBA from Macquarie University.

# 8 :Historical Financial Position

Section



The historical results for each of the years ended 30 June 2002 and 2003 set out in section 8.1 below and the audited balance sheet at 30 June 2003 set out in section 8.3 below have been extracted from the Company's financial statements for the year ended 30 June 2003 which were audited by PricewaterhouseCoopers. The Investigating Accountant's Report on the historical financial information is set out in section 9 of this Prospectus. The financial information should be read in conjunction with the assumptions in this section, the risk factors in section 11 and other information contained in this Prospectus.

#### 8.1 Overview of Financial Performance

|  | 2003          | 2002        |
|--|---------------|-------------|
|  | \$            | \$          |
| Revenue  |               |             |
| Interest received                                  | 284,417       | 43,456      |
| Grant revenue                                      | 975,974       | 645,533     |
| Rental income                                      | 41,441        | _           |
| Other  | 1,617         | _           |
| Revenues from ordinary activities                  | \$1,303,449   | \$688,989   |
| Other expenses from ordinary activities            |               |             |
| Research and development expenses                  | (1,789,762)   | (1,151,212) |
| Administration expenses                            | (981,476)     | (140,012)   |
| Profit/(loss) before income tax expense            | (1,467,789)   | (602,235)   |
| Income tax expense/(credit)                        | _             | _           |
| Net profit/(loss)                                  | \$(1,467,789) | \$(602,235) |
| Depreciation and amortisation included in expenses |               |             |
| Depreciation of plant and equipment                | 169,812       | 46,829      |
| Amortisation of intangible assets                  | 85,922        | 83,289      |
|  | \$255,734     | \$130,118   |

### 8.2 Review of Historical Results

#### Period from incorporation to 30 June 2002

In the period from incorporation to 30 June 2002 (approximately four years) the Company spent approximately \$2.9 million on research and development costs and \$200,000 on administration expenses. Government research grants provided funds of approximately \$1.6 million in this period and interest income earned on cash balances contributed approximately \$100,000 over the period. The balance of funding requirements of \$1.4 million was contributed as equity invested by the shareholders.

#### Year ended 30 June 2003

Revenue increased significantly in 2003 reflecting increased research grant revenue and increased interest revenue, a result of the Company's available funds increasing as discussed below. In addition rental income was received for the first time as a result of a sub-leasing arrangement on the Company leased facilities at Frenchs Forest, NSW.

In 2002, the Company received support from four separate government research grants. The two smaller grants effectively completed at 30 June 2002, the third continuing until 30 September 2002, and the fourth and significantly larger grant continuing through until 30 June 2003. In June of 2003 the Company was awarded a new \$3 million Commonwealth R&D Start Grant to assist in the clinical development of Bronchitol for cystic fibrosis. This large grant had an effective start date of 6 March 2003 and \$380,000 of this particular grant was recorded as revenue in the period to June 2003. Refer to section 8.5 below for details of the Company's accounting policies in relation to the recognition of grant revenue.

A share placement in August 2002 raised approximately \$9.5 million. The cash was invested in bank money market deposit accounts and bank accepted commercial bills, and resulted in the significant increase in interest income in 2003 as noted above.

The significant increase in expenses during 2003 reflects the Company's transition from a 'virtual company' based at the ANU, to a growing organisation with its own dedicated facilities and employees.

On 1 November 2002, the Company leased 1,400 square metres of facilities in Frenchs Forest, NSW providing the Company with clean room manufacturing facilities, laboratory facilities, accounting and administration offices, and space for future expansion. One floor of this facility is currently sublet. Also on 1 November 2002, a small office suite was rented in Canberra as a base for the clinical trial group. In conjunction with the leasing of suitable premises to provide its own base of operations, the Company employed manufacturing, quality control, clinical trial, accounting and administration staff. Over the remainder of the fiscal year the Company installed manufacturing equipment at Frenchs Forest to produce its Bronchitol and Aridol™ products for clinical trials, while preparations for the trials commenced.

The manufacturing and administration activities established at Frenchs Forest and the preparation for clinical trials have consequently been the primary reasons for the increase in both administration expenses and the research and development expenses in 2003.





# 8.3 Pro Forma Consolidated Balance Sheet

The pro forma balance sheet has been adjusted for the minimum \$21 million of gross proceeds from the issue of shares under this Offer less estimated costs associated with the issue of \$1.7 million, as if these transactions had occurred at 30 June 2003. Refer to Section 4.8 in relation to oversubscriptions.

|  | Ref | Audited<br>30 June 2003<br>\$ | Effect of the Initial<br>Public Offering<br>\$ | Pro Forma<br>\$ |
|--|-----|-------------------------------|--|-----------------|
| Current Assets                               |     |                               |  |                 |
| Cash and bank accepted commercial bills      | 8.7 | 7,383,923                     | 19,300,000                                     | 26,683,923      |
| Receivables – government research grants     |     | 62,582                        |  | 62,582          |
| Other  |     | 84,235                        |  | 84,235          |
| Total Current Assets                         |     | 7,530,740                     | 19,300,000                                     | 26,830,740      |
| Non-current Assets                           |     |                               |  |                 |
| Property, plant and equipment                | 8.8 | 1,515,016                     |  | 1,515,016       |
| Intangible assets                            | 8.9 | 1,205,000                     |  | 1,205,000       |
| Other – security deposits                    |     | 243,800                       |  | 243,800         |
| Total Non-current Assets                     |     | 2,963,816                     |  | 2,963,816       |
| Total Assets                                 |     | 10,494,556                    | 19,300,000                                     | 29,794,556      |
| Current Liabilities                          |     |                               |  |                 |
| Accounts payable                             |     | 231,736                       |  | 231,736         |
| Other liabilities – deferred research grants |     | 318,563                       |  | 318,563         |
| Provisions                                   |     | 52,697                        |  | 52,697          |
| Total Current Liabilities                    |     | 602,996                       |  | 602,996         |
| Non-current Liabilities                      |     |                               |  |                 |
| Provisions                                   |     | 1,499                         |  | 1,499           |
| Total Non-current Liabilities                |     | 1,499                         |  | 1,499           |
| Total Liabilities                            |     | 604,495                       |  | 604,495         |
| Net Assets                                   |     | \$9,890,061                   | \$19,300,000                                   | \$29,190,061    |
| Shareholders' Equity                         |     |                               |  |                 |
| Share capital                                |     | 12,804,529                    | 19,300,000                                     | 32,104,529      |
| Retained earnings                            |     | (2,914,468)                   |  | (2,914,468)     |
| Total Shareholders' Equity                   |     | \$9,890,061                   | \$19,300,000                                   | \$29,190,061    |

### 8.4 Cash Flow Statements

The table below summarises the Company's historical cash flows for each of the years ended 30 June 2002 and 2003.

|   | 2003        | 2002        |
|---|-------------|-------------|
|   | \$          | \$          |
| Cash Flows from Operating Activities        |             |             |
| Research grant receipts from governments    | 1,290,093   | 785,716     |
| Payments to suppliers and employees         | (2,773,124) | (1,191,765) |
| Interest received                           | 269,543     | 43,456      |
| Rental income                               | 45,585      | -           |
| Tax paid                                    | -           | -           |
| Net cash flows from operating activities    | (1,167,903) | (362,593)   |
| Cash Flows from Investing Activities        |             |             |
| Payment for properties, plant and equipment | (1,569,278) | (11,241)    |
| Payment for patents                         | (83,075)    | (25,092)    |
| Net cash flows from investing activities    | (1,652,353) | (36,333)    |
| Cash Flows from Financing Activities        |             |             |
| Issuance of shares                          | 9,630,000   | _           |
| Transaction costs on share issue            | (176,579)   |             |
| Cancellation of shares                      | (101)       |             |
| Net cash flows from financing activities    | 9,453,320   | _           |
| Net increase (decrease) in cash held        | 6,633,064   | (398,926)   |
| Cash at the beginning of the financial year | 750,859     | 1,149,785   |
| Cash at the end of the financial year       | \$7,383,923 | \$750,859   |

# 8.5 Summary of Significant Accounting Policies

The principal accounting policies adopted by the Company are discussed below to assist in a general understanding of the financial information set out in this section. These policies have been consistently applied unless otherwise indicated.

#### 8.5.1 Basis of accounting

The financial information in this section has been prepared in accordance with Accounting Standards and other mandatory professional reporting requirements in Australia. Some of the disclosure requirements under these Accounting Standards have not been included where the information that would be disclosed is not considered material or relevant to potential investors. The financial information has been prepared in accordance with the historical cost convention.

#### 8.5.2 Operating revenue

Revenues are recognised at fair value of the consideration received net of any applicable taxes.

Interest revenue is recognised as it accrues, taking into account the effective yield on the financial instruments.

Government research and development grant income is recognised as and when the relevant research expenditure is incurred. When the Company receives income in advance of incurring the relevant expenditure, it is treated as deferred income as the Company does not control the income until the relevant expenditure has been incurred.

#### 8.5.3 Research and development costs

Internally generated research and development costs are expensed as incurred.

#### 8.5.4 Inventories

Research and development stores and materials manufactured for clinical trials are expensed as incurred. Raw materials for clinical trials are stated at the lower of cost or net realisable value.

#### 8.5.5 Cash

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

#### 8.5.6 Depreciation of plant and equipment

Items of plant and equipment, including leasehold improvements, are depreciated/amortised over their estimated useful life to the Company, ranging from three years to 10 years using either the straight line or reducing balance method. Assets are depreciated or amortised from the date of acquisition and up to the date of disposal.

#### 8.5.7 Trade and other creditors

These amounts represent liabilities for goods and services provided to the Company prior to the end of the financial year and which are unpaid. The amounts are unsecured and are usually paid within 45 days of recognition.

#### 8.5.8 Wages, salaries and annual leave

Liabilities for wages, salaries and annual leave are recognised, and are measured as the amount unpaid at the reporting date at current pay rates in respect of employees' services up to that date.

#### **8.5.9** Superannuation

The Company contributes to standard defined contribution superannuation funds on behalf of all employees and directors at 9% of employee gross salary.

#### 8.5.10 Employee share options

The value of options granted under share option plans is not charged as an employee entitlement expense.

#### 8.5.11 Long service leave

A liability for long service leave is recognised, and is 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 interest rates on national government guaranteed securities with terms to maturity that match, as closely as possible, the estimated future cash outflows.

#### 8.5.12 Intangible assets

Costs of purchase of patent licences and application costs for new patents are capitalised and amortised over the period in which the related benefits are expected to be realised.

#### 8.5.13 Income tax

Tax effect accounting procedures are followed whereby the income tax expense in the statement of financial performance is matched with the accounting profit after allowing for permanent differences. The future tax benefit relating to tax losses is not carried forward as an asset unless the benefit is virtually certain of realisation. Income tax on cumulative timing differences is set aside to the deferred income tax or the future income tax benefit accounts at the rates which are expected to apply when those timing differences reverse.

#### 8.5.14 Foreign currency translation

Foreign currency transactions are initially translated into Australian currency at the rate of exchange at the date of the transaction. At balance date amounts payable and receivable in foreign currencies are translated to Australian currency at rates of exchange current at that date. Resulting exchange differences are brought to account in determining the profit or loss for the year.

#### 8.5.15 Lease payments

Lease payments for operating leases, where substantially all the risks and benefits remain with the lessor, are charged as expense in the periods in which they are incurred.

#### 8.5.16 Acquisitions of assets

The cost method of accounting is used for all acquisitions of assets regardless of whether shares or other assets are acquired. Cost is determined as the fair value of the assets given up at the date of acquisition plus costs incidental to the acquisition.

#### 8.5.17 Non-current assets

The carrying amounts of non-current assets are reviewed to determine whether they are in excess of their recoverable amount at balance date. If the carrying amount of a non-current asset exceeds its recoverable amount, the asset is written down to the lower amount.

In assessing recoverable amounts of non-current assets the relevant cash flows have been discounted to their present value.

#### 8.5.18 Contributed equity

Issued and paid up capital is recognised at the fair value of the consideration received by the Company.

Any transaction costs arising on the issue of shares are recognised directly in equity as a reduction of the share proceeds received

### 8.6 Income Tax

|                                       | 2003<br>\$ |
|---------------------------------------|------------|
| Future income tax benefit not booked: |            |
| Tax losses                            | 776,207    |
| Timing differences                    | 10,675     |
|                                       | 786,882    |

The future income tax benefits will only be obtained if:

- i. The Company derives future assessable income of a nature and of an amount sufficient to enable the benefit from the deductions for the losses to be realised, and
- ii. The Company continues to comply with the conditions for deductibility imposed by tax legislation, in particular those conditions that deal with the impact of changes in ownership and the business typically associated with the development and funding of new businesses, and
- iii. No change in tax legislation adversely affects the Company in realising the benefit from the deductions for the losses.

## 8.7 Cash and Bank Accepted Commercial Bills

|                                | 2003<br>\$ |
|--------------------------------|------------|
| Cash at bank                   | 71,752     |
| Cash on hand                   | 447        |
| Cash on deposit                | 1,319,508  |
| Bank accepted commercial bills | 5,992,216  |
|                                | 7,383,923  |

Bank accepted commercial bills matured in July 2003 and are rolled over approximately every 30 days. The average interest rate on the bank accepted commercial bills is 4.7%.

# 8.8 Plant and Equipment

|                                  | 2003<br>\$ |
|----------------------------------|------------|
| Plant and equipment – at cost    | 1,644,526  |
| Less: Accumulated depreciation   | (224,679)  |
|                                  | 1,419,847  |
| Leasehold improvements – at cost | 120,264    |
| Less: Accumulated depreciation   | (25,095)   |
|                                  | 95,169     |
|                                  | 1,515,016  |

## 8.9 Intangible Assets

(refer to licence agreement summaries in section 12 of this Prospectus)

|                                | 2003      |
|--------------------------------|-----------|
|                                | \$        |
| Patents and licences – at cost | 1,511,571 |
| Less: Accumulated amortisation | (306,571) |
|                                | 1,205,000 |

## 8.10 Operating Lease Commitments

|   | 2003<br>\$              |
|---|-------------------------|
| Lease commitments  Commitments for minimum lease payments in relation to non-cancellable operating leases are payable as follows: |                         |
| Payable no later than one year Payable later than one year, not later than five years Capital commitments                         | 351,064<br>699,340<br>– |
|   | 1,050,404               |

## 8.11 Contingent Liabilities

Included in the government research grants received by the Company and discussed in section 8.2 above, are three Commonwealth Government research grants under the R&D Start Grant Program, two of which have now completed. The Commonwealth 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:

- the Company fails to use its best endeavours to commercialise the relevant grant project within a reasonable time of completion of the project; or
- 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 R&D Start Grant.

The total amount received by the Company since incorporation under the Start Grant Program at 30 June 2003 was \$2,394,159, of which \$318,563 was recorded as deferred research grants liability at 30 June 2003.

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

## 8.12 Share Capital

For details of the share capital and options of the Company, refer to Section 12.2 and 12.3 of this Prospectus.



Section



# PRICEV/ATERHOUSE COPERS @

The Directors
Pharmaxis Ltd
Unit 2, 10 Rodborough Road
FRENCHS FOREST NSW 2086

26 September 2003

PricewaterhouseCoopers Securities Ltd ACN 003 311 617 ABN 54 003 311 617 Holder of dealer's licence No 11203

Darling Park Tower 2 201 Sussex Street GPO BOX 2650 SYDNEY NSW 1171 DX 77 Sydney Australia www.pwc.com/au Telephone +61 2 8266 0000 Facsimile +61 2 8266 9999

**Dear Directors** 

## **Investigating Accountant's Report**

We have prepared this report on the historical financial information of Pharmaxis Ltd (the Company) for inclusion in a Prospectus dated on or about 26 September 2003 (the Prospectus) relating to the issue of 42 million ordinary shares in the Company with the ability to accept oversubscriptions for a further 8 million ordinary shares (the Offer).

Expressions defined in the Prospectus have the same meaning in this report.

The nature of this Report is such that it should be given by an entity which holds a dealer's licence under the Corporations Act 2001 (Cwlth). PricewaterhouseCoopers Securities Ltd is wholly owned by PricewaterhouseCoopers and holds the appropriate dealer's licence.

## Background

The Company was formerly known as Pharmaxis Pty Ltd and following conversion to a public company on 5 September 2003 changed its name to Pharmaxis Ltd. The current capital structure of the Company (assuming conversion of the existing preference shares occurs on listing), together with details of the existing Employee Option Plan is set out in Section 12.3 of the Prospectus.

## Scope

You have requested PricewaterhouseCoopers Securities Ltd to prepare an Investigating Accountant's Report (the Report) covering the following information:

## **Historical Financial Information**

- (a) the historical financial performance of the Company for each of the years ended 30 June 2002 and 30 June 2003; and
- (b) the historical statement of financial position as at 30 June 2003 and the pro forma statement of financial position as at 30 June 2003 which assumes completion of the contemplated transactions disclosed in Section 8 of the Prospectus (the pro forma transactions).

(collectively, the Historical Financial Information)

This Report has been prepared for inclusion in the Prospectus. We disclaim any assumption of responsibility for any reliance on this Report or on the Historical Financial Information to which it relates for any purposes other than for which it was prepared.

# PRICEWATERHOUSE COPERS @

## Scope of review of Historical Financial Information

The Historical Financial Information set out in Section 8 of the Prospectus has been extracted from the audited financial statements of the Company, which were audited by PricewaterhouseCoopers who issued an unmodified audit opinion on the financial statements. The Directors are responsible for the preparation of the Historical Financial Information.

We have conducted our review of the Historical Financial Information in accordance with Australian Auditing Standard AUS 902 "Review of Financial Reports". We made such inquiries and performed such procedures as we, in our professional judgement, considered reasonable in the circumstances including:

- an analytical review of the audited financial performance of the Company for the relevant historical period;
- · a review of work papers, accounting records and other documents;
- a review of the assumptions used to compile the pro forma statement of financial position;
- a comparison of consistency in application of the recognition and measurement principles in Accounting Standards and other mandatory professional reporting requirements in Australia, and the accounting policies adopted by the Company disclosed in Section 8 of the Prospectus; and
- · enquiry of directors, management and others.

These procedures do not provide all the evidence that would be required in an audit, thus the level of assurance provided is less than given in an audit. We have not performed an audit and, accordingly, we do not express an audit opinion.

## Review statement on Historical Financial Information

Based on our review, which is not an audit, nothing has come to our attention which causes us to believe that:

- the pro forma statement of financial position has not been properly prepared on the basis of the pro forma transactions;
- the pro forma transactions do not form a reasonable basis for the pro forma statement of financial position;
- the Historical Financial Information, as set out in Section 8 of the Prospectus does not present fairly:
  - (a) the historical financial performance of the Company for each of the years ended 30 June 2002 and 30 June 2003, and
  - (b) the historical and pro forma statement of financial position of the Company as at 30 June 2003.

in accordance with the recognition and measurement principles prescribed in Accounting Standards and other mandatory professional reporting requirements in Australia, and accounting policies adopted by the Company disclosed in Section 8 of the Prospectus.

## Subsequent events

Apart from the matters dealt with in this Report, and having regard to the scope of our Report, to the best of our knowledge and belief no material transactions or events outside of the ordinary business of the Company have come to our attention that would require comment on, or adjustment to, the information referred to in our Report or that would cause such information to be misleading or deceptive.

## Independence or disclosure of interest

PricewaterhouseCoopers Securities Ltd does not have any interest in the outcome of this Offer other than the preparation of this Report and participation in due diligence procedures for which normal professional fees will be received.

Yours faithfully

Glen Hadlow

Authorised Representative

Stere Hellen

PricewaterhouseCoopers Securities Ltd

# Report on Intellectual Property

Section



VENABLE

575 7th Street, NW Washington, DC 20004-1601 Telephone 202-344-4000 Facsimile 202-344-8300 www.venable.com

## Pharmaxis Ltd

2/10 Rodborough Road Frenchs Forest, New South Wales, 2086, Australia Phone 61 2 9451 5961 Facsimile 61 02 9451 3622

**VENABLE LLP**Attorneys at Law

9 September 2003

This report about patents and patent applications in the name of, or licensed to, Pharmaxis Ltd or its predecessors in interest is provided for inclusion in a prospectus to be issued by Pharmaxis Ltd.

## Background

Venable LLP is a firm of attorneys that includes members concentrating in the law and practice relating to intellectual property, of which significant number are registered United States patent attorneys and agents. All partners, associates and patent agents of Venable LLP who are involved in patent prosecution matters are registered members of the patent bar of the United States Patent and Trademark Office ("PTO"). A substantial part of the firm's patent practice focuses on pharmaceutical and biotechnology-related inventions. All members of the firm's patent prosecution group who work in the life sciences and chemistry have academic qualifications (Bachelors, Masters or Doctoral degrees) in chemistry or the life sciences, including biochemistry, molecular biology, immunology and the like.

The term "Intellectual property" encompasses a group of rights granted by a government which provide varying degrees of protection of products, processes, designs and trademarks/service marks, in commerce and industry. Patents are a form of intellectual property that covers "inventions" and are granted a quid pro quo in exchange for an inventors' full disclosure of his invention to the public. This report is concerned with patents and patent applications which are the property of, or are licensed to, Pharmaxis Ltd, and which patents concern primarily novel small molecule inhibitors of immunity and inflammation that are useful in treating autoimmune and related diseases and conditions.

Patents represent a monopolistic right granted separately by jurisdiction (generally by country) which grant the patent owner a limited right to exclude others from practicing (making, using, or selling) the patented subject matter throughout the relevant jurisdiction. Patents have a finite term which in many countries of the world runs 20 years from the date of the filing of a complete application, subject to the payment of regular maintenance, renewal or annuity fees. Commercialization of developments, improvements or new uses of patented products and processes by third parties are often subject to the temporary monopoly afforded by the earlier existing patent(s), and require the party wishing to use such developments to obtain a license and pay the patent holder royalties. Remedies to the patent owner for infringement of his patent by a third party, which vary by country, may include money damages, equitable remedies such as injunctions, and bars to importation of infringing goods.

## 10: Report on Intellectual Property CONTINUED

The schedule of patents and patent applications provided herein refers to the expiration date of the patent term, which is based on the standard statutory term of the patent monopoly provided in a particular jurisdiction. In the case of certain pharmaceuticals/therapeutic products or medical devices that require regulatory approval prior to marketing and sale, the patent term may be extended in certain jurisdictions by a prescribed period, generally not exceeding five years. Patent term extensions generally relate to pharmaceutical compositions per se or medical devices for which regulatory or marketing approval has been obtained.

Patent rights are obtained by filing a patent application, which includes (1) a patent specification that describes the invention, and (2) claims which define the specific invention to be protected. In the United States, Australia and other jurisdictions, a "provisional" patent application may be filed to establish the "priority date" for the invention disclosed in that application. However, it is not possible to obtain a patent merely on the basis of a provisional patent application, which is never examined. Rather, an associated complete or formal application must be filed within 12 months of the filing date of the provisional application, and this latter application is subjected to examination by the relevant patent office and is either granted or rejected.

In today's patent regime, the filing of a provisional patent application (most commonly in an applicant's home country) serves as a possible first step in obtaining patent rights in countries throughout the world, with each foreign patent application being entitled to claim priority from the initial national (e.g., U.S. or Australian) provisional application. A simplified means for filing multiple international patent applications was created under the provisions of the Patent Cooperation Treaty ("PCT") administered by the World Intellectual Property Organization. The PCT permits the filing of a single international patent application (termed a "PCT application") which must designate a priori the countries in which the applicant may subsequently wish to proceed. At the end of either 20 or 30 months from the earliest priority date, the applicant must file national (or regional, in the case of the European Patent Office and other regional patent offices) patent applications in some or all of those designated countries. Alternatively, or additionally, patent applications may be filed directly in a country of interest within 12 months of the priority date. Under the Paris Convention of 1883, member countries honor a foreign patent application by according it a priority date that corresponds to its priority date in its home country.

A patent application is examined by the patent office of each country (or region) in which it was filed. Subject to the results of the examination, a patent may be granted. Common requirements for obtaining a patent around the world include that the invention be (1) useful or industrially applicable, (2) novel, and (3) not obvious such that an inventive step was involved in its conception. Such requirements are generally judged as of the application's filing date. Novelty in the patent sense is judged in relation to what was known, used or "on sale" on the date the application was filed. The United States patent law (unlike most countries) provides a one year grace period for public disclosure prior to the filing date. Inventiveness, or unobviousness, generally requires a distinct advance over what was previously known. As a consequence, patent protection may not be obtained for trivial or obvious improvements or modifications. Because of differences in the patent laws and examination procedures around the world, the same patent application may result in the granting of different claims in various jurisdictions. In the medical arena, certain countries' laws do not permit patenting methods to treat the human body or to methods of diagnosis that are carried out within the body, although alternative claiming strategies may be available to obtain effective patent protection for such uses. We note also that the order in which various claims appear in a patent or application has no bearing on their commercial importance or enforceability.

Patents and patent applications are assets as property right that, like real property, is capable of sale, transfer, license, recordal of legal interest, and the like. A patent and patent application may be in the name of one or more entities, depending upon whether more than one inventor was responsible for the invention. In most of the world, applications are filed in the name of companies/employers. In the United States, the inventor(s) are the applicants for, and recipients of, patents, but may be required contractually to assign their rights to their respective employers. Generally, absent specific agreement to the contrary, joint patent owners are considered to hold equal undivided interests in a patent.

## Pharmaxis Ltd Patents/Patent Applications

Set forth below are details of patents and patent applications licensed to, or owned by Pharmaxis Ltd or its predecessors in interest, Pharmaxis Pty Ltd or Praxis Pharmaceuticals Australia Pty (Ltd). This report relies on the representations of Pharmaxis Ltd with respect to its licenses from third party patent owners as set forth below. We have been advised by Pharmaxis Ltd that it has:

- (1) secured a license to intellectual property of Central Sydney Area Health Service relating to the use of mannitol of a certain particle size for assessment of bronchial hyperresponsiveness consistent with active asthma, for monitoring steroid use in asthma patients and for the management of diseases such as cystic fibrosis and bronchiectasis (Patent Family 1, below).
- (2) entered into an agreement with ANUTECH Pty Ltd (as agent for and on behalf of the Australian National University) to exclusively license intellectual property of the university in the area of phosphosugars and their analogues as anti-inflammatory agents (Patent Families 2 and 3, below).

In some countries, such as Australia,¹ entitlement as a licensee to an interest in a patent is a "prescribed particular" which must be recorded. In general, if this has not yet been done, it is advisable to record the licenses in each of the countries where patents have been granted, including all of the European validations, as well as in those countries in which applications are still pending, so as to place the fact that Pharmaxis Ltd has an interest in the patents or applications on the official record.

Information concerning the status of patent applications outside the United States is based upon reports provided to us between about 21 June and 8 September 2003, by various corresponding patent firms around the world. Their reports are variously based on inspection of public records and/or databases of their national (or regional) patent offices. Information concerning U.S. patents/applications are based upon search of U.S. patent office records, including assignment recordations, or upon the internal files of Venable LLP for the patent applications of Families 5 and 6, below.

The portfolio of patent and patent application rights listed below is divided by individual patents/applications and, where appropriate, the resultant family of corresponding international patents/applications based on the same priority document.

Other than Family 1, the remaining groups of patents or applications are related to novel compounds of several different classes that share a common effect of suppressing unwanted immune and inflammatory responses. Some of these compounds have been shown to act by inhibiting emigration of immune system cells (T lymphocytes) from the circulation to the tissues where cell-mediated damage is effected. The patents relate further to pharmaceutical compositions comprising these compounds and methods of using these compounds and compositions to inhibit T lymphocyte-mediated immunity and the ensuing inflammatory processes. These methods are applicable to the treatment of diseases such as arthritis, multiple sclerosis and various other autoimmune/inflammatory diseases. Patent Family 1 involves use of mannitol and other compounds for (1) testing airway function in and susceptibility to, asthma, as well as (2) promoting airway clearance, thereby treating conditions that require clearance of excess mucus.

The actual patent claims already granted, or those that may be granted, in each national jurisdiction could vary depending on individual differences in patent laws and regulations.

<sup>&</sup>lt;sup>1</sup> as we have been informed by our Australian associates

## 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                | Pending • Request for Exam 18-Jan-2002; • Official action 09-Jul-2003; • Response due 09-Jan-2004 | 23-Feb-2015 |
| Europe (EPO)<br>(designating Austria, Belgium,<br>Switzerland, Germany, Denmark,<br>Spain, Finland, France, UK,<br>Greece, Ireland, Italy, Liechtenstein,<br>Luxembourg, Monaco, Netherlands,<br>Portugal, Sweden) | 95910331.8             | Pending 23-Feb-201  • 1st Examination report 12-Jun-2003  • Response due 12-Oct-2003)             |             |
| Japan  | 7-522021               | Pending 23-Feb-2015 • Request for examination and amendment filed 21-Feb-2002                     |             |
| Malaysia   | PI9603590              | Approved – grant fee paid Jun-2003 23-Feb-2015<br>Awaiting Grant Certificate                      |             |
| New Zealand  | 281522                 | Granted   | 23-Feb-2015 |
| P.R. China   | 95191808.7             | Granted – 05-Dec-2001   | 25-Feb-2015 |
| Republic of Korea  | 96-704666              | Granted – 16-May-2003   | 23-Feb-2015 |
| Singapore  | 34525                  | Granted – 19-Dec-1997   | 19-Dec-2015 |
| The Philippines  | I-54034                | Pending • Allowed - Jun-2003 • Acceptance fee paid; grant expected                                | 23-Feb-2015 |
| USA  | 5,817,028              | Issued – 06 Oct-1998  | 06 Oct-2015 |
| Vietnam  | SC0131/96              | Granted – 21 Mar-2002   | 23-Feb-2015 |

This series of patents and patent applications are held in the name of Central Sydney Area Health Service and stem from an initial Australian provisional patent application PM4114 filed 25-Feb-1994. Subsequently, complete applications were filed via a PCT application (PCT/AU/95/00086; 23-Feb-1995). Based on the information we have received, maintenance or annuity fees for all these patents and applications have been timely paid, so that the patents and applications are in good standing. See Appendix A for due dates of the next maintenance/annuity payments. Subject to continued payment of these prescribed fees, most of these patents are expected to run for a term of 20 years expiring on 23 or 25 Feb-2015 (see above). Exceptions to this are U.S. Patent 5,817,028 which expires on 06 Oct-2015 and Singapore patent 34525 which expires on 19 Dec-2015.

Pharmaxis Ltd has represented that it has licensed these patents.

## 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 No. | Status                      | Expires                  |
|------------------|------------|-----------------------------|--------------------------|
| Australia        | 627500     | Granted - 21-Dec-1992       | 18-Aug-2009 <sup>2</sup> |
| European states: |            |                             |                          |
| Austria          |            |                             | 17/18 Aug-2009           |
| Belgium          |            |                             | 17/18 Aug-2009           |
| France           |            |                             | 17/18 Aug-2009           |
| Germany          |            |                             | 17/18 Aug-2009           |
| Italy            |            |                             | 17/18 Aug-2009           |
| Liechtenstein    | 0429522    | Granted (EP) – 30-June-1996 | 17/18 Aug-2009           |
| Luxembourg       |            |                             | 17/18 Aug-2009           |
| Netherlands      |            |                             | 17/18 Aug-2009           |
| Sweden           |            |                             | 17/18 Aug-2009           |
| Switzerland      |            |                             | 17/18 Aug-2009           |
| United Kingdom   |            |                             | 17/18 Aug-2009           |
| Japan            | 509079/89  | Granted 03-Dec-1999         | 18-Aug-2009              |
| USA              | 5,506,210  | Issued 09-Apr-1996          | 09-Apr-2013              |

This family of patents is owned by The Australian National University ("ANU") and claims priority to Australian Provisional application P19942/88 filed on 19-Aug-1988. Subsequently, complete applications were based on a PCT application (PCT/AU89/00350) filed 18-Aug-1989). Based on the information we have received, maintenance fees for all these patents have been timely paid, so that the patents and applications are in good standing. See Appendix A for due dates of the next maintenance/annuity payments. Subject to continued payment of these prescribed fees, most of the listed patents are set to expire on about 17 Aug-2009 (see above). An exception to this is U.S. patent 5,506,210 which is set to expire on 09-Apr-2013.

Pharmaxis Ltd has represented that it has licensed these patents.

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 No. | Status              | Expires  |
|-----------|------------|---------------------|--|
| Australia | 728393     | Granted 26 Apr-2001 | 17-Oct-2017<br>(extension may<br>be available) |
| USA       | 6,294,521* | Issued 25-Sep-2001  | 18-Oct-2017                                    |

<sup>\*</sup> A number of typographical/printing errors were identified in the printed U.S. patent which errors should not have any substantive impact on its validity. These errors can most likely be corrected by applying for a Certificate of Correction (cost-free if due to PTO errors).

<sup>&</sup>lt;sup>2</sup> According to our Australian associates, an extension may be available.

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. Based on the information we have received, maintenance or annuity fees for all these patents and applications have been timely paid, so that these patents are in good standing. See Appendix A for due dates of the next maintenance/annuity payments. Subject to the continued payment of these prescribe fees, each of the patents will run for a term expiring on about 17 October 2017.

Pharmaxis Ltd has represented that it has licensed these patents.

## 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   | Application No.                      | Status   | Expires     |
|---|--------------------------------------|--|-------------|
| Australia   | 2001270356<br>(formerly 70356/01)    | Pending  • Awaiting direction to request examination  • Examination not yet requested by applicant   | 11-Jul-2021 |
| Canada  | 2415214                              | Pending 11-Jul-202  • Request for examination due 11-Jul-2006  |             |
| Europe<br>(designating Austria, Belgium,<br>Switzerland/ Liechtenstein, Cyprus,<br>Germany, Denmark, Spain, Finland,<br>France, UK, Greece, Ireland, Italy,<br>Luxembourg, Monaco, Netherlands,<br>Portugal, Sweden, Turkey). | 01949109.1                           | Pending  • Examination fee paid upon entry;  • Awaiting EPO supplemental search report  • Will have 6 months from report to confirm desire for examination |             |
| New Zealand   | 523565<br>(filing date: 05 Jan 2003) | Pending: • Official action pending   | 11-Jul-2021 |
| USA   | 10/338,679<br>(filed: 09 Jan-2003)   | Pending 11-Jul-2021  • Assignment recorded  • Preliminary amendment filed for procedural reasons   |             |

This family of patent applications was originally filed in the name of Praxis Pharmaceuticals Australia Pty Ltd, which we are advised, as noted above, was predecessor in title of Pharmaxis Pty Ltd and Pharmaxis Ltd. 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. For the U.S. application, Official Filing Receipt notes that this is a "continuation-in-part application, meaning that new subject matter was added at some stage of filing compared to the priority document. Based on the information we have received, for those applications requiring annuities, these have been timely paid, so that these applications are in good standing. See Appendix A for due dates of the next maintenance/annuity payments. Any patents granted from these applications will run for a term expiring on about 11 July 2021, provided that payment of prescribed maintenance fees for the applications (if required), and patents granted therefrom, are timely paid.

We understand that the inventors have yet to assign the Australian application to Pharmaxis Ltd. Also, if not yet done, the change of name from Praxis Pharmaceuticals Australia Pty Ltd to Pharmaxis Ltd should be recorded in each country in which this application has been filed.

## 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   |
|---------|-----------------|--|
| USA     | 60/471,716      | • Filed 20-May-2003  |
|         |                 | • Must be filed as complete national or international application by 20 May 2004 |

This U.S. provisional application was prepared and filed by our firm in the name of Pharmaxis Pty Ltd on 20 May 2003, which will serve as the worldwide priority date for this Patent Family provided that national stage applications and/or an international (PCT) application is filed by 20 May 2004. We are advised that Pharmaxis Ltd will expect Venable LLP to be responsible for future U.S. national stage and international filings. The filing fee was timely paid and the provisional application will lapse on 20 May 2004. The inventors have not yet executed a formal assignment of their rights to Pharmaxis Ltd, but will be asked to do so in due course during the provisional year.

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

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

| Country | Application No. | Status   |
|---------|-----------------|--|
| USA     | 60/498,288      | • Filed 28-Aug-2003; provisional fee paid  |
|         |                 | • Must be filed as complete national and/or international application by 28-Aug-2004 |

This U.S. provisional application was prepared and filed by Venable LLP on 28-Aug-2003. This date will serve as the worldwide priority date for this Patent Family provided that national stage applications and/or an international (PCT) application is filed by 28-Aug-2004. We are advised that Pharmaxis Ltd will expect Venable LLP to be responsible for future U.S. national stage and international filings. The filing fee was timely paid and the provisional application will lapse on 28-Aug-2004, one year after its filing date. The inventors have not yet executed a formal assignment of their rights to Pharmaxis Ltd, but will be asked to do so in due course during the provisional year.

## **General Statements about Patent Status**

The status of each of the patents and patent applications listed herein has been verified by reference to records of the various national or regional patent offices, through the use of computer databases and/or manual examination of patent office records, as well as our firm's own records for Patent Families 5 and 6. For non U.S. patents or applications, we have obtained information directly from firms of patent attorneys in the relevant countries, in some cases the firm responsible for a particular patent or application in its jurisdiction, or from the Australian firm overseeing the worldwide patent prosecution.

In certain patent offices, a third party opposition to a granted patent is available, and/or third party observations may be filed during the course of examination (which is laid open to the public). We are advised that none of the above granted patents are known to have been involved in such proceedings. We are further advised by associates in the various countries that none of the granted patents have been involved in legal proceedings in courts of the relevant jurisdictions.

## 10: Report on Intellectual Property CONTINUED

During examination, a separate "divisional" patent application may arise from a single "parent" application as a result of a formal requirement<sup>3</sup> of examination to split the claims into two or more separate applications (e.g., one for compositions, another for methods). A patent from such a divisional application results in the grant of a separate patent right for the particular embodiments claimed therein. We are not aware that any divisional or "continuation" applications (which would also be based on the same underlying specification as the applications/patents listed above) are currently pending. Such applications could result in the granting of patent claims not only to additional embodiments, but possibly to broader claims covering the same embodiments.

## Change of Corporate Name

We are advised that Pharmaxis Ltd ceased doing business as Pharmaxis Pty Ltd and changed it name to Pharmaxis Ltd on September 5, 2003. This change of name remains to be formally recorded in respect of the relevant patents and patent applications which were either owned by or licensed to Praxis Pharmaceuticals Australia Pty Ltd or Pharmaxis Pty Ltd. These are formal, procedural steps that, once taken, would not be expected to compromise the validity or standing of any of the foregoing patents or patent applications in any jurisdiction.

## Patentability, Patent Validity and Infringement of Third Party Rights

It should be noted that the patent applications listed above that are not labeled as "granted" or "issued" remain pending. There can be no assurance that any or all of these applications will result in the grant of a patent after examination (for novelty, inventive step or otherwise) in the particular patent office. Further, there can be no assurance that any claims granted in these applications will have the scope of the originally filed claims or the pending claims.

In addition, there can be no assurance that any of the already granted patents, or any new patent granted on any of the above applications,<sup>4</sup> will be valid or enforceable in the particular country in which it was granted, or that the scope of protection provided by any granted patent will be identical to the scope of (a) the invention disclosed in the application as filed, or (b) claims granted in a corresponding application in a different jurisdiction.

There can be no assurance that the patents as granted, even if valid, will adequately cover any commercial product or process made or sold by Pharmaxis Ltd or its licensees or sublicensees.

There can be no assurance that practice of any aspect of the foregoing patents in any jurisdiction will not infringe the patent rights of third parties who may have (a) dominating patents to the Pharmaxis Ltd products or methods, or (b) patents that cover a part or all of the production processes that Pharmaxis Ltd or its licensee deems most advantageous to employ in manufacturing the patented products.

## Independence

Venable LLP currently acts as patent attorneys in relation to two of the applications noted above (Patent Family 5 and 6), and has prepared this report for inclusion in the Pharmaxis Ltd prospectus based on available information. Venable LLP will be paid its usual professional fees for the preparation of this report.

**Venable LLP**Dr Shmuel Livnat
Partner

<sup>&</sup>lt;sup>3</sup> which may differ among different jurisdictions

<sup>&</sup>lt;sup>4</sup> or patents granted on divisional or continuation application derived from these applications

## Status of Maintenance Fee/Annuity Payments<sup>5</sup>

| Patent | F:     | . 1 |
|--------|--------|-----|
| Patent | Family | , , |
|        |        |     |

| Country                   | Patent/Application No. | Last fee paid               | Next Annuity/Maint. Fee due    |
|---------------------------|------------------------|-----------------------------|--------------------------------|
| Australia                 | 682756                 | 30-Jan-2003                 | 23 Feb-2004                    |
| Canada                    | 2183471                | 23-Feb-2003                 | 23-Feb-2004                    |
| European Patent Office    | 95910331.8             | 28-Feb-2003                 | 29-Feb-2004                    |
| Japan                     | 7-522021               | N/A                         | after grant                    |
| Malaysia                  | Pl9603590              | Grant fee – Jun-2003        | begins after Grant Certificate |
| New Zealand               | 281522                 | 18-02-2002                  | 23-02-2005                     |
| Peoples Republic of China | 95191808.7             | Not known                   | 25-05-2004                     |
| Republic of Korea         | 96-704666              | 16-May-2003                 | 16-May-2006                    |
| Singapore                 | 34525                  | 23-Feb-2003                 | 23-Feb-2004                    |
| The Philippines           | l-54034                | [Acceptance fee, June 2003] | **undetermined**               |
| USA                       | 5817028                | 21-Mar-2002                 | 06-Oct-2005 – 06-Apr-2006      |
| Vietnam                   | SC0131/96              | Paid through<br>23-Feb-2004 | 23-Aug-2003 – 23-Feb-2004      |

## Patent Family 2

| Country  | Patent No. | Last fee paid                   | Next Annuity/Maint. Fee due |
|--|------------|---------------------------------|-----------------------------|
| Australia  | 627500     | 15-May-2002                     | 18-Aug-2003-18-Feb-2004     |
| European Patent Office<br>(granted in Austria, Belgium,<br>France, Germany, Italy,<br>Luxembourg, Sweden,<br>Switzerland/Liechtenstein,<br>Netherlands0, UK) | 0429522    | 18-Aug-2002<br>in all countries | Aug-2003                    |
| Japan  | 509079/89  | 27-Nov-2002                     | 03-Dec-2003                 |
| USA  | 5,506,210  | 08-Oct-1999                     | 09-Apr-2003 – 09-Oct-2003   |

## Patent Family 3

| Country   | Patent No. | Last fee paid | Next Annuity/Maint. Fee due |
|-----------|------------|---------------|-----------------------------|
| Australia | 728393     | 22-Jul-2002   | 17-Oct-2003                 |
| USA       | 6,294,521  | n/a           | 27-Sep-2004 to              |
|           |            |               | 27-Mar-2005                 |

<sup>&</sup>lt;sup>5</sup>not yet applicable for Patent Family 5 and Patent Family 6

# 10:Report on Intellectual Property CONTINUED

| Patent Family 4        |                 |               |                             |
|------------------------|-----------------|---------------|-----------------------------|
| Country                | Application No. | Last fee paid | Next Annuity/Maint. Fee due |
| Australia              | 2001270356      | n/a           | 1st annuity: 11-Jul-2006    |
| Canada                 | 2415214         | 11-Jul-2003   | 11-Jul-2004                 |
| European Patent Office | 01949109.1      | Feb-2003      | 31-Jul-2004                 |
| New Zealand            | 523565          | filing fee    | after grant                 |
| USA                    | 10/338,679      | filing fee    | after grant                 |

# 11

# :Investment Risks

## Section



## Introduction

Potential investors should be aware that an investment in the Company involves various risks. The Company's business activities are subject to risk factors both specific to its business activities and those of a general nature. If any of the risks associated with the Company occur, the Company's business, results of operations, financial condition and prospects could be materially and adversely affected, which could result in the loss of all or part of your investment. Some of these factors can be mitigated by appropriate commercial action, but many are outside of the control of the Company and cannot be mitigated. In addition, potential investors should be aware that the value of the Company's securities on the ASX may rise and fall depending on a range of factors that affect the market price of securities. These include local, regional and global economic conditions and sentiment towards equity markets in general.

The Company is at an early research and development stage, with no pre-tax profit. Any profitability in the future will be dependent on the successful research, development, manufacture, sales and marketing of the Company's products. The Shares issued under this Prospectus carry no guarantee with respect to the profitability, the payment of dividends, return of capital or the price at which the Shares may trade on the ASX.

# The Shares being issued under this Prospectus should be considered speculative given the current stage of development of the Company.

Potential investors should carefully consider these risk factors, together with the other information in this Prospectus and seek their own professional advice in relation to the risks associated with an investment in the Company and should make their own assessment as to whether to invest in the Company. The principal risk factors applicable to the Company include, but are not limited to, the following:

## Pharmaceutical industry

The ability of the Company to research, develop, manufacture and market a pharmaceutical product will depend on a number of critical factors including, in particular:

- the ability of the Company to raise further capital in addition to the Offer to fund the continued research and development of the Company's projects;
- the success of the Company's research and development;
- prompt regulatory approval of the Company's products;
- the Company's ability to manufacture and market its products;
- achieving and maintaining necessary approvals for the manufacturing facilities; and
- the success of sales and marketing and adequate market uptake of the Company's products.

## Pharmaceutical research and development

Pharmaceutical research and development involves long lead times and is costly. In addition, there is no guarantee that:

- the Company's research and development activities will be successful;
- each phase of the clinical trials will be successful in showing efficacy and clinical utility;
- that the required regulatory approvals will be obtained in the jurisdictions in which the Company wishes to market its products;
- the Company's products will be capable of being produced in commercial quantities at an acceptable cost;

- any products, if introduced, will achieve market acceptance; and
- · that the cost of the products will be reimbursed by government or health maintenance organisations at an acceptable level.

As a result, significant monies invested and management time may be rendered unproductive and worthless. However, in respect of Bronchitol and Aridol™, the Directors believe that much of the risk in the research of these products is reduced as much of the initial research on these projects has already been successfully carried out. The products that are at an earlier stage of research, development and testing pose a higher degree of risk than those products that are more advanced. The Company has not yet completed the development of any pharmaceutical products, nor has it developed a pharmaceutical product through to commercialisation.

## Pharmaceutical manufacturing, marketing and sales

The Company is required to obtain raw materials for the production of certain of its products. The inability of the Company to secure the raw materials at a commercially acceptable price may have a material effect on the Company.

If approved for commercial production, the Company will either need to outsource the manufacturing of the products or upgrade its existing manufacturing facility or build or obtain access to a suitable manufacturing plant for commercial production. The Company's existing manufacturing facilities are unlikely to be adequate for large scale production of the Company's products. If the Company decides to build or acquire a suitable manufacturing facility, then the Company may be exposed to a number of costs and undetermined risk factors. It is anticipated that the cost of establishing or acquiring such a facility would be significant. If the Company chooses to outsource the production of its products, the Company will have a lesser degree of control over the production of the product and may be subject to increases in the unit cost of production. There may also be additional occurrences outside the control of the Company that may prevent or interfere with the production of the Company's product for trials or sale.

The market's acceptance of the Company's products is uncertain. These uncertainties can be caused by difficulties in marketing any of the Company's products including problems with market acceptance associated with price, or the claims that can be made about the product and other competitive products. If approved for marketing, there can be no assurance that the Company's products will be successful in the market or that the Company will receive any profits from the sale of its products.

The failure to obtain the support of key respiratory clinicians and patient support foundations may make it more difficult to market the Company's most developed products which as a result could have a material adverse effect on the Company.

The Company may be required to enter into additional commercial agreements with others to manufacture, market and sell the Company's products. There can be no assurance that the Company will be able to enter into any such additional commercial agreements on acceptable terms, if at all. Furthermore, there can be no assurance that any third parties would perform their obligations under any such agreement and comply with any regulatory requirements or requirements imposed by the Company. If the Company is not able to enter into additional commercial agreements it could encounter delays in the development, manufacture or sale of the Company's products.

## Regulatory approvals

The approval process for new products is likely to take many years and will involve substantial expenditure by the Company. In addition, the regulations may change and additional regulations may be imposed that could delay or prevent the approval of the Company's products.

The Company and its products are subject to complex Australian and international legislation and regulations, which are subject to change. These regulations create uncertainty as to whether the Company will be able to market its pharmaceutical products. There can be no assurance that regulatory approvals will be provided for a product. Delays, or failure to obtain regulatory approval for a product in Australia and other international markets is likely to have a material adverse effect on the financial performance of the Company.

The Company is subject to ongoing regulatory restrictions. There can be no assurance that additional regulations and legislation will not be enacted to which the Company and its agents will be required to comply. Such additional regulations and legislation can impose significant unanticipated cost burdens on the Company that may have a material adverse effect. Furthermore, the Company will be subject to ongoing regulatory requirements that may impose restrictions on its products, the manufacture of its products or the Company including the recall or withdrawal of the products from the market.

## **GMP** compliance

The ability of the Company to offer its products for clinical trial or for sale and marketing depends on licences being maintained and the Company receiving favourable audit reports from the regulatory authority of the country in which the products are being offered for sale. Receipt of an unfavourable audit can impose unbudgeted cost burdens that may have a material adverse effect on the ability of the Company to conduct its business. In extreme cases the Company may have its licence revoked which would prevent the Company from offering any of its products for sale.

## **Technological developments**

The pharmaceutical industry is characterised by change, evolving industry standards, frequent introduction of new products and services, continuing advances in technology and changes in customer requirements and preferences. A failure by the Company to secure a leading market position for its products and adapt to these changes could lead to a loss of market opportunities and adversely impact on the Company's operating results and financial position. No assurance is given that technological developments will not cause the Company's technology to be rendered obsolete or non-competitive.

## Competition

The Company conducts business in a highly competitive industry in which there are a number of well established competitors that have substantially greater financial resources, sales and marketing organisations, market penetration and research and development capabilities, as well as broader product offerings and greater market presence and name recognition. The Company's business is risky, but this risk is increased in such an industry with such competitors.

There can be no assurance given in respect of the Company's ability to compete in the competitive markets in which it operates. Amongst other things, competition will affect the Company's ability to obtain and sustain proprietary rights to technology, marketing, sales and distribution of products and developing products for existing and new markets. No assurances can be given that the actions of existing and future competitors will not have material adverse effects on the Company's ability to implement its business plan and on the Company's operating and financial performance. Competition and new technologies can reduce product prices and profit margins and decrease the financial value of products or research projects and render costly research and development obsolete.

## Patents and proprietary rights

The ability of the Company to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties is an integral part of the Company's business. Competition in obtaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes. In addition, the granting of a patent does not guarantee that the rights of others are not infringed or that competitors will not develop technology to avoid the patented technology. There can be no assurance that any patents which the Company may own or control will afford the Company commercially significant protection of its technology or its products or have commercial application.

The Company will pursue both its existing and all future patent applications. No guarantee can be given that the patents will be granted nor does the grant of a patent guarantee that the patent concerned is valid or that the technology (patented or otherwise) does not infringe the rights of others.

The Company licenses some of its intellectual property. There can be no assurance that any third party will abide by and perform their obligations under any such agreement. There is also a risk that the licences may be terminated in the event of breach. The risks in relation to patents referred to above are also applicable to the patents which the Company licenses.

Risks associated with the Company's patents are also set out in the Report on Intellectual Property in section 10 of this Prospectus.

## Healthcare funding

The Company's business may be adversely affected by changes to the healthcare reimbursement regimes in Australia and international jurisdictions.

#### Reimbursement

The level of commercial benefit from the sales of its products will to a large degree be dependent on the ability of the Company to negotiate and obtain appropriate levels of reimbursements from governments on the cost of the Company's products.

## Key personnel

The key personnel employed by the Company have a high degree of expertise and the Company is reliant on their continued service to maintain and develop its business. The loss of a key employee or the inability to recruit and retain high calibre staff to manage future anticipated growth could have a material adverse effect on the Company. The additions of new employees and departures of existing employees, particularly in key positions, can be disruptive and could also have a material adverse effect on the Company.

## Product liability or other claims

The Company's business activities could result in claims against the Company including product liability claims from research and development, clinical trials, manufacturing, marketing and use of the Company's products. The Company attempts to reduce the risk of some of these losses through disclaimers and liability limitation clauses. However, the Company may not have obtained adequate legal protection in all instances. The Company will also seek to maintain adequate product liability insurance. However, adequate insurance coverage may not be forthcoming and any insurance coverage may not be adequate and any product liability claim for damages could be substantial. There can be no assurance that adequate or necessary insurance coverage will be available at an acceptable cost or in sufficient amounts. In the event of product liability claims, insufficient insurance coverage could have a material adverse effect on the Company's results of operations and financial condition.

If there is a problem that is attributable to the Company's products or services, the market perception of the effectiveness of the Company's products and services could also be harmed.

## **Business strategy**

If the Company undertakes any acquisitions of businesses or technologies, it may face a number of difficulties in integrating those new businesses or technologies. The Company may be unable to obtain financing for acquisitions on favourable terms or at all. The Company may finance its activities through the issuance of additional shares that could dilute the ownership interests of the Company's existing shareholders. The Company's business strategy may introduce new risks and prove to be disruptive and divert management resources.

## Additional funding requirements

The continued research and development, manufacturing, marketing and sales is dependent on the Company's ability to obtain funding over a long period of time. It is difficult to predict the level of funding required with accuracy and additional development costs may arise which are not currently contemplated by the Company. The continued development of the Company's business is dependent on the Company's ability to obtain necessary financing through additional debt or equity funding. There is no assurance that additional funding will be available or can be secured on acceptable terms. If funds are not available, there will be a material adverse effect on the Company's business.

## Government assistance

The Company has received government assistance in various forms of funding and incentives to assist in the undertaking of research and development. The continuance of this funding cannot be assured. The terms of the R&D Start Grant provide that the grant money may be repaid in certain limited circumstances if the Company is in breach of the agreement.

## Share market risk

There are a number of risks associated with a stock market investment. The market price of the Shares may be subject to general movements in local and international stock exchanges, economic conditions and interest rates. The Shares may trade at a price above or below the Offer Price depending on a range of factors including the performance of the market generally, the performance of the pharmaceutical sector of the market, market perceptions of the Company and the performance of the Company generally.

## Income and capital risk

No assurances can be given in relation to the future earnings or working capital requirements of the Company. Changes in inflation rates, exchange rates, taxation or other legal regulations or government policies may negatively impact on the revenue generating capacity and future profitability of the Company. This investment is speculative in nature and the Company, its officers or any other person do not guarantee any returns from that capital. The speculative nature of the investment poses a risk that no income will be generated and capital may be lost. It is likely that the Company will record losses and is unlikely to pay a dividend for a number of years.

## Other risks

The Directors of the Company have attempted to address relevant risks. However, there are other factors which are not specific to the Company, which may impact on the Company, including:

- government economic policies;
- · interest rate charges;
- · taxation policies;
- · inflation rate changes;
- business confidence and consumer sentiment;
- · changes in investors' attitudes towards pharmaceutical companies;
- the state of world stock markets; and
- the state of the Australian economy and global economies.

# 2 : Additional Information

Section



## Incorporation

The Company was incorporated on 29 May 1998 and is registered in the Australian Capital Territory.

## Year end date

The Company's financial year end is 30 June each year.

## Company tax status

The Company will be taxed as an Australian public company limited by shares.

## Board of the company

The current board of Directors of the Company consists of five non-executive Directors and two executive Directors.

- Denis Hanley is the non-executive Chairman who was appointed on 24 October 2001.
- Alan Robertson is the Chief Executive Officer who was appointed on 25 July 2000.
- Brett Charlton is the executive Medical Director who was appointed on 1 June 1998.
- Carrie Hillyard is a non-executive Director who was appointed on 28 August 2002.
- Charles Kiefel is a non-executive Director who was appointed on 2 May 2003.
- Malcolm McComas is a non-executive Director who was appointed on 4 July 2003.
- Brigitte Smith is a non-executive Director who was appointed on 22 October 1999.
- David McGarvey is the Company Secretary who was appointed on 6 December 2002.

## **Audit Committee**

The audit committee of the Company comprises Charles Kiefel (as chairperson), Malcolm McComas and Denis Hanley.

## **Remuneration Committee**

The remuneration committee of the Company comprises Carrie Hillyard, Brigitte Smith and Denis Hanley.

## Scientific Advisory Board

The scientific advisory board comprises Sandra Anderson, Norbert Berend, Malcolm Fisher and Richard Morgan.

## Corporate governance

The Company has or will adopt appropriate corporate governance policies and practices as provided by the Listing Rules and the principles of the ASX Corporate Governance Council (as applicable and appropriate for the Company). The Company will adopt a share trading policy which, amongst other things, provides that the Directors and employees of the Company may not trade the securities of the Company in the 30 days prior to the announcement of the Company's half year and full year financial results.

## 12.1 Constitution and Share Rights

On the issue and allotment of Shares under this Prospectus there will be only one class of Shares and all will rank equally. The Shares issued under this Prospectus will be fully paid Shares. Detailed provisions relating to the rights attaching to Shares are set out in the Company's constitution and the Corporations Act.

On the issue and allotment of Shares under this Prospectus, the Company's constitution will be of the kind usually adopted by a public company listed on the ASX. The following is a broad summary of the key provisions in the constitution and the rights attaching to Shares.

## **General meetings**

Each shareholder is entitled to receive notice of and be present, to vote and speak at general meetings of the Company.

## Voting rights

At a general meeting every shareholder present (in person or by proxy, attorney or representative) has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) has one vote per fully paid Share on a poll, except in respect of each partly paid share held by a shareholder, where the shareholder has a fraction of a vote for each partly paid share they hold. This is subject to any other rights or restrictions which may be attached to any Shares.

## Dividend rights

Subject to any special rights or restrictions attached to a Share, each holder of a fully paid Share will participate in all dividends declared after their issue and rank equally with all existing Shares.

Dividends are declared by the board of Directors at its discretion and, subject to any special rights, are payable on all Shares in proportion to the amount of capital for the time being paid up or credited as paid up on those Shares.

## Rights on winding up

Subject to any special rights and restrictions attached to Shares, on a winding up any surplus must be divided among the shareholders in the proportion that the amount paid up on the shares bears to the total amount paid up on all shares on issue. Subject to any special rights and restrictions attached to shares, on a winding up, a liquidator of the Company may, with the sanction of a special resolution of shareholders, divide among shareholders the whole or any part of the property of the Company and may decide how to distribute the property as between the shareholders.

## Transfer of shares

Subject to the constitution of the Company, the Corporations Act, the Listing Rules and any escrow arrangements, generally, shares are freely transferable.

## Future changes in capital

Subject to Listing Rules and the constitution of the Company, the board of Directors may issue, grant options over, or otherwise dispose of shares on such conditions, at such times and with the preferred, deferred or other special rights or restrictions as the Directors think fit. Subject to the Corporations Act and the Listing Rules, the Company may by resolution, consolidate and divide its share capital or reduce its share capital and buy back its shares.

## Variation of rights

The Company may only vary or cancel the rights attaching to any class of shares, or convert shares from one class to another, by a special resolution of the Company and a special resolution passed at a meeting of the holders of shares in that class or the written consent of shareholders with at least 75% of the votes in that class.

## Proportional takeover

The constitution of the Company contains a proportional takeover provision which may be renewed from time to time in accordance with the Corporations Act.

## Copy of constitution

A copy of the constitution of the Company may be inspected at the registered office of the Company during normal business hours by appointment with the Company Secretary.

## 12.2 Employee Option Plan

The Company adopted an Employee Option Plan in 1999 which was amended in 2003. The objective of the Employee Option Plan is to assist in the recruitment, reward, retention and motivation of employees of the Company. The Directors believe this is important for the long-term development of the Company. The Company currently has on issue 10,184,000 options under the Employee Option Plan. The following table sets out details of the existing employee options currently on issue. To satisfy the admission requirements of the Listing Rules, the ASX has provided in principle advice that it will grant the Company a waiver in respect of the options with an exercise price below \$0.20. Following is a summary of the material terms and conditions of the Employee Option Plan, by expiry date.

| Numbers of options | Number of options which have vested | Exercise price \$ | Expiry date |  |
|--------------------|-------------------------------------|-------------------|-------------|--|
| 2,400,000          | 2,400,000                           | 0.1250            | 30/11/2009  |  |
| 384,000            | 288,000                             | 0.1250            | 30/06/2010  |  |
| 96,000             | 72,000                              | 0.1250            | 31/12/2010  |  |
| 160,000            | 80,000                              | 0.1250            | 30/11/2011  |  |
| 640,000            | 640,000                             | 0.3125            | 30/08/2011  |  |
| 4,640,000          | 1,880,000                           | 0.3125            | 30/06/2012  |  |
| 480,000            | -                                   | 0.3125            | 30/11/2012  |  |
| 224,000            | -                                   | 0.3125            | 30/04/2013  |  |
| 200,000            | -                                   | 0.3125            | 03/07/2013  |  |
| 960,000            | -                                   | 0.3125            | 30/06/2013  |  |
| 10,184,000         | 5,360,000                           |                   |             |  |

## Eligibility

The Directors, the Chief Executive Officer of the Company and the Remuneration Committee may offer options over ordinary Shares to any person considered by the board of Directors to be an employee of the Company and its subsidiaries, including executive Directors and non-executive Directors.

## Entitlement

Each option issued under the Employee Option Plan entitles the holder to subscribe for one fully paid Share. When issued, each Share will rank equally with all other Shares then on issue.

## Issue of options

Subject to the Corporations Act and Listing Rules, the Directors determine the issue price for the options and the terms and vesting conditions of the options.

## **Exercise of options**

Any exercise conditions determined by the Board must be satisfied before the employee options vest and become exercisable. The employee options may only be exercised in accordance with the Corporations Act and the Listing Rules. Options typically vest over a four year period subject to employee performance.

## Lapse of options

The employee options lapse on such date as determined by the board of Directors at the time the employee options are granted or on termination of employment with the Company and in certain other specified instances. Lapse occurs either immediately on termination or after a period of time.

## Exercise price

Subject to the Listing Rules, the exercise price of the employee options will be the amount determined by the board of Directors at the time of granting the employee options.

## New issues, bonus issues, rights issues and capital reorganisations

The impact on the employee options as a result of new issues, bonus issues, rights issues and capital reorganisations will be dealt with in accordance with the Listing Rules.

## Restrictions on issue

The maximum number of employee options that may be granted under the Employee Option Plan is limited to the lesser of 15% of the total number of Shares on issue or such other number as is consistent with the Listing Rules and the Corporations Act.

#### No transfers

Except by transmission on death or with the prior written consent of the board of Directors employee options may not be transferred, encumbered, assigned or otherwise disposed of.

## Voting

Subject to the Listing Rules and the Corporations Act, the employee options do not confer:

- a right to notices of general meetings, except as may be required by law;
- · a right to attend or speak at general meetings of the Company; and
- a right to vote at any such general meetings of the Company.

#### Amendment

The board of Directors may amend the Employee Option Plan at any time in accordance with the Employee Option Plan and the Listing Rules.

## 12.3 Control of the Company

On the issue and allotment of Shares under this Prospectus, the ownership interests of the Company's existing shareholders will be as set out in the tables below. The first table includes the effect of the firm commitments of existing shareholders, Directors and management to acquire 12,000,000 Shares in the Offer (and the effect of a total of 450,000 Shares that certain shareholders will receive from the Underwriter in lieu of fees).

|                                       | Pre Offer  | 0/0  | Post Offer  | Approximate % |
|---------------------------------------|------------|------|-------------|---------------|
| Shares held by existing shareholders, |            |      |             |               |
| Directors and management              | 58,016,000 | 100% | 70,466,000  | 70%           |
| Shares held by new shareholders       | _          | _    | 29,550,000  | 30%           |
| Total number of Shares                | 58,016,000 | 100% | 100,016,000 | 100%          |

The following table includes the total number of Shares on issue and the effect of the exercise of the 10,184,000 million options already on issue.

|                             | Pre Offer  | %    | Post Offer  | Approximate % |
|-----------------------------|------------|------|-------------|---------------|
| Total number of Shares      | 58,016,000 | 85%  | 100,016,000 | 91%           |
| Existing options            | 10,184,000 | 15%  | 10,184,000  | 9%            |
| Total diluted share capital | 68,200,000 | 100% | 110,200,000 | 100%          |

Notes to the above tables:

- (i) At the date of this Prospectus the Company has preference shares on issue. These preference shares convert automatically to the number of Shares detailed above on the issue and allotment of Shares under this Prospectus. The table assumes the conversion of all preference shares to Shares.
- (ii) Certain existing shareholders, Directors and management of the Company have entered into firm commitment agreements to subscribe for 12,000,000 Shares under the Prospectus. Section 12.6.3 of this Prospectus details the commitments made by the Directors and the vehicles associated with those Directors. The acquisition of Shares by existing shareholders, Directors and management of the Company is included in 'Post Offer' calculations above. The table includes the impact of an aggregate total of 450,000 Shares that certain shareholders receive from the Underwriter in lieu of certain fees (more fully described in section 12.6.4).
- (iii) The Company plans to issue the new Shares pursuant to this Prospectus. Accordingly, the persons who are ultimately to be allotted Shares are to be determined by the Company after considering Applications received. For the purposes of the above calculation it has been assumed that none of the Company's existing shareholders, Directors and management (other than those referred to in Note (ii)) subscribe for Shares in the Offer. If the Company's other existing shareholders, Directors and management subscribe for Shares pursuant to the Prospectus, the above figures will change accordingly.
- (iv) Excludes shares issued by way of acceptance of oversubscriptions.

Substantial shareholders in the Company as at the date of this Prospectus:

| Beneficial shareholder              | Number of Shares |
|-------------------------------------|------------------|
| The Australian Bioscience Trust     | 19,200,000       |
| Praxis Pharmaceuticals Inc          | 11,200,000       |
| Mooroolbark Technology Pty Ltd      | 7,520,000        |
| CM Capital Investment Trust No 3    | 7,200,000        |
| Bioscience Ventures II              | 6,400,000        |
| The Australian National University  | 3,200,000        |
| Australia Venture Capital Fund L.P. | 2,400,000        |

#### Notes:

- (i) The table assumes the conversion of all preference shares to ordinary Shares which occurs automatically on the issue and allotment of Shares under this Prospectus.
- (ii) The Australian Bioscience Trust, Bioscience Ventures II, CM Capital Investment Trust No 3 and Australia Venture Capital Fund L.P. through their respective trustees, managers and general partners have given firm commitments to subscribe for an aggregate total of 10,000,000 new Shares under the Prospectus, as detailed in section 12.6.3 of this Prospectus. These shareholders will also receive a cumulative total of 450,000 Shares from the Underwriter in lieu of fees, as detailed in section 12.6.4 of this Prospectus.
- (iii) The interests of Directors in these entities is set out in section 12.6.3 of this Prospectus.

## Restricted securities

The ASX may, as a condition of granting the Company's application for official quotation of the Shares, classify certain existing Shares and options or both as restricted securities. If so, prior to the official quotation of the Shares, the holders of restricted securities will be required to enter into a restriction agreement. The Directors expect that the escrow arrangements will prohibit the transfer of effective ownership or control of some or all of the Shares and options held by existing shareholders and optionholders of the Company for a period of up to 24 months from the date of quotation of the Company without the holders of those Shares and options first obtaining written consent of the ASX to the transfer. The Directors anticipate that up to 28% of the Company's securities will be regarded as restricted securities and subject to escrow for a period of 24 months (however this figure is subject to the discretion of ASX and may be higher or lower).

## Voluntary escrow arrangements

In addition to the escrow arrangements required by the Listing Rules, all Directors and management of the Company and all shareholders whose Shares held prior to this Offer represent greater than 5% of the then issued share capital of the Company, have entered into voluntary restriction agreements agreeing not to transfer effective ownership or control of any of their Shares held prior to the Offer (or if the Listing Rules escrow requirements apply to that shareholder, to the balance of their Shares held prior to the Offer that are not subject to the Listing Rule escrow requirements) for a period of six months from the date of quotation of the Shares on the ASX. The restrictions do not otherwise restrict the rights attaching to the Shares (including voting rights and the right to attend general meetings). The restrictions will not preclude the relevant shareholders from accepting a takeover offer where holders of at least 50% of the bid class of securities (that are not subject to escrow) have accepted the offer and also to enable the Shares to be transferred or cancelled as part of a merger by way of scheme of arrangement. In relation to a takeover offer, the release from escrow would be conditional on the restrictions being reapplied if the takeover bid does not become unconditional. The Directors anticipate that the cumulative affect of the mandatory ASX and voluntary escrow arrangements is that up to 57% of the Company's securities will be subject to escrow arrangements in the six months from the date of quotation of the Shares on ASX (however this figure is subject to the discretion of ASX and may be higher or lower).

The entry into the restriction agreements described above may give the Company a 'relevant interest' in the securities for the purpose of the Corporations Act. The Company has sought relief from ASIC from the Corporations Act to ensure that the Company does not acquire such relevant interest as a result of those restriction agreements.

## 12.4 Material Contracts

The following are a summary of the key terms of the Company's material contracts. The summaries do not purport to contain the actual contractual terms entered into by the Company.

## 12.4.1 Underwriting agreement between the Company and Wilson HTM dated 26 September 2003

The Company and the Underwriter have entered into an agreement for the underwriting of the 42 million Shares under the Offer not including oversubscriptions.

## Commission and expenses

The Company has agreed to pay the Underwriter:

- a retainer of \$25,000;
- a management fee equal to 1.5% of the total funds raised under the Offer of the 42 million Shares (exclusive of any GST) being \$315,000;
- a commission equal to 4.5% of the total funds raised under the Offer of the 42 million Shares (exclusive of any GST) being \$945,000;
- an underwriting commission equal to 6% (exclusive of any GST) of all oversubscriptions accepted by the Company; and
- reimbursement of all outgoings, costs and expenses reasonably incurred by the Underwriter in connection with the Offer.

The Underwriter must pay all sub-underwriting fees, brokerage or other fees payable to sub-underwriters, brokers, licenced dealers in securities and investment advisors arising as a result of the issue of Shares under the Offer.

#### Termination

The Underwriter may terminate its obligations to satisfy a shortfall under the agreement by notice to the Company at any time prior to the date on which the Shares are issued and allotted under the Offer as a result of any one or more of the following events:

- approval by the ASX for the admission of the Company to the ASX is refused or not granted earlier than two days before the Closing Date or if approval is granted, such approval is subsequently withdrawn;
- the S&P ASX 200 Health Care Index is at any time prior to issue and allotment of the Shares more than 12.5% lower than the level of the index on the close of the trading on the business day before the date of the Underwriting Agreement;
- the NASDAQ Biotechnology Index is at any time prior to issue and allotment of the Shares more than 12.5% lower than the level of the index on the close of the trading on the business day before the date of the Underwriting Agreement;
- a materially adverse change occurs in the assets, liabilities, financial position or performance, profits, losses or prospects of the Company;
- any circumstance arises that results in the Company either repaying money to Applicants or offering Applicants an
  opportunity to withdraw their Applications and be repaid their Application Money (other than to Applicants whose
  Applications are not accepted in whole or in part);

The ability for the Underwriter to terminate its obligations to satisfy a shortfall are qualified by the requirement that the Underwriter must believe, on reasonable grounds, that the relevant termination has, or is likely to have a materially adverse effect on the outcome of the Offer or could give rise to a material liability for the Underwriter under any law or regulation. These qualified events of termination include:

- a statement contained in the Prospectus is misleading or deceptive, a matter is omitted from the Prospectus, the issue of
  the Prospectus is misleading or deceptive, or any other information supplied to the Underwriter by the Company (including
  the due diligence report associated with this Offer) is false, misleading or deceptive;
- any material adverse change or disruption occurs in the existing financial markets, political or economic conditions of Australia, Japan, the United Kingdom, the U.S. or in the international financial markets or any material adverse change occurs in national or international political, financial or economic conditions, in each case the effect of which is that, in the

reasonable opinion of the Underwriter reached in good faith after consultation with the Company, it is impracticable to market the Offer or to enforce contracts to issue and allot the Shares or that the success of the Offer is likely to be adversely affected;

- the Prospectus does not contain all information required by the Corporations Act;
- the Company fails to lodge a supplementary or replacement prospectus in a form acceptable to the Underwriter in circumstances where the Company is prohibited by the Corporations Act from offering the Shares without further disclosure;
- the termination or material amendment of any material contract of the Company;
- there is an outbreak of hostilities political or civil unrest (whether or not war has been declared), or a major escalation in
  existing hostilities political or civil unrest occurs, involving any one or more of Australia, New Zealand, the U.S., the United
  Kingdom, any member state of the European Union, Japan, Indonesia, North Korea or the Peoples Republic of China or a
  significant terrorist act is perpetrated on any of those countries or any diplomatic, military, commercial or political
  establishment of any of those countries anywhere in the world;
- there is introduced, or there is a public announcement of a proposal to introduce, into the Parliament of Australia, or any State or Territory of Australia, a new law, or the Reserve Bank of Australia, or any Commonwealth, State or Territory authority, adopts or announces a proposal to adopt a new policy (other than a law or policy which has been announced before the date of the Underwriting Agreement), any of which does or is likely to have a material adverse effect on the success of the Offer;
- a change in the board of Directors or senior management of the Company occurs;
- a director of the Company is charged with an indictable offence or is disqualified from acting as a director;
- · material legal proceedings are commenced against the Company;
- other than to adopt the constitution of the public listed company immediately prior to the issue and allotment of Shares or as otherwise contemplated by this Prospectus, the Company changes its constitution or the capital structure of the Company without the prior written consent of the Underwriter
- there is a material contravention by the Company of the Corporations Act, the Listing Rules, the Company's constitution, or any of the Listing Rules, or the Prospectus or any aspect of the Offer does not materially comply with the Corporations Act, the Listing Rules or any other applicable law or regulation;
- ASIC gives notice of an intention to hold a hearing under section 739(2) Corporations Act or issues an order under sections 739(1) or (3) Corporations Act;
- an application is made by ASIC for an order under Part 9.5 Corporations Act in relation to the Prospectus or ASIC commences any investigation or hearing under Part 3 of the Australian Securities and Investments Commission Act 2001 (Cth) in relation to the Prospectus;
- any person who is required under the Corporations Act to consent to the lodgement of the Prospectus, withdraws their consent
- there is a material default by the Company in the performance of any of their obligations under the Underwriting Agreement or a warranty contained in the Underwriting Agreement by the Company is not true or correct.
- an event specified in section 652C(1) or 652C(2) of the Corporations Act (substituting the Company for "target") occurs in relation to the Company;
- an event specified in the timetable contained in the Underwriting Agreement is delayed for more than 3 Business Days (other than as a result of actions taken by the Underwriter) without the Underwriter's prior written consent.

#### **Indemnities**

The Company has also agreed to indemnify and keep indemnified the Underwriter and its officers, employees, advisors and related bodies corporate and to hold them harmless from and against all third party claims, demands, damages, losses, costs, expenses and liabilities suffered or incurred as a result, whether directly or indirectly, of:

- this Prospectus and the Offer;
- the issue and allotment of Shares;
- any of the representations and warranties given by the Company contained in the Underwriting Agreement not being true and correct;
- a breach by the Company of its obligations under the Underwriting Agreement;
- the occurrence of a termination event under the Underwriting Agreement;
- any announcement, statement, advertising, publicity or public information made in relation to the Prospectus or the Offer; or
- any claim of liability under the Corporations Act or any other applicable law in relation to the Prospectus or the Offer.

The indemnity provided by the Company does not extend to any claims, demands, damages, losses, costs, expenses and liabilities arising out of the fraud, wilful misconduct, negligence or breach of contract of an indemnified party.

## 12.4.2 CSAHS Licence between the Company and Central Sydney Area Health Service dated 10 October 2001

## Licence

CSAHS has granted the Company an exclusive, world-wide sub-licensable licence to exploit the CSAHS Intellectual Property. The Company must bear the cost of maintaining the registered CSAHS Intellectual Property and must use its reasonable commercial endeavours to exploit and undertake research and development of the CSAHS Intellectual Property.

## Term

The term of the CSAHS Licence in each relevant country is for the longer of 10 years from the first commercial sale of products which exploits the CSAHS Intellectual Property in that country until the expiry of the last registered patent in that country unless the CSAHS Licence is terminated earlier for breach of the agreement by the Company or insolvency of the Company or if the Company determines in its commercial judgement that it is not prudent to continue the CSAHS Licence.

## New intellectual property rights and improvements

With respect to any new patentable inventions arising in the course of exploiting the CSAHS Intellectual Property, the Company may at its own cost prosecute new patent applications in the name of the Company. If the Company does not seek patent protection for the new patentable invention in any country, CSAHS may at its own cost file patent applications.

## Royalty

The following royalties are payable by the Company to CSAHS for the term of the CSAHS Licence on net sales of products and services which exploit the CSAHS Intellectual Property:

- (a) in respect of the upper and lower airway function test application of the patents:
  - no royalties until aggregate net sales of products and services from all countries of A\$500,000 have been achieved;
  - a royalty of 4% of the gross margin if the net sales of the products or services by the Company achieve a gross margin of 20% or less;
  - a royalty of 8% of the gross margin if the net sales of the products or services by the Company achieve a gross margin between 20% and 40%;
  - a royalty of 10% of the gross margin if the net sales of the products or services by the Company achieve
    a gross margin greater than 40%; and
  - 20% of any royalty received from a sub-licensee;

(b) in respect of the mucociliary clearance and sputum induction applications of the patents:

- no royalties until sales representing a gross margin of \$1 million have been achieved then, when the gross margin achieved by the product sales is between \$1 million and \$25 million a royalty equal to 3% of the gross margin will apply, when it is between \$25 million and \$75 million a royalty equal to 2.5% of the gross margin will apply and when it is greater than \$75 million a royalty equal to 2% of the gross margin will apply; and
- 20% of any royalty received from a sub-licensee.

## Indemnity

The Company has agreed to indemnify CSAHS against all loss and damage that CSAHS may sustain or incur as a result of any actions, claims, suits, proceedings or demands arising directly or indirectly out of the breach of the CSAHS Licence by the Company.

Both parties have agreed to indemnify the other party against all loss and damage that the other party may sustain or incur as a result of any damage to the other party's property or injury to or death of any of the other party's personnel arising out of the CSAHS Licence.

#### Insurance

Subject to a policy being available on commercially reasonable terms, the Company must maintain a product liability insurance policy naming CSAHS, both during and for a period of six months after the termination of the CSAHS Licence.

## 12.4.3 Anutech Licence between the Company and Anutech Pty Limited dated 14 October 1999

#### Licence

As agent for and on behalf of the ANU, Anutech has granted the Company an exclusive, world-wide sub-licensable licence to, within the field of phosphosugars as ethical therapeutics:

- exploit, make or dispose of any thing which arises from the use of, among other things, the ANU Intellectual Property; and
- use the ANU Intellectual Property for the purposes of further research and development and to exploit the results of such research and development.

The Company must reimburse Anutech for one third of any costs incurred in filing, maintaining and renewing the ANU Intellectual Property whether those costs were incurred before or after the date of the Anutech Licence.

The Company must provide to Anutech:

- a report every 12 months detailing the activities by the Company for the prior 12-month period and future plans to achieve its objectives under the Anutech Licence; and
- a brief report every six months describing the Company's progress against prior plans outlined in the 12-monthly report described above.

The Company must use its reasonable endeavours to exploit the ANU Intellectual Property and has agreed to commence the sale of products which incorporates or arises from the whole or partial use of the ANU Intellectual Property by 2011.

## Term

The term of the Anutech Licence in respect of each patent is for the life of each of the licensed patents unless the Anutech Licence is terminated earlier for breach of the agreement by the Company or insolvency of the Company.

Refer to section 11 of this Prospectus in relation to specific risks associated with the Anutech Licence.

## New intellectual property rights and improvements

Any new intellectual property acquired or developed by the Company during the term of the Anutech Licence becomes the property of the Company.

Anutech must advise the Company of the filing of any patent application or the issue of any patent which is legally or beneficially owned by ANU or Anutech which is dominated by the patents included in the ANU Intellectual Property or relates to the product arising wholly or partially from the ANU Intellectual Property. The Company has the option of having any such intellectual property included as part of the ANU Intellectual Property without an increase to any royalty rate payable.

## Royalty

A royalty of 2% of revenue (net of expenses) received by the Company in connection with its use of the ANU Intellectual Property is payable by the Company to Anutech. The obligation to pay the royalty survives termination of the ANU Licence.

## Indemnity

The Company has agreed to indemnify ANU and Anutech and any of their directors, officers, employees, staff, students and agents against all loss, liability, damage, claim, cost and expense arising from or in connection with, amongst other things:

- a breach by the Company of its warranties or obligations under the Anutech Licence; and
- the Company's use of the ANU Intellectual Property.

#### Insurance

The Company must maintain a \$10 million product liability insurance policy in respect of products covered by the Anutech Licence.

## 12.4.4 Employment agreements

The Company has entered into employment agreements with Alan Robertson as Chief Executive Officer, Brett Charlton as executive Medical Director, William Cowden as Chief Scientific Officer, David McGarvey as Company Secretary and Chief Financial Officer and John Crapper as Chief Operations Officer. Each of the employment agreements are on substantially the same terms. A summary of the key terms of their employment agreements are as follows:

- they are to devote substantially the whole of their time and attention to the business of the Company;
- they are bound by usual confidentiality and intellectual property assignment provisions;
- · they are subject to usual commercial non-competition clause during the course of the employment and after employment;
- the employment can be terminated immediately by the Company for serious misconduct, with one months' notice if the employee becomes mentally or physically unfit to perform or carry out their employment, with two months' notice on the grounds of redundancy and with three months' notice without cause; and
- each of the agreements terminate automatically on 30 June 2005 unless the Company extends the agreement in writing or a further agreement is entered into.

The current remuneration payable to each of the executives which includes base remuneration, superannuation and a variable bonus (payable on the employee achieving certain milestones) is as follows:

- Alan Robertson \$270,750
- Brett Charlton \$171,700
- William Cowden \$171,700
- David McGarvey \$206,200
- John Crapper \$195,300

## 12.4.5 Services Agreement between the Company and Anutech Pty Ltd dated 9 December 2002

## Services

The Company has agreed to pay Anutech to use its best endeavours to:

- provide the Company with research staff on employment terms acceptable to the Company; and
- provide human resource management services to the Company.

The Company has an arrangement with the John Curtin School of Medical Research (part of ANU) to provide the research staff employed under the Services Agreement with access to the John Curtin School of Medical Research.

## Term

The term of the Services Agreement is until 1 January 2005 unless extended or terminated earlier for breach or insolvency.

#### Fees

The Company must pay a fee to Anutech determined by adding the staff salaries and any salary related expenses (including superannuation, payroll tax etc) (currently \$318,272 per annum) and a management fee (currently \$47,741 per annum). The management fee is calculated as 15% of the staff salaries and salary related expenses. At the date of this Prospectus, Anutech currently provides the services of six research staff under this arrangement.

## Intellectual property

Any intellectual property created by the research staff under the Services Agreement is owned by and vests in the Company. The Company has granted the ANU a royalty free, irrevocable and perpetual non-exclusive licence to use the Company's intellectual property and confidential information generated under the Services Agreement for non-commercial research purposes.

## Indemnity

Anutech will not be liable for any direct, consequential, or other damages suffered by the Company, any licensee or any others resulting from the use of the research results or any such invention or product.

## 12.4.6 Deeds of access, indemnity and insurance

The Company has entered into Deeds of Access, Indemnity and Insurance with each of the officers of the Company. Each deed provides each respective officer with the following:

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

## 12.4.7 Rodborough Road Lease between the Company and Trust Company of Australia Ltd dated 15 October 2002

## Lease

The Company has a lease over Unit 2, 10 Rodborough Road, Frenchs Forest, New South Wales. The lease is on usual commercial terms. The Company may use the premises for commercial offices and warehousing and facilities for research and development, and for the manufacture and supply of biomedical and medical devices.

## Term

The Rodborough Road Lease expires on 21 June 2006, with an option to renew for a further five years.

## Rent

The Company currently pays \$233,244 annually, increasing by 3% in June of each year. The Company must also pay for certain outgoings. The Company has a bank guarantee in place for an amount equivalent to six months' rent in respect of the Rodborough Road lease.

# 12.4.8 R&D Start Program Grant Agreement between the Commonwealth of Australia and the Company dated 17 June 2003

## Grant

Subject to the satisfaction of certain specified technical milestones and conditions, the Commonwealth of Australia having sufficient funding available and the Company demonstrating satisfactory progress and expenditure on a project for the development of a new treatment for cystic fibrosis, the Commonwealth of Australia has provided the Company with a grant of 50% of the Company's eligible expenditure on a project for the development of a new treatment for cystic fibrosis up to a maximum grant amount of A\$3,013,658 payable over the period to 31 March 2005.

The Company must use the grant solely for the development of new treatments for cystic fibrosis. Grant payments are made in accordance with an agreed schedule and on completion of specified milestones.

The Company must use its best endeavours to commercialise the cystic fibrosis project on normal commercial terms within a reasonable time of completion of the project.

The Directors have no reason to believe that the Company will not continue to meet the milestones required by the grant.

## Report

The Company must provide a report to the Commonwealth of Australia every three months relating to the conduct of the project and the commercialisation of its outcomes.

#### **Termination**

The Commonwealth of Australia may terminate the R&D Start Grant for breach of the agreement by the Company or failure to undertake the required research. In certain limited circumstances where the Company fails to use its best endeavours to commercialise the relevant grant project within a reasonable time of completion of the project or upon termination of a grant due to breach of agreement or insolvency, the Commonwealth of Australia may require the Company to repay some or all of the grant paid to the Company.

## 12.5 Litigation

The Company is not involved in any significant legal proceedings. The Directors are not aware of any pending legal proceedings.

## 12.6 Directors' Interests

## 12.6.1 Other than as set out below or elsewhere in this Prospectus:

- (a) no Director or proposed Director has, or has had in the two years before the date of this Prospectus, any interests in:
  - the formation or promotion of the Company;
  - property acquired or proposed to be acquired by the Company in connection with:
    - its formation or promotion;
    - the Offer; or
  - the Offer; and
- (b) no amounts have been paid or agreed to be paid and no benefits have been given or agreed to be given to:
  - any Director or proposed Director to induce him or her to become, or to qualify as, a Director of the Company; or
  - any Director or proposed Director for services which he or she has provided in connection with the formation or promotion of the Company or the Offer.

## 12.6.2 Remuneration of Directors

Non-executive Directors are entitled to be remunerated as determined in general meeting of the Company to be apportioned between them as the Directors agree. For the current financial year ending 30 June 2004, the maximum aggregate amount of remuneration that may be paid to non-executive Directors' is \$300,000.

Executive Directors are full time employees of the Company. The remuneration of Alan Robertson and Brett Charlton is set out at section 12.4.4. No Directors' fees (or alternate Directors' fees) are payable to these executives by the Company in addition to their remuneration.

A Director may be paid all travelling and other expenses properly incurred by them in attending meetings of Directors of committees of the Company or shareholder meetings of the Company or otherwise in connection with the execution of their duties as Directors.

A Director may be paid fees or other amounts as the Directors may determine where a Director performs special duties or otherwise performs services outside the scope of the ordinary directors. A Director may also be reimbursed for out of pocket expenses incurred as a result of his or her directorship or any special duties.

## 12.6.3 Directors' Share and option holdings

The Directors and their associated entities will have the following interests in the Company's shares on the issue and allotment of Shares under this Prospectus:

| Director                        | Ordinary shares                                      | <b>Employee options over Shares</b> |  |  |
|---------------------------------|--|-------------------------------------|--|--|
| Denis Hanley®                   | 160,000  |                                     |  |  |
|                                 | Firm commitment for a further 400,000                | 1,040,000                           |  |  |
| Alan Robertson <sup>(ii)</sup>  |  | 2,080,000                           |  |  |
| Brett Charlton(iii)             | 11,200,000   | 1,600,000                           |  |  |
| Carrie Hillyard(iv)             | 9,600,000  |                                     |  |  |
|                                 | Firm commitment and will receive a further 5,225,000 |                                     |  |  |
| Charles Kiefel <sup>(v)</sup>   | Firm commitment of 400,000                           | 200,000                             |  |  |
| Malcolm McComas <sup>(vi)</sup> |  | 200,000                             |  |  |
| Brigitte Smith(vii)             | 25,600,000   |                                     |  |  |
|                                 | Firm commitment and will receive a further 5,225,000 |                                     |  |  |

### Notes:

- (i) Denis Hanley holds 160,000 Shares and has given Wilson HTM a firm committment to subscribe for a further 400,000 Shares in the Offer. Denis Hanley holds 640,000 unlisted options with an expiry date of 30 August 2011 and an exercise price of \$0.3125 and 400,000 unlisted options with a lapse date of 30 June 2012 and an exercise price of \$0.3125;
- (ii) Alan Robertson holds 1,120,000 unlisted options with an expiry date of 30 November 2009 and an exercise price of \$0.125 and 960,000 unlisted options with a lapse date of 30 June 2012 and an exercise price of \$0.3125;
- (iii) Brett Charlton will until the issue and allotment of Shares under this Prospectus be associated with Praxis Pharmaceuticals Inc. Praxis Pharmaceuticals Inc holds 11,200,000 Shares. Brett Charlton holds 640,000 unlisted options with an expiry date of 30 November 2009 and an exercise price of \$0.125 and 960,000 unlisted options with a lapse date of 30 June 2012 and an exercise price of \$0.3125.
- (iv) Carrie Hillyard is associated with CM Capital Investment Pty Ltd, CM Capital Investment Trust No 3, CIBC Australia VC Fund LLC and the Australia Venture Capital Fund L.P.
  - CM Capital Investments Pty Ltd as trustee of the CM Capital Investment Trust No 3 will on issue and allotment of Shares hold 7,200,000 existing Shares. CM Capital Investments Pty Ltd as trustee for CM Capital Investments Trust No 3 has given Wilson HTM a firm commitment to subscribe for 3,750,000 new Shares under the Prospectus and will as a result receive a firm commitment and naming fee from Wilson HTM which will be satisfied by Wilson HTM subscribing for 168,750 new Shares (included in the table above) and then transferring them to CM Capital Investments Pty Ltd as trustee of the CM Capital Investment Trust No 3.
  - CIBC Australia VC Fund LLC as general partner of the Australia Venture Capital Fund L.P. will on issue and allotment of Shares under this Prospectus hold 2,400,000 existing Shares. CIBC Australia VC Fund LLC as general partner of the Australia Venture Capital Fund L.P. has given Wilson HTM a firm commitment to subscribe for 1,250,000 new Shares under the Prospectus and as a result will receive a firm commitment and naming fee from Wilson HTM which will be satisfied by Wilson HTM subscribing for 56,250 new Shares (included in the table above) and then transferring them to CIBC Australia VC Fund LLC as general partner of the Australia Venture Capital Fund L.P.
- (v) Charles Kiefel holds unlisted options with a lapse date of 30 April 2013 with an exercise price of \$0.3125.
- (vi) Malcolm McComas holds unlisted options with a lapse date of 3 July 2013 with an exercise price of \$0.3125.
- (vii) Brigitte Smith is associated with GBS Venture Partners Ltd, The Australian Bioscience Trust and Bioscience Ventures II.

On the issue and allotment of Shares under this Prospectus, Perpetual Trustees Nominees Limited as trustee of The Australian Bioscience Trust will hold 19,200,000 existing Shares. GBS Venture Partners Ltd as manager of The Australian Bioscience Trust has given Wilson HTM a firm commitment to subscribe for 1,000,000 new Shares to be held on trust by Perpetual Trustees Nominees Limited and GBS Venture Partners Ltd as manager of The Australian Bioscience Trust will as a result receive a firm commitment and naming fee from Wilson HTM which will be satisfied by Wilson HTM subscribing for 45,000 new Shares (included in the table above) and then transferring them to Perpetual Trustees Nominees Limited as trustee of The Australian Bioscience Trust.

On the issue and allotment of Shares under this Prospectus, GBS Venture Partners Ltd as trustee and manager of Bioscience Ventures II will hold 6,400,000 existing Shares. GBS Venture Partners Ltd as manager of Bioscience Ventures II has given Wilson HTM a firm commitment to subscribe for 4,000,000 new Shares and as a result will receive a firm commitment and naming fee from Wilson HTM which will be satisfied by Wilson HTM subscribing for 180,000 new Shares (included in the table above) and then transferring them to GBS Venture Partners Ltd as trustee and manager of Bioscience Ventures II.

(viii) Directors and their associated entities are entitled to subscribe for additional Shares in this Offer which are not reflected in this table (other than as described above).

## 12.6.4 Other interests of Directors

Neysa Investments Pty Ltd, a vehicle associated with Brett Charlton, provided scientific consultancy services to the Company between 29 June 2001 and 1 July 2002 and was paid a total of approximately \$50,004.

Charles Kiefel is a director of WHTM Asset Management Ltd, Wilson HTM Charities Ltd and WHTM Capital Management Ltd and owns shares in Wilson HTM Investment Group Limited which are associated with the Underwriter.

The Principals Funds Management Pty Ltd, a vehicle associated with Denis Hanley and Charles Kiefel provided consulting services to the Company in 2002 and was paid a total of approximately \$150,000. The Principals Funds Management Pty Ltd will be paid a fee of \$45,000 from Wilson HTM being a 3% firm commitment fee and a 1.5% naming fee calculated on the amount of firm commitments to subscribe for Shares in the Prospectus given by certain existing shareholders and Directors of the Company.

CM Capital Investments Pty Ltd, CM Capital Venture Trust No 3, CIBC Australia VC Fund LLC and the Australia Venture Capital Fund L.P. are vehicles associated with Carrie Hillyard. In consideration of the entry into the firm commitment agreements described in section 12.6.3 of this Prospectus:

- CM Capital Investments Pty Ltd as trustee of CM Capital Venture Trust No 3 will be paid a firm commitment fee of 3% of the amount committed to be invested and a naming fee of 1.5% of the amount committed to be invested (fees equivalent to \$84,375). These fees will be satisfied by Wilson HTM subscribing for 168,750 Shares and then transferring them to CM Capital Investments Pty Ltd as trustee of CM Capital Trust No 3.
- CIBC Australia VC Fund LLC as general partner of the Australia Venture Capital Fund L.P. will be paid a firm commitment fee of 3% of the amount committed to be invested and a naming fee of 1.5% of the amount committed to be invested (fees equivalent to \$28,125). These fees will be satisfied by Wilson HTM subscribing for 56,250 new Shares and then transferring them to CIBC Australia VC Fund LLC as general partner of the Australia Venture Capital Fund L.P.

GBS Venture Partners Ltd, The Australian Bioscience Trust and Bioscience Ventures II are vehicles associated with Brigitte Smith. In consideration of the entry into the firm commitment agreements described in section 12.6.3 of this Prospectus:

- GBS Venture Partners Ltd as manager of The Australian Bioscience Trust will be paid a firm commitment fee of 3% of the amount invested and a naming fee of 1.5% of the amount invested (fees totalling \$22,500) by Wilson HTM. This amount will be satisfied by Wilson HTM subscribing 45,000 new Shares and then transferring them to Perpetual Trustees Limited as trustee of The Australian Bioscience Trust.
- GBS Venture Partners Ltd as manager of Bioscience Ventures II will be paid a firm commitment fee of 3% of the amount invested and a naming fee of 1.5% of the amount invested (fees totalling \$90,000) by Wilson HTM. This amount will be satisfied by Wilson HTM subscribing for 180,000 new Shares and then transferring them to GBS Venture Partners Ltd as manager and trustee of Bioscience Ventures II.

## 12.6.5 Disclosure of interests of non-Directors

Other than as set out below or elsewhere in this Prospectus:

- (a) no promoter of the Company or person named in this Prospectus as having performed a function in a professional, advisory or other capacity in connection with the preparation or distribution of this Prospectus has, or has in the two years before the date of this Prospectus had, any interest:
  - in the formation or promotion of the Company;
  - in property acquired or proposed to be acquired by the Company in connection with:
    - its formation or promotion;
    - the Offer; or
  - the Offer: and
- (b) no amounts have been paid or agreed to be paid and no benefits have been given or agreed to be given to any promoter of the Company, stockbroker or underwriter to the Offer or other person named in this Prospectus as having performed a function in a professional, advisory or other capacity in connection with the preparation or distribution of this Prospectus or provided in connection with the formation or promotion of the Company or the Offer.

## 12.7 Expenses of the Offer

The expenses of the Offer are estimated to be \$1.7 million, covering fees payable to the Underwriter, legal advisor, the investigating accountant, the Company's patent attorneys, the share registrar, the Company's financial communication consultants, the printing costs of the Offer, ASX and ASIC costs and other related expenses. These expenses have been paid or will be payable by the Company. The interests and the amounts payable to experts and advisors are as follows:

Wilson HTM Corporate Finance Ltd acts as Underwriter and Lead Manager in respect of the Offer and will be paid an underwriting fee and management fee totalling 6% of the funds raised under the Offer for its services, in addition to a \$25,000 fee paid on initial engagement.

Piper Alderman acts as legal advisor to the Company in respect of this Prospectus and the Offer and will be paid approximately \$117,000 (exclusive of GST) for its services to the date of this Prospectus and will be reimbursed for disbursements, with further amounts payable for any additional services relating to this Prospectus and the Offer, if any, to be paid in accordance with its usual hourly charge out rates.

PricewaterhouseCoopers Securities Ltd acts as investigating accountant and to the Company in respect of the Offer and will be paid approximately \$50,000 (exclusive of GST) for its services to the date of this Prospectus and will be reimbursed for disbursements, with further amounts payable for any additional services relating to this Prospectus and the Offer, if any, to be paid in accordance with its usual hourly charge out rates.

Venable, Baetjer, Howard and Civiletti, LLP acts as patent attorney and prepared the Report on Intellectual Property for inclusion in this Prospectus and will be paid \$33,000 for work provided in relation to this Prospectus and the Offer and will be reimbursed for disbursements, with further amounts payable for any additional services relating to this Prospectus and the Offer, if any, to be paid in accordance with its usual hourly charge out rates.

Computershare Investor Services Pty Ltd acts as share registrar for the Company and will be paid approximately \$8,000 (exclusive of GST) for its services to the date of this Prospectus and will be reimbursed for disbursements, with further amounts payable for any additional services relating to this Prospectus and the Offer, if any, to be paid in accordance with its usual rates.

## 12.8 Consents

Wilson HTM Corporate Finance Ltd has given, and has not before the lodgement of this Prospectus with ASIC withdrawn, its consent to being named as Underwriter and Lead Manager in this Prospectus in the form and context in which it is named. Wilson HTM Corporate Finance Ltd has made no statement included in this Prospectus or on which a statement in this Prospectus is based.

Emerging Growth Capital Pty Ltd has given, and has not before lodgement of this Prospectus with ASIC withdrawn, its consent to being named as co-manager of the Offer in this Prospectus in the form and context in which it is named. Emerging Growth Capital Pty Ltd has made no statement included in this Prospectus or on which a statement in this Prospectus is based.

Piper Alderman has given, and has not before the lodgement of this Prospectus with ASIC withdrawn, its consent to being named as legal advisor to the Company in this Prospectus in the form and context in which it is named. Piper Alderman has made no statement included in this Prospectus or on which a statement in this Prospectus is based.

PricewaterhouseCoopers has given, and has not before the lodgement of this Prospectus with ASIC withdrawn, its consent to being named as auditor in this Prospectus in the form and context in which it is named. PricewaterhouseCoopers has made no statement included in this Prospectus or on which a statement in this Prospectus is based.

PricewaterhouseCoopers Securities Ltd has given, and has not before the lodgement of this Prospectus with ASIC withdrawn, its consent to being named as investigating accountant in this Prospectus in the form and context in which it is named. PricewaterhouseCoopers Securities Ltd has made no statement included in this Prospectus or on which a statement in this Prospectus is based other than the Investigating Accountant's Report included in section 9 of this Prospectus.

Venable, Baetjer, Howard and Civiletti, LLP has given, and has not before the lodgement of this Prospectus with ASIC withdrawn, its consent to being named as patent attorney in this Prospectus in the form and context in which it is named. Venable, Baetjer, Howard and Civiletti, LLP has made no statement in this Prospectus or on which a statement in this Prospectus is based other than the Report on Intellectual Property included in section 10 of this Prospectus.

Computershare Investor Services Pty Ltd has given, and has not before the lodgement of this Prospectus with ASIC withdrawn, its consent to being named as share registry in this Prospectus in the form and context in which it is named. Computershare Investor Services Pty Ltd has made no statement included in this Prospectus or on which a statement in this Prospectus is based.

# 13 : Definitions and Glossary

## Section



## **Definitions and Key Terms**

In this Prospectus, unless the context otherwise requires:

ADEC Australian Drug Evaluation Committee.

ANU means the Australian National University.

ANU Intellectual Property means the patents and associated intellectual property and knowledge

set out in the Report on Intellectual Property in section 10 of this Prospectus

under the headings 'Patent Familly 2' and 'Patent Family 3'.

Anutech means Anutech Pty Ltd ACN 008 548 650.

Anutech Licence means the licence between the Company and Anutech dated 14 October 1999

described in section 12.4.3 of this Prospectus.

**Applicant** means an applicant for Shares who duly completes an Application Form

and pays the applicable Application Money.

**Application Form** means the application form accompanying this Prospectus.

**Application Money** means the aggregate amount of money payable for Shares applied for

in the Application Form.

**Application Period** means the period between the opening and the closing date of this Prospectus.

ASIC means the Australian Securities and Investments Commission.

ASX means Australian Stock Exchange Limited ACN 008 624 691.

autoimmune means having the property of responding immunologically to tissues in one's

wn body.

**bronchiectasis** means a disease characterised by irreversible dilation and destruction

of bronchial walls.

**Business Day** means any day which is defined to be a Business Day pursuant to Listing Rule

19.12 of the Listing Rules of the ASX.

CHESS means Clearing House Electronic Sub-register System of ASX Settlement

and Transfer Corporation Pty Ltd ACN 008 504 532.

**chronic bronchitis** means the clinical definition associated with the presence of a chronic productive

cough without a discernible cause for at least three months out of the year,

for two successive years.

**chronic obstructive pulmonary disease** is a group of lung diseases characterised by limited airflow with variable degrees

of air sac enlargement and lung tissue destruction. Emphysema and chronic bronchitis are the most common forms of chronic obstructive pulmonary disease.

Closing Date means 31 October 2003 or such other date as may be determined by the Directors.

Company means Pharmaxis Ltd ACN 082 811 630/ABN 75 082 811 630.

Corporations Act means the Corporations Act 2001 (Cth).

CSAHS means Central Sydney Area Health Service.

**CSAHS Intellectual Property** means the patents and associated intellectual property and knowledge

set out in the Report on Intellectual Property in section 10 of this Prospectus

under the heading 'Patent Family 1, The Use of Inhaled Mannitol'.

CSAHS Licence means the licence agreement between the Company and CSAHS dated

10 October 2001 which is summarised in section 12.4.2 of this Prospectus.

**Directors** means the directors of the Company.

dollars or \$ means dollars in Australian currency (unless otherwise stated).

**Employee Option Plan** means the employee option plan of the Company as amended from time

to time which is summarised in section 12.2 of this Prospectus.

**EST** means Eastern Standard Time under the Standard Time Act 1987 (NSW).

**FDA** means the U.S. Food and Drug Administration.

firm offer means that part of the Offer which is open to Australian resident investors

and institutional investors who are offered a firm allocation of Shares from the Underwriter or other brokers participating in the Offer which indicates

that it is a firm offer.

general offer means that part of the Offer open to members of the general public who are

resident in Australia and institutions who have not been offered a firm offer.

**GMP** means good manufacturing practice.

ICH means International Committee on Harmonisation.

**Listing Rules** means the Listing Rules of the ASX.

**non-ionic osmolyte** means a chemical substance that is not a salt that promotes osmosis.

**Offer** means the offer of Shares under this Prospectus.

**Offer Price** means the offer price of \$0.50.

**Opening Date** means 7 October 2003 or such other date as may be determined by the Directors.

osmosis the passage of water from a region of high water concentration through a

semi-permeable membrane to a region of low water concentration.

Pharmaxis means Pharmaxis Ltd ACN 082 811 630.

**Prospectus** means this prospectus.

PXS25 means the compound PXS25 and any compounds derived from it.

PXS2000 means the compound PXS2000 and any compounds derived from it.

**Report on Intellectual Property** means the report on intellectual property in section 10 of this Prospectus. **R&D Start Grant** means the R&D Start Program Grant Agreement entered into between

the Company and the Commonwealth of Australia on 17 June 2003 which

is summarised in section 12.4.8 of this Prospectus.

**rheumatoid arthritis** is a disease characterised by an immune response to one's own body,

usually manifesting as inflammation of the joints.

SCH Business Rules means the business rules of ASX Settlement and Transfer Corporation Pty Ltd

ACN 008 504 532 as the approved Securities Clearing House under the

Corporations Act.

Services Agreement means the services agreement between the Company and Austech dated

9 December 2002 which is summarised in section 12 of this Prospectus.

Share means a fully paid ordinary share in the Company.

TGA means the Therapeutic Goods Administration.

Underwriter or Lead Manager means Wilson HTM.

Underwriting Agreement means the underwriting agreement entered into between the Company and

Wilson HTM in respect of this Prospectus which is summarised at section

12.4.1 of this Prospectus.

Venable means Venable, Baetjer, Howard and Civiletti, LLP.

Wilson HTM means Wilson HTM Corporate Finance Ltd ACN 057 547 323.



This Prospectus is dated 26 September 2003 and is issued by Pharmaxis Ltd.

The lodgement of this Prospectus with ASIC was consented to by every Director of the Company.

**Denis Hanley** 

Chairman



## **Public Share Offer**

| Broker Reference Stamp Only |  |  |  |
|-----------------------------|--|--|--|
|                             |  |  |  |
|                             |  |  |  |
|                             |  |  |  |

| Application Form  |                          |                       |                         | Broker Code            | Advisor Code                     |
|---|--------------------------|-----------------------|-------------------------|------------------------|----------------------------------|
| A Shares applied for  | В                        | Amount                |                         |                        |                                  |
| No of Shares per Share  |                          |                       |                         |                        |                                  |
| <b>x</b> A\$0.50  | A\$                      |                       |                         |                        |                                  |
| Must be a minimum of 5,000 Shares. Applications for more than 5,000 | Shares must be in multip | oles of 1,000 Shares. |                         |                        |                                  |
| C Write your name below   |                          |                       | Please ensure your appl | lication is in a valid | format. See reverse for guidance |
|   |                          |                       |                         |                        |                                  |
| Name of Joint Applicant or < Account Name >                         |                          |                       |                         |                        |                                  |
|   |                          |                       |                         |                        |                                  |
| Name of Joint Applicant or < Account Name >                         |                          |                       |                         |                        |                                  |
|   |                          |                       |                         |                        |                                  |
| Write your postal address below                                     |                          |                       |                         |                        |                                  |
| Unit Street No. Street Name   |                          |                       |                         |                        |                                  |
|   |                          |                       |                         |                        |                                  |
|   |                          |                       |                         |                        |                                  |
| City/Suburb/Town  |                          |                       |                         | State                  | Postcode                         |
|   |                          |                       |                         |                        |                                  |
| E Chess HIN (If Applicable)   |                          |                       |                         |                        |                                  |
| X   |                          |                       |                         |                        |                                  |
| F Email Address (optional)  |                          |                       |                         |                        |                                  |
|   |                          |                       |                         |                        |                                  |
| G Telephone Number  |                          |                       |                         |                        |                                  |
| Area Code Home Telephone  | Area Code Work T         | elephone              |                         |                        |                                  |
|   |                          |                       |                         |                        |                                  |
| This will help if we have any questions                             |                          |                       |                         |                        |                                  |
| Cheque Details  |                          |                       |                         | THIS FORM              | I DOES NOT HAVE TO BE SIGNED     |
| Name of drawer of cheque  | Cheque No                | BSB No                | Account No              | Am                     | ount A\$                         |
|   |                          |                       |                         | AS                     | .00                              |
|   |                          |                       |                         | AS                     | \$ .00                           |
|   |                          |                       | Total Amount            | Enclosed AS            | \$ .00                           |

## Declaration

I/we declare that by lodging this Application Form, I/we represent and acknowledge that I/we have received a paper or electronic Prospectus with the Application Form or a complete print out of the electronic Prospectus with the Application Form and I/we have read and understood the Prospectus to which this Application Form relates. I/we hereby apply for such number of Shares as maybe calculated in accordance with the terms of the Prospectus and agree to be bound by the constitution of Pharmaxis Ltd. I/we hereby authorise Pharmaxis Ltd to complete and execute any documents necessary to effect the allotment or transfer of any shares. To meet the requirements of the Corporations Act, this Application Form must not be distributed to any other person unless accompanied by a complete unaltered version of the Prospectus. By lodging this Application Form, I/we declare that this Application is completed and lodged according to the Prospectus and that all statements made by me/us are complete and accurate. I/we represent and warrant that by lodging this Application Form, I am/we are in compliance with all laws of any jurisdiction outside the Commonwealth of Australia relevant to this Application. I/we acknowledge that I am/we are residents of Australia and I/we make the representations described in the Important Information section of the Prospectus.

WARNINGS: This Application Form is for Shares under the Prospectus. The Prospectus contains information relevant to a decision to invest in Pharmaxis Ltd and it is advisable that the Prospectus be read in full before an application is made. The Prospectus is available at www.pharmaxis.com.au using the same means as necessary to access the Application. Any supplementary or replacement documents that Pharmaxis Ltd issues while the Offer is open (if any) will also be available at www.pharmaxis.com.au and will be accessible by the same means. The Corporations Act prohibits a person from passing this Application Form to any person unless it is attached to the Prospectus and any relevant supplementary documents. While the Prospectus is current, persons who receive an electronic copy of the Prospectus are entitled to obtain a paper copy of the Prospectus free of charge by contacting Pharmaxis Ltd.

## **Guide to Completing the Application Form**

## Shares Applied for

Enter the number of Shares you wish to apply for. The application must be for a minimum of 5,000 Shares. Applications for greater than 5,000 Shares must be in multiples of 1,000 Shares.

## Application Monies

R

E

Enter the amount of Application Monies. To calculate the amount, multiply the number of Shares applied for by the price per Share.

## Registration Name(s)

Enter the full name(s) you wish to appear on the statement of shareholdings. This must be either your own name or the name of a company. Up to three joint Applicants may register. You should refer to the table below for the correct forms of registration. Applications using the wrong form of name may be rejected. Clearing House Electronic Sub-Register System (CHESS) participants should complete their name and address in the same format as those that are presently registered in the CHESS system.

#### Postal Address

Enter your postal address for all correspondence. All communications to you from the share registry will be mailed to the person(s) and address as shown. For joint Applicants, only one address can be entered.

## **CHESS HIN (if applicable)**

Pharmaxis Ltd will apply to the ASX to participate in CHESS, operated by ASX Settlement and Transfer Corporation Pty Ltd, a wholly owned subsidiary of Australian Stock Exchange Limited. In CHESS, the Company will operate an electronic CHESS subregister of shareholdings and an electronic Issuer Sponsored subregister of shareholdings. Together the two subregisters will make up the Company's principal register of Shares. The Company will not be issuing certificates to applicants in respect of Shares allotted.

If you are a CHESS participant (or are sponsored by a CHESS participant) and you wish to hold Shares allotted to you under this Application in uncertificated form on the CHESS subregister, enter your CHESS HIN. Otherwise, leave the section blank and on allotment, you will be sponsored by Pharmaxis Ltd and a Shareholder Reference Number (SRN) will be allocated to you.

## Fmail Address

Enter your email address. This may be used to communicate other matters to you.

## **Telephone Number**

Enter your telephone number. This is not required but will assist us if there are any problems with your application.

#### Payment

Make your cheque or bank draft payable to 'Pharmaxis Ltd Trust Account' in Australian currency and cross it 'Not Negotiable'. Your cheque or bank draft must be drawn on an Australian Bank

Complete the Payment section and cheque details in the boxes provided. The amount must agree with the amount shown in box 'B'.

## Sufficient cleared funds should be held in your account.

Pin (do not staple) your cheque(s) to the Application Form where indicated.

BEFORE COMPLETING THE APPLICATION FORM THE APPLICANT(S) SHOULD READ THE DISCLOSURE DOCUMENT TO WHICH THE APPLICATION RELATES. BY LODGING THE APPLICATION FORM, THE APPLICANT(S) AGREES THAT THIS APPLICATION IS FOR SHARES IN PHARMAXIS LTD UPON AND SUBJECT TO THE TERMS OF THE OFFER, AGREES TO TAKE ANY NUMBER OF SHARES EQUAL TO OR LESS THAN THE NUMBER OF SHARES INDICATED IN BOX 'A' THAT MAY BE ALLOTTED TO THE APPLICANT(S) PURSUANT TO THE OFFER AND DECLARES THAT ALL DETAILS AND STATEMENTS MADE ARE COMPLETE AND ACCURATE. IT IS NOT NECESSARY TO SIGN THE APPLICATION FORM.

#### **Lodgement of Applications**

Applicants who received a firm offer (as described in section 4.4 of the Prospectus) should return their completed Application Forms and Application Money to Wilson HTM or the broker from whom they received their firm offer of Shares (unless instructed otherwise). Applicants who have received a general offer should return their Application Form with cheque(s) attached to:

PHARMAXIS Ltd PHARMAXIS Ltd

Computershare Investor Services Pty Ltd Computershare Investor Services Pty Ltd GPO Box 7115 Level 3

Sydney NSW 2001 60 Carrington Street

Sydney NSW 2000

Application must be received at the Sydney office of Computershare Investor Services Pty Limited no later than 5.00pm Sydney time on 31 October 2003 or such other date as the Directors may determine.

## **Correct forms of Registration**

Note that ONLY legal entities are allowed to hold Shares. Applications must be in the name(s) of natural persons, companies or other legal entities acceptable to Pharmaxis Ltd. At least one full given name and the surname is required for each natural person. The name of the beneficial holder or any other registrable name may be included by way of an account designation if completed exactly as described in the examples of correct forms of registrable names below.

| Type of Investor   | Correct Form   | Examples of Incorrect Form             |
|--|--|--|
| Individuals Use given names – not initials   | John Alfred Smith  | J.A.Smith                              |
| Company Use company title, not abbreviations   | ABC Pty Ltd  | ABC P/L<br>ABC Co                      |
| <b>Trusts</b> Use trustee(s) personal name(s) Do not use the name of the trust   | Janet Smith <janet a="" c="" family="" smith=""></janet>                     | Janet Smith Family Trust               |
| Deceased Estates Use executor(s) personal name(s) Do not use name of deceased  | Michael Smith<br><est a="" c="" john="" smith=""></est>                      | Estate of late John Smith              |
| Partnerships Use partners' personal names, Do not use the name of the partnership                                      | John Smith and Michael Smith<br><john &="" a="" c="" smith="" son=""></john> | John Smith & Son                       |
| Clubs/Unincorporated Bodies/Business Names Use office bearer(s) personal name(s) Do not use the name of the clubs etc. | Janet Smith <abc a="" association="" c="" tennis=""></abc>                   | ABC Tennis Association                 |
| Superannuation Funds Use name of trustee of fund Do not use the name of the fund                                       | John Smith Pty Ltd<br><super a="" c="" fund=""></super>                      | John Smith Pty Ltd Superannuation Fund |

# 15:Corporate Directory

## Section



## **Directors' Information**

Denis Hanley (Chairman)
Alan Robertson (CEO)
Brett Charlton (Medical Director)
Carrie Hillyard
Charles Kiefel
Malcolm McComas
Brigitte Smith

# Company Secretary and Chief Financial Officer

David McGarvey

## **Registered Office**

Frenchs Forest NSW 2086 Australia Telephone: +61 2 9451 5961 Fax: +61 2 9451 3622 Email: info@pharmaxis.com.au Web: www.pharmaxis.com.au

Unit 2, 10 Rodborough Road

## **Underwriter and Lead Manager**

Wilson HTM Corporate Finance Ltd Level 21 Riverside Centre 123 Eagle Street Brisbane QLD 4000 Australia

## Co-Manager

Emerging Growth Capital Pty Ltd Level 2, 52 Phillip Street Sydney NSW 2000 Australia

## Legal Advisor

Piper Alderman Level 23, Governor Macquarie Tower 1 Farrer Place Sydney NSW 2000 Australia

## Auditor

PricewaterhouseCoopers Darling Park Tower 2 201 Sussex Street Sydney NSW 1171 Australia

## **Investigating Accountant**

PricewaterhouseCoopers Securities Ltd Darling Park Tower 2 201 Sussex Street Sydney NSW 1171 Australia

## **Patent Attorney**

Venable, Baetjer, Howard And Civiletti, LLP 810 Towers Crescent Drive, Suite 300 Vienna, Virginia, 22182 United States of America

## Share Registry (on listing)

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

## Home Stock Exchange (on listing)

Sydney

## **Enquiry Line**

1800 805 226

pharmaxis