

SECURITIES AND EXCHANGE COMMISSION  
Washington D.C. 20549

FORM 20-F

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g)  
OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2004

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-49843

**PRANA BIOTECHNOLOGY LIMITED**

(Exact name of Registrant as specified in its charter  
and translation of Registrant's name into English)

**Australia**

(Jurisdiction of incorporation or organization)

**Level 2, 369 Royal Parade, Parkville, Victoria 3052 Australia**

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act: **None**

Securities registered or to be registered pursuant to Section 12(g) of the Act:

**American Depositary Shares, each representing ten Ordinary Shares**

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or  
common stock as of the close of the period covered by the annual report:

Ordinary Shares, as of June 30, 2004.....115,984,380

Indicate by check mark whether the registrant (1) has filed all reports required to be filed  
by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12  
months (or for such shorter period that the registrant was required to file such reports),  
and (2) has been subject to such filing requirements for the past 90 days.

Yes X No   

Indicate by check mark which financial statement item the registrant has elected to  
follow:

Item 17 X Item 18

## INTRODUCTION

Prana Biotechnology Limited was incorporated under the laws of the Commonwealth of Australia on November 11, 1997. Our mission is to develop therapeutic drugs designed to treat the underlying causes of degeneration of the brain and the eye as the aging process progresses, initially focusing on Alzheimer's disease. Other potential applications for our therapies include age-related cataracts, Creutzfeldt-Jakob disease (the human variant of Mad Cow disease), Motor Neuron disease and Parkinson's disease. The principal listing of our ordinary shares and listed options to purchase our ordinary shares is on the Australian Stock Exchange. Since September 5, 2002 our American Depository Receipts, or ADRs, have traded on the NASDAQ SmallCap Market under the symbol "PRAN." The Bank of New York, acting as depository, issues our ADRs, each of which evidences an American Depositary Share, which in turn represents ten of our ordinary shares. As used in this annual report, the terms "we," "us," "our" and "Prana" mean Prana Biotechnology Limited, an Australian company, and its subsidiaries, unless otherwise indicated.

Except for the historical information contained in this annual report, the statements contained in this annual report are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, as amended, with respect to our business, financial condition and results of operations. Such forward-looking statements reflect our current view with respect to future events and financial results. We urge you to consider that statements which use the terms "anticipate," "believe," "do not believe," "expect," "plan," "intend," "estimate," "anticipate" and similar expressions are intended to identify forward-looking statements. Neither our registered independent accounting firm, nor any other independent accountants, have compiled, examined, or performed any procedures, with respect to the prospective financial information contained herein nor have they expressed any opinion or any other form of assurance on such information or its achievability, and assume no responsibility for, and disclaim any association with, the prospective financial information. We remind readers that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements expressed or implied by such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly release any update or revision to any forward-looking statements to reflect new information, future events or circumstances, or otherwise after the date hereof. We have attempted to identify significant uncertainties and other factors affecting forward-looking statements in the Risk Factors section that appears in Item 3.D. "Key Information-Risk Factors"

We have not obtained or applied for trademarks registrations. Any trademarks and trade names appearing in this annual report are owned by their respective holders.

Our financial statements appearing in this annual report are prepared in Australian dollars and in accordance with accounting principles generally accepted in Australia. In this prospectus, all references to “U.S. dollars” or “US\$” are to the currency of the United States of America, and all references to “Australian dollars” or “A\$” are to the currency of Australia.

Statements made in this annual report concerning the contents of any contract, agreement or other document are summaries of such contracts, agreements or documents and are not complete descriptions of all of their terms. If we filed any of these documents as an exhibit to this annual report or to any registration statement or annual report that we previously filed, you may read the document itself for a complete description of its terms.

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## **PART I**

### **ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS**

Not applicable.

### **ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not applicable.

### **ITEM 3. KEY INFORMATION**

#### **A. SELECTED FINANCIAL DATA**

The following table presents our selected financial data as of the dates and for each of the periods indicated. You should read the selected financial data set forth below together with Item 5. "Operating and Financial Review and Prospects" as well as our financial statements and notes thereto appearing elsewhere in this annual report.

The selected financial data as of June 30, 2004 and 2003 and for each of the three years in the period ended June 30, 2004 have been derived from our audited financial statements and notes thereto included elsewhere in this annual report. The selected financial data as of June 30, 2002, 2001 and 2000 and for the years ended June 30, 2001 and 2000 have been derived from our audited financial statements and notes thereto which are not included in this annual report.

We prepare our financial statements in accordance with accounting principles generally accepted in Australia, or A-GAAP, which differ in certain significant respects from accounting principles generally accepted in the United States, or U.S. GAAP. Please refer to Note 25 to the financial statements for a description of the differences between A-GAAP and U.S. GAAP as they relate to us, and a reconciliation of net loss and total equity for the periods and as of the dates therein indicated.

**Statements of Financial Performance Data:**
**Year Ended June 30,**

	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
	(in A\$, except per share and share data)				
<i>A-GAAP:</i>					
Revenue from ordinary activities .....	2,321,227	1,816,478	793,970	516,182	78,758
Depreciation and amortization expense.....	(1,195,006)	(1,185,973)	(1,160,595)	(1,140,658)	(654,977)
Patents, research and development expense.....	(5,232,581)	(1,861,295)	(2,498,486)	(2,376,404)	(421,933)
Legal expense.....	(1,650,467)	(848,660)	(923,816)	(252,675)	(13,082)
Employee benefits expense.....	(1,060,730)	(760,980)	(378,853)	(122,199)	-
Consulting fee expense.....	(1,706,809)	(567,730)	(604,873)	(306,530)	(179,998)
Corporate compliance expense.....	(419,708)	(395,604)	(339,383)	(196,629)	(75,999)
Other expenses from ordinary activities.....	(941,540)	(781,074)	(336,431)	(260,066)	(59,057)
Net loss.....	(9,885,614)	(4,584,838)	(5,448,467)	(4,138,979)	(1,326,288)
Loss per share – basic and diluted (1).....	(0.13)	(0.08)	(0.10)	(0.08)	(0.04)
Weighted average number of ordinary shares outstanding - basic and diluted.....	75,701,818	61,131,313	57,623,389	53,090,491	37,342,158
<i>U.S. GAAP(2):</i>					
Net loss.....	(9,208,199)	(3,244,397)	(4,728,019)	(3,048,784)	(3,798,792)
Loss per share – basic and diluted.....	(0.12)	(0.05)	(0.08)	(0.06)	(0.11)
Weighted average number of ordinary shares outstanding - basic and diluted.....	75,701,818	61,131,313	57,623,389	53,090,491	37,342,158

**Statements of Financial Position Data:**
**June 30,**

	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>
	(in A\$ )				
<i>A-GAAP:</i>					
Cash assets	29,580,398	3,463,783	3,585,014	6,854,873	4,469,589
Working capital	27,033,245	3,093,745	2,840,984	6,454,969	4,684,284
Total assets	41,415,397	16,389,926	17,581,319	22,287,460	20,876,444
Contributed equity	49,505,493	16,741,023	13,001,486	12,276,892	7,474,343
Accumulated deficit during development stage	(25,464,876)	(15,579,262)	(10,994,424)	(5,545,957)	(1,406,978)
Total equity	38,702,559	15,823,703	16,668,986	21,392,877	20,729,307
<i>U.S. GAAP:</i>					
Total assets	34,197,794	7,944,306	7,231,703	10,298,744	7,294,213
Accumulated deficit during development stage	(24,108,881)	(14,900,682)	(11,656,285)	(6,928,266)	(3,879,482)
Total equity	31,484,956	7,378,083	6,715,803	9,404,161	7,347,076

(1) Per share amounts during the year ended June 30, 2000 have been restated to reflect the share splits that occurred during that year. See Item 10.B., “Additional Information - Memorandum and Articles of Association.”

## Exchange Rate Information

The following tables set forth, for the periods and dates indicated, certain information regarding the rates of exchange of A\$1.00 into the US\$ based on the noon market buying rate in New York City for cable transfers in Australian dollars as certified for customs purposes by the Federal Reserve Bank of New York, or the noon buying rate.

<u>Month</u>	<u>High</u>	<u>Low</u>
March 2004.....	0.7732	0.7323
April 2004.....	0.7691	0.7223
May 2004.....	0.7332	0.6851
June 2004.....	0.7153	0.6831
July 2004.....	0.7347	0.6875
August 2004.....	0.7262	0.6954

The noon buying rate on September 21, 2004 was US\$0.70458 = A\$1.00

<u>Year</u>				
<u>Ended June 30,</u>	<u>At Period End</u>	<u>Average Rate</u>	<u>High</u>	<u>Low</u>
2000.....	0.5971	0.6237	0.6560	0.5708
2001.....	0.5100	0.5320	0.5996	0.4828
2002.....	0.5614	0.5682	0.5747	0.4858
2003.....	0.6713	0.5623	0.6729	0.5280
2004.....	0.6903	0.7139	0.8005	0.6345

### B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

### C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

### D. RISK FACTORS

*Investing in our American Depositary Shares involves a high degree of risk and uncertainty. You should carefully consider the risks and uncertainties described below before investing in our American Depositary Shares. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be harmed. In that case, the daily price of our depositary shares could decline, and you could lose all or part of your investment.*

### ***Risks Related To Our Business***

**We are a development stage company at an early stage in the development of pharmaceutical products and our success is uncertain.**

We are a development stage company at an early stage in the development of our pharmaceutical products that are designed to treat the underlying causes of degeneration of the brain and the eye as the aging process progresses. We have not sufficiently advanced the development of any of our product candidates, including our new lead product candidate, PBT-2, to market or generate revenues from its commercial application. We cannot make any assurances that any of our product candidates, if successfully developed, will generate sufficient or sustainable revenues to enable us to be profitable.

**There is a high risk that we may not be able to complete the development of PBT-1, PBT-2 or develop other pharmaceutical products.**

Although we entered into a licensing and research collaboration with Schering A.G., a major international pharmaceutical company, and Neurosciences Victoria Ltd., a consortium of Australian universities, research institutes and teaching hospitals, under which Schering A.G. will provide to us funding of up to A\$2.7 million for specified research and development projects that we will conduct, including the development of a new Alzheimer's diagnostic, we cannot make any assurances that we will be able to develop our current or any future pharmaceutical product candidates adequately to attract a suitable collaborative partner. Nor can we assure you that the projects initially specified in connection with such collaboration or the associated funding by Schering A.G. will not change with the changing interests of either Schering A.G. or Prana, or that any such change may change the budget for the projects under the collaboration. We are also unable to assure you that our research will lead to the discovery of additional product candidates, or that any of our current and future product candidates will be successfully developed, prove to be safe and efficacious in clinical trials, meet applicable regulatory standards and receive regulatory approval, be capable of being produced in commercial quantities at reasonable costs, or be successfully or profitably marketed, either by us or a collaborative partner. We also cannot make any assurances that the products we develop will be able to penetrate the potential market for a particular therapy or indication or gain market acceptance among health care providers, patients and third-party payors. We cannot predict if or when PBT-1, PBT-2, or any of our other pharmaceutical products under development will be commercialized.

**We will not be able to commercialize any of our product candidates if we fail to adequately demonstrate their safety, efficacy and superiority over existing therapies.**

Before obtaining regulatory approvals for the commercial sale of any of our pharmaceutical products, we must demonstrate through pre-clinical testing and clinical studies that our product candidates are safe and effective for use in humans for each target indication. Conducting pre-clinical testing and clinical studies is an expensive, protracted and time-consuming process. Likewise, results from early clinical trials may not be predictive of results obtained in large-scale, later-stage clinical testing. In addition, even though a potential drug product shows promising results in clinical trials, regulatory authorities may not grant the necessary approvals without sufficient safety and efficacy data.

We cannot make any assurances that we will be able to undertake further clinical trials of PBT-1 or commence clinical trials of PBT-2 or our proposed vaccine as planned, or to demonstrate the safety and efficacy or superiority of PBT-1 or PBT-2 over existing therapies, or other therapies under development, or enter into any collaborative arrangement to commercialize PBT-1 or PBT-2 on terms acceptable to us, or at all. Clinical trial results that show insufficient safety and efficacy could have a material adverse effect on our business, financial condition and results of operations.

**We may experience delays in our clinical trials that could adversely affect our business and operations.**

We do not know whether planned clinical trials will begin on time or whether we will complete any of our clinical trials on schedule or at all. Our ability to commence and complete clinical trials may be delayed by many factors, including:

- government or regulatory delays, including delays in obtaining approvals from applicable hospital ethics committees and internal review boards;
- slower than expected patient recruitment;
- our inability to manufacture sufficient quantities of our new proprietary compound or our other product candidates or matching controls;
- unforeseen safety issues; and
- lack of efficacy or unacceptable toxicity during the clinical trials.

Patient enrollment is a function of, among other things, the nature of the clinical trial protocol, the existence of competing protocols, the size and longevity of the target patient population, and the availability of patients who comply with the eligibility criteria for the clinical trial. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials. Moreover, we rely on third parties to assist us in managing and monitoring clinical trials. Any failure by these third parties to perform under their agreements with us may cause the trials to be delayed or result in a failure to complete the trials.

Product development costs to our collaborators and us will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. Significant delays could have a material adverse effect on the commercial prospects of our product candidates and our business, financial condition and results of operations.

**We have limited manufacturing experience, and delays in manufacturing sufficient quantities of PBT-1 or PBT-2 for pre-clinical and clinical trials may negatively impact our business and operations.**

We cannot make any assurances that we will be able to manufacture sufficient quantities of PBT-1, PBT-2 or any of our other product candidates in a cost-effective or timely manner. Any delays in production would delay our pre-clinical and human clinical trials which could have a material adverse effect on our business, financial condition and results of operations.

We may be required to enter into contracting arrangements with third parties to manufacture PBT-1, PBT-2 and our other product candidates for large-scale, later-stage clinical trials. We cannot make any assurances that we will be able to make the transition to commercial production. We may need to develop additional manufacturing resources, enter into collaborative arrangements with other parties who have established manufacturing capabilities, or have third parties manufacture our products on a contract basis. We cannot make any assurances that we will have access on acceptable terms to the necessary and substantial financing that would be required to scale-up production and develop effective commercial manufacturing processes and technologies. We also cannot make any assurances that we will be able to enter into collaborative or contracting arrangements on acceptable terms with parties that will meet our requirements for quality, quantity and timeliness.

**We may require substantial additional financing in the future to sufficiently fund our operations and research.**

We have been unprofitable to date and expect to incur losses over the next several years as we expand our drug discovery and development programs and pre-clinical testing and as we conduct clinical trials of our product candidates. Although we believe that our existing cash and cash equivalents and revenue resources will be adequate to satisfy the requirements of our current and planned operations for the foreseeable future, we cannot make any assurances that such funds will be available or sufficient to meet our actual operating expenses and capital requirements on a long-term basis. Our actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including:

- the continued progress of our research and development programs;
- the timing, scope, results and costs of pre-clinical studies and clinical trials;
- the cost, timing and outcome of regulatory submissions and approvals;
- determinations as to the commercial potential of our product candidates;
- our ability to successfully expand our contract manufacturing services;
- our ability to establish and maintain collaborative arrangements;
- the status and timing of competitive developments; and
- other factors.

We anticipate that we will require substantial additional funds in order to achieve our long-term goals and complete the research and development of our pharmaceutical product candidates. In addition, we will require additional funds to pursue regulatory clearances, and defend our intellectual property rights, establish commercial scale manufacturing facilities, develop marketing and sales capabilities and fund operating expenses. We intend to seek such additional funding through public or private financings and/or through strategic alliances or other arrangements with corporate partners. We cannot, however, be certain that such additional financing will be available from any sources on acceptable terms, or at all, or that we will be able

to establish new strategic alliances or other arrangements with corporate partners on acceptable terms, or at all. Any shortfall in funding could result in our having to curtail our operations, including our research and development activities, which could have a material adverse effect on our business, financial condition and results of operations.

**We have a history of operating losses and may not achieve or maintain profitability in the future.**

We have incurred losses in every period since we began operations in 1997. We expect to continue to incur additional operating losses over at least the next several years and to increase our cumulative losses substantially as we expand our research and development and pre-clinical activities and commence additional clinical trials of PBT-1 and PBT-2. We reported a net loss of A\$9,885,614, A\$4,585,838 and A\$5,448,467 during the fiscal years ended June 30, 2004, 2003 and 2002, respectively. As of June 30, 2004, our accumulated deficit was A\$25,464,876. We cannot assure you that we will achieve or maintain profitability.

**Our success depends upon our ability to protect our intellectual property and our proprietary technology.**

Our success will depend in large part on whether we can:

- obtain and maintain patents to protect our own products;
- obtain licenses to the patented technologies of third parties;
- operate without infringing on the proprietary rights of third parties; and
- protect our trade secrets and know-how.

Patent matters in biotechnology are highly uncertain and involve complex legal and factual questions. Accordingly, the availability and breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. While we intend to seek patent protection for our therapeutic products and technologies, we cannot be certain that any of the pending or future patent applications filed by us or on our behalf will be approved, or that we will develop additional proprietary products or processes that are patentable or that we will be able to license any other patentable products or processes.

Our commercial success will also depend, in part, on our ability to avoid infringement of patents issued to others. If a court determines that we were infringing any third party patents, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities. We cannot be certain that the licenses required under patents held by third parties would be made available on terms acceptable to us or at all. To the extent that we are unable to obtain such licenses, we could be foreclosed from the development, manufacture or commercialization of the product requiring such license or encounter delays in product introductions while we attempt to design around such patents, and any of these circumstances could have a material adverse effect on our business, financial condition and results of operations.

We may have to resort to litigation to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. Any such litigation, regardless of outcome, could be expensive and time consuming, and adverse determinations in any such proceedings could prevent us from developing, manufacturing or commercializing our products and could have a material adverse effect on our business, financial condition and results of operations.

**Our products may infringe on the intellectual property rights of others, which could increase our costs and negatively affect our profitability.**

Third parties have in the past and may in the future assert against us infringement claims or claims that we have infringed a patent, copyright, trademark or other proprietary right belonging to them. Any infringement claim, even if not meritorious, could result in the expenditure of significant financial and managerial resources and could negatively affect our profitability.

**If we do not obtain the necessary governmental approvals we will be unable to commercialize our pharmaceutical products.**

Our ongoing research and development activities are, and the production and marketing of our pharmaceutical product candidates derived therefrom will be, subject to regulation by numerous governmental authorities in Australia, principally the Therapeutics Goods Administration, or TGA, and the Food and Drug Administration, or FDA, in the United States, the Medicines Control Agency in the United Kingdom and the European Medicines Evaluation Authority. Prior to marketing, any therapeutic product developed must undergo rigorous pre-clinical testing and clinical trials, as well as an extensive regulatory approval process mandated by the TGA and, to the extent that any of our pharmaceutical products under development are marketed abroad, by foreign regulatory agencies, including the FDA in the United States and the Medicines Control Agency in the United Kingdom. These processes can take many years and require the expenditure of substantial resources. Delays in obtaining regulatory approvals would adversely affect the development and commercialization of our pharmaceutical product candidates. We cannot be certain that we will be able to obtain the clearances and approvals necessary for clinical testing or for manufacturing and marketing our pharmaceutical products candidates.

**Our research and development efforts will be seriously jeopardized if we are unable to retain key personnel and cultivate key academic and scientific collaborations.**

Our future success depends to a large extent on the continued services of our senior management and key scientific personnel. We have entered into employment agreements with these individuals. The loss of their services could negatively affect our business. Our success is highly dependent on the continued contributions of our scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions and scientists. Competition among biotechnology and pharmaceutical companies for qualified employees is intense, and we cannot be certain that we will be able to continue to attract and retain qualified scientific and management personnel critical to our success. We also have relationships with leading academic and scientific collaborators who conduct research at our request or assist us in formulating our research and development strategies. These academic and scientific collaborators are not our employees and may have commitments to, or consulting or advisory

contracts with, other entities that may limit their availability to us. In addition, these collaborators may have arrangements with other companies to assist such companies in developing technologies that may prove competitive to ours.

**If we are unable to successfully keep pace with technological change or with the advances of our competitors, our technology and products may become obsolete or non-competitive.**

The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. Our competitors in Australia and elsewhere are numerous and include major pharmaceutical companies, biotechnology firms, universities and other research institutions. These competitors may develop technologies and products that are more effective than any that we are developing, or which would render our technology and products obsolete or non-competitive. Many of these competitors have greater financial and technical resources and manufacturing and marketing capabilities than we do. In addition, many of our competitors have much more experience than we do in pre-clinical testing and human clinical trials of new or improved drugs, as well as in obtaining FDA, TGA and other regulatory approvals.

We know that competitors are developing or manufacturing various technologies or products for the treatment of diseases that we have targeted for product development. Some of these competitive products use therapeutic approaches that compete directly with certain of our product candidates. Our ability to further develop our products may be adversely affected if any of our competitors were to succeed in obtaining regulatory approval for their competitive products sooner than us.

**Acceptance of our products in the marketplace is uncertain, and failure to achieve market acceptance will negatively impact our business and operations.**

We cannot make any assurances that our products will achieve market acceptance even if they are approved by the TGA and the FDA. The degree of market acceptance of our products will depend on a number of factors, including:

- the receipt and timing of regulatory approvals for the uses that we are studying;
- the establishment and demonstration to the medical community of the safety, clinical efficacy and cost-effectiveness of our product candidates and their potential advantages over existing therapeutics and technologies; and
- the pricing and reimbursement policies of governments and third-party payors.

Physicians, patients, payors or the medical community in general may be unwilling to accept, use or recommend any of our products.

**The failure to establish a sales, marketing and distribution capability would materially impair our ability to successfully market and sell our pharmaceutical products.**

We currently have no experience in marketing, sales or distribution of pharmaceutical products. If we develop any commercially marketable pharmaceutical products and decide to perform our own sales and marketing activities, we will require additional management, will need to hire sales and marketing personnel, and will require additional capital. We cannot make

any assurances that qualified personnel will be available in adequate numbers or at a reasonable cost, that additional financing will be available on acceptable terms, or at all, or that our sales staff will achieve success in their marketing efforts. Alternatively, we may be required to enter into marketing arrangements with other parties who have established appropriate marketing, sales and distribution capabilities. We cannot make any assurances that we will be able to enter into marketing arrangements with any marketing partner or that if such arrangements are established, our marketing partners will be able to commercialize our products successfully. Other companies offering similar or substitute products may have well-established and well-funded marketing and sales operations in place that will allow them to market their products more successfully. Failure to establish sufficient marketing capabilities would materially impair our ability to successfully market and sell our pharmaceutical products.

**If healthcare insurers and other organizations do not pay for our products, or impose limits on reimbursement, our business may suffer.**

The drugs we hope to develop may be rejected by the marketplace due to many factors, including cost. The continuing efforts of governments, insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce healthcare costs may affect our future revenues and profitability and those of our potential customers, suppliers and collaborative partners, as well as the availability of capital. In Australia and certain foreign markets, the pricing or profitability of prescription pharmaceuticals is already subject to government control. We expect initiatives for similar government control at both the state and federal level to continue in the United States. The adoption of any such legislative or regulatory proposals could have a material adverse effect on our business and prospects.

Our ability to commercially exploit our products successfully will depend in part on the extent to which reimbursement for the cost of our products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Third-party payors, such as government and private health insurers, are increasingly challenging the price of medical products and services. Uncertainty exists as to the reimbursement status of newly approved health care products thereafter and in foreign markets, including the United States. If third-party coverage is not available to patients for any of the products we develop, alone or with collaborators, the market acceptance of these products may be reduced, which may adversely affect our future revenues and profitability. In addition, cost containment legislation and reductions in government insurance programs may result in lower prices for our products and could materially adversely affect our ability to operate profitably.

**We may be exposed to product liability claims, which could harm our business.**

The testing, marketing and sale of human health care products also entails an inherent risk of product liability. We may incur substantial liabilities or be required to limit development or commercialization of our products if we cannot successfully defend ourselves against product liability claims. We have obtained no fault compensation insurance (of A\$10 million) with respect to our recent clinical trial and extension study and intend to obtain similar coverage for future clinical trials. We cannot be certain that such coverage will be available in the future on acceptable terms, or at all. This may result in our inability to pursue further clinical trials or to obtain adequate protection in the event of a successful claim. No assurance can be given that we will be able to obtain product liability insurance in the event of the commercialization of a

product or that it will be available on commercially reasonable terms. Even if we have adequate insurance coverage, product liability claims or recalls could result in negative publicity or force us to devote significant time, attention and financial resources to those matters.

**Changes in government legislation and policy may adversely affect us.**

While we do not anticipate in the near future any specific material changes in government legislation that may adversely affect us, any material changes in interest rate, exchange rate, relevant taxation and other legal regimes and government policies may adversely affect us and the market price of our securities.

**We are dependent upon a sole supplier of our key component and could incur significant costs if we are unable to promptly find a replacement.**

Our lead compound, PBT-2, and our earlier product, PBT-1, are manufactured by one manufacturer, the Institute of Drug Technology Limited. We intend to continue this relationship with further compounds if it remains financially viable. We have not had any prior manufacturer of PBT-1 cease its relationship with our company. We cannot assure you that we will be able to promptly find a replacement manufacturer, if required, without incurring material additional costs.

***Risks Relating to Our Ordinary Shares***

**Our stock price may be volatile and the U.S. trading market for our American Depositary Shares is limited.**

The market price for our securities, like that of the securities of other pharmaceutical and biotechnology companies, has fluctuated substantially and may continue to be highly volatile in the future. The market price for our ordinary shares has ranged from as low as A\$0.435 to a high of A\$2.39 during the last two fiscal years and the market price of our American Depositary Shares has ranged from as low as US\$2.95 to a high of US\$12.80 since our listing on the NASDAQ SmallCap Market on September 5, 2002 and until June 30, 2004. The market price for our ordinary shares has been affected by both broad market developments and announcements relating to actual or potential developments concerning products under development. We believe that the following factors, in addition to other risk factors described above and elsewhere in this annual report, will continue to significantly affect the market price of our ordinary shares:

- the results of pre-clinical testing and clinical trials by us and our competitors;
- developments concerning research and development, manufacturing, and marketing alliances or collaborations by us and our competitors;
- announcements of technological innovations or new commercial products by us and our competitors;
- determinations regarding our patent applications and those of others;
- publicity regarding actual or potential results relating to medicinal products under development by us and our competitors;

- proposed governmental regulations and developments in Australia, the United States and elsewhere;
- litigation;
- economic and other external factors; and
- period-to-period fluctuations in our operating results.

In addition, stock markets have experienced extreme price and volume fluctuations. These fluctuations have especially affected the stock market price of many high technology and healthcare related companies, including pharmaceutical and biotechnology companies, and, in many cases, are unrelated to the operating performance of the particular companies.

### **New corporate governance regulations could increase the cost of our operations**

As a result of recent corporate governance scandals and the legislative and litigation environment resulting from those scandals, the costs of being a public company in general have increased. The Sarbanes-Oxley Act of 2002 requires changes in some of our corporate governance and securities disclosure or compliance practices. We expect that the on-going implementation of these regulations will further increase our legal compliance costs and will make some activities more time consuming. We are presently evaluating and monitoring regulatory developments and cannot estimate the magnitude of additional costs we may incur as a result of such developments. This and other proposed legislation may increase the fees of our professional advisors and our insurance premiums.

### **Holders of our ordinary shares or American Depositary Shares who are U.S. residents face adverse income tax consequences.**

There is a risk that we will be classified as a passive foreign investment company, or PFIC. Our treatment as a PFIC could result in a reduction in the after-tax return to the holders of our ordinary shares or American Depositary Shares and would likely cause a reduction in the value of such shares. For U.S. federal income tax purposes, we will be classified as a PFIC for any taxable year in which either (i) 75% or more of our gross income is passive income, or (ii) at least 50% of the average value of all of our assets for the taxable year produce or are held for the production of passive income. For this purpose, passive income includes dividends, interest, royalties, rents, annuities and the excess of gains over losses from the disposition of assets which produce passive income. As a result of our cash position, which may increase if a substantial portion of our outstanding options are exercised, there is a risk under the asset test described above that we will be declared a PFIC in the event the price of our ordinary shares declines substantially. If we were determined to be a PFIC for U.S. federal income tax purposes, highly complex rules would apply to U.S. holders owning ordinary shares. Accordingly, you are urged to consult your tax advisors regarding the application of such rules. However, because the determination of whether we are a PFIC is based upon the composition of our income and assets from time to time, this determination can not be made with certainty until the end of the calendar year.

**We do not anticipate paying dividends on our ordinary shares.**

We have never declared or paid cash dividends on our ordinary shares and do not expect to do so in the foreseeable future.

***Risks Relating to our Location in Australia***

**It may be difficult to enforce a judgment in the United States against us and most of our officers and directors or to assert U.S. securities laws claims in Australia or serve process on most of our officers and directors.**

We are incorporated in Australia. All but two of our executive officers and directors are nonresidents of the United States. Therefore, it may be difficult for an investor, or any other person or entity, to enforce a U.S. court judgment based upon the civil liability provisions of the U.S. federal securities laws in an Australian court against us or any of those persons or to effect service of process upon these persons in the United States. Additionally, it may be difficult for an investor, or any other person or entity, to enforce civil liabilities under U.S. federal securities laws in original actions instituted in Australia.

**ITEM 4. INFORMATION ON THE COMPANY**

**A. HISTORY AND DEVELOPMENT OF THE COMPANY**

Our legal and commercial name is Prana Biotechnology Limited. We were incorporated under the laws of the Commonwealth of Australia on November 11, 1997 and began limited operations shortly thereafter. Our registered office is located at Suite 2, 1233 High Street, Armadale, Victoria, 3143, Australia and our telephone number is 011-61-3-9824-8166. Our principal executive office is located at Level 2, 369 Royal Parade, Parkville, Victoria 3052, Australia and our telephone number is 011-61-3-9349-4906. Our address on the Internet is [www.pranabio.com](http://www.pranabio.com). The information in our website is not incorporated by reference into this annual report.

From our inception until our initial public offering registering our shares on the Australian Stock Exchange, or ASX, on March 28, 2000, we financed our operations with loans from two of our directors, totaling A\$2,038,728. On March 28, 2000, we sold 16,000,000 of our ordinary shares and 8,000,000 options to purchase our ordinary shares in an initial public offering. We received net proceeds of A\$7,474,323 from the sale of shares and exercise of options. On February 15, 2001, we completed a private placement of 6,666,666 ordinary shares to institutional investors at a price per share of A\$0.75 and received net proceeds of A\$4,745,599 from the private placement. During the years ended June 30, 2003 and 2002, we received net proceeds of A\$3,569,792 and A\$580,345, respectively, for the exercise of 7,427,584 and 1,160,690 options (including the conversion of 7,289,310 listed options in March 2003), which funds were added to our working capital. In September 2003, we raised an additional A\$4,675,019 (net of issuance costs) through a private placement of 7,102,853 ordinary shares to institutional and accredited investors at a subscription price of A\$0.70 per share. In April 2004, we raised A\$26,352,147 (net of issuance costs) in a private placement in the United States, which was held in escrow pending receipt of the requisite approval of the transaction by our shareholders that was obtained on June 1, 2004, through the sale of 4,000,000 ADRs to institutional and accredited investors at a subscription price of US\$0.50 per share and five-year

warrants to purchase 3,000,000 ADRs at an exercise price of US\$8.00 per ADR. In the fiscal year ended June 30, 2004, we also received net proceeds of A\$757,166 for the exercise of options to purchase 1,325,000 ordinary shares, which funds were added to our working capital. Additionally, during the fiscal year ended June 30, 2004 we issued ordinary shares for nil consideration at a cost of A\$3,167 which was subtracted from our working capital. As at June 30, 2004, we had A\$29,580,398 in cash and cash equivalents and our working capital was A\$27,033,245.

Our mission is to develop therapeutic drugs designed to treat the underlying causes of degeneration of the brain and the eye as the aging process progresses, initially focusing on Alzheimer's disease. Other potential applications for our therapies include age-related cataracts, Creutzfeldt-Jakob disease (the human variant of Mad Cow disease), Motor Neuron disease and Parkinson's disease. Our technology is the outcome of many years of intense research from some of the leading scientists in the world in the area of age-related degenerative diseases.

Since completing our initial public offering and listing process on the ASX on March 28, 2000, we have concentrated our resources toward the pursuit of our diseases targets and in particular the progress of our clinical trial for PBT-1, as a successful therapeutic for the treatment of Alzheimer's disease. We commenced our planned phase II human clinical trial for PBT-1 in August 2000 at the Mental Health Research Institute and the Royal Melbourne Hospital. The trial was completed in January 2002 and in April 2002, Professor Colin Masters, Chairman of our Scientific Advisory Board, reported at the Seventh International Geneva/Springfield Symposium on Advances in Alzheimer Therapy in Geneva that the trial had demonstrated a significant slowing in the rate of progression of cognition (as measured by the ADAS-cog score) in patients with initial ADAS-cog scores of 25-40. Professor Masters presented that this provided encouraging proof of concept for PBT-1 and the  $\beta$ Amyloid theory of Alzheimer's disease. The results were published in the Archives of Neurology in December 2003. All patients from this study were then provided the opportunity to roll into a further 48 week extension study. A complete set of results from this study have yet to be published however speaking at the eighth International Springfield/Montreal Symposium on Advances in Alzheimer's disease, Professor Masters was able to report that extended use of PBT-1 appears relatively well tolerated and appears to provide continued effectiveness in slowing the progress of cognitive function associated with Alzheimer's disease.

In early August 2003, we announced that a new lead MPAC molecule for Alzheimer's disease designated as PBT-2 that had been selected for development. PBT-2 is the result of rational drug design. It has been built "from the ground up" to fulfill very specific criteria. It was designed so that it will have no patent ambiguities, be orally bioavailable and cross the blood brain barrier. PBT-2 has been selected from over 300 Prana-developed compounds and has demonstrated significantly greater effectiveness in both pre-clinical in-vitro and in-vivo testing and has been designed to have an improved safety and efficacy profile compared to PBT-1. In February 2004, Prana was awarded a second research and development START grant of A\$1.35 million to take PBT-2 through safety testing and Phase I clinical trials for Alzheimer's disease, PBT-2 is progressing through formal preclinical toxicology testing and is expected to be ready for human trialing in early 2005.

In March 2003, we announced our first major licensing and research collaboration with Schering A.G., or Schering, a major international pharmaceutical company, and Neurosciences Victoria Ltd., or NSV, an organization of the Universities of Melbourne and Monash, established to promote, commercialization of discoveries emanating from Victoria, Australia universities and medical research institutes. Under such collaboration, we appointed NSV to act as our agent for the purpose of receipt of funding from Schering for certain specified research and development projects that we will conduct and to facilitate the licensing of intellectual property to Schering, all under the terms of a separate research and collaboration agreement between Schering and NSV. Among other projects, we will concentrate on the development of a new Alzheimer's diagnostic. We are seeking to develop the first highly reliable diagnostic for Alzheimer's disease using brain imaging of specific compounds as markers to measure the debilitating amyloid deposits. Under the collaboration, Schering is providing to us funding of up to A\$2.7 million over the life of the projects, with additional milestone payments and royalties from discoveries. While Schering has focused its Alzheimer's disease development efforts at diagnostics and imaging, this funding will allow discovery research for additional therapeutic and diagnostic targets and technologies.

We have also identified and provisionally patented a novel target for an Alzheimer's vaccine. We are currently collaborating with Prima Biomed Ltd., another publicly traded Australian biotech company, as well as utilizing the resources of the Austin Research Institute, the University of Melbourne and the Mental Health Research Institute to pursue this therapeutic approach. The research is investigating the feasibility of developing a vaccine to prevent the onset or progression of Alzheimer's. The research will assess the ability of the immune system to selectively produce specific antibodies which target the "toxic linked" forms of beta amyloid (not 'normal' beta amyloid) associated with the pathology of the disease, as an effective Alzheimer's treatment. The Commonwealth of Australia government has provided a A\$227,252 Biotechnology Innovation Fund, or BIF, grant for this work.

Since inception, we have not been required to invest material amounts for capital expenditures since our development efforts have taken place at research facilities operated by institutions with whom we have relationships. In the three fiscal years ended June 30, 2004 our capital expenditures have totaled A\$272,980. We have not incurred any material capital expenditures since July 1, 2004.

## **B. BUSINESS OVERVIEW**

### **Prana's Background**

Medical science has made a significant number of breakthroughs over the past century. The average life span in western cultures has substantially increased. The diseases associated with aging have, however, yet to be fully understood or effectively treated. It is now believed that a number of age-related diseases may be capable of being treated.

Our platform technology was developed over a period of many years with the financial support of various institutions and from various grants. The majority of these funds were directed at research into Alzheimer's disease, however the outcomes demonstrated by this research have created strong implications for other age-related degenerative disorders where the

pathology of the disease is based on the inter-relationship between metals and proteins. Published studies in animal models of Parkinson's disease have reported positive effects of the lead compound PBT-1 and strengthen the "theory of metal related toxicity" in many neurodegenerative diseases. There is currently no cure or prevention for Alzheimer's disease nor any successful cure for any of the principal forms of neuron-generating diseases which comprise our disease targets.

The protein believed to be involved in Alzheimer's disease is  $\beta$ Amyloid. Very little was known about  $\beta$ Amyloid protein until 1984 when Professors Colin Masters, Konrad Beyreuther and the late Dr. Glenner sequenced the chemistry of the protein which has since become the dominant focus world-wide of Alzheimer's disease research.

In 1987, Drs. Masters and Beyreuther and Professor Rudolph Tanzi of Harvard Medical School discovered how  $\beta$ Amyloid was produced and in 1994 Professor Ashley Bush of Harvard Medical School discovered that the interaction between metals and  $\beta$ Amyloid is associated with the toxicity seen in Alzheimer's disease, hopefully paving the way for the development of therapeutic drugs to treat the disease.

Our intellectual property has been developed over an extended period through the collaborative efforts of highly regarded scientists and research institutions in this field.

### **Research Institutions**

The intellectual property owned by our company has been developed at several internationally recognized institutional research facilities:

- The Massachusetts General Hospital, Genetics and Aging Unit in Boston. Massachusetts General Hospital is the largest teaching hospital for Harvard Medical School;
- The University of Melbourne, Department of Pathology; and
- The Biomolecular Research Institute in Melbourne.

Work conducted at the first two of these institutions identified an initial preferred compound codenamed PBT-1 which was used in our phase II human clinical trials. Our research program also aims to find further and potentially more effective preferred compounds for the treatment of Alzheimer's disease as well as for our other major disease targets. These efforts have led to the development of PBT-2, a small molecular weighed chemical entity that demonstrates a significant improvement over PBT-1 and a portfolio of almost 400 other MPAC molecules. Initially concentrating on the development of novel MPAC within the same chemical class as PBT-1, the successful design and synthesis of PBT-2 the chemistry towards the synthesis of novel MPACs has now expanded to include multiple other chemical classes.

### **Platform Technology**

We regard our intellectual property as a "platform technology" since we believe that it addresses the causes of a broad spectrum of age related diseases based on the interrelationship of metals and proteins. The most advanced research aimed at our disease targets is its potential

therapeutics for the treatment of Alzheimer's disease. However, we believe that the platform technology may also be applicable for:

- Age-related cataracts;
- Creutzfeldt-Jakob disease (CJD or Mad Cow disease);
- Motor Neuron disease; and
- Parkinson's disease.

### **Clinical Trials**

Having demonstrated the effectiveness of PBT-1 in the laboratory, we received official Ethics Committee approval from the Royal Melbourne Hospital, Victoria, Australia, to test PBT-1 in human subjects. Phase II human clinical trials for PBT-1 commenced during August 2000 and were completed in January 2002 and an academic paper outlining the findings was published in the peer reviewed journal *Archives of Neurology* in December 2003. The clinical trials were conducted principally at our sponsored facilities at the Royal Melbourne Hospital and the Mental Health Research Institute, both based in Melbourne. Prescribed dosages of our preferred compound PBT-1 were administered to 50% of the study candidates, the other 50% received a placebo. The trial is a "double blind trial" so neither the administering medical personnel nor the patients involved in the trial process were aware of who received PBT-1 and who received the placebo. All subjects were asked to perform various prescribed cognitive tests to determine if the introduction of PBT-1 had a demonstrable effect as compared to those subjects receiving the placebo. On completion of the initial 36 weeks of dosing all subjects were invited to continue into an extension arm where they received treatment with PBT-1 for an additional 48 weeks.

The trial was performed to contemporary "best practice" clinical trial standards. Prana contracted Kendle Pty Ltd., or Kendle, to manage the clinical trials, ensuring compliance to the required international standards of Good Clinical Practice as set out by the International Conference on Harmonisation. These protocols provide strict guidelines for the performance of clinical trials in an ethical and scientifically sound manner, and are mandatory for applications to international regulatory authorities for market access.

The Institutional Ethics Committee overseeing the trial carefully addressed safety concerns as follows:

- The dose of clioquinol to be used in the clinical trial is below the dose previously recommended for use as a short term antidiarrhea agent. All patients commenced on 250 mg per day, increasing to a maximum of 750 mg per day.
- The underlying biochemical mechanism associated with clioquinol toxicity is not fully understood. Recent work suggests that clioquinol may alter absorption and/or renal excretion of Vitamin B12. All patients in the study received supplementary Vitamin B12.
- The trial protocol required close monitoring of all patients by a safety committee of clinical experts. This committee independently monitored all

patient data including laboratory results and neurological test results on a regular basis

In April 2002, Professor Masters reported that the trial achieved its targeted benchmarks and that the two major initial findings of the study were:

- The  $\beta$ Amyloid protein, which was a target of the activity of PBT-1, was significantly reduced in the blood of mild to moderate patients in the treatment group compared to an increase in the placebo group; and
- The progression of Alzheimer's disease was slowed down in the more severely affected patients in the treatment group compared to the placebo group. The initial findings of the study indicate the rate of cognitive deterioration was slowed in these patients.

In April 2004, the top-line findings of the 48-week extension study were presented for the first time by Professor Colin Masters at the 8th International Springfield/Montreal Symposium on Advances in Alzheimer's disease. The details of the trial findings have not been published as yet.

PBT-2 successfully completed in-house preclinical screening in 2003 and at present formal toxicology screening is being completed. If successful, it is intended that PBT-2 will move into clinical trials in early 2005. No assurance can be given that PBT-2 will succeed in formal toxicology testing or that such future clinical studies will commence, or if initiated will be completed and prove to be successful, or that we will be able to commercialize drugs based on our  $\beta$ Amyloid theory of Alzheimer's disease.

It was reported that approximately 4.5 million persons in the United States suffered from Alzheimer's disease in 2000, more than double the number of persons in the United States who suffered from the disease in 1980. We and our scientific advisory board believe that our technology, if proven successful, will place our company among the leaders in the world in terms of developing a therapeutic means to treat Alzheimer's disease.

### **Rational Drug Design**

Rational drug design employs computer-generated models, which target the molecular composition of various substances (in the case of Alzheimer's disease the  $\beta$ Amyloid Protein) and design new chemical entities with the propensity to influence the targeted substances (proteins).

To date, our scientists have developed a pipeline of compounds that target the interaction of specific metals and the  $\beta$ Amyloid Protein. These compounds continue to undergo the required early phase screening test before they are available for human testing. Based on the results of initial screening, our medicinal chemists continue to develop new chemical entities with novel design features.

Although we believe that we have demonstrated "proof of principle" in our phase II trials utilizing PBT-1, we also believe that rational drug design will provide new and specifically designed drugs which will display greater efficacy in disaggregating aggregation-prone proteins

such as  $\beta$ Amyloid, paving the way for future therapeutics. PBT-2 is the first such new and specifically designed compound to move into formal development.

In early August 2003, we announced that PBT-2, a new lead MPAC molecule for Alzheimer's disease, had been selected for development. PBT-2 is the result of rational drug design. It has been built "from the ground up" to fulfill very specific criteria. It was designed so that it will have no patent ambiguities, be orally bioavailable and cross the blood brain barrier. PBT-2 has been selected from over 400 Prana-developed compounds and has demonstrated significantly greater effectiveness in both pre-clinical in-vitro and in-vivo testing and has been designed to have an improved safety and efficacy profile compared to PBT-1.

### **Creutzfeldt-Jakob Disease**

In 2001, British studies revealed a much greater potential for the spread of fatal brain diseases such as Creutzfeldt-Jakob disease, or CJD, the human variant of Mad Cow disease. In August 2000, the London-based Medical Research Council warned that the disease could be more widespread than previously thought and that healthy appearing animals can be carriers of the disease. Mad Cow disease entered the human food chain in the 1980's leading to a collapse of the entire beef trade in the United Kingdom at the time. There is currently no cure for this fatal disease. In early 2001, the scientific journal Biochemistry published research results by Prana-sponsored scientist Dr. Roberto Cappai and colleagues confirming the role of metals in the aggregation and neurotoxicity of the abnormal form of the prion protein (PrP), believed to be responsible for the transmissible spongiform encephalopathics. Studies conducted by the University of Melbourne are ongoing to identify compounds that inhibit prion formation based on the PrP metal binding site. At present we are not undertaking specific research into the development of specific MPACs for prion diseases such as CJD, however through our close relationship with Professor Masters and his world-leading independent laboratory at the University of Melbourne, we believe that we have the capability to rapidly move into this field when and if it is deemed appropriate.

### **Age-Related Cataracts**

Basic research in this area is being conducted by several independent groups of researchers around the world. Preliminary animal data suggests that the deposition of some proteins in age related cataracts may be related to the inappropriate interaction of metals and amyloid species. We are aware of the growing evidence in this area and when adequate information becomes available, will assess the data and determine if further company funds will be invested in this area.

### **Motor Neuron Disease (or Amyotrophic Lateral Sclerosis)**

Amyotrophic Lateral Sclerosis, or ALS, is a fatal disease, manifested by progressive paralysis over five to ten years. There is currently no effective therapy for this tragic illness. The disease involves degeneration of the nerve cells in the spinal column, which has now been related to mutations of a protein that interacts with metal ions.

Studies through other internationally recognized research groups are progressing, and preliminary animal experiments are in progress to identify the role of SOD1 (superoxide dismutase) aggregation in Motor Neuron disease. The mechanisms underlying this disease have

not been fully discovered, but the oxidative changes associated with the aggregation of critical proteins in the spinal cord and brain stem continue to be at the center of a world-wide research effort. It is possible that the oxidative changes associated with ALS may be susceptible to treatment with Prana's drug technology. A more specific drug target is expected to emerge in the near future.

### **Parkinson's Disease**

Parkinson's disease is another crippling disease of the aging population. It causes a progressive slowing of movement, tremor and the loss of fine motor control. Increasingly, dementia is being recognized as a significant component of Parkinson's disease. Existing therapies may provide some short term symptomatic relief but do not address the underlying cause of the disease. We believe that our platform technology may affect the aggregation of the proteins concerned and may provide a pathway for reversing the disease. Parkinson's disease is believed to affect 150 people per 100,000 or 2.5% of persons over the age of 85. It has been reported that approximately four million people suffer from Parkinson's disease worldwide.

The Melbourne research team is working on the key protein which aggregates to form the diagnostic marker of this disease. The aggregated form of this protein is susceptible to the same therapeutic strategy that is being used for Alzheimer's disease, and scientists associated with Prana have published results in the peer reviewed journal *Neuron* in March 2003, indicating that PBT-1 can prevent the neurotoxicity seen in the MPTP mouse model of Parkinson's disease. Experiments to confirm that other Prana MPACs have a similar effect and that these findings are applicable in human Parkinson's disease are planned but have not been conducted as yet.

## Patent Portfolio

Invention	Status	Comments
Cation - APP Modulators for use in Alzheimer's disease, entitled, "A method for assaying and treating Alzheimer's disease" Prana	Five patents granted, two in Australia and one in Europe, Japan and in US. An application in US and in Canada is under examination.	The invention includes claims directed to the use of specified modulators of cation interaction with APP and the use of these agents in the treatment of Alzheimer's disease. Granted European claims include the use of zinc binding agents for oral administration in the treatment of Alzheimer's disease.
Metal binding domain inhibitors of $\beta$ -amyloid, entitled, "Beta amyloid peptide inhibitors" Prana/University of Melbourne	This International (PCT) application has entered national phase in Europe, Canada, Japan, US and Australia. Currently under examination in Australia and pending elsewhere.	The invention encompasses claims to agents capable of inhibiting binding of specified metal ions to the N-terminus of $\beta$ -amyloid and the use of these agents in the treatment of amyloid related conditions including Alzheimer's disease.
A screen for $\beta$ -amyloid formation and inhibitors, entitled, "An in vitro system for determining the formation of Ab Amyloid" General Hospital Corporation	One patent granted in the US and Japan. Examination is pending for a further US and Japanese application. An application is under examination in Canada.	The invention is directed to an assay for the formation of $\beta$ -amyloid in a biological sample and inhibitors of $\beta$ -amyloid formation.
A differential screen for 40/42 $\beta$ -amyloid, entitled, "A diagnostic assay for Alzheimer's disease" General Hospital Corporation	One patent granted in the US and a further US application is under examination. Examination is pending in Canada.	The invention is directed to an antibody based diagnostic assay for the detection and quantification of $\beta$ -amyloid species.
Known metal binding agents for treatment of Amyloidosis, entitled, "Identification of agents for use in the treatment of Alzheimer's disease" General Hospital Corporation	Patent accepted in Australia and in Japan. Examination is pending in the Europe and Canada. A divisional application has been filed in Australia. An Appeal Brief has been filed in an US application.	The invention is directed to the use of specified metal binding agents to reduce $\beta$ -amyloid mediated neurotoxicity and assays to identify agents capable of modifying neurotoxic properties of $\beta$ -amyloid. The accepted case in Australia is under opposition
Clioquinol for treatment of Alzheimer's disease, entitled, "Use of Clioquinol for the therapy of Alzheimer's disease" General Hospital Corporation/Prana	A US continuation application is currently under examination.	The invention includes claims directed to the use of clioquinol for the treatment of Alzheimer's disease and clioquinol pharmaceutical compositions.
Clioquinol and known metal binding agents for use in Amyloidosis, entitled, "Agents for use in the treatment of Alzheimer's disease"	One patent granted in the US and a further US continuation application is under examination. An Australian application has been accepted and a	The invention is directed to compositions containing clioquinol and known metal binding agents and their use in

General Hospital Corporation	further divisional case has been filed. Examination is pending in Canada and Japan. The case has been allowed in Europe.	the treatment of amyloid related diseases. The accepted case in Australia is under opposition.
Screen for agents which alter $\beta$ -amyloid neurotoxic properties, entitled, “ <i>Method for Screening drugs useful for treating Alzheimer’s disease</i> ” General Hospital Corporation	A continuation-in-part application has been granted in the US and further divisional case has been filed. Examination is pending in Europe Canada, Japan and Australia.	The invention is primarily directed to specified assays that identify agents capable of modifying neurotoxic properties of $\beta$ -amyloid.
Immunotherapy, entitled, “ <i>Neuro toxic Oligomers</i> ” General Hospital Corporation/Prana	The International (PCT) Application has entered national phase in Australia, Canada, Europe, Japan, NZ, China and the US and is pending examination.	The invention is directed to an immunotherapy strategy using tyrosine cross-linked protein aggregates. The immunotherapeutic approach may be used in the treatment of Alzheimer’s disease and other amyloid related conditions.
Cataracts, entitled, “ <i>Methods for the Identification of Agents that Inhibit or Promote Cataracts and Uses thereof</i> ” General Hospital Corporation	The International (PCT) Application has entered national phase in Australia, Europe, Japan and the US and is pending examination.	The invention is directed to assays for the detection of agents useful in the treatment of cataract and a method of treatment utilizing specified chelators.
APP Copper Binding Domain agonists, entitled, “ <i>Methods of screening for inhibitors of Alzheimer’s disease</i> ” Prana/University of Melbourne	This case has entered national phase in the US and is pending examination.	The invention encompasses claims to the identification of agents functioning as copper agonists and the use the agents in the treatment of amyloid related conditions including Alzheimer’s disease.
8-OHq role in cognition, entitled, “ <i>Treatment of Neurodegenerative Conditions</i> ” Prana	Filed as a provisional application in the US, continued as an International (PCT) application pending national phase entry.	The invention encompasses the utility of the 8-hydroxyquinoline MPAC class in the treatment of neurodegenerative cognitive changes.
8-OHq MPAC class, entitled, “ <i>8-Hydroxyquinoline derivatives</i> ” Prana	International (PCT) Application pending national phase entry.	The invention is directed to chemical structures of the 8-hydroxyquinoline MPAC class and their utility in the treatment of neurological conditions.
‘Follow up’ MPAC classes, entitled, ‘Neurologically-Active Compounds’ Prana	International (PCT) Application pending national phase entry.	The invention is directed to alternative MPAC chemical structures and their utility in the treatment of neurological conditions.
MPAC ‘class V’ compounds, entitled, ‘Compound V’	Australian provisional application	The invention is directed to ‘compound V’ MPAC chemical

Prana		structures and their utility in the treatment of neurological conditions.
MPAC 'class VI' compounds, entitled, 'Compound VI' Prana	Australian provisional application	The invention is directed to 'compound VI' MPAC chemical structures and their utility in the treatment of neurological conditions.
'F2' MPAC compounds, entitled, 'Neurologically-Active Compounds' Prana	Australian provisional application	The invention is directed to 'F2' MPAC chemical structures and their utility in the treatment of neurological conditions.
'F4' MPAC compounds, entitled, 'Neurologically- Active Compounds' Prana	Australian provisional application	The invention is directed to 'F4' MPAC chemical structures and their utility in the treatment of neurological conditions.

## Patent Matters

Patent matters in biotechnology are highly uncertain and involve complex legal and factual questions. Accordingly, the availability and breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. Statutory differences in patentable subject matter may limit the protection we can obtain on some or all of our inventions outside Australia or prevent us from obtaining patent protection outside Australia, either of which could have a material adverse effect on our business, financial condition and results of operations. For example, methods of treating humans are not patentable in many countries outside Australia and the United States. Moreover, since patent applications are not published until at least 18 months from their first filing date and the publication of discoveries in the scientific literature often lags behind actual discoveries, we cannot be certain that we or any of our licensors were the first creator of inventions covered by pending patent applications or that we or our licensors were the first to file patent applications for such inventions. Additionally, the enforceability of a patent is dependent on a number of factors that may vary between jurisdictions. These factors may include the novelty of the invention, the requirement that the invention not be obvious in the light of prior art (including prior use or publication of the invention), the utility of the invention, and the extent to which the patent clearly describes the best method of working the invention.

While we intend to seek patent protection for our therapeutic products and technologies, we cannot be certain that any of the pending or future patent applications filed by us or on our behalf will be approved, or that we will develop additional proprietary products or processes that are patentable or that we will be able to license any other patentable products or processes. We also cannot be certain that others will not independently develop similar products or processes, duplicate any of the products or processes developed or being developed by us or licensed to us, or design around the patents owned or licensed by us, or that any patents owned or licensed by us will provide us with competitive advantages. Furthermore, we cannot be certain that patents held by third parties will not prevent the commercialization of products incorporating the technology

developed by us or licensed to us, or that third parties will not challenge or seek to narrow, invalidate or circumvent any of the issued, pending or future patents owned or licensed by us.

Our commercial success will also depend, in part, on our ability to avoid infringement of patents issued to others. If a court determines that we were infringing any third party patents, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities. We cannot be certain that the licenses required under patents held by third parties would be made available on terms acceptable to us or at all. To the extent that we are unable to obtain such licenses, we could be foreclosed from the development, manufacture or commercialization of the product requiring such license or encounter delays in product introductions while we attempt to design around such patents, and any of these circumstances could have a material adverse effect on our business, financial condition and results of operations.

We may have to resort to litigation to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. Such litigation could result in substantial costs and diversion of effort by us. We may have to participate in opposition proceedings before the Australian Patent and Trademark Office or another foreign patent office, or in interference proceedings declared by the United States Patent and Trademark Office, to determine the priority of invention for patent applications filed by competitors. Any such litigation, interference or opposition proceeding, regardless of outcome, could be expensive and time consuming, and adverse determinations in any such proceedings could prevent us from developing, manufacturing or commercializing our products and could have a material adverse effect on our business, financial condition and results of operations.

In addition to patent protection, we rely on unpatented trade secrets and know-how and proprietary technological innovation and expertise that are protected in part by confidentiality and invention assignment agreements with our employees, advisors and consultants.

## **Competition**

We believe that we will face competition in differing levels of intensity in all of the areas in which we are conducting research. Our competitors in Australia and elsewhere are numerous and include, among others, major pharmaceutical companies, biotechnology firms, universities and other research institutions. These competitors may develop technologies and products that are more effective than any that we are developing, or which would render our technology and products obsolete or non-competitive. Many of these competitors have greater financial and technical resources and manufacturing and marketing capabilities than we do. In addition, many of our competitors have much more experience than we do in pre-clinical testing and human clinical trials of new or improved drugs, as well as in obtaining FDA, TGA and other regulatory approvals.

## **Regulatory Considerations**

Our ongoing research and development activities are, and the production and marketing of our pharmaceutical product candidates derived therefrom will be, subject to regulation by numerous governmental authorities in Australia, principally the TGA, and by the FDA in the United States, the Medicines Control Agency in the United Kingdom and the European Medicines Evaluation Authority. Prior to marketing, any therapeutic product developed must

undergo rigorous pre-clinical testing and clinical trials, as well as an extensive regulatory approval process mandated by the TGA and, to the extent that any of our pharmaceutical products under development are marketed abroad, by foreign regulatory agencies, including the FDA in the United States and the Medicines Control Agency in the United Kingdom. Clinical trials are conducted in three sequential phases but the phases may overlap.

Pre-clinical studies involve laboratory evaluation of product characteristics and animal studies to assess the initial efficacy and safety of the product. Clinical trials involve the administration of the investigational product to humans under the supervision of a qualified principal investigator. Phase I clinical trials may be performed in healthy human subjects or, depending on the disease, in patients. The goal of phase I clinical trials is to establish initial data about the safety and tolerance of the product in humans. In phase II clinical trials, in addition to safety, the efficacy of the product is evaluated in limited patients with the target disease. Phase III trials typically involve additional testing for safety and clinical efficacy in expanded, large-scale, multi-center studies of patients with the target disease.

Clinical trials can take many years to complete and require the expenditure of substantial resources. The length of time varies substantially according to the type, complexity, novelty and intended use of the product candidate. Delays in obtaining regulatory approvals could adversely affect the development and commercialization of our pharmaceutical product candidates and could have a material adverse impact on our business, financial condition and results of operations.

We completed a phase II human clinical trial of PBT-1 in late 2002 and its associated extension study in 2003 and will need to complete further and more detailed trials before we will be able to make any application to any of the governmental authorities. We have completed a detailed in-house review of requirements to progress the development of PBT-1 to enable application to regulatory agencies. Initially the focus is on FDA requirements for registration in the United States. Harmonization of regulatory requirements through the International Conference on Harmonization (ICH) and the Common Technical Document (CTD), will enable the regulatory application for the United States to be utilized for applications in Europe and other countries including Australia, providing some limited country specific requirements are addressed. A decision on the path forward with PBT-1 will be made based on this assessment, taking account of the potential requirements of future partners and the progress with PBT-2 and other future compounds. We cannot make any assurances that we will enter further clinical trials with PBT-1.

We cannot make any assurances that we will be able to enter into a collaborative arrangement with a large pharmaceutical or biotechnology company to commercialize PBT-1. Nor can we make any assurances that once clinical trials are completed by us or a collaborative partner, we will be able to submit as scheduled a marketing approval request to the applicable governmental regulatory authority, or that such request and application will be reviewed and cleared by such governmental authority in a timely manner, or at all. Although we intend to make use of fast-track and abbreviated regulatory approval programs when possible, we cannot be certain that we will be able to obtain the clearances and approvals necessary for clinical testing or for manufacturing and marketing our pharmaceutical products candidates.

During the course of clinical trials and toxicology studies, product candidates may exhibit unforeseen and unacceptable drug-related toxicities or side effects. If any unacceptable toxicities or side effects were to occur, we may, or regulatory authorities may require us to, interrupt, limit, delay or abort the development of our potential products. In addition, unacceptable toxicities could ultimately prevent the clearance of our product candidates by the TGA or the FDA for any or all targeted indications. Even after being cleared by the TGA or the FDA, any of our products may later be shown to be unsafe or not to have its purported effect, thereby preventing widespread use or requiring withdrawal from the market. We cannot make any assurances that PBT-1 or any of our other product candidates will be safe or effective when administered to patients.

### **Manufacturing and Raw Materials**

We use a third party manufacturer to produce the primary drug product (API) and secondary drug forms for our clinical supplies of PBT-1 and PBT-2. We have not faced any difficulty in obtaining raw materials for our research and development activities or our clinical studies to date, although recognize that this is a costly, complex and time consuming process. Future supplies of PBT-2 for clinical trials have been commissioned within Australia, while supplies of PBT-1 will most likely be manufactured outside Australia. No assurance can be given that we would be able to replace this supplier on a timely basis, if we were required to find another source of PBT-1 or PBT-2.

### **Government Grants**

We announced on July 26, 2001 that we were granted a START grant from the Australian Industry Research and Development Board, or IR&D Board, to expand our core intellectual property for drug treatment of neuro-degenerative diseases. Under the terms of the grant, we received A\$1.7 million during the three year period commencing January 1, 2001 for up to 50% of the project costs related to our development of a treatment for Alzheimer's disease. The grant was payable on the achievement of each of six milestones and we received the final payment under the START grant in October 2003.

In May 2003, we announced that the IR&D Board approved our application for funding under the BIF grant for the amount of A\$227,252 for research into the development of an immunotherapy for Alzheimer's disease.

In the first quarter of 2004, we were granted a new START grant from the Australian IR&D Board to support further development of PBT-2 and other Alzheimer's disease research. Like the first START grant, the grant is payable, in arrears, on the achievement of pre-specified milestones. We can make no assurances that we can achieve these milestones or receive all of the A\$1.35 million made available over a two year period under the grant.

### **Business Plan**

To date, the majority of our research efforts have been directed at research into the Alzheimer's disease. Our initial findings have provided strong indications that the pathology for other certain age-related and degenerative disorders may also be based on the inter-relationship between certain metals and proteins. These diseases include:

- Age-related cataracts
- Creutzfeldt-Jakob disease
- Motor Neuron disease/Amyotrophic Sclerosis (ALS)
- Parkinson's disease

We believe that our phase II human clinical trial of PBT-1 has demonstrated proof of principle of our theory of Alzheimer's disease and that rational drug design will provide new and specifically designed drugs which will display greater efficacy in disaggregating aggregation prone proteins such as  $\beta$ -amyloid, paving the way for the development of new therapeutic agents. To that end, we have established a drug discovery and development program at the School of Chemistry, and Department of Pathology at the University of Melbourne and the Mental Health Research Institute of Victoria.

### **Rational Drug Design**

Our medicinal chemistry program is based at the University of Melbourne. Rational drug design employs computer-generated models, which target the molecular composition of various substances, in the case of Alzheimer's disease the  $\beta$ -amyloid protein, and designs new chemical entities with the propensity to influence the targeted proteins and metal-mediated oxyradical formation which leads to neurodegenerative changes.

A series of *in vitro* assays have been established to screen compounds developed by the medicinal chemistry group. During 2002/03 a program to undertake preliminary *in vivo* pharmacology and kinetic studies of the new compounds demonstrating activity in the *in vitro* screens has been established. The transgenic mouse model that demonstrated efficacy of PBT-1 is continuing to be used to evaluate *in vivo* efficacy and confirm lead compounds to take to formal pre clinical studies.

In early August 2003, we announced that PBT-2, a new lead MPAC molecule for Alzheimer's disease, had been selected for development. PBT-2 is the result of rational drug design. It has been built "from the ground up" to fulfill very specific criteria. It was designed so that it will have no patent ambiguities, be orally bioavailable and cross the blood brain barrier. PBT-2 has been selected from over 400 Prana-developed compounds and has demonstrated significantly greater effectiveness in both pre-clinical in-vitro and in-vivo testing and has been designed to have an improved safety and efficacy profile compared to PBT-1. The new drug is expected to enter into Phase I human clinical trials in 2005, following a formal toxicology program.

Data generated by *in vitro* and *in vivo* screens will also be incorporated into the medicinal chemistry program to further refine development strategies for new compounds.

### **Commercial Collaboration**

In March 2003, we announced that Schering A.G. (FSE:SCH, NYSE:SHR) of Germany will fund and license discoveries on new drug targets, especially in the area of diagnostics, under project agreements between us and Neurosciences Victoria Ltd. and a separate research and

collaboration agreement between Schering A.G. and Neurosciences Victoria Ltd. The commercial arrangements that we entered into in connection with such collaboration are subject to ongoing confidentiality. Under the collaboration, Schering A.G. is providing to us up to A\$2.7 million of funding for new discovery research over the life of specified research and development projects that we will conduct, with additional milestone payments and royalties from discoveries. See Item 4A. "Information on the Company - History and Development of the Company."

In August 2003, we and Prima Biomed, or Prima (ASX code: PRR) formed a collaboration with the Austin Research Institute and the University of Melbourne to develop the world's first vaccine for Alzheimer's disease. The collaboration will enable Prima Biomed's highly encouraging new Panvax vaccine technology, called DCtag, to be used in conjunction with our metal protein attenuating compounds (MPAC) to assist the body's immune system to recognize the protein or peptide extracts associated with Alzheimer's disease. DCtag has already been shown to be effective in targeting diseases such as malaria and cancer. In February 2003, Panvax announced the results of animal studies confirming the potential of DCtag technology for the development of vaccines and immunotherapies. The research and development will be conducted by the Austin Research Institute and the University of Melbourne and is supported by a Commonwealth government grant of A\$227,252. The research will assess the feasibility of developing a vaccine to prevent the onset or progression of Alzheimer's disease. It will also assess the effectiveness of the technology to enhance the production of antibodies as an effective Alzheimer's disease treatment. We and Prima will jointly share in the benefit of any intellectual property produced from the collaboration including milestone payments and royalties that may accrue as a consequence of producing a successful vaccine therapy.

### **Research programs**

*Alzheimer's disease.* Research is ongoing to increase our understanding of the neuropathology of Alzheimer's disease. In the next 12 months, our research will focus on the structure and function of  $\beta$ -amyloid and its precursor, and protein structural studies specifically around the sites of interaction between metals, metal complexes and our MPACs and the significant proteins in Alzheimer's disease such as APP and  $\beta$ -amyloid. Phase I clinical trials are planned for 2005 in order to advance PBT-2 toward commercialization. Leading clinical institutes in both the United States and Europe are investigating the possibility of clinical trials with PBT-1. Prana is investigating the possibility of partnering with these institutes to optimize the clinical trials they are planning. The possibility of partnering with these institutions or leading the development of PBT-1 through these institutes is under investigation. We can give no assurance that trials will be initiated with either PBT-1 or PBT-2, or if initiated that they will be completed or prove to be successful.

The research and development projects under our licensing and research collaboration with Schering A.G. and Neurosciences Victoria Ltd. will concentrate on the development of a new Alzheimer's diagnostic. We are seeking to develop the first highly reliable diagnostic for Alzheimer's disease using brain imaging of specific compounds as markers to measure the debilitating amyloid deposits. See Item 4A. "Information on the Company - History and Development of the Company."

*Creutzfeldt-Jakob disease.* In early 2001, the scientific journal *Biochemistry* published research results by our sponsored scientist, Dr. Roberto Cappai, and his colleagues confirming the role of metals in the aggregation and neurotoxicity of the abnormal form of the prion protein (PrP), believed to be responsible for the transmissible spongiform encephalopathies.

*Age-Related Cataracts.* Basic research in this area is continuing with ongoing studies. Data to date indicate that some age-related cataracts contain the same protein aggregation as that seen in Alzheimer's disease. At present Prana is not undertaking active research in this area, although through the close ties with Professor Masters and the University of Melbourne Prana retains the ability and opportunity to investigate the usefulness of its MPAC portfolio in treating and/or preventing Age Related Cataracts, if and when additional evidence arises to prioritise this opportunity. We can give no assurance that such research will continue or if continuing will be successful.

*Motor Neuron disease/Amyotrophic Lateral Sclerosis.* Collaborative studies with other internationally recognized research groups are progressing, and preliminary animal experiments are in progress to identify the role of SOD<sub>1</sub> (superoxide dismutase) aggregation in Motor Neuron disease. The mechanisms underlying this disease have not been fully elucidated, but the oxidative changes associated with the aggregation of critical proteins in the spinal cord and brain stem continue to be at the center of a world-wide research effort. A drug target is expected to emerge in the near future.

*Parkinson's disease.* Our Melbourne research team is working on the key protein (alpha-synuclein) that aggregates to form the diagnostic marker of this disease. We believe that the aggregated form of this protein is susceptible to the same therapeutic strategy that is being used for Alzheimer's disease, and laboratory tests are in progress to confirm this approach. Experimental animal models are developed and are being integrated into the rationale drug design screening regime. Further targets for drug development are expected to be available within the next 12 months. The molecules already developed as part of the Alzheimer's disease program are being used to clarify the rationale drug development strategy required to optimize molecules for Parkinson's disease. This testing is expected to continue through 2005.

### **C. ORGANIZATIONAL STRUCTURE**

In August 2004, we established two wholly owned subsidiaries, Prana Biotechnology Inc., incorporated in the United States, and Prana Biotechnology UK plc, incorporated in the United Kingdom. Prana Biotechnology Inc. was established in the United States due to the increase in our U.S. operations, including the appointment of Mr. Jonas Alsenas, a U.S.-based director, as our Chief Executive Officer, and the increase in U.S. investors in our company. Prana Biotechnology UK plc was established in the United Kingdom to allow us to conduct commercial and clinical operations in the United Kingdom.

## **D. PROPERTY, PLANTS AND EQUIPMENT**

We own computer equipment, office furniture and lab equipment, the major item being a mass spectrometer that is being used at the University of Melbourne. We are party to a three year property lease signed in May 2004 that provides executive office space at 369 Royal Parade, Parkville, Victoria 3052, Australia, at an annual rental of A\$105,551, which is increased by 3.5% on a cumulative basis on the May anniversary of the lease.

## **ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

### **A. OPERATING RESULTS**

You should read the following discussion and analysis in conjunction with Item 3A., “Key Information - Selected Financial Data”, as well as our financial statements and related notes which appear elsewhere in this annual report.

All of our revenues are generated in Australian dollars and the majority of our expenses are incurred in Australian dollars.

#### **Overview**

We are a development stage enterprise at an early stage in the development of our pharmaceutical products that are designed to treat the underlying causes of degeneration of the brain and the eye as aging progresses. We have incurred net losses since inception and expect to incur substantial and increasing losses for the next several years as we expand our research and development activities and move our product candidates into later stages of development. All of our product candidates are in early stages of development and we face the risks of failure inherent in developing drugs based on new technologies. The process of carrying out the development of our products to later stages of development may require significant additional research and development expenditures, including pre-clinical testing and clinical trials, as well as for obtaining regulatory approval. To date, we have funded our operations primarily through the sale of equity securities, proceeds from the exercise of options, government grants and interest income.

#### **Recently Issued But Not Yet Adopted Accounting Pronouncements Applicable to Us**

##### **Australian Pronouncements**

The revised Australian Accounting Standard AASB 1020, “Income Taxes,” is applicable to financial years ended on or after December 31, 2005 (fiscal year 2006 for our company). The key implication of this revised standard is that for our intangible assets that have previously been revalued upwards, we will recognize the equivalent deferred tax liability. When these assets are subsequently depreciated, the additional depreciation will be tax effected and will result in an increased profit after tax compared to the existing standard. We have not yet completed an assessment of the impact of this revised standard on our results of operations or financial position.

On July 3, 2002, the Australian Financial Reporting Council announced that Australia would adopt International Financial Reporting Standards, or IFRS, for financial years beginning on or after January 1, 2005 (fiscal year 2006 for our company). Our management is assessing

the significance of these changes and preparing for their implementation. We are of the opinion that the key differences in our accounting policies which will arise from the adoption of IFRS are:

- Our policy is to expense the value of shares issued in lieu of payment for goods or services by valuing them at their cost under the respective contract; however, under IFRS we will be required to expense the cost of such shares based on the fair value (i.e., market price) of the shares. Additionally, under IFRS we will be required to expense the cost of share options issued based on the fair value of the options at the grant date. Currently, we do not recognize compensation cost for option grants.
- We currently have intangible assets which were revalued upward by A\$14.7 million in 1999, which are being amortized over their useful life of up to 15 years. For the revaluation increment to continue to be recognized under IFRS there must be an active market in which the intangible can be traded. The intangible assets must also be the result of contractual or legal rights or separable from the business. It is anticipated that the intangible assets will not be able to be separately identified and that there will be no active market in which to value the intangible assets. As a result, the revaluation increment may be derecognized from the statement of financial position and the amortization previously taken up may be reversed.

### **United States Pronouncements**

In January 2003, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities--an Interpretation of ARB No. 51," or FIN 46. FIN 46 is applicable immediately for Variable Interest Entities, or VIEs, created after January 31, 2003 and is effective for us on July 1, 2003 for VIEs created prior to February 1, 2003. FIN 46 addresses consolidation by business enterprises of VIEs that either: (1) do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support or (2) the equity investors lack an essential characteristic of a controlling financial interest. In December 2003, the FASB published a revision to FIN 46, or FIN 46R, to clarify some of the provisions of FIN 46 and to defer the effective date of implementation for certain entities. Under the guidance of FIN 46R, public companies that have interests in VIEs that are commonly referred to as special purpose entities are required to apply the provisions of FIN 46R for periods ending after December 15, 2003. A public company that does not have any interests in special purpose entities but does have a variable interest in a VIE created before February 1, 2003 must apply the provisions of FIN 46R by the end of the first reporting period ending after March 14, 2004. The adoption of FIN 46 and FIN 46R during the year ended June 30, 2004 did not have a material impact on our financial condition or results of operations.

### **Differences Between Australian Accounting Standards and U.S. Accounting Standards**

We prepare our financial statements in accordance with A-GAAP, which differ in certain significant respects from U.S. GAAP. The following table sets forth a comparison of our net loss and total equity in accordance with A-GAAP and U.S. GAAP as of the dates and for the periods indicated:

	<u>As of and for the years ended June 30,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Net loss in accordance with:			
A-GAAP.....	(9,885,614)	(4,584,838)	(5,448,467)
U.S. GAAP .....	(9,208,199)	(3,244,397)	(4,728,019)
Total equity in accordance with:			
A-GAAP.....	38,702,559	15,823,703	16,668,986
U.S. GAAP .....	31,484,956	7,378,083	6,715,803

See Note 25 to our financial statements for a description of the differences between A-GAAP and U.S. GAAP as they relate to us, and a reconciliation of net loss and total equity for the dates and periods indicated therein. Differences between A-GAAP and U.S. GAAP that have a material effect on net loss and total equity relate to share-based compensation and intangible assets.

### **Critical Accounting Policies**

We prepare our financial statements in accordance with A-GAAP. As such, we are required to make certain estimates, judgments, and assumptions that management believes are reasonable based upon the information available. These estimates, judgments and assumptions affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the periods presented. The significant accounting policies listed in Note 1 of the financial statements that management believes are the most critical to aid in fully understanding and evaluating our financial condition and results of operations under A-GAAP are discussed below.

*Recoverable amount of non-current assets.* Each reporting period, our Board of Directors assesses the recoverable amount of all non-current assets. Where the carrying amount of a non-current asset is greater than its recoverable amount, the asset is revalued down to its recoverable amount. The recoverable amount is estimated based on expected net cash flows discounted to their present values using a market-determined, risk-adjusted discounted rate.

*Intangible assets and patents, research and development expense.* Until December 1999, costs associated with the acquisition and development of our core intellectual property were capitalized as intangible assets. After considering an independent valuation of our core intellectual property at December 1999, our Board of Directors revalued the assets upwards by A\$14,661,942 to A\$16,500,000. The revaluation was recorded in the asset revaluation reserve in equity. Subsequent to the revaluation, all costs associated with the acquisition and development of core intellectual property are charged to patents, research and development expense. On July 1, 2000 our Board of Directors deemed the revalued carrying amount of core intellectual property to be cost for financial reporting purposes.

Our core intellectual property is being amortized on a straight-line basis over a period of 15 years, the period in which the future benefits are expected to arise.

*Revenue recognition.* We recognize revenue to the extent that it is probable that the economic benefits will flow to us and the revenue can be reliably measured.

- Interest income is recognized as earned and collectibility is reasonably assured.
- Government grants are recorded as income when key milestones set within each agreement are achieved and accepted by all parties to the grant. The agreements provide for payments at different phases based on product development. Milestones are based on the phases of each product development, for example phase 1, phase 2 and phase 3. Revenue is not recognized prior to acceptance that the milestones have been achieved, as collectibility is not assured until this point is reached. Once each milestone is reached and approved, the grantor is obligated to pay and there are no further significant obligations as to that part of the milestone. Grant income for achievement of such milestones is agreed between the parties in legally binding contracts. Revenue for each milestone achieved is fixed up front. The START grant is expected to complete advance toxicology in December 2004, commence Phase 1 clinical trials in March 2005 and conclude Phase 1 trials in August 2005. The BIF grant is expected to confirm proof of principle in January 2005.
- Reimbursements of expenses are recognized as revenue when the reimbursement is received and the related expenses have been incurred.
- Corporate partner revenues are comprised of amounts received for certain research and development activities under our collaboration with Schering A.G. and Neurosciences Victoria Ltd. Revenues are recognized as earned on a straight line basis over the lives of the respective agreements that we entered into with Neurosciences Victoria Ltd. in connection with the collaboration. The straight line basis is considered appropriate as such agreements do not contain clearly defined milestones. Such agreements are performed on a “best efforts” basis with no guarantee of either technological or commercial success.

### **Significant Costs and Expenses**

*Depreciation and amortization expense.* Depreciation of equipment is provided on a straight-line basis over the estimated useful lives of three to 14 years. Amortization of our core intellectual property is provided on a straight-line basis over the estimated useful lives of 15 years. See Notes 1(c) and 1(d) to the financial statements.

*Patents, research and development expenses.* Our patents, research and development expenses consist primarily of compensation and related costs for research and development personnel, expenses for testing facilities and payments under our research agreements. Such costs are charged to operations as incurred. Patents, research and development expenses also include costs associated with the acquisition and development of patents, which have been expensed subsequent to December 1999. See Note 1(d) to the financial statements.

*Legal expenses.* Our legal expenses consist of fees paid to our outside counsel for various legal matters dealt with in the ordinary course of business as well as legal fees associated with patent applications and for the defense of patents.

*Consulting fee expenses.* Our consulting fee expenses consist primarily of directors fees and other consultancy fees paid to members of our Scientific Advisory Board.

*Employee benefits expenses.* Employee benefit expenses consist primarily of payments to employees for their services as employees.

*Corporate compliance expenses.* Corporate compliance expenses consist primarily of costs incurred by us to satisfy the requirements under Australian and U.S. listing and accounting standards. Costs include items such as share register fees, listing fees, audit fees and accounting and administration attributed to corporate compliance.

*Other expenses from ordinary activities.* Other expenses from ordinary activities consist primarily of foreign exchange gains / losses, accounting and administrative services, travel, insurance, marketing and overhead expenses.

## **Results of Operations**

### **Year ended June 30, 2004 compared to year ended June 30, 2003**

#### *Revenues from ordinary activities*

Revenues from ordinary activities increased to A\$2,321,227 for the year ended June 30, 2004 from A\$1,816,478 for the year ended June 30, 2003, an increase of A\$504,749, or 27.8%. Revenues in the year ended June 30, 2004 consisted of A\$211,327 interest income, A\$647,400 government grant income, and A\$1,462,500 received under the licensing and research collaboration we entered into with Schering A.G. and Neurosciences Victoria Ltd. in March 2003. Revenues in the year ended June 30, 2003 consisted of A\$111,686 interest income, A\$967,000 government grant income, A\$231,304 reimbursements attributable to an agreement with the Bank of New York (under which 50% of the costs associated with the NASDAQ listing were reimbursed) and A\$506,250 under our licensing and research collaboration with Schering A.G. and Neurosciences Victoria Ltd. The increase in revenues is attributable to our collaboration with Schering A.G. and Neurosciences Victoria Ltd. which was in force during the entire 2004 fiscal year, as well as the increase in interest income arising primarily from the funds we received in June 2004 in connection with our US\$20 million private placement. We estimate that our revenues in the 2005 fiscal year will consist of A\$260,000 interest income, A\$920,660 government grant income and A\$843,750 under our collaboration with Schering A.G. and Neurosciences Victoria Ltd. Initially, we entered into three agreements in connection with our collaboration with Schering A.G. and Neurosciences Victoria Ltd, one of which expired in fiscal year 2004. We are currently renegotiating the remaining two agreements. We expect that our revenues under the agreements being renegotiated in connection with such collaboration will be substantially the same as if the existing two agreements continued in full force and effect, however the new agreements could result in a different level of revenues in fiscal year 2005 than estimated.

#### *Depreciation and amortization expenses*

Depreciation and amortization expenses remained substantially consistent at A\$1,195,006 for the year ended June 30, 2004 compared to A\$1,185,973 for the year ended June 30, 2003.

### *Patents, research and development expenses*

Patents, research and development expenses increased to A\$5,232,581 for the year ended June 30, 2004 from A\$1,861,295 for the year ended June 30, 2003, an increase of A\$3,371,286, or 181.1%. The increase in expenses is attributable to expenses of A\$1,873,125 incurred in connection with the licensing and research collaboration we entered into with Schering A.G. and Neurosciences Victoria Ltd. and pre-clinical trial fees of A\$1,984,181 in connection with the new government START grant that commenced in September 2003. See Item 5C. "Operating and Financial Review and Prospects – Research and Development, Patents and Licenses". We expect that our patents, research and development expenses will increase in the 2005 fiscal year to approximately A\$17,000,000, primarily due to an increase in research expenses for clinical development as PBT-1 may advance into Phase II and III trials and PBT-2 is expected to begin Phase I clinical trials.

### *Legal expenses*

Legal expenses increased to A\$1,650,467 for the year ended June 30, 2004 from A\$848,660 for the year ended June 30, 2003, an increase of A\$801,807, or 94.5%. The increase in legal expenses was primarily due to the settlement of the dispute with P.N. Gerolymatos S.A for which a provision of A\$971,764 was made in the 2004 fiscal year.

### *Employee benefits expense*

Employee benefits expenses increased to A\$1,060,730 for the year ended June 30, 2004 from A\$760,980 for the year ended June 30, 2003, an increase of A\$299,750, or 39.4%. The increase in employee benefits expenses was primarily due to an increase in staff from six persons to 12 persons. The increase in staff in fiscal 2004 was due to the increase of research and development for our new lead product candidate PBT-2 during such period, in addition to our earlier product PBT-1, and our move towards commercialization.

### *Consulting fee expenses*

Consulting fee expenses increased to A\$1,706,809 for the year ended June 30, 2004 from A\$567,730 for the year ended June 30, 2003, an increase of A\$1,139,079, or 200.6%. The increase in consulting fee expenses was primarily due to a A\$777,721 increase in fees paid (in cash, shares and options) to Professor Ashley Bush under his new contract (see Item 5B. "Operating and Financial Review and Prospects – Liquidity and Capital Resources") as well as an increase in directors' fees. In the 2003 fiscal year we engaged the outside expertise of Mercer Human Resources to determine the appropriate level of compensation for directors. This resulted in an increase in directors' fees of A\$467,746 (consisting of part cash and 249,999 ordinary shares valued at A\$120,000) during the year ended June 30, 2004 to bring the directors fees into line with industry standards. These increases are partially offset by a A\$106,388 decrease in consulting fees paid to other various consultants in the year ended June 30, 2004, primarily due to a decrease in the activities of our scientific advisory board and scientific commercial optimization group, the latter of which was disbanded in 2003 because it was not providing our company the advice it required, and in the 2003 fiscal year we received services from a number of one-off consultants that were longer required in fiscal 2004.

### *Corporate compliance expenses*

Corporate compliance expenses remained substantially consistent at A\$419,708 for the year ended June 30, 2004 compared to A\$395,604 for the year ended June 30, 2003.

### *Other expenses from ordinary activities*

Other expenses from ordinary activities increased to A\$941,540 for the year ended June 30, 2004 from A\$781,074 for the year ended June 30, 2003, an increase of A\$160,466, or 20.5%. The increase in expenses from ordinary activities is primarily due to an increase in foreign exchange loss because the funds that we received in connection with our June 2004 private placement in the United States are being held in U.S. dollars.

## **Year ended June 30, 2003 compared to year ended June 30, 2002**

### *Revenues from ordinary activities*

Revenues from ordinary activities increased to A\$1,816,478 for the year ended June 30, 2003 from A\$793,970 for the year ended June 30, 2002, an increase of A\$1,022,508, or 128.8%. Revenues in the in year ended June 30, 2003 consisted of A\$945,250 government research grants, A\$111,686 interest income, A\$253,054 reimbursements attributable to an agreement with the Bank of New York (whereby 50% of the costs associated with the NASDAQ listing were reimbursed) and A\$506,250 received under the licensing and research collaboration we entered into with Schering A.G. and Neurosciences Victoria Ltd. in March 2003. Revenues in year ended June 30, 2002 consisted of A\$567,250 from government research grants and A\$226,720 of interest income.

### *Depreciation and amortization expenses*

Depreciation and amortization expenses increased to A\$1,185,973 for the year ended June 30, 2003 from A\$1,160,595 for the year ended June 30, 2002, an increase of A\$25,378 or 2.2%. The increase in expenses is attributable to the depreciation of the equipment purchased during the year ended June 30, 2003.

### *Patents, research and development expenses*

Patents, research and development expenses decreased to A\$1,861,295 for the year ended June 30, 2003 from A\$2,498,486 for the year ended June 30, 2002, a decrease of A\$637,191, or 26%. The decrease in expenses is attributable to a reduction in our expenditure on phase II human clinical trials of PBT-1 (which concluded in early 2002) and a reduction in the amounts paid to certain of our research partners (including the effect of the appreciating of the Australian dollar on certain of these payments which are contracted in U.S. dollars), as well as the acquisition of additional patents that were charged to expense.

### *Legal expenses*

Legal expenses decreased to A\$848,660 for the year ended June 30, 2003 from A\$923,816 for the year ended June 30, 2002, a decrease of A\$75,156, or 9%. The decrease in

legal expenses was primarily due to a reduction in legal costs associated with patent litigation and in prosecuting patent claims.

#### *Employee benefits expense*

Employee benefits expenses increased to A\$760,980 for the year ended June 30, 2003 from A\$378,853 for the year ended June 30, 2002, an increase of A\$382,127, or 101%. The increase in employee benefits expenses was primarily due to an increase in key employees from four employees as at June 30, 2002 to six employees as at June 30, 2003.

#### *Consulting fee expenses*

Consulting fee expenses decreased to A\$567,730 for the year ended June 30, 2003 from A\$604,873 for the year ended June 30, 2002, a decrease of A\$37,143, or 6%. The decrease in consulting fee expenses was primarily due to an increase in employees, reducing the cost of outside consultants.

#### *Corporate compliance expenses*

Corporate compliance expenses increased to A\$395,604 for the year ended June 30, 2003 from A\$339,383 for the year ended June 30, 2002, an increase of A\$56,221, or 16.6%. The increase in corporate compliance expenses is primarily attributable to the costs related to our listing on the NASDAQ SmallCap Market in September 2002.

#### *Other expenses from ordinary activities*

Other expenses from ordinary activities increased to A\$ 781,074 for the year ended June 30, 2003 from A\$336,431 for the year ended June 30, 2002, an increase of A\$444,643, or 132%. The increase in expenses from ordinary activities is primarily due to the increase in operations, which resulted in increases in rental expense, office overhead costs, marketing expenses (primarily in the United States) and overseas travel expense. Much of this additional expenditure was due to our increasing discussions with potential corporate partners and our listing on the NASDAQ SmallCap Market.

### **Inflation and Seasonality**

Management believes inflation has not had a material impact on our company's operations or financial condition and that our operations are not currently subject to seasonal influences.

### **B. LIQUIDITY AND CAPITAL RESOURCES**

We are a development stage company and have had no sales income to date, and as of June 30, 2004 are accumulated deficit totaled \$25,464,876. From inception until our initial public offering in March 2000 we financed our operations primarily through borrowings from two of our directors, which were repaid from the proceeds of such offering. Since our initial public offering we have financed our operations primarily through sales of equity securities,

proceeds from the exercise of options, government grants, licensing and research collaborations and interest earned on investments.

In March 2003, we completed the conversion of our 7,289,310 outstanding listed options into ordinary shares. As a result of the conversion, we received A\$3.5 million in net proceeds, which funds were added to our working capital.

In September 2003, we raised an additional A\$4.7 million, net of issuance costs, through a private placement of 7.1 million ordinary shares to institutional and accredited investors at a subscription price of A\$0.70 per share.

In April 2004, we raised US\$20 million before issuance costs (A\$26.4 million net of issuance costs) in a private placement in the United States, which was held in escrow pending receipt of the requisite approval of the transaction by our shareholders that was obtained on June 1, 2004. The private placement was for 4,000,000 ADRs to institutional and professional investors at a price of US\$5.00 per ADR. The private placement also involved the acquisition by the investors of five-year warrants to purchase an additional 3,000,000 ADRs at an exercise price of US\$8.00 per ADR. Should these warrants be exercised in full, we would raise an additional US\$24 million.

Cash and cash equivalents totaled A\$29,580,398 at June 30, 2004, compared to A\$3,463,783 at June 30, 2003.

Net cash used in operating activities was A\$5,347,420, A\$3,590,613 and A\$3,799,515 during the years ended June 30, 2004, 2003 and 2002, respectively. Our payments to suppliers and employees during the years ended June 30, 2004, 2003 and 2002 were A\$7,896,711, A\$5,293,087 and A\$4,885,444, respectively. The increase in payments from the year ended June 30, 2003 to the year ended June 30, 2004 consisted primarily of the increase in directors' fees, costs associated with the preclinical trials, expenses associated with our collaboration with Schering A.G and Neurosciences Victoria Ltd. and the increase of costs associated with Professor Ashley Bush's new consultancy agreement. During the years ended June 30, 2004, 2003 and 2002, our payments to suppliers and employees were offset by government grants of A\$909,946, A\$836,335 and A\$843,714, respectively, and interest income of A\$176,845, A\$106,835 and A\$242,215, respectively. Additionally, during the years ended June 30, 2004 and 2003, our payments to suppliers and employers were further offset by A\$1,462,500 and A\$506,250, respectively, for research funding attributable to our collaboration with Schering A.G. and Neurosciences Victoria Ltd.

Net cash used in investing activities was A\$134,362 during the year ended June 30, 2004 and A\$87,929 during the year ended June 30, 2003 and A\$50,689 during the year ended June 30, 2002. The increase in the 2004 fiscal year was primarily the result of fit-out costs associated with the move to our new premises.

Net cash provided by financing activities was A\$31,781,165, A\$3,569,792 and A\$580,345 during the years ended June 30, 2004, 2003 and 2002, respectively. Cash flows from financing activities during the year ended June 30, 2004 reflected net proceeds of A\$4,675,019 from a private placement in September 2003, net proceeds of A\$26,352,147 from a private placement of

our ADRs to institutional and professional investors in the United States and net proceeds of A\$757,166 from the exercise of our publicly traded options. Additionally, during the fiscal year ended June 30, 2004 we issued ordinary shares for nil consideration at a cost of A\$3,167. Cash flows from financing activities during the years ended June 30, 2003 and 2002 reflected the exercise of options into ordinary share capital.

From inception to June 30, 2004, our capital expenditures totaled A\$506,523 consisting of computer equipment, furniture and fixtures, fit-out costs and laboratory equipment that is being used in connection with our research at the University of Melbourne. Capital expenditures for equipment are being depreciated on a straight-line basis over the estimated useful lives of three to 14 years, with a net balance at June 30, 2004 of A\$180,971. We currently do not have significant capital spending requirements, but we expect to continue to engage in capital spending consistent with anticipated growth in our operations and personnel.

As of June 30, 2004, our principal commitments consisted of obligations under our agreements with Neurosciences Victoria Ltd. (in connection with our collaboration with Neurosciences Victoria Ltd. and Schering A.G.) and Professor Ashley Bush. In accordance with the terms of our current project agreements with Neurosciences Victoria Ltd. in connection with such collaboration, we are obliged to spend A\$759,375 on research and development activities at the University of Melbourne during the nine months ending March 31, 2005, however we are currently renegotiating our contracts with Neurosciences Victoria Ltd. and such amount may change. Under the ten year contract we recently entered into with Professor Ashley Bush, we agreed to pay Professor Bush a consulting fee of US\$100,000 per year, to issue to Professor Bush 1,650,000 ordinary shares, of which 825,000 were issued during the 2004 fiscal year, and to grant Professor Bush options to purchase 824,000 ordinary shares at an exercise price \$0.50 per share, of which options to purchase 412,000 ordinary shares were granted during the 2004 fiscal year. We also have a commitment under a three year lease for our new principal office that we moved to in June 2004. The total lease commitment over the three year period is A\$306,781.

Under our agreement with Kendle, a director-related company, we are required to pay A\$1,280-A\$1,520 per day for their services in connection with the commercialization of our technology. In fiscal year 2004, we paid Aroma Science, a director-related company, on arms length commercial rates, for computer, administration and meeting facilities. This agreement ended following our move to our new premises. We also pay Malvern Administrative Services Pty Ltd. A\$15,000 per month under an ongoing agreement for administrative, accounting, company secretarial services and corporate advice.

We believe our existing cash and cash equivalents as well as anticipated cash flow from government grants, a licensing and research collaboration agreement and potential option exercises will be sufficient to support our current operating plan to December 31, 2005; however, we have based this estimate on assumptions that may prove to be incorrect. Our future funding requirements will depend on many factors, including, but not limited to:

- costs and timing of obtaining regulatory approvals;
- the costs and timing of obtaining, enforcing and defending our patent and intellectual property;

- the progress and success of pre-clinical and clinical trials of our product candidates; and
- the progress and number of our research programs in development.

### **Conditions in Australia**

We are incorporated under the laws of, and our principal offices and research and development facilities are located in, the Commonwealth of Australia. Therefore, we are directly affected by political and economic conditions in Australia.

### **C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES**

Our primary activity since incorporation in 1997 has been the acquisition and development of patents as well as research and development of our core technology. Research and development expenses amounted to A\$5,232,581, A\$1,717,770 and A\$1,827,536 during the years ended June 30, 2004, 2003 and 2002, respectively. In addition to these expenses, A\$143,525 and A\$670,950 was spent in relation to patent costs during the years ended June 30, 2003 and 2002, respectively. We did not incur any patent costs during the year ended June 30, 2004.

Our patents, research and development expenses consist primarily of compensation and related costs for research and development personnel, expenses for testing facilities and payments under our research agreements. Such costs are charged to operations as incurred. Research and development expenses also include costs associated with the acquisition and development of patents subsequent to December 1999. See Note 1(d) to the financial statements.

In March 2003, we announced our first major licensing and research collaboration with Schering A.G., a major international pharmaceutical company, and Neurosciences Victoria Ltd.. Under such collaboration, Schering A.G. is providing to us funding of up to A\$2.7 million over the life of specified research and development projects that we will conduct, with additional milestone payments and royalties from discoveries. See Item 4A., “Information on the Company - History and Development of the Company.”

We have also identified and provisionally patented a novel target for an Alzheimer’s vaccine. We are collaborating with Prima Biomed Ltd., a publicly traded Australian biotech company, and use the resources of the Austin Research institute, the University of Melbourne and the Mental Health Research Institute to pursue this therapeutic approach. The research is investigating the feasibility of developing a vaccine to prevent the onset or progression of Alzheimer’s. The research is assessing the ability of the immune system to selectively produce specific antibodies which target the “toxic linked” forms of beta amyloid (not ‘normal’ beta amyloid) associated with the pathology of the disease, as an effective Alzheimer’s treatment. The Commonwealth of Australia government has provided a A\$227,252 BIF grant for this work.

We announced on July 26, 2001 that we were granted a START grant from the Australian IR&D Board in the amount of A\$1.74 million to expand our core intellectual property for drug treatment of neuro-degenerative diseases. Under the terms of the grant we received A\$1.7 million during the three year period commencing January 1, 2001, for up to 50% of the project

costs related to our development of a treatment for Alzheimer's disease. The grant was payable on the achievement of each of six milestones and we received the final payment under the START grant in October 2003.

On May 7, 1999, we entered into a patent assignment and license agreement with the University of Melbourne. The agreement provided for the assignment of various patents and patent rights to us. In consideration of the assignment of the patents, we were required to make certain payments to the University of Melbourne and to pay a royalty of 1.5% on the net price of products sold utilizing such patents. In addition we must also pay the lesser of 1.5% of the net invoice price of products sold or 10% of royalties received from any license or sub-licensee we appoint to utilize the patents.

Under the terms of a research funding and intellectual property assignment agreement dated December 1, 2000 between us and the University of Melbourne, we are required to pay the University for research projects an agreed minimum of A\$297,000 (inclusive of goods and services tax), each year for a period of three years from December 1, 2000. Since the natural expiration of such agreement, the parties have continued to conduct research and perform all other acts and obligations in accordance with the terms and conditions of the agreement as if it had remained in full force and effect, and in addition have incorporated into such agreement the projects under the agreements we entered into with Neurosciences Victoria Ltd. in March 2003 (see Item 4A. "Information on the Company – History and Development of the Company"). We are currently negotiating the renewal of our research funding and intellectual property assignment agreement with the University of Melbourne (see Item 10C. "Additional Information – Material Contracts"). Although we have every intention of continuing our relationship with the University of Melbourne and Mental Health Research Institute of Victoria to support our drug screening program, we cannot give any assurance that this can be or will be undertaken.

On February 8, 2000, we entered into a patent assignment agreement with The Biomolecular Research Institute, or BRI. The agreement provides for the assignment of various patent applications and patent rights from BRI to us. In consideration of the assignment of the patents, we are required to pay BRI a royalty of 1.5% on the net invoiced price of products sold utilizing such patents.

Under the terms of a license agreement between us and GHC, we were required to pay GHC a total of US\$166,590 for the 30 month period beginning January 1, 2001 and US\$182,000 for a period of 30 months from August 1, 2001 for the right to use the results of research under a license for certain patent rights. These obligations have subsequently been satisfied.

On January 1, 2001, we entered into another license agreement with GHC whereby we obtained an exclusive license with respect to certain patents and permits us to sublicense the patent rights to others. In consideration of the license we are required to pay GHC royalties of 1.5% of the net sales price of products sold utilizing patents exclusively licensed to us.

Under the terms of our strategic alliance agreement with Kendle, Kendle provides us with consultancy services in relation to the coordination, planning and management of intellectual property, research and development, planning, management and commercialization strategy. Kendle provides its services to us at a rate of A\$1,280-A\$1,520 per day. For the years ended

June 30, 2004, 2003 and 2002, fees earned by Kendle amounted to A\$379,045, A\$475,289 and A\$537,327, respectively. These fees are included in our statements of financial performance as consulting fees.

**D. TREND INFORMATION**

We are a development stage company and it is not possible for us to predict with any degree of accuracy the outcome of our research or commercialization efforts.

**E. OFF-BALANCE SHEET ARRANGEMENTS**

We are not a party to any material off-balance sheet arrangements. In addition, we have no unconsolidated special purpose financing or partnership entities that are likely to create material contingent obligations.

**F. TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS**

The following table summarizes our minimum contractual obligations and commercial commitments as of June 30, 2004 and the effect we expect them to have on our liquidity and cash flow in future periods.

Contractual Obligations	Payments due by period				
	Total	less than 1 year	1-3 years	3-5 years	more than 5 years
Operating lease obligations.....	A\$ 316,955	A\$ 108,432	A\$ 205,883	A\$ 2,640	A\$ --
Purchase obligations *.....	2,408,515	1,109,363	352,186	287,686	659,280
Total.....	A\$ 2,725,470	A\$ 1,217,795	A\$ 558,069	A\$ 290,326	A\$ 659,280

\* Includes obligations under our contract with Professor Ashley Bush and under our licensing and research collaboration with Neurosciences Victoria Ltd. and Schering A.G.

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**A. DIRECTORS AND SENIOR MANAGEMENT**

Our directors and executive officers are as follows:

Name	Age	Position
Geoffrey P. Kempler .....	49	Chairman of the Board of Directors
Jonas V. Alsenas.....	43	Chief Executive Officer and Director
Ross Thomas Murdoch.....	39	President and Chief Operating Officer
Richard Revelins .....	42	Chief Financial Officer and Secretary
Dianne Angus .....	44	Senior Vice President of Intellectual Property, Business Development and Research

Name	Age	Position
Colin L. Masters .....	57	Director
Brian D. Meltzer .....	50	Director
George W. Mihaly .....	51	Director

**Geoffrey Paul Kempler** has served as Chairman of our Board of Directors since November 1997, and between November 1997 and August 2004, served as our Chief Executive Officer. Mr. Kempler is one of the founders of our company and has been primarily responsible for the successful negotiation of our company's existing contractual relationships with Massachusetts General Hospital, the University of Melbourne and the Biomolecular Research Institute. Mr. Kempler is a qualified psychologist and the major shareholder of Aroma Science Pty Ltd., which holds the Australian distribution and marketing rights to the Aveda range of products. Mr. Kempler, who has extensive experience in investment and business development, has managed our operations to date and has been responsible for the implementation of our strategic plan and the commercialization of our technology. Mr. Kempler has a B.Sc degree in science from Monash University and Grad. Dip. App. Soc. Psych. degree from Swinburne University.

**Dr. Jonas Vytautas Alsenas** has served as a director of our company since March 2004 and was appointed as our Chief Executive Officer in August 2004. Prior to joining us, Dr. Alsenas was a leading U.S. biotechnology and pharmaceutical company analyst. Until December 2003, Dr. Alsenas served as a Managing Director (Research Analyst/Portfolio Manager) of ING Investment Management, New York, where he co-managed a hedge fund with an emphasis on investments in biotechnology. From April 1996 through June 2000, Dr. Alsenas was Principal and ultimately Managing Director as a research analyst at the investment banking firm Furman Selz, LLC and its successor ING Barings, LLC, where he provided research coverage of the biotechnology sector. Dr. Alsenas began his career in 1991 with Scheer & Company in Branford, Connecticut, where he provided strategic consulting and due diligence for biotechnology and pharmaceutical industry clients and investors, including venture capital groups and portfolio managers. Dr. Alsenas received a Doctor of Veterinary Medicine (DVM) degree from the Ohio State University and a B.A. from Northwestern University.

**Dr. Ross Thomas Murdoch** has served as Chief Operating Officer and Head of Research and Development of our company since July 2002 and was appointed President of our company in July 2004. Dr. Murdoch has almost 16 years of experience in the local and international pharmaceutical industry and has accumulated extensive experience in all the scientific, operational and commercial aspects of drug research and development. Prior to joining our company and since February 2001, Dr. Murdoch served as chief executive officer and chief scientific officer of Kinacia Pty Ltd, an Australian based pharmaceutical company. Previously and since June 1998, Dr. Murdoch was employed by Astra Merck and after its merger with Zeneca he served as global head of clinical project management for AstraZeneca. From 1990 to May 1998, Dr. Murdoch was employed by SmithKline Beecham, where he managed its Australian research program until his transfer to SmithKline Beecham in the United States in 1995, where he became a director in global project management, leading drug development in

the cardiovascular, pulmonary and metabolism therapeutic areas. Dr. Murdoch has a B.Sc degree with honors from Monash University, a PhD in Pharmacology from the University of Melbourne, a postgraduate certificate in health economics from the Monash University Business School, and is a graduate of the Australian Institute of Company Directors.

**Richard Revelins** has served as our company Secretary since February 2000 and was appointed Chief Financial Officer of our company in June 2004. Mr. Revelins is an executive director and principal of Peregrine Corporate Limited, an Australian based investment bank. Mr. Revelins has held senior positions in international merchant banks and is currently a director of a number of companies listed on the Australian Stock Exchange, including Prima Biomed Limited, IM Medical Limited, Gaming and Entertainment Group Limited, Yamarna Goldfields Limited and Cangold Inc., a company listed on the Canadian Venture Exchange. Mr. Revelins serves as our Chief Financial Officer on a part-time basis and devotes approximately one to two work days a week to such position.

**Dianne Angus** has served as Vice President of Intellectual Property and Licensing of our company since August 2002 and was promoted to Senior Vice President of Intellectual Property, Business Development and Research in July 2004. From October 1997 to June 2000, Ms. Angus was the Manager for Intellectual Property for Florigene Limited. From June 2000 to August 2002, Ms. Angus was a Director of Dianne Angus and Associates Pty Ltd. providing strategic business development and intellectual property services to the biotech sector. Ms. Angus has worked in the commercial biotechnology sector for 12 years, directing technology evaluation and acquisition and product licensing. During such time, Ms. Angus has managed large and diverse intellectual property portfolios, conducting global patent and trademark prosecution, contract rights and enforcement. Ms. Angus has also negotiated many commercial licenses, research and product development agreements ranging from major entities such as Novartis, Monsanto, Suntory, Du Pont to numerous Australian, Japanese and American research institutes. Ms. Angus has undertaken due diligence assessments on several Australian biotechnology companies for investment brokers. Ms. Angus has a Bachelor of Science (Education) and a Bachelor of Science (Honour's) degree from the University of Melbourne, a Masters degree in Biotechnology from Monash University, a Graduate Diploma in Intellectual Property Law from the University of Melbourne, a Diploma in Intellectual Property Practice from the Institute of Patent and Trade Mark Attorneys of Australia and is a registered Australian Patent and Trade Mark Attorney.

**Professor Colin Louis Masters** has served as director of our company since December 1999. Professor Masters graduated with a degree in Medicine from the University of Western Australia in 1970. Since such time, Professor Masters has held many senior scientific research positions predominantly in the area of Alzheimer's disease research and is currently a Professor and Head of the Department of Pathology at the University of Melbourne. Professor Masters is Chief of Neuropathology and Director of Research Laboratories at the Mental Health Research Institute of Victoria and Consultant in Pathology at the Royal Melbourne Hospital. Professor Masters chairs our Scientific Advisory Board and is primarily responsible for the implementation of the research strategy of our company. Professor Masters has a B.Med.Sci. degree with Honours, an M.B., B.S., M.D., F.R.C. Path (U.K.) degree and F.R.C. Path (Aust), F.A.A. degree, all from the University of Western Australia.

**Brian Derek Meltzer** has served as a director of our company since December 1999. Mr. Meltzer is a merchant banker with the international investment bank Babcock & Brown. He has 20 years experience in finance, including 12 years at AIDC Ltd where he was Director of Non-Executive Director Investment Advisory Services. He is a director of Momentum Ventures Limited, licensed by the government as an Innovation Investment Fund with venture capital investments including biotechnology. Mr. Meltzer is a non-executive director on the boards of a number of private companies. He is also a director on the boards of the Australia-Israel Chamber of Commerce and the Paraplegic and Quadriplegic Association of Victoria (Paraquad). Mr. Meltzer is also a member of our Audit Committee. Mr. Meltzer has B. Com. and MEc. degrees from the University of Auckland and Monash University, respectively.

**Dr. George William Mihaly** has served as director of our company since December 1999. Dr. Mihaly has had an extensive and successful career spanning the research and commercial facets of the pharmaceutical industry. During the period from mid. 1994 to early 2000, Dr. Mihaly was the founding Executive Chairman and Managing Director of Synermedica Pty Ltd., or Synermedica, one of Australia's leading independent consultant research organizations, or CRO, to the pharmaceutical industry. Synermedica merged with the global CRO, Kendle International Inc., in April 2000 and Dr. Mihaly continues as Managing Director of the merged entity in Australia (now called Kendle Pty Ltd.). Over the course of the last 22 years in academia and industry, Dr. Mihaly has amassed extensive experience in both the science and logistics of setting up, monitoring, managing and evaluating results from Phase I, II, III and IV clinical trials. Dr. Mihaly has B.Pharm., M.Sc. and Ph.D. degrees and is a fellow of the Australian Institute of Company Directors.

## **B. COMPENSATION**

Compensation of directors and officers is determined by our Board of Directors and reviewed by our Audit Committee.

The Audit Committee assesses the appropriateness of the nature and amount of emoluments on a periodic basis by reference to relevant employment market conditions with the overall objective of ensuring maximum shareholder benefit from the retention of a high quality board of directors and executive officers.

Remuneration for the services of Dr. J Alsenas, a director and our Chief Executive Officer, is formalized in a service agreement. See Item 6C., "Directors, Senior Management and Employees - Board Practices - Directors' Service Contract."

The following table sets forth all compensation we paid to each of our directors and with respect to all of our directors and executive officers as a group for the year ended June 30, 2004:

	Salaries, fees, commissions and bonuses	Pension, retirement and other similar benefits
Geoffrey P. Kempler .....	A\$266,818	A\$18,182
Jonas V. Alsenas .....	A\$32,365	-
Colin L. Masters .....	A\$48,333	-
Brian D. Meltzer .....	A\$90,000	-
George W. Mihaly .....	A\$118,858	347
All directors and officers as a group, then consisting of eight persons.....	A\$943,618	A\$53,381

As of June 30, 2004, our directors and executive officers as a group, then consisting of eight persons, held options to purchase an aggregate 11,187,167 of our ordinary shares, at an exercise price of A\$0.50 per share. Of such options, options to purchase 10,767,500 ordinary shares expire on December 1, 2004 and options to purchase 419,667 ordinary shares expire on June 30, 2005. Options to purchase 724,667 ordinary shares were granted to our directors and executive officers during the 2004 fiscal year, of which options to purchase 450,000 ordinary shares were exercised.

### C. BOARD PRACTICES

Our Board of Directors is elected by and accountable to our shareholders. Our Board of Directors' responsibilities are divided into operating activities, financial and capital markets activities and scientific activities. The Chairman of our Board of Directors, currently Mr. Geoffrey Kempler, is responsible for the management of the Board of Directors and its functions.

Our Board of Directors currently has five directors, of which two are non-executive directors under Australian law. The NASDAQ Stock Market currently requires us, as a foreign private issuer, to have at least two independent directors on our Board of Directors and to establish an audit committee comprised solely of independent directors. However, under a letter from NASDAQ dated August 29, 2002, NASDAQ granted us an exemption from such NASDAQ rules, which is in effect until July 31, 2005. Under NASDAQ rules promulgated pursuant to the Sarbanes-Oxley Act of 2002, by July 31, 2005 a majority of our Board of Directors must qualify as independent directors and we will be required to have at least three independent directors on our Audit Committee. Mr. Brian Meltzer is the only director that currently qualifies as an independent director under the NASDAQ Stock Market and Securities and Exchange Commission requirements.

#### Term of Directors

Directors are elected at our annual general meeting of shareholders. Under our Constitution, the term of office of our directors are staggered, such that at every annual general meeting of shareholders one-third, or the nearest whole number, of the directors, except a Managing Director, must retire from office and may offer himself/herself for re-election. No director, except a Managing Director, shall retain office for a period in excess of three years without submitting for re-election. Under Australian law, directors who have reached the age of 72 must stand for re-election annually. Our Board of Directors has the power to appoint any person to be a director, either to fill a vacancy or as an additional director (provided that the total

number of directors does not exceed the maximum allowed by law), and any director so appointed may hold office only until the next annual general meeting when he or she shall be eligible for election. Mr Kempler must retire and may stand for re-election at our 2004 annual general meeting of shareholders. Messrs. Meltzer and Mihaly must retire and may stand for re-election at our 2005 annual general meeting of shareholders. Dr. Masters must retire and may stand for re-election at our 2006 annual general meeting of shareholders. Jonas Alsenas, as Managing Director, is not subject to the rotation provisions of our Constitution but is required to be elected by the shareholders at the 2004 annual general meeting of shareholders. A Managing Director would cease to serve in such capacity if he/she ceased to be eligible to be a director of a company under the relevant provisions of the Australian Corporations Law.

### **Directors' Service Contracts**

On July 1, 2004, we entered into an employment contract with Dr. Jonas Alsenas, which was subsequently amended by a letter agreement dated September 20, 2004, effective as of the date of the original agreement, under which Dr. Alsenas agreed to serve as our Chief Executive Officer as of such date. Dr. Alsenas agreed to devote his best efforts and full business time and attention to the performance of service to our company. We agreed to provide Dr. Alsenas the following payments and benefits: (i) base annual salary of US\$200,000 per year (which may be increased at the discretion of the Board of Directors); (ii) annual bonus of US\$100,000 for the first year of employment, which will be paid upon completion of the first 15 months of employment. Thereafter the annual bonus will be based on Dr. Alsenas's success in satisfying pre-established performance targets to be mutually agreed upon, in an amount no less than US\$100,000; (iii) options to purchase 380,000 ADRs at an exercise price of US\$5.00 per ADR. The options will vest over a period of four years, in four equal installments, at the end of each of the four years following the option grant. The options will expire at the end of the eight years from the date of grant. Such option grant is subject to shareholder approval and our shareholders will be asked to approve the grant at our 2004 annual general meeting of shareholders to be held in November 2004. The options will be granted under a new share option plan that will be subject to shareholder approval at our 2004 annual general meeting of shareholders; (iv) up to 20 days vacation a year. Vacation days that are not used in any calendar year will be carried over for use in the following year to a maximum carry of two years; and (v) reimbursement of reasonable business expenses incurred in the performance of his duties. Dr. Alsenas will be entitled to participate in the employee benefits established by our company, as applicable to executives, including, without limitation, a Section 401(k) retirement plan, health, dental, life insurance and short and long term disability plans.

In the event of termination of Dr. Alsenas's employment:

- By our company without Cause (as defined in the agreement) or by Dr Alsenas with Good Reason (as defined in the agreement), Dr Alsenas's shall be entitled to: (i) a lump sum of US\$300,000 within 20 days of the termination date; (ii) business expenses that have not been reimbursed and accrued, unused vacation days; and (iii) the acceleration of the vesting of any unvested options to purchase ADRs, which may be purchased during the remainder of the exercise period for such options.

- By our company with Cause (as defined in the agreement) or by Dr. Alsenas without Good Reason (as defined in the agreement), Dr Alsenas' bonus compensation will be pro-rated if the termination occurs in the first year and he will be entitled to business expenses that have not been reimbursed and accrued, unused vacation days. He will not be able to exercise any unvested options to purchase ADRs.
- Due to death or Disability (as defined in the agreement), we shall pay Dr. Alsenas or his estate, as applicable, all accrued base salary, pro-rata bonus, business expenses that have not been reimbursed and accrued, unused vacation days (and in the case of disability, less such amounts under any disability policy maintained by our company). Dr. Alsenas or his estate, as applicable, will be entitled to exercise vested options for ADRs.

The agreement contains customary confidentiality provisions.

### **Indemnification of Directors and Officers**

Our Constitution provides that, subject to the Australian Corporations Act, every director, secretary, manager or officer of our company or any person employed by our company as auditor shall be indemnified out of our funds against all liability incurred by such person as a director or officer in defending proceedings, whether civil or criminal, in which judgment is given in the persons favor or in which the person is acquitted in connection with any application under the Australian Corporations Act in which relief is granted to the person by a Court.

Under our Constitution no director, auditor or other officer shall be liable for any acts, receipts, neglect or defaults of any other director or officer for joining in any receipt or other act for conformity or for any loss or expense that may happen to us through the inefficiency or deficiency of title to any property acquired by order of the directors or on our behalf or for the inefficiency or deficiency of any security in or upon which any of our monies shall be invested or for any loss or damage arising from bankruptcy, insolvency or tortuous act of any person with whom any monies, securities or effects shall be deposited or for any loss occasioned by any error of judgment, omission, default or oversight on the persons part or for an other loss damage or misfortune whatsoever which shall happen in relation to those things unless the same shall happen through the persons own negligence, default, breach or duty, breach of trust or dishonesty.

In addition, our Constitution provides that to the extent permitted by law, we may pay, or agree to pay, a premium in respect of a contract insuring a person who is liable or has been an officer of our company or one of our subsidiaries against a liability:

- incurred by the person in his or her capacity as an officer of our company or a subsidiary of our company provided that the liability does not arise out of a conduct involving a willful breach of duty in relation to our company or a subsidiary of our company; or
- for costs and expenses incurred by that person defending proceedings, whatever their outcome.

We have established a policy for the indemnification of our directors and officers against certain liabilities incurred as a director or officer, including costs and expenses associated in successfully defending legal proceedings.

### **Audit Committee**

Our Audit Committee, which was established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, assists our Board of Directors in overseeing the accounting and financial reporting processes of our company and audits of our financial statements, including the integrity of our financial statements, compliance with legal and regulatory requirements, our independent public accountants' qualifications and independence, the performance of our internal audit function and independent public accountants, and such other duties as may be directed by our Board of Directors. The Audit Committee is also required to assess risk management.

Our Audit Committee currently consists of one board member who satisfies the respective "independence" requirements of the Securities and Exchange Commission and NASDAQ for audit committee members. By July 31, 2005, we will be required to have at least three independent directors on our Audit Committee. See Item 6B. "Directors, Senior Management and Employees - Compensation." Our Audit Committee is currently composed of Messrs. Meltzer and Alsenas. The Audit Committee meets at least once each quarter.

### **Scientific Advisory Board**

Our Scientific Advisory Board oversees and administers our research activities. Our company's Scientific Advisory Board is comprised of a number of the leading scientists in the field of age related degenerative disorders. Professor Colin Masters is the Chairman of our Scientific Advisory Board. The current members of our Scientific Advisory Board are as follows:

*Professor Colin Louis Masters* has served as an executive director of our company since December 1999. Professor Masters graduated with a degree in Medicine from the University of Western Australia in 1970. Since such time Professor Masters has held many senior scientific research positions predominantly in the area of Alzheimer's disease research and is Professor and Head of the Department of Pathology at the University of Melbourne. Professor Masters is Chief of Neuropathology and Director of Research Laboratories at the Mental Health Research Institute of Victoria and Consultant in Pathology at the Royal Melbourne Hospital. Professor Masters chairs our Scientific Advisory Board and is primarily responsible for the implementation of the research strategy of our company. Professor Masters has a B.Med.Sci. degree with Honors, an M.B., B.S., M.D., F.R.C. Path (U.K.) degree and F.R.C. Path (Aust), F.A.A. degree, all from the University of Western Australia.

*Professor Ashley Ian Bush* is the Director of the Laboratory for Oxidation Biology within the Genetics and Aging Unit at the Massachusetts General Hospital and Associate Professor in the Department of Psychiatry of Harvard Medical School. Professor Bush is also Principal Fellow/Associate Professor, Departments of Pathology and Psychiatry, University of Melbourne. Professor Bush, born and educated in Melbourne, established his laboratory at the Massachusetts General Hospital after receiving the distinguished Harness Fellowship in 1992.

His discovery of the role of metals and oxidative stress in Neurological disorders has formed the basis of our platform technology.

**Professor Rudolph Emile Tanzi** is Professor of Neurology at the Harvard Medical School and Associate Geneticist, Neurology Services, the Director of Genetics and the Aging Unit, at the Massachusetts General Hospital. Professor Tanzi played a lead role in the discovery of genes and the mechanisms that underlie the cause of Alzheimer’s disease, particularly as they relate to the molecular genetics of this disorder. His laboratory at the Massachusetts General Hospital is one of the leaders in the field. Over the last ten years Professor Tanzi has helped guide the development of our platform technology.

**D. EMPLOYEES**

At June 30, 2004, we had 12 employees. Of such employees, five persons were employed in research and development, five persons in management and administration and two persons in operations.

At June 30, 2003, we had eight employees. Of such employees, three persons were employed in research and development, three persons in management and administration and two persons in operations.

At June 30, 2002, we had four employees including two directors. Of such employees, two persons were employed in research and development, no persons in management and administration and two persons in operations.

During the fiscal years ended June 30, 2004, 2003 and 2002, all of our employees were located in Australia.

Australian labor laws and regulations are applicable to all of our employees. The laws concern various matters, including severance pay rights at termination, retirement or death, length of work day and work week, minimum wage, overtime payments and insurance for work-related accidents.

**E. SHARE OWNERSHIP**

**Beneficial Ownership of Executive Officers and Directors**

The following table sets forth certain information as of August 16, 2004 regarding the beneficial ownership of our ordinary shares by each of our directors and executive officers and by all of our directors and executive officers as a group :

Name	Number of Ordinary Shares Beneficially Owned (1)	Percentage of Ownership (2)
Geoffrey P. Kempler .....	26,222,500(3)(4)	15.68%
Jonas V. Alsenas.....	70,000 (5)	*
Richard Revelins .....	92,808(6)(7)	*
Ross Thomas Murdoch.....	331,667	*
Dianne Angus .....	30,000	*
Colin L. Masters .....	1,101,333 (8)	*
Brian D. Meltzer.....	543,333 (9)(10)	*

George W. Mihaly .....	443,333 (11)(12)	*
All directors and executive officers as a group (eight persons).....	28,834,974	17.24%

\* Less than 1%

- (1) Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting or investment power with respect to securities. Ordinary shares relating to options currently exercisable or exercisable within 60 days of the date of this annual report are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them.
- (2) The percentages shown are based on 167,253,547 ordinary shares issued and outstanding as of August 16, 2004.
- (3) Of such shares, 30,000 ordinary shares are held directly by Mr. Kempler, 13,965,000 ordinary shares are held of record by Baywick Pty Ltd., an Australian corporation owned by Mr. Kempler, 90,000 ordinary shares are held of record by Crystal Triangle Pty Ltd., an Australian corporation owned by Mr. Kempler and 2,970,000 ordinary shares are held of record by NRB Developments Pty Ltd., an Australian corporation in which Mr. Kempler holds a 50% interest. Mr. Kempler may be deemed to be the beneficial owner of the ordinary shares held directly by Baywick Pty Ltd., Crystal Triangle Pty Ltd. and NRB Developments Pty Ltd.
- (4) Includes 9,167,500 ordinary shares issuable upon the exercise of options expiring in December 2004 (of which, options to purchase 1,000,000 ordinary shares are held by Mr. Kempler, options to purchase 6,682,500 ordinary shares are held by Baywick Pty Ltd., and options to purchase 1,485,000 ordinary shares are held by NRB Developments Pty Ltd.). All of such options have an exercise price of A\$0.50 per share.
- (5) Of such shares, 70,000 ordinary shares are held by ANZ Nominees Ltd., an Australian corporation which holds ADR's on behalf of U.S. investors.
- (6) Of such shares, 42,808 are held of record by Darontack Pty Ltd., an Australian corporation owned by Mr. Revelins.
- (7) Includes 50,000 ordinary shares issuable upon the exercise of options expiring in June 2005 that have an exercise price of A\$0.50 per share which are held by Darontack Pty Ltd., an Australian corporation owned by Mr. Revelins. These options are held under the Employee and Consultants Option Plan 2000.
- (8) Of such shares, 16,000 ordinary shares are held by Helen Masters, Dr. Masters' wife, 1,000 ordinary shares are held by Seth Masters, Dr. Masters' son, and 1,000 ordinary shares are held by Kate Masters, Dr. Masters' daughter.

- (9) Of such shares, 243,333 ordinary shares are held by Navon Pty Ltd., an Australian corporation owned by Mr. Meltzer.
- (10) Includes 300,000 ordinary shares issuable upon the exercise of options expiring in December 2004. All of such options have an exercise price of A\$0.50 per share and are held by Navon Pty Ltd, an Australian corporation owned by Mr. Meltzer.
- (11) Of such shares 4,000 ordinary shares are held by each of Kieren Mihaly and Warwick Mihaly, Dr. Mihaly's sons, and 52,000 ordinary shares are held of record by Waide Pty Ltd., an Australian corporation owned by Mr. Mihaly.
- (12) Includes 300,000 ordinary shares issuable upon the exercise of options expiring in December 2004 . All of such options have an exercise price of A\$0.50 per share.

### **Employee and Consultants Option Plan 2000**

In November 2000, we adopted our Employee and Consultants Option Plan 2000, or the Plan. The Plan is designed to reward executives, employees and consultants for their contributions to our company and to provide a method of retaining key personnel for the growth and development of our intellectual property rights. The Plan is administered by our Board of Directors, who have the power to determine procedures for the administration of the Plan, amend or modify the Plan, and resolve conclusively all questions of fact or interpretation arising in connection with the Plan. The number of ordinary shares issuable upon exercise of options granted under the Plan from time to time, that have not expired and have not been exercised, will not exceed 3,000,000. Options granted under the Plan are exercisable (irrespective of the date of grant) at any time from 12 months after the date of issue until October 31, 2004. The exercise price of options granted under the Plan is A\$0.50 per share. The options cannot be transferred and will not be quoted on the ASX.

A holder of options under the Plan will be permitted to participate in any new pro-rata issue of securities of our company, subject to the prior exercise of the options.

As of June 30, 2004, options to purchase 1,360,441 ordinary shares had been issued under the Plan, at an exercise price of A\$0.50 per share. Of such options, options to purchase 463,274 ordinary shares have been exercised and options to purchase 897,167 ordinary shares are outstanding and exercisable. 1,639,559 ordinary shares are available for future option grants under the Plan.

## **ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

### **A. MAJOR SHAREHOLDERS**

The following table sets forth certain information, as of August 16 , 2004, regarding the beneficial ownership by all shareholders known to us to own beneficially more than 5% of our ordinary shares. The voting rights of our major shareholders do not differ from the voting rights of other holders of our ordinary shares.

<u>Name</u>	<u>Number of Ordinary Shares Beneficially Owned (1)</u>	<u>Percentage of Outstanding Ordinary Shares (2)</u>
Geoffrey P. Kempler.....	26,222,500 (3)(4)	15.68%
Jagen Nominees Pty Ltd .....	20,691,000 (5)	12.37%
OrbiMed Advisers LLC .....	15,624,000(6)	9.34%

- 
- (1) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Ordinary shares relating to options currently exercisable or exercisable within 60 days of the date of this annual report are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares shown as beneficially owned by them.
- (2) The percentages shown are based on 167,253,547 ordinary shares issued and outstanding as of August 16, 2004.
- (3) Of such shares, 30,000 ordinary shares are held directly by Mr. Kempler, 13,965,000 ordinary shares are held of record by Baywick Pty Ltd., an Australian corporation owned by Mr. Kempler, 90,000 ordinary shares are held of record by Crystal Triangle Pty Ltd., an Australian corporation owned by Mr. Kempler and 2,970,000 ordinary shares are held of record by NRB Developments Pty Ltd., an Australian corporation in which Mr. Kempler holds a 50% interest. Mr. Kempler may be deemed to be the beneficial owner of the ordinary shares held directly by Baywick Pty Ltd., Crystal Triangle Pty Ltd. and NRB Developments Pty Ltd.
- (4) Includes 9,167,500 ordinary shares issuable upon the exercise of options expiring in December 2004 (of which, options to purchase 1,000,000 ordinary shares are held by Mr. Kempler, options to purchase 6,682,500 ordinary shares are held by Baywick Pty Ltd., and options to purchase 1,485,000 ordinary shares are held by NRB Developments Pty Ltd.). All of such options have an exercise price of A\$0.50 per share.
- (5) Includes 6,682,500 ordinary shares issuable upon the exercise of options expiring in December 2004. All of such options have an exercise price of A\$0.50 per share. Mr. Boris Liberman may be deemed to hold the voting and investment powers for the ordinary shares held by Jagen Nominees Pty Ltd.
- (6) Includes 6,000,000 ordinary shares, or 600,000 ADRs, issuable upon the exercise of currently exercisable five-year warrants, exercisable at an exercise price of US\$8.00 per ADR.

## **Significant Changes in the Ownership of Major Shareholders**

In June 2004, we completed a private placement of four million ADRs and five-year warrants to purchase an additional three million ADRs to institutional and professional investors, as a result of which the ownership interest of our major shareholders at such time was diluted. Fifteen of the investors, who appointed OrbiMed Advisors LLC as their nominee, acquired 8,000,000 ADRs and warrants to purchase 6,000,000 ADRs. See Item 5B. "Operating and Financial Review and Prospects - Liquidity and Capital Resources."

## **Record Holders**

As of August 16, 2004, there were 2,164 holders of record of our ordinary shares. Based on a review of the information provided to us by our transfer agent, eight record holders, holding approximately 0.40% of our ordinary shares, had registered addresses in the United States. The majority of trading by our U.S. investors is done by means of ADRs which are held by ANZ Nominees Ltd. on our share registry. As of August 16, 2004, ANZ Nominees Ltd. held 44.96% of our ordinary shares.

## **B. RELATED PARTY TRANSACTIONS**

Dr. Mihaly serves as a director of Kendle, formerly known as Synermedica Pty Ltd. Kendle provides analysis and review of the commercialization of our technology, intellectual property management and clinical trial management and monitoring. An ongoing agreement at normal commercial rates that is terminable at will exists between us and Kendle, with costs incurred on a daily basis. We paid Kendle A\$379,045 in the year ended June 30, 2004 for its services. On August 9, 2004, we received invoices from Kendle totaling A\$65,817 for services it has provided to us to date in the 2005 fiscal year.

Aroma Science, a company owned by Mr. Kempler, provided us with computer, administration and meeting facilities. We paid Aroma Science A\$81,470 for its services in the fiscal year ended June 30, 2004. These services are no longer provided as we moved to new premises in Parkville in June 2004.

See Note 21 to the financial statements.

## **C. INTERESTS OF EXPERTS AND COUNSEL**

Not applicable.

## **ITEM 8. FINANCIAL INFORMATION**

### **A. FINANCIAL STATEMENTS AND OTHER FINANCIAL INFORMATION**

See our financial statements, including the notes thereto in Item 17.

## **Legal Proceedings**

On July 28, 2004, we and The General Hospital Corporation of Massachusetts settled all outstanding litigation with P.N. Gerolymatos S.A., or P.N.G., regarding the exploitation rights to

certain patents relating to pharmaceutical compositions and uses of clioquinol or PBT-1. Pursuant to the settlement agreement, all patent oppositions in Europe and Australia will be withdrawn and the law suits then pending before the U.S. District Court for the District of Columbia and the Court of Athens in Greece have been dismissed. Under the settlement agreement, we and P.N.G. agreed to recognize the rights of each other to develop clioquinol in our respective territories. As a result of the settlement agreement, we now hold the rights to selected uses of clioquinol and pharmaceutical compositions in the United States and selected uses clioquinol in Japan, while P.N.G. holds certain patent rights on the uses of clioquinol for Europe and other territories. Under the settlement agreement, we issued 1,350,000 of our ordinary shares to P.N.G., which are being held in escrow for 12 months, and made a payment to of US\$150,000 to it. Such settlement in the total value of A\$971,764 was expensed in fiscal 2004 (see Note 9 to the financial statements). Under the settlement agreement we also agreed to pay a sales royalty to P.N.G on sales of PBT-1 in the United States and Japan and we are entitled to receive a percentage of P.N.G.'s income on sales of PBT-1 in the other territories.

We are not involved in any legal proceedings. See Note 16 to the financial statements.

### **Dividend Distribution Policy**

We have never paid cash dividends to our shareholders. We intend to retain future earnings for use in our business and do not anticipate paying cash dividends on our ordinary shares in the foreseeable future. Any future dividend policy will be determined by the Board of Directors and will be based upon conditions then existing, including our results of operations, financial condition, current and anticipated cash needs, contractual restrictions and other conditions as the Board of Directors may deem relevant.

### **B. SIGNIFICANT CHANGES**

In August 2004, we established two wholly owned subsidiaries, Prana Biotechnology Inc., incorporated in the United States, and Prana Biotechnology UK plc, in the United Kingdom. Prana Biotechnology Inc. was established in the United States due to the increase in our U.S. operations, including the appointment of Jonas Alsenas, a U.S.-based director, as our Chief Executive Officer, and the increase in U.S. investments in our company. Prana Biotechnology UK plc was established in the United Kingdom to allow us to conduct commercial and clinical operations in the United Kingdom.

Other than as disclosed above or referred to elsewhere in this annual report, there have been no further significant changes in the operation or financial condition of our company since June 30, 2004.

## **ITEM 9. THE OFFER AND LISTING**

### **A. OFFER AND LISTING DETAILS**

#### **Australian Stock Exchange**

Our ordinary shares have traded on the ASX since our initial public offering on March 29, 2000. The following table sets forth, for the periods indicated, the high and low market quotations for our ordinary shares, as quoted on the ASX.

	<u>Per Ordinary Share (A\$)</u>	
	<u>High</u>	<u>Low</u>
<u>Fiscal Year Ended June 30,</u>		
2000 (since March 29).....	1.05	0.22
2001.....	1.29	0.36
2002.....	2.60	0.50
2003.....	2.39	0.435
2004.....	1.18	0.445
 <u>Fiscal Year Ended June 30, 2003:</u>		
First Quarter .....	2.39	1.55
Second Quarter.....	2.07	1.20
Third Quarter.....	1.50	0.77
Fourth Quarter.....	0.80	0.435
 <u>Fiscal Year Ended June 30, 2004:</u>		
First Quarter .....	1.15	0.55
Second Quarter.....	0.72	0.445
Third Quarter.....	0.65	0.48
Fourth Quarter.....	1.18	0.58
 <u>Month Ended:</u>		
March 2004 .....	0.63	0.58
April 2004 .....	1.18	0.58
May 2004.....	0.95	0.64
June 2004.....	0.65	0.73
July 2004 .....	0.69	0.51
August 2004 .....	0.58	0.51

### **NASDAQ SmallCap Market**

Since September 5, 2002 our Level II ADR's have traded on the NASDAQ SmallCap Market under the symbol "PRAN." The following table sets forth, for the periods indicated, the range of high ask and low bid prices of our Level II ADR's on the NASDAQ SmallCap Market:

	<u>Per ADR (US\$)</u>	
	<u>High</u>	<u>Low</u>
<u>Fiscal Year Ended June 30,</u>		
2003 (from September 5).....	12.80	2.96
2004.....	10.50	2.95
 <u>Fiscal Year Ended June 30, 2003:</u>		
First Quarter (from September 5).....	12.80	11.00
Second Quarter.....	11.50	6.86

Third Quarter .....	8.15	4.40
Fourth Quarter.....	5.19	2.96
<u>Fiscal Year Ended June 30, 2004:</u>		
First Quarter .....	7.49	3.87
Second Quarter.....	5.65	2.95
Third Quarter.....	5.21	3.69
Fourth Quarter.....	10.50	4.43
<u>Month Ended:</u>		
March 2004 .....	5.21	3.69
April 2004 .....	10.50	4.50
May 2004.....	7.13	4.78
June 2004.....	5.00	4.43
July 2004 .....	5.19	3.60
August 2004 .....	4.41	3.55

**B. PLAN OF DISTRIBUTION**

Not applicable.

**C. MARKETS**

The principal listing of our ordinary shares and listed options to purchase ordinary shares is on the ASX. As of April 5, 2002, our ADRs were eligible to trade on the NASDAQ SmallCap OTC Bulletin Board in the United States and since September 5, 2002, our ADRs have traded on the NASDAQ SmallCap Market under the symbol "PRAN." We entered into a Deposit Agreement with the Bank of New York under which the Bank of New York, acting as depository, issues ADRs, each of which evidences an American Depositary Share, or ADS, which in turn represents ten of our ordinary shares.

**D. SELLING SHAREHOLDERS**

Not applicable.

**E. DILUTION**

Not applicable.

**F. EXPENSES OF THE ISSUE**

Not applicable.

**ITEM 10. ADDITIONAL INFORMATION**

**A. SHARE CAPITAL**

Not applicable.

**B. MEMORANDUM AND ARTICLES OF ASSOCIATION**

Incorporated by reference to our Registration Statement on Form 20-F dated August 26, 2002.

**C. MATERIAL CONTRACTS**

On May 7, 1999, we entered into an agreement for the assignment of patents and intellectual property licensing with the University of Melbourne. The agreement provides for the assignment of various patents and patent rights to our company. In consideration of the assignment of the patents, we agreed to make certain payments to the University of Melbourne and to pay a royalty of 1.5% on the net price of products sold utilizing such patents. In addition, we agreed to pay the lesser of 1.5% of the net invoice price of products sold or 10% of royalties received from any license or sub-licensee we appoint to utilize the patents.

Under the terms of a research funding and intellectual property assignment agreement dated December 1, 2000, between us and the University of Melbourne, we were required to pay the University of Melbourne for research projects an agreed minimum of A\$297,000 (inclusive of goods and services tax) each year for a period of three years from December 1, 2000. Since the natural expiration of such agreement, the parties have continued to conduct research and perform all other acts and obligations in accordance with the terms and conditions of the agreement as if it had remained in full force and effect, and in addition have incorporated into such agreement the projects under the agreements we entered into with Neurosciences Victoria Ltd. in March 2003 (see Item 4A. "Information on the Company – History and Development of the Company"). We are currently finalizing with the University of Melbourne a new research funding and intellectual property assignment agreement with an increased budget, which will be deemed to be effective on the date of expiration of the original agreement, with a three-year term expiring on December 1, 2006, and will incorporate any changes that may be made to our agreements with Neurosciences Victoria Ltd. that we are currently renegotiating.

We have paid the University of Melbourne a total of A\$3,312,043 through June 30, 2004 under our agreements dated May 7, 1999 and December 1, 2000.

On February 8, 2000, we entered into an agreement for the assignment of patents and intellectual property licensing with BRI. The agreement provides for the assignment of various

patent applications and patent rights from BRI to us. In consideration of the assignment of the patents, we are required to pay BRI a royalty of 1.5% on the net invoiced price of products sold utilizing such patents. In addition, we must also pay the lesser of 1.5% of the net invoice price of products sold or 10% of royalties received from any licensee or sub-licensee we appoint to utilize such patents, or a minimum of A\$2,000 a year. If the patent rights are assigned before a total of A\$20,000 has been paid as royalties, the difference between the royalties paid and A\$20,000 must be paid to BRI.

On January 1, 2001, we entered into a license agreement with GHC, whereby we obtained an exclusive license with respect to certain patents that permits us to sublicense the patent rights to others. The agreement also provides us with the non-exclusive right to use materials, substances and information that were used by GHC in research sponsored by us. In consideration of the license, we are required to pay GHC royalties of 1.5% of the net sales price of products sold utilizing patents exclusively licensed to us. We are also required to pay certain advance milestone payments, to be reduced from the royalties. In addition to the royalties we are obligated to pay GHC 1.5% of any and all non-royalty payments, including license fees received from our affiliates. Each party to the agreement may terminate the agreement if the other party defaults in its material obligations and does not remedy the default within sixty days after notice is given. GHC can terminate the licenses and rights granted to us under the agreement in any country in the event that after the first commercial sale in that country there will be a continuous one year period in which no products are sold.

Under the terms of our strategic alliance agreement dated 6 January 2004, with Kendle, it provides us with consultancy services in relation to the co-ordination, planning and management of intellectual property, research and development, planning, management and commercialization strategy. Kendle provides its services to us at a rate of A\$70-A\$200 per hour. For the years ended June 30, 2004, 2003 and 2002, we paid Kendle A\$379,045, A\$475,289 and A\$537,327, respectively.

In March 2003, we announced our first major licensing and research collaboration with Schering A.G., a major international pharmaceutical company, and Neurosciences Victoria Ltd. Under such collaboration, Schering A.G. is providing to us funding of up to A\$2.7 million over the life of specified research and development projects that we will conduct, with additional milestone payments and royalties from discoveries. See Item 4A. "Information on the Company - History and Development of the Company."

We entered into a consulting agreement dated January 17, 2000 with Professor Ashley Bush for the provision of research and development services relating to inventions and treatments for diseases caused by metal-mediated oxidative stress, which expired in January 2003. On January 8, 2004, we entered into a new consulting agreement with Professor Bush, under which Professor Bush agreed to provide us with consulting services for a period of ten years. In consideration of his services, we agreed to pay Professor Bush an annual consulting fee of US\$100,000, to issue to Professor Bush 1,650,000 ordinary shares, of which 825,000 ordinary shares were issued during the 2004 fiscal year, and to grant Professor Bush options to purchase 824,000 ordinary shares at an exercise price \$0.50 per share, of which options to purchase 412,000 ordinary shares were granted during the 2004 fiscal year.

On July 28, 2004, we entered into a settlement agreement with P.N. Gerolymatos S.A., or P.N.G, under which we issued 1,350,000 of our ordinary shares to P.N.G., which are being held in escrow for 12 months, and made a payment of US\$150,000 to it. Under the settlement agreement, we agreed to pay a sales royalty to P.N.G on the sales of PBT-1 in the United States and Japan, and we are entitled to receive a percentage of P.N.G.'s income on sales of PBT-1 in the other territories. See Item 8A., "Financial Information - Financial Statements and Other Financial Information - Legal Proceedings."

#### **D. EXCHANGE CONTROLS**

Australia has largely abolished exchange controls on investment transactions. The Australian dollar is freely convertible into U.S. dollars. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital, or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Cash Transaction Reports Agency, which monitors such transactions, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply.

#### **The Foreign Acquisitions and Takeovers Act 1975**

Under Australian law, foreign persons are prohibited from acquiring more than a limited percentage of the shares in an Australian company without approval from the Australian Treasurer or in certain other limited circumstances. These limitations are set forth in the Australian Foreign Acquisitions and Takeovers Act, or the Takeovers Act.

Under the Takeovers Act, as currently in effect, any foreign person, together with associates, is prohibited from acquiring 15% or more of our outstanding shares (or else the Treasurer may make an order requiring the acquirer to dispose of those shares within a specified period of time). In addition, if a foreign person acquires shares in our company and as a result the total holdings of all foreign persons and their associates exceeds 40% in aggregate without the approval of the Australian Treasurer, then the Treasurer may make an order requiring the acquirer to dispose of those shares within a specified time. Under the current Australian foreign investment policy, however, it is unlikely that the Treasurer would make such an order where the level of foreign ownership exceeds 40% in the ordinary course of trading, unless the Treasurer finds that the acquisition is contrary to the national interest. The same rule applies if the total holdings of all foreign persons and their associates already exceeds 40% and a foreign person (or its associate) acquires any further shares, including in the course of trading in the secondary market of the ADRs.

If the level of foreign ownership exceeds 40% at any time, we would be considered a foreign person under the Takeovers Act. In such event, we would be required to obtain the approval of the Treasurer for our company, together with our associates, to acquire (i) more than 15% of an Australian company or business with assets totaling over A\$5 million; or (ii) any direct or indirect ownership interest in Australian residential real estate.

The percentage of foreign ownership in our company would also be included in determining the foreign ownership of any Australian company or business in which it may choose to invest. Since we have no current plans for any such acquisitions and do not own any property, any such approvals required to be obtained by us as a foreign person under the Takeovers Act will not affect our current or future ownership or lease of property in Australia.

Our Constitution does not contain any additional limitations on a non-resident's right to hold or vote our securities.

Australian law requires the transfer of shares in our company to be made in writing. No stamp duty will be payable in Australia on the transfer of ADRs.

## **E. TAXATION**

### ***Australian Tax Consequences***

In this section we discuss the material Australian tax considerations that apply to non-Australian tax residents with respect to the acquisition, ownership and disposal by the absolute beneficial owners of ADSs, which are evidenced by ADRs. This discussion is based upon existing Australian tax law as of the date of this annual report, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian income tax law which may be important to particular investors in light of their individual investment circumstances, such as ADSs or shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any foreign or state tax considerations, other than stamp duty. Prospective investors are urged to consult their tax advisors regarding the Australian and foreign income and other tax considerations of the purchase, ownership and disposition of the ADSs or shares.

### **Nature of ADRs for Australian Taxation Purposes**

ADSs held by a U.S. holder will be treated for Australian taxation purposes as held under a 'bare trust' for such holder. Consequently, the underlying ordinary shares will be regarded as owned by the ADS holder for Australian income tax and capital gains tax purposes. Dividends paid on the underlying ordinary shares will also be treated as dividends paid to the ADS holder, as the person beneficially entitled to those dividends. Therefore, in the following analysis we discuss the tax consequences to non-Australian resident holders of ordinary shares which, for Australian taxation purposes, will be the same as to U.S. holders of ADSs.

### **Taxation of Dividends**

Australia operates a dividend imputation system under which dividends may be declared to be 'franked' to the extent of tax paid on company profits. Fully franked dividends are not subject to dividend withholding tax. Dividends payable by our company to non-Australian resident stockholders will be subject to dividend withholding tax, to the extent the dividends are unfranked. Dividend withholding tax will be imposed at 30%, unless a stockholder is a resident of a country with which Australia has a double taxation agreement. Under the provisions of the

current Double Taxation Convention between Australia and the United States, the Australian tax withheld on unfranked dividends paid by us to which a resident of the United States is beneficially entitled is generally limited to 15% if the U.S. resident holds less than 10% of the voting rights of our company, unless the shares are effectively connected to a permanent establishment or fixed base in Australia through which the stockholder carries on business or provides independent personal services, respectively. Where the U.S. resident holds 10% or more of the voting rights of our company, the withholding tax rate is reduced to 5%.

### **Tax on Sales or other Dispositions of Shares - Capital Gains Tax**

Non-Australian resident stockholders will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of our shares, unless they, together with associates, hold 10% or more of our issued capital at any time during the five years before the disposal of the shares.

If a non-Australian resident stockholder did own a 10% or more interest, that stockholder would be subject to Australian capital gains tax to the same extent as Australian resident stockholders. The Australian Taxation Office maintains the view that the Double Taxation Convention between the United States and Australia does not limit Australian capital gains tax. Australian capital gains tax applies to net capital gains at a taxpayer's marginal tax rate but for certain stockholders a discount of the capital gain may apply if the shares have been held for 12 months or more. For individuals, this discount is 50%. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains.

### **Tax on Sales or other Dispositions of Shares - Stockholders Holding Shares on Revenue Account**

Some non-Australian resident stockholders may hold shares on revenue rather than on capital account, for example, share traders. These stockholders may have the gains made on the sale or other disposal of the shares included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia.

Non-Australian resident stockholders assessable under these ordinary income provisions in respect of gains made on shares held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 29%. Some relief from the Australian income tax may be available to such non-Australian resident stockholders under the Double Taxation Convention between the United States and Australia, for example, because the stockholder does not have a permanent establishment in Australia.

To the extent an amount would be included in a non-Australian resident stockholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the stockholder would not be subject to double tax on any part of the income gain or capital gain.

### **Dual Residency**

If a stockholder were a resident of both Australia and the United States under those countries' domestic taxation laws, that stockholder may be subject to tax as an Australian resident. If, however, the stockholder is determined to be a U.S. resident for the purposes of the

Double Taxation Convention between the United States and Australia, the Australian tax would be subject to limitation by the Double Taxation Convention. Stockholders should obtain specialist taxation advice in these circumstances.

### **Stamp Duty**

Any transfer of shares through trading on the Australian Stock Exchange, whether by Australian residents or foreign residents are not subject to stamp duty within Australia.

### **Australian Death Duty**

Australia does not have estate or death duties. No capital gains tax liability is realized upon the inheritance of a deceased person's shares. The disposal of inherited shares by beneficiaries, may, however, give rise to a capital gains tax liability.

### **Goods and Services Tax**

The issue or transfer of shares will not incur Australian goods and services tax and does not require a stockholder to register for Australian goods and services tax purposes.

### ***United States Federal Income Tax Consequences***

The following is a summary of certain material U.S. federal income tax consequences that generally apply to U.S. Holders who hold ADRs as capital assets. This summary is based on the United States Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated thereunder, judicial and administrative interpretations thereof, the bilateral taxation convention between Australia and the United States, or the Tax Treaty, all as in effect on the date hereof and all of which are subject to change either prospectively or retroactively. This summary does not address all tax considerations that may be relevant with respect to an investment in ADRs. This summary does not discuss all the tax consequences that may be relevant to a U.S. Holder in light of such holder's particular circumstances or to U.S. Holders subject to special rules, including broker-dealers, financial institutions, certain insurance companies, investors liable for alternative minimum tax, tax-exempt organizations, regulated investment companies, non-resident aliens of the United States or taxpayers whose functional currency is not the U.S. dollar, persons who hold the ADRs through partnerships or other pass-through entities, persons who acquired their ADRs through the exercise or cancellation of any employee stock options or otherwise as compensation for their services, investors that actually or constructively own 10% or more of our voting shares, and investors holding ADRs as part of a straddle or appreciated financial position or as part of a hedging or conversion transaction.

This summary does not address the effect of any U.S. federal taxation other than U.S. federal income taxation. In addition, this summary does not include any discussion of state, local or foreign taxation.

You are urged to consult your tax advisors regarding the foreign and U.S. federal, state and local tax considerations of an investment in ADRs.

For purposes of this summary, the term “U.S. Holder” means an individual who is a citizen or, for U.S. federal income tax purposes, a resident of the United States, a corporation or other entity taxable as a corporation created or organized in or under the laws of the United States or any political subdivision thereof, an estate whose income is subject to U.S. federal income tax regardless of its source, or a trust if (a) a court within the United States is able to exercise primary supervision over administration of the trust, and one or more U.S. persons have the authority to control all substantial decisions of the trust or (b) it has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

### **Taxation of Dividends**

For U.S. federal income tax purposes, U.S. Holders of ADRs will be treated as owning the underlying ordinary shares, or ADSs, represented by the ADRs held by them. The gross amount of any distributions received with respect to the underlying ordinary shares represented by the ADRs, including the amount of any Australian taxes withheld there from, will constitute dividends for U.S. federal income tax purposes, to the extent of our current and accumulated earnings and profits as determined for U.S. federal income tax principles. You will be required to include this amount of dividends in gross income as ordinary income (see “Tax Law Applicable to Dividends and Long-Term Capital Gain” below). Distributions in excess of our earnings and profits will be treated as a non-taxable return of capital to the extent of your tax basis in the ADRs, and any amount in excess of your tax basis will be treated as gain from the sale of ADRs. See “Disposition of ADRs” below for the discussion on the taxation of capital gains. Dividends will not qualify for the dividends-received deduction generally available to corporations under Section 243 of the Code.

Dividends that we pay, including the amount of any Australian taxes withheld there from, will be included in your income in a U.S. dollar amount calculated by reference to the exchange rate in effect on the day such dividends are received. A U.S. Holder who receives payment in A\$ and converts A\$ into U.S. dollars at an exchange rate other than the rate in effect on such day may have a foreign currency exchange gain or loss that would be treated as ordinary income or loss. U.S. Holders should consult their own tax advisors concerning the U.S. tax consequences of acquiring, holding and disposing of our ADRs.

Any Australian withholding tax imposed on such dividends will be a foreign income tax eligible for credit against a U.S. Holder’s U.S. federal income tax liability, subject to certain limitations set out in the Code (or, alternatively, for deduction against income in determining such tax liability). The limitations set out in the Code include computational rules under which foreign tax credits allowable with respect to specific classes of income cannot exceed the U.S. federal income taxes otherwise payable with respect to each such class of income (see “Tax Law Applicable to Dividends and Long-Term Capital Gain” below). Dividends generally will be treated as foreign-source passive income or financial services income for U.S. foreign tax credit purposes. Foreign income taxes exceeding the credit limitation for the year of payment or accrual may be carried back for two taxable years and forward for five taxable years in order to reduce U.S. federal income taxes, subject to the credit limitation applicable in each of such years. Other restrictions on the foreign tax credit include a prohibition on the use of the credit to reduce liability for the U.S. individual and corporation alternative minimum taxes by more than 90%. A U.S. Holder will be denied a foreign tax credit with respect to Australian income tax withheld

from dividends received with respect to the underlying ordinary shares represented by the ADRs to the extent such U.S. Holder has not held the ADRs for at least 16 days of the 30-day period beginning on the date which is 15 days before the ex-dividend date or to the extent such U.S. Holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a U.S. Holder has substantially diminished its risk of loss on the ADRs are not counted toward meeting the 16-day holding period required by the statute. The rules relating to the determination of the foreign tax credit are complex, and you should consult with your personal tax advisors to determine whether and to what extent you would be entitled to this credit.

### **Disposition of ADRs**

If you sell or otherwise dispose of ADRs, you will recognize gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amount realized on the sale or other disposition and your adjusted tax basis in the ADRs. Subject to the discussion below under the heading “Passive Foreign Investment Companies,” such gain or loss generally will be capital gain or loss and will be long-term capital gain or loss if you have held the ADRs for more than one year at the time of the sale or other disposition. In general, any gain that you recognize on the sale or other disposition of ADRs will be U.S.-source for purposes of the foreign tax credit limitation; losses will generally be allocated against U.S. source income. Deduction of capital losses is subject to certain limitations under the Code.

In the case of a cash basis U.S. Holder who receives A\$ in connection with the sale or disposition of ADRs, the amount realized will be based on the U.S. dollar value of the A\$ received with respect to the ADRs as determined on the settlement date of such exchange. A U.S. Holder who receives payment in A\$ and converts A\$ into U.S. dollars at a conversion rate other than the rate in effect on the settlement date may have a foreign currency exchange gain or loss that would be treated as ordinary income or loss.

An accrual basis U.S. Holder may elect the same treatment required of cash basis taxpayers with respect to a sale or disposition of ADRs, provided that the election is applied consistently from year to year. Such election may not be changed without the consent of the Internal Revenue Service, or the IRS. In the event that an accrual basis U.S. Holder does not elect to be treated as a cash basis taxpayer (pursuant to the Treasury regulations applicable to foreign currency transactions), such U.S. Holder may have a foreign currency gain or loss for U.S. federal income tax purposes because of differences between the U.S. dollar value of the currency received prevailing on the trade date and the settlement date. Any such currency gain or loss would be treated as ordinary income or loss and would be in addition to gain or loss, if any, recognized by such U.S. Holder on the sale or disposition of such ADRs.

### **Tax Law Applicable to Dividends and Long-Term Capital Gain**

Dividends received by noncorporate U.S. Holders from certain foreign corporations, and long-term capital gain realized by noncorporate U.S. Holders, generally are subject to U.S. federal income tax at a reduced maximum tax rate of 15 percent through December 31, 2008. Dividends received with respect to the underlying ordinary shares represented by the ADRs should qualify for the 15 percent rate. The rate reduction does not apply to dividends received

from “foreign investment companies,” “foreign personal holding company” or “passive foreign investment companies” (see below), or in respect of certain short-term or hedged positions in the ordinary shares or in certain other situations. There are special rules for computing the foreign tax credit limitation of a taxpayer who receives dividends subject to the rate reduction. U.S. Holders of ADRs should consult their own tax advisors regarding the implications of these rules in light of their particular circumstances.

### **Passive Foreign Investment Companies**

For U.S. federal income tax purposes, we will be considered a passive foreign investment company, or PFIC, for any taxable year in which either (i) 75 percent or more of our gross income is passive income, or (ii) at least 50 percent of the average value of all of our assets for the taxable year produce or are held for the production of passive income. For this purpose, passive income includes dividends, interest, royalties, rents, annuities and the excess of gains over losses from the disposition of assets which produce passive income. If we were determined to be a PFIC for U.S. federal income tax purposes, highly complex rules would apply to U.S. Holders owning ADRs. Accordingly, you are urged to consult your tax advisors regarding the application of such rules.

Based on our current and projected income, assets and activities, we believe that we are not currently a PFIC nor do we expect to become a PFIC in the foreseeable future. However, because the determination of whether we are a PFIC is based upon the composition of our income and assets from time to time, there can be no assurances that we will not become a PFIC for any future taxable year.

If we are treated as a PFIC for any taxable year, then, unless you elect either to treat your investment in ADRs as an investment in a “qualified electing fund”, OR a “QEF election”, or to “mark-to-market” your ADRs, as described below, dividends would not qualify for the reduced maximum tax rate, discussed above, and:

- you would be required to allocate income recognized upon receiving certain dividends or gain recognized upon the disposition of ADRs ratably over the holding period for such ADRs,
- the amount allocated to each year during which we are considered a PFIC other than the year of the dividend payment or disposition would be subject to tax at the highest individual or corporate tax rate, as the case may be, in effect for that year and an interest charge would be imposed with respect to the resulting tax liability allocated to each such year,
- the amount allocated to the current taxable year and any taxable year before we became a PFIC, would be taxable as ordinary income in the current year, and
- you would be required to make an annual return on IRS Form 8621 regarding distributions received with respect to the underlying ordinary shares represented by the ADRs and any gain realized on your ADRs.

If you make either a timely QEF election or a timely mark-to-market election in respect of your ADRs, you would not be subject to the rules described above. If you make a timely QEF election, you would be required to include in your income for each taxable year your pro rata share of our ordinary earnings as ordinary income and your pro rata share of our net capital gain as long-term capital gain, whether or not such amounts are actually distributed to you. You would not be eligible to make a QEF election unless we comply with certain applicable information reporting requirements.

Alternatively, if the ADRs are considered “marketable stock” and if you elect to “mark-to-market” your ADRs, you will generally include in income any excess of the fair market value of the ADRs at the close of each tax year over your adjusted basis in the ADRs. If the fair market value of the ADRs had depreciated below your adjusted basis at the close of the tax year, you may generally deduct the excess of the adjusted basis of the ADRs over its fair market value at that time. However, such deductions generally would be limited to the net mark-to-market gains, if any, that you included in income with respect to such ADRs in prior years. Income recognized and deductions allowed under the mark-to-market provisions, as well as any gain or loss on the disposition of ADRs with respect to which the mark-to-market election is made, is treated as ordinary income or loss.

### **Backup Withholding and Information Reporting**

Payments in respect of ADRs may be subject to information reporting to the U.S. Internal Revenue Service and to U.S. backup withholding tax at a rate equal to the fourth lowest income tax rate applicable to individuals (which, under current law, is 28%). Backup withholding will not apply, however, if you (i) are a corporation or come within certain exempt categories, and demonstrate the fact when so required, or (ii) furnish a correct taxpayer identification number and make any other required certification.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a U.S. Holder’s U.S. tax liability, and a U.S. Holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS.

Any U.S. holder who holds 10% or more in vote or value of our ordinary shares will be subject to certain additional U.S. information reporting requirements.

### **U.S. Gift and Estate Tax**

An individual U.S. Holder of ADRs will be subject to U.S. gift and estate taxes with respect to ADRs in the same manner and to the same extent as with respect to other types of personal property.

### **F. DIVIDEND AND PAYING AGENTS**

Not applicable.

## **G. STATEMENT BY EXPERTS**

Not applicable.

## **H. DOCUMENTS ON DISPLAY**

We are subject to the reporting requirements of the United States Securities Exchange Act of 1934, as amended, as applicable to “foreign private issuers” as defined in Rule 3b-4 under the Exchange Act, and in accordance therewith, we are required to file annual and interim reports and other information with the Securities and Exchange Commission.

As a foreign private issuer, we are exempt from certain provisions of the Exchange Act. Accordingly, our proxy solicitations are not subject to the disclosure and procedural requirements of Regulation 14A under the Exchange Act, transactions in our equity securities by our officers and directors are exempt from reporting and the “short-swing” profit recovery provisions contained in Section 16 of the Exchange Act. We make our Securities and Exchange Commission filings electronically and they are available on the Securities and Exchange Commission’s website. We are not required under the Exchange Act to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we will distribute annually to our shareholders an annual report containing financial statements that have been examined and reported on, with an opinion expressed by, an independent public accounting firm, and we will file reports with the Securities and Exchange Commission on Form 6-K containing unaudited financial information for the first six months of each fiscal year.

This annual report and the exhibits thereto and any other document that we have to file pursuant to the Exchange Act may be inspected without charge and copied at prescribed rates at the Securities and Exchange Commission public reference room at 450 Fifth Street, N.W., Judiciary Plaza, Room 1024, Washington, D.C. 20549; and on the Securities and Exchange Commission Internet site (<http://www.sec.gov>). You may obtain information on the operation of the Securities and Exchange Commission’s public reference room in Washington, D.C. by calling the Securities and Exchange Commission at 1-800-SEC-0330 or by visiting the Securities and Exchange Commission’s website at <http://www.sec.gov>. The Exchange Act file number for our Securities and Exchange Commission filings is 000-49843.

The documents concerning our company which are referred to in this annual report may also be inspected at our offices located at Suite 2, 1233 High Street, Armadale, Victoria, Australia, 3133.

## **I. SUBSIDIARY INFORMATION**

Not applicable.

**ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISKS**

We invest our excess cash in interest-bearing accounts and time deposits with government-insured institutions. Certain of our cash equivalents are subject to interest rate risk. Due to the short duration and conservative nature of these instruments, we do not believe that we have a material exposure to interest rate risk. Our major market risk is changes in foreign exchange rates as we have approximately A\$26.7 million in time deposits held in U.S. dollars as of June 30, 2004. A hypothetical 10% adverse movement in end-of-period exchange rates would reduce the cash balance by approximately A\$2.7 million. We are currently reviewing our cash balances in order to reduce foreign currency exchange risk. We do not utilize derivative financial instruments or other financial instruments subject to market risk.

We conduct our activities almost exclusively in Australia. However, we are required to make certain payments in U.S. dollars and other currencies. A hypothetical 10% adverse movement in end-of-period exchange rates would not have a material impact on future earnings.

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

Not applicable.

**PART II**

**ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

Not applicable.

**ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS**

Not applicable

**ITEM 15. CONTROLS AND PROCEDURES**

At June 30, 2004, we carried out an evaluation, under the supervision and with the participation of our senior management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13(a)-14 of the Securities Exchange Act of 1934. Based upon that evaluation, our management, including our chief executive officer and chief financial officer, concluded that our company's disclosure controls and procedures are effective in timely alerting them to material information relating to us required to be included in the our periodic SEC filings.

There have been no significant changes in our internal controls or other factors which could significantly affect internal controls subsequent to the date of the evaluation.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

**ITEM 16. RESERVED**

**ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our Board of Directors has determined that Mr. Brian Meltzer, an independent director, meets the definition of an audit committee financial expert, as defined in Item 401(h) of Regulation S-K.

**ITEM 16B. CODE OF ETHICS**

We have adopted a code of ethics that applies to our chief executive officer and all senior financial officers of our company, including the chief financial officer, chief accounting officer or controller, or persons performing similar functions. The code of ethics is publicly available on our website at [www.pranabio.com](http://www.pranabio.com). Written copies are available upon request. If we make any substantive amendment to the code of ethics or grant any waivers, including any implicit waiver, from a provision of the codes of ethics, we will disclose the nature of such amendment or waiver on our website.

**ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

**Fees Paid to Principal Accountants**

Aggregate fees billed to us for the fiscal years ended June 30, 2004 and 2003 by our principal accounting firm, Deloitte Touche Tohmatsu, the other member firms of Deloitte Touche Tohmatsu and their respective affiliates, were as follows.

	Year Ended June 30,			
	2004		2003	
Services Rendered	Fees	Percentages	Fees	Percentages
Audit (1) .....	A\$129,522	66%	A\$126,178	80%
Audit-related (2) .....	-	-	-	-
Tax (3) .....	A\$59,580	30%	A\$23,400	15%
Other (4) .....	A\$6,900	4%	A\$7,400	5%
Total .....	A\$196,002		A\$156,978	

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.

- (2) Audit-related fees relate to assurance and associated services that traditionally are performed by the independent accountant, including: attest services that are not required by statute or regulation; accounting consultation and audits in connection with mergers, acquisitions and divestitures; employee benefit plans audits; and consultation concerning financial accounting and reporting standards.
- (3) Tax fees relate to services performed by the tax division for tax compliance, planning, and advice.
- (4) Other fees relate to services performed in respect of the audit of grants.

**Pre-Approval Policies and Procedures**

Our Audit Committee has adopted policies and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm, Deloitte Touche Tohmatsu. Pre-approval of an audit or non-audit service may be given as a general pre-approval, as part of the audit committee’s approval of the scope of the engagement of our independent registered public accounting firm, or on an individual basis. Any proposed services exceeding general pre-approved levels also requires specific pre-approval by our audit committee. The policy prohibits retention of the independent registered public accounting firm to perform the prohibited non-audit functions defined in Section 201 of the Sarbanes-Oxley Act or the rules of the Securities and Exchange Commission, and also requires the audit committee to consider whether proposed services are compatible with the independence of the registered public accounting firm.

**ITEM 16D. EXEMPTIONS FROM THE LISTING REQUIREMENTS AND STANDARDS FOR AUDIT COMMITTEE**

Not applicable.

**ITEM 16E. PURCHASE OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATES AND PURCHASERS**

**Issuer Purchase of Equity Securities**

Neither we, nor any affiliated purchaser of our company, have purchased any of our securities during the year ended June 30, 2004.

**ITEM 17. FINANCIAL STATEMENTS**

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## **ITEM 18. FINANCIAL STATEMENTS**

Our company has elected to furnish financial statements and related information specified in Item 17.

## **ITEM 19. EXHIBITS**

### Index to Exhibits

<u>Exhibit</u>	<u>Description</u>
1.1	Constitution of Registrant (1)
2.1	Deposit Agreement dated March 23, 2001, among the Registrant and the Bank of New York, as Depository, and owners and holders of American Depositary Receipts issued thereunder, including the Form of American Depositary Receipts (2)
4.1	Research Funding and Intellectual Property Assignment Agreement dated December 1, 2000, between the Registrant and the University of Melbourne(1)
4.2	Agreement for the Assignment of Patents and Intellectual Property Licensing dated May 7, 1999, between the Registrant and the University of Melbourne University of Melbourne University of Melbourne (1)
4.3	Agreement for the Assignment of Patents and Intellectual Property Licensing dated February 8, 2000, between Registrant and the Biomolecular Research Institute (1)
4.4	License Agreement dated January 1, 2001, between the Registrant and The General Hospital Corporation (1)
4.5	Variation Agreement dated August 8, 2001, between the Registrant and The General Hospital Corporation, which amends the License Agreement dated January 1, 2001, between the parties (1)
4.6	Second Amendment to Exclusive License Agreement dated January 1, 2001, between the Registrant and The General Hospital Corporation, dated March 15, 2004, between the between the Registrant and The General Hospital Corporation
4.7	Agreement for Services dated February 7, 2000, between the Registrant and Prof. Colin Masters (1)
4.8	Agreement to Provide Accounting, Administration, Corporate Advice and Company Secretarial Services dated February 23, 2000, between the Registrant and Malvern Administrative Services (1)
4.9	Form of Indemnity for Clinical Trials dated September 2000, between the Registrant and Melbourne Health (Royal Melbourne Hospital Campus), Royal Melbourne Hospital Research Foundation Incorporated, University of Melbourne, Mental Health Research Institute of Victoria (1)

- 4.10 Commitment dated November 7, 2001, between the Registrant and University of Melbourne (1)
- 4.11 Grant Deed agreement dated August 25, 2003, commencing August 1, 2003, between the Registrant and the Industry Research and Development Board on behalf of the Commonwealth of Australia
- 4.12 Grant Agreement, commencing September 1, 2003, between the Registrant and the Industry Research and Development Board on behalf of the Commonwealth of Australia
- 4.13 Letter agreement dated January 6, 2004, between the Registrant and Kendle Pty Ltd. regarding strategic alliance.
- 4.14 Project Agreement dated March 11, 2004, between the Registrant and Neurosciences Victoria Ltd.
- 4.15 Project Agreement dated March 11, 2004, between the Registrant and Neurosciences Victoria Ltd.
- 4.16 Project Agreement dated March 11, 2004, between the Registrant and Neurosciences Victoria Ltd.
- 4.17 Purchase Agreement dated April 27, 2004, among the Registrant and the investors signatory thereto (3)
- 4.18 Registration Rights Agreement dated April 27, 2004, among the Registrant and the investors signatory thereto (4)
- 4.19 Form of Warrant (5)
- 4.20 Employment Agreement dated July 1, 2004, among the Registrant and Dr. Alsenas
- 4.21 Settlement Agreement dated July 28, 2004, among the Registrant, P.N. Gerolymatos S.A, or PNG, Mr. Gerolymatos, The General Hospital Corporation of Massachusetts, or The GHC, Professor Ashley Bush, Dr. Rudolph Tanzi and Dr. Robert Cherny and the ancillary agreements of even date therewith exhibited thereto, including the Patent Assignment and Settlement Agreement among the Registrant and PNG, Patent Rights Security Agreement among the Registrant and PNG and the Derivatives Agreement among the Registrant and PNG
- 4.22 Prana Biotechnology Limited, Employees and Consultants Option Plan 2000 (1)
- 23.1 Consent of Deloitte Touche Tohmatsu, Independent Registered Public Accounting Firm.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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- (1) Incorporated by reference to our Registration Statement on Form 20-F filed with the Securities and Exchange Commission on May 28, 2002 (File No. 000-49843).
- (2) Incorporated by reference to our Registration Statement on Form F-6 filed with the Securities and Exchange Commission on March 9, 2001 (File No. 333-13264).
- (3) Incorporated by reference to Item 1 of our Report on Form 6-K for the month of April, 2004 (File No. 000-49843).
- (4) Incorporated by reference to Item 2 of our Report on Form 6-K for the month of April, 2004 (File No. 000-49843).
- (5) Incorporated by reference to Item 3 of our Report on Form 6-K for the month of April, 2004 (File No. 000-49843).

**PRANA BIOTECHNOLOGY LIMITED**  
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**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Prana Biotechnology Limited

We have audited the accompanying statements of financial position of Prana Biotechnology Limited (a development stage enterprise) (the "Company") as of 30 June 2004 and 2003, and the related statements of financial performance, stockholders' equity and cash flows for each of the three years in the period ended 30 June 2004 and for the period from 11 November 1997 (date of inception) to 30 June 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such financial statements present fairly, in all material respects, the financial position of Prana Biotechnology Limited as of 30 June 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended 30 June 2004 and for the period from 11 November 1997 (date of inception) to 30 June 2004, in conformity with accounting principles generally accepted in Australia.

Accounting principles generally accepted in Australia differ in certain significant respects from accounting principles generally accepted in the United States of America. The application of the latter would have affected the determination of net loss for each of the three years in the period ended 30 June 2004 and the determination of total equity as of 30 June 2004 and 2003, to the extent summarized in Note 25 to the financial statements.

/s/ Deloitte Touche Tohmatsu

DELOITTE TOUCHE TOHMATSU

Chartered Accountants

Melbourne, Australia

13 September, 2004 except for Notes 11(f), 17  
and 25 as to which the date is 24 September, 2004

**PRANA BIOTECHNOLOGY LIMITED**  
(A Development Stage Enterprise)

**STATEMENTS OF FINANCIAL POSITION**  
(in Australian dollars)

	Notes	<b>30 June</b>	
		<b>2004</b>	<b>2003</b>
<b>Current assets</b>			
Cash assets		29,580,398	3,463,783
Receivables	5	92,917	143,823
Other	6	72,769	52,362
<b>Total Current Assets</b>		<b>29,746,084</b>	<b>3,659,968</b>
<b>Non Current Assets</b>			
Equipment	7	180,971	141,611
Intangible assets	8	11,488,343	12,588,347
<b>Total Non Current Assets</b>		<b>11,669,314</b>	<b>12,729,958</b>
<b>Total Assets</b>		<b>41,415,398</b>	<b>16,389,926</b>
<b>Current Liabilities</b>			
Payables	9	2,661,950	541,217
Provisions	10	42,597	23,831
<b>Total Current Liabilities</b>		<b>2,704,547</b>	<b>565,048</b>
<b>Non-Current Liabilities</b>			
Provisions	10	8,292	1,175
<b>Total Non-Current Liabilities</b>		<b>8,292</b>	<b>1,175</b>
<b>Total Liabilities</b>		<b>2,712,839</b>	<b>566,223</b>
<b>Net Assets</b>		<b>38,702,559</b>	<b>15,823,703</b>
<b>Equity</b>			
Contributed equity	11	49,505,493	16,741,023
Reserve	12	14,661,942	14,661,942
Accumulated deficit during the development stage	12	(25,464,876)	(15,579,262)
<b>Total Equity</b>		<b>38,702,559</b>	<b>15,823,703</b>

See notes to the financial statements.

**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**STATEMENTS OF FINANCIAL PERFORMANCE**  
**(in Australian dollars)**

	Notes	<u>Years ended 30 June</u>			<b>Period from Inception (11 November 1997) to 30 June 2004</b>
		<b>2004</b>	<b>2003</b>	<b>2002</b>	
<b>Revenue from ordinary activities</b>	2	2,321,227	1,816,478	793,970	5,526,615
Depreciation and amortization expense	3	(1,195,006)	(1,185,973)	(1,160,595)	(5,337,209)
Patents, research and development expense	3	(5,232,581)	(1,861,295)	(2,498,486)	(12,390,699)
Legal expense		(1,650,467)	(848,660)	(923,816)	(3,688,700)
Employee benefits expense		(1,060,730)	(760,980)	(378,853)	(2,246,528)
Consulting fee expense		(1,706,809)	(567,730)	(604,873)	(3,365,940)
Corporate compliance expense		(419,708)	(395,604)	(339,383)	(1,427,323)
Other expenses from ordinary activities		<u>(941,540)</u>	<u>(781,074)</u>	<u>(336,431)</u>	<u>(2,535,092)</u>
<b>Loss from ordinary activities before income tax expense</b>		(9,885,614)	(4,584,838)	(5,448,467)	(25,464,876)
<b>Income tax expense relating to ordinary activities</b>	4	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
<b>Net loss</b>	12(b)	<u>(9,885,614)</u>	<u>(4,584,838)</u>	<u>(5,448,467)</u>	<u>(25,464,876)</u>
<b>Loss per share (basic and diluted)</b>	18	<u>(0.13)</u>	<u>(0.08)</u>	<u>(0.10)</u>	<u>N/a</u>

See notes to the financial statements.

**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**STATEMENTS OF CASH FLOWS**

(in Australian dollars)

Years Ended 30 June

		2004	2003	2002	Period from Inception (11 November 1997) to 30 June 2004
	Notes				
<b>Cash Flows from Operating Activities</b>					
Payments to suppliers and employees		(7,896,711)	(5,271,577)	(4,885,444)	(21,678,446)
Interest received		176,845	106,835	242,215	857,830
Government grant received		909,946	836,575	843,714	2,590,235
Nasdaq reimbursements received		-	231,304	-	231,304
Neuroscience Victoria monies received		1,462,500	506,250	-	1,968,750
		<hr/>	<hr/>	<hr/>	<hr/>
Net cash flows used in operating activities	13 (a)	(5,347,420)	(3,590,613)	(3,799,515)	(16,030,327)
		<hr/>	<hr/>	<hr/>	<hr/>
<b>Cash Flows from Investing Activities</b>					
Payments for purchase of equipment		(134,362)	(87,929)	(50,689)	(306,523)
		<hr/>	<hr/>	<hr/>	<hr/>
Net cash flows used in investing activities		(134,362)	(87,929)	(50,689)	(306,523)
		<hr/>	<hr/>	<hr/>	<hr/>
<b>Cash Flows from Financing Activities</b>					
Proceeds from issue of shares		33,853,606	-	-	46,854,565
Payment of share issue costs		(2,834,941)	-	-	(3,618,478)
Proceeds from exercise of options		762,500	3,713,792	580,345	5,059,138
Payment of underwriting costs		-	(144,000)	-	(144,000)
Repayment of borrowings		-	-	-	(2,038,728)
		<hr/>	<hr/>	<hr/>	<hr/>
Net cash flows from financing activities		31,781,165	3,569,792	580,345	46,112,497
		<hr/>	<hr/>	<hr/>	<hr/>
Net increase/(decrease) in cash held		26,299,383	(108,750)	(3,269,859)	29,775,647
Opening cash brought forward		3,463,783	3,585,014	6,854,873	-
Exchange rate adjustments on the balance of cash held in foreign currencies		(182,768)	(12,481)	-	(195,249)
		<hr/>	<hr/>	<hr/>	<hr/>
<b>Closing cash carried forward</b>	13 (b)	29,580,398	3,463,783	3,585,014	29,580,398
		<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

See notes to the financial statements.

**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
(in Australian dollars)

	<u>Number of Shares</u>	<u>Contributed Equity</u>	<u>Accumulated Deficit During Development Stage</u>	<u>Asset Revaluation Reserve</u>	<u>Total</u>
<b>Balance, 11 November 1997 (Inception)</b>	-	-	-	-	-
Net loss	-	-	(690)	-	(690)
Issuance of shares to founders	20	20	-	-	20
<b>Balance, 30 June 1998</b>	20	20	(690)	-	(670)
Net loss	-	-	(80,000)	-	(80,000)
<b>Balance, 30 June 1999</b>	20	20	(80,690)	-	(80,670)
Net loss	-	-	(1,326,288)	-	(1,326,288)
Revaluation of intangible assets to directors' valuation	-	-	-	14,661,942	14,661,942
297 for 1 share split	5,920	-	-	-	-
Issuance of shares in connection with private placement	960	960	-	-	960
5,000 for 1 share split	34,493,100	-	-	-	-
Issuance of shares in connection with initial public offering, net of issue costs	16,000,000	7,470,863	-	-	7,470,863
Issuance of shares in connection with exercise of options	5,000	2,500	-	-	2,500
<b>Balance, 30 June 2000</b>	50,505,000	7,474,343	(1,406,978)	14,661,942	20,729,307
Net loss	-	-	(4,138,979)	-	(4,138,979)
Issuance of shares in connection with private placements, net of issue costs	6,666,666	4,745,599	-	-	4,745,599
Compensation expense attributable to issuance of shares to consultants	88,600	48,950	-	-	48,950
Compensation expense attributable to issuance of options to consultants	-	8,000	-	-	8,000
<b>Balance, 30 June 2001</b>	57,260,266	12,276,892	(5,545,957)	14,661,942	21,392,877
Net loss	-	-	(5,448,467)	-	(5,448,467)
Issuance of shares in connection with exercise of options	1,160,690	580,346	-	-	580,346
Compensation expense attributable to issuance of shares to consultants	191,794	144,230	-	-	144,230
<b>Balance, 30 June 2002</b>	58,612,750	13,001,468	(10,994,424)	14,661,942	16,668,986

**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY continued**  
**(in Australian dollars)**

	<b>Number of Shares</b>	<b>Contributed Equity</b>	<b>Accumulated Deficit During Development Stage</b>	<b>Asset Revaluation Reserve</b>	<b>Total</b>
Net loss	-	-	(4,584,838)	-	(4,584,838)
Issuance of shares in connection with exercise of options, net of underwriting costs	7,427,584	3,569,792	-	-	3,569,792
Compensation expense attributable to issuance of shares to consultants	146,969	169,763	-	-	169,763
<b>Balance, 30 June 2003</b>	<u>66,187,303</u>	<u>16,741,023</u>	<u>(15,579,262)</u>	<u>14,661,942</u>	<u>15,823,703</u>
Net loss	-	-	(9,885,614)	-	(9,885,614)
Issuance of shares in connection with private placements, net of issue costs	47,102,853	31,018,665	-	-	31,018,665
Issuance of shares in connection with exercise of options	1,325,000	762,500	-	-	762,500
Compensation expense attributable to issuance of shares to consultants and directors	1,369,224	983,305	-	-	983,305
<b>Balance, 30 June 2004</b>	<u>115,984,380</u>	<u>49,505,493</u>	<u>(25,464,876)</u>	<u>14,661,942</u>	<u>38,702,559</u>

See notes to the financial statements.

**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**NOTES TO FINANCIAL STATEMENTS– in Australian dollars (unless otherwise noted)**

**1 BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Background**

Prana Biotechnology Limited (“Prana” or the “Company”) was incorporated on 11 November 1997 in Melbourne, Australia and is a development stage enterprise engaged in the research and development of therapeutic drugs designed to treat the underlying cause of degeneration of the brain and the eye as the aging process progresses.

On 28 March 2000, the Company completed its initial public offering in Australia and listed on the Australian Stock Exchange. In September 2002, the Company’s shares were approved for listing on the Nasdaq SmallCap Market (Code: PRAN).

**Financial Reporting Framework**

The financial report is a general purpose financial report which has been prepared in accordance with the requirements of the Corporations Act 2001, Accounting Standards and Urgent Issues Group Consensus Views and complies with other requirements of the law.

The financial report has been prepared on the basis of historical cost and except where stated, does not take into account changing money values or current valuations of non-current assets. Cost is based on the fair values of the consideration given in exchange for assets.

**Development Stage – Risks and uncertainties**

As a development stage enterprise, the Company’s prospects are subject to the risks, expenses and uncertainties frequently encountered by companies, which have not yet commercialized any applications of their technology, particularly in new and evolving markets. Prana’s operating results may fluctuate significantly in the future as a result of a variety of factors, including capital expenditure and other costs relating to establishing, maintaining and expanding the operations, the number and mix of potential customers, potential pricing of future products by the Company and its competitors, new technology introduced by the Company and its competitors, delays or expense in obtaining necessary equipment, economic and social conditions in the biotechnology industry and general economic conditions.

Prana will continue to review the need to seek additional funding through public and private financing and/or through collaboration or other arrangements with corporate partners. The Company cannot be certain that they will be able to raise any required funding or capital, on favorable terms or at all, or that they will be able to establish corporate collaborations on acceptable terms, if at all. If the Company is unable to obtain such additional funding or capital, they may be required to reduce the scope of their development plans.

Prana’s experience in exploiting their technology is limited. The Company cannot be certain that their operations will be profitable in the short-term, or at all. If Prana fails in any of their efforts to establish or expand their business, the results of operations, financial condition and liquidity of the Company could be materially adversely affected. The Company cannot be certain that they will be able to obtain or retain any permits required by the Company to market, sell and deliver its technology. Any of these factors could result in the cessation of Prana’s operations.

**Significant Accounting Policies**

Accounting policies are selected and applied in a manner which ensures that the resulting financial information satisfies the concepts of relevance and reliability, thereby ensuring that the substance of the underlying transactions or other events is reported.

The following significant accounting policies have been adopted in the preparation and presentation of the financial report:

**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**1 BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES continued**

**(a) Cash and cash equivalents**

For the purposes of the Statement of Cash Flows, cash includes cash on hand and in banks and money market investments readily convertible to cash.

**(b) Recoverable amount of non-current assets**

Each reporting period, the directors assess the recoverable amount of all non-current assets. Where the carrying amount of a non-current asset is greater than its recoverable amount, the asset is revalued down to its recoverable amount. The recoverable amount is estimated based on expected net cash flows discounted to their present values using a market-determined, risk-adjusted discounted rate.

**(c) Equipment**

Equipment consists of computer, laboratory equipment and costs associated with the fitout of our premises at Parkville and is recorded at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of three to 14 years.

**(d) Intangible assets and research and development expense**

Until December 1999, costs associated with the acquisition and development of the Company's core intellectual property were capitalized as intangible assets. After considering an independent valuation of the Company's core intellectual property at December 1999, the directors revalued the assets upwards by \$14,661,942 to \$16,500,000. The revaluation was recorded in the asset revaluation reserve in equity. Subsequent to the revaluation, all costs associated with the acquisition and development of core intellectual property are charged to patents, research and development expense.

Core intellectual property is being amortised on a straight-line basis over a period of 15 years, being the period in which the future benefits are expected to arise. The directors regularly review the carrying value of core intellectual property to ensure its carrying value does not exceed its recoverable amount.

In accordance with Australian Accounting Standard AASB 1041: *Revaluation of Non-Current Assets* ("AASB 1041"), on 1 July 2000 the directors deemed the revalued carrying amount of core intellectual property to be cost for financial reporting purposes.

**(e) Payables**

Liabilities for trade creditors and other amounts are carried at cost, which is the fair value of the consideration to be paid in the future for goods and services received, whether or not billed to the Company.

Payables to related parties are carried at the principal amount.

**(f) Share capital**

Ordinary share capital is recognized at the fair value of the consideration received by the Company, as determined by the directors.

**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**1 BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES continued**

**(g) Revenue recognition**

Revenue is recognized to the extent that it is probable that the economic benefits will flow to the entity and the revenue can be reliably measured.

Interest

Interest income is recognized as earned and collectibility is reasonably assured.

Government grants

Government grants are recorded as income when key milestones set within each agreement are achieved and accepted by all parties to the grant. The agreements comprise different phases based on product development. Milestones are based on the phases of each product development, for example Phase 1, Phase 2 and Phase 3. Revenue is not recognized prior to acceptance that the milestones have been achieved, as collectibility is not assured until this point is reached. Once each milestone is reached and approved, the grantor is obligated to pay and there are no further significant obligations as to that part of the milestone. Grant income for achievement of such milestones is agreed between the parties in legally binding contracts. Revenue for each milestone achieved is fixed up front.

Reimbursements

Reimbursements of expenses are recognized as revenue when the reimbursement is received and the related expenses have been incurred.

Corporate partner revenues

Corporate partner revenues are comprised of amounts earned under agreements with Schering A.G. and Neuroscience Victoria Ltd. for certain research and development activities. Revenues are recognized as earned on a straight line basis over the lives of the relevant agreements. The straight line basis is considered appropriate as the agreements do not contain clearly defined milestones. Such agreements are performed on a "best efforts" basis with no guarantee of either technological or commercial success.

**(h) Income tax**

Tax-effect accounting is applied using the liability method whereby income tax is regarded as an expense and is calculated on the accounting profit after allowing for permanent differences. To the extent timing differences occur between the time items are recognized in the financial statements and when items are taken into account in determining taxable income, the net related taxation benefit or liability, calculated at current rates, is disclosed as a future income tax benefit or a provision for deferred income tax. The net future income tax benefit relating to tax losses is not carried forward as an asset unless the benefit is virtually certain of being realized. The future income tax benefit relating to timing differences is not carried forward as an asset unless its realization is assured beyond reasonable doubt.

Where assets are revalued, no provision for potential capital gains tax has been made.

**PRANA BIOTECHNOLOGY LIMITED**  
**(A Development Stage Enterprise)**

**1 BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES continued**

**(i) Employee entitlements**

Provision is made for employee entitlement benefits accumulated as a result of employees rendering services up to the reporting date. These benefits include wages and salaries, annual leave and long service leave.

Employee entitlements expenses and revenues arising in respect of the following categories:

- Wages and salaries, non-monetary benefits, annual leave, long service leave, sick leave and other leave entitlements; and
- Other types of employee entitlements;

are charged against profits on a net basis in their respective categories.

The value of the options issued under the Employee and Consultants Option Plan 2000 described in Note 15 (b) is not being charged as an expense.

**(j) Loss per share**

Basic loss per share is determined by dividing the loss from ordinary activities after income tax by the weighted average number of ordinary shares outstanding during the period. The computation of diluted loss per share is similar to basic loss per share, except that it assumes the potentially dilutive securities, such as share options, were converted to shares as of the beginning of the period. For all periods presented, diluted loss per share is equivalent to basic loss per share as the potentially dilutive securities are excluded from the computation of diluted loss per share because the effect is anti-dilutive. See Note 18.

**(k) Financial instruments issued by the Company**

Debt and equity instruments

Debt and equity instruments are classified as either liabilities or as equity in accordance with the substance of the contractual arrangement.

Transaction costs on the issue of equity instruments

Transaction costs arising on the issue of equity instruments are recognized directly in equity as a reduction of the proceeds of the equity instruments to which the costs relate. Transaction costs are the costs that are incurred directly in connection with the issue of those equity instruments and which would not have been incurred had those instruments not been issued.

Interest and dividends

Interest and dividends are classified as expenses or as distributions of profit consistent with the Statements of Financial Position classification of the related debt or equity instruments or component parts of compound instruments.

**(l) Goods and services tax**

Revenues, expenses and assets are recognized net of the amount of goods and services tax (GST), except:

- i. Where the amount of GST incurred is not recoverable from the taxation authority, it is recognized as part of the cost of acquisition of an asset or as part of an item of expense; or  
For receivables and payables which are recognized inclusive of GST.

The gross amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables.

Cash flows attributable to GST are included in the Statements of Cash Flows on a gross basis.

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**1 BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES continued**

**(m) Receivables**

Trade receivables and other receivables are recorded at amounts due less any provision for doubtful debts.

**(n) Foreign currency**

All foreign currency transactions during the financial year are brought to account using the exchange rate in effect at the date of the transaction. Accounts payable and receivable balances at reporting date are translated at the exchange rate in effect at that date.

**(o) Start-up and organization costs**

Costs of start-up activities and organizational costs are expensed as incurred.

**(p) Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year presentation.

**(q) Adoption of Australian Equivalents to International Financial Reporting Standards**

Australia is currently preparing for the introduction of International Financial Reporting Standards ("IFRS") effective for financial years commencing 1 January 2005. This requires the production of accounting data for future comparative purposes at the beginning of the next financial year.

The Company's management is assessing the significance of these changes and preparing for their implementation. The Company will seek to keep stakeholders informed as to the impact of these new standards as they are finalized.

The directors are of the opinion that the key differences in the Company's accounting policies which will arise from the adoption of IFRS are:

**Share-based Payments** - The Company currently has the policy of expensing shares issued in lieu of payment for goods or services by valuing them at their cost under the contract; however, under IFRS the Company will be required to expense the cost of such shares based on the fair value (i.e., market price) of the shares. Additionally, under IFRS the Company will be required to expense the cost of share options based on the fair value of the options at the grant date. Currently, the Company does not recognize compensation cost for option grants.

**Intellectual Property** - The Company currently has intangible assets which were revalued upward by \$14,661,942 in December 1999. For the revaluation increment to continue to be recognized under IFRS there must be an active market in which the intangible can be traded. The intangible assets must also be the result of contractual or legal rights or separable from the business. It is anticipated that the intangible assets will not be able to be separately identified and that there will be no active market in which to value the intangible assets. As a result, the revaluation increment may be derecognized from the Statement of Financial Position and the amortization previously taken up may be reversed.

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	Years Ended 30 June		
	2004	2003	2002
<b>2 REVENUE FROM ORDINARY ACTIVITIES</b>			
Interest - Other persons/corporations	211,327	111,686	226,720
Government grant (i)	647,400	967,000	567,250
Nasdaq reimbursements (ii)	-	231,304	-
Corporate partner revenues (iii)	1,462,500	506,250	-
Other revenues	-	238	-
	<u>2,321,227</u>	<u>1,816,478</u>	<u>793,970</u>

(i) On 26 July 2001, the Company announced the grant of a \$1.74 million START grant from the Australian Industry Research and Development Board to expand the Company's core intellectual property for drug treatment of neurodegenerative diseases. During the year ended 30 June 2001, \$226,000 of the grant was recognized as revenue as the Company received written notification of the grant prior to 30 June 2001 and met the revenue recognition criteria disclosed in Note 1(g) for this portion of the grant. During the years ended 30 June 2003 and 2002, the Company met the revenue recognition criteria to record an additional \$967,000 and \$567,250, respectively, of this grant as revenue. This grant was completed ahead of schedule on 30 June 2003. At 30 June 2003, revenue was over accrued by \$21,750.

On 5 May 2003, the Company announced a Biotechnology Innovation Fund grant of \$227,252 from the Australian Industry Research and Development Board to research the development of an immunotherapy from Alzheimer's Disease. During the year ended 30 June 2004, the Company met the revenue recognition criteria to record revenue of \$125,515.

On 18 February 2004, the Company announced a further START grant of \$1.35 million from the Australian Industry Research and Development Board to take its second generation drug candidate for Alzheimer's disease, PBT-2, through safety testing and Phase 1 Clinical Trials. During the year ended 30 June 2004, the Company met the revenue recognition criteria to record revenue of \$543,635.

(ii) In September 2002, the Company listed on the Nasdaq SmallCap Market. Under an agreement with the Bank of New York, 50% of the costs associated with the listing were reimbursed. This reimbursement of \$231,304 is recognized as revenue in the year ended 30 June 2003.

(iii) In March 2003, Prana entered into various agreements with Schering A.G. and Neuroscience Victoria Ltd. for certain research and development activities. The revenue under these agreements is recognized as earned on a straight line basis over the lives of the relevant agreements.

	Years Ended 30 June		
	2004	2003	2002
<b>3 EXPENSES FROM ORDINARY ACTIVITIES</b>			
Depreciation of non-current assets			
Equipment	95,002	85,971	60,591
Amortization of non-current assets			
Core intellectual property	1,100,004	1,100,002	1,100,004
	<u>1,195,006</u>	<u>1,185,973</u>	<u>1,160,595</u>
Total depreciation and amortization expense			
Patents, research and development expense			
Research and development	5,232,581	1,717,770	1,827,536
Patents	-	143,525	670,950
Total patents, research and development expense	<u>5,232,581</u>	<u>1,861,295</u>	<u>2,498,486</u>

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	Years Ended 30 June		
	2004	2003	2002
<b>4 INCOME TAX</b>			
(a) Prima facie income tax benefit calculated at 30% on the loss from ordinary activities before income tax	2,965,684	1,375,451	1,634,540
Tax losses not previously recognized	1,052,868	-	-
Non-deductible amortization	(330,001)	(330,001)	(330,001)
Other non-deductible expenses	(497,360)	(300,312)	(169,528)
Timing differences and tax losses not brought to account as future income tax benefits (Note 4(b))	(3,191,191)	(745,138)	(1,135,011)
Income tax expense relating to ordinary activities	-	-	-
(b) Potential future tax benefits at 30% not brought to account attributable to:			
Tax losses – revenue	6,097,949	3,005,525	2,269,938
Timing differences	108,318	9,551	7,500
	<u>6,206,267</u>	<u>3,015,076</u>	<u>2,277,438</u>

The Company has future income tax benefits of tax losses not recognized as assets because recovery is not virtually certain. Such benefits will only be obtained if:

- (i) future assessable income is derived of a nature and of an amount sufficient to enable the benefit to be realized;
- (ii) the conditions for deductibility imposed by tax legislation continue to be complied with; and
- (iii) no changes in tax legislation adversely affect the Company in realizing the benefit.

The Company has no franking credits available at year end.

	30 June	
	2004	2003
<b>5 RECEIVABLES (CURRENT)</b>		
Government grant receivable (inclusive of GST)	1,390	108,675
Sundry debtors and other	39,571	23,312
Goods and services tax receivable	51,956	11,836
	<u>92,917</u>	<u>143,823</u>
<b>6 OTHER ASSETS (CURRENT)</b>		
Prepayments	71,609	52,362
Withholding tax	1,160	-
	<u>72,769</u>	<u>52,362</u>

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		<b>30 June</b>	
		<b>2004</b>	<b>2003</b>
<b>7</b>	<b>EQUIPMENT</b>		
		Notes	
	Gross carrying amount		
	Balance at beginning of year	372,161	284,232
	Additions	134,362	87,929
	Disposals	-	-
		506,523	372,161
	Balance at end of year		
	Accumulated depreciation		
	Balance at beginning of year	(230,550)	(144,579)
	Disposals	-	-
	Depreciation expense	3 (95,002)	(85,971)
		(325,552)	(230,550)
	Balance at end of year		
	Net book value at end of year	180,971	141,611

Aggregate depreciation allocated during the year is recognized as an expense and disclosed in Note 3.

**8 INTANGIBLE ASSETS**

	Core intellectual property – at deemed cost		16,500,000	16,500,000
	Accumulated amortization		(5,011,657)	(3,911,653)
			11,488,343	12,588,347

Aggregate amortization allocated during the year is recognized as an expense and disclosed in Note 3.

**9 PAYABLES (CURRENT)**

	Trade creditors		336,779	151,755
	Accrual for settlement of patent dispute	16	971,764	-
	Other creditors		1,095,110	340,002
	Amounts payable to Directors		205,258	-
	Amounts payable to Director-related entity	21	53,039	49,460
			2,661,950	541,217

**10 PROVISIONS**

<u>Current</u>				
	Annual leave		15 42,597	23,831
<u>Non-Current</u>				
	Long service leave	15	8,292	1,175

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	30 June		
	2004	2003	2002
<b>11 CONTRIBUTED EQUITY</b>			
<b>(a) Contributed equity</b>			
Ordinary shares fully paid	49,505,493	16,733,023	12,993,468
Options fully paid	-	8,000	8,000
	<u>49,505,493</u>	<u>16,741,023</u>	<u>13,001,468</u>

**(b) Movements in shares on issue**

	30 June					
	2004		2003		2002	
	Number of Shares	\$	Number of Shares	\$	Number of Shares	\$
Beginning of the year	66,187,303	16,733,023	58,612,750	12,993,468	57,260,266	12,268,892
Movement during the year	49,797,077	32,772,470	7,574,553	3,739,555	1,352,484	724,576
End of the year	115,984,380	49,505,493	66,187,303	16,733,023	58,612,750	12,993,468

Details of share issuances are as follows:

Date	Details	Notes	Number	Issue Price	\$
4 February 2002	Exercise of options		134,000	0.50	67,000
12 February 2002	Exercise of options		2,000	0.50	1,000
22 February 2002	Exercise of options		76,000	0.50	38,000
27 February 2002	Exercise of options		40,000	0.50	20,000
6 March 2002	Exercise of options		90,000	0.50	45,000
8 March 2002	Non-cash share issue in consideration for services provided by consultants	(i)	191,794	0.75	144,230
12 March 2002	Exercise of options		272,690	0.50	136,346
14 March 2002	Exercise of options		10,000	0.50	5,000
20 March 2002	Exercise of options		12,000	0.50	6,000
21 March 2002	Exercise of options		100,000	0.50	50,000
25 March 2002	Exercise of options		3,000	0.50	1,500
9 April 2002	Exercise of options		32,500	0.50	16,250
10 April 2002	Exercise of options		2,500	0.50	1,250
11 April 2002	Exercise of options		102,500	0.50	51,250
10 May 2002	Exercise of options		100,000	0.50	50,000
23 May 2002	Exercise of options		180,000	0.50	90,000
16 June 2002	Exercise of options		3,500	0.50	1,750
Year ended 30 June 2002	Total		<u>1,352,484</u>		<u>724,576</u>

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**11 CONTRIBUTED EQUITY (continued)**

<b>Date</b>	<b>Details</b>	<b>Notes</b>	<b>Number</b>	<b>Issue Price</b>	<b>\$</b>
8 July 2002	Exercise of options		4,000	0.50	2,000
10 July 2002	Exercise of options		13,274	0.50	6,637
12 July 2002	Non-cash share issue in consideration for services provided by consultants	(i)	13,550	2.02	27,371
18 September 2002	Exercise of options		32,000	0.50	16,000
30 September 2002	Exercise of options		25,000	0.50	12,500
15 October 2002	Exercise of options		20,081	0.50	10,040
20 November 2002	Exercise of options		113,000	0.50	56,500
22 November 2002	Exercise of options		33,072	0.50	16,536
25 November 2002	Exercise of options		7,000	0.50	3,500
4 December 2002	Non-cash share issue in consideration for services provided by consultants	(i)	15,318	1.74	26,653
12 December 2002	Exercise of options		50,000	0.50	25,000
8 January 2003	Exercise of options		50,000	0.50	25,000
22 January 2003	Exercise of options		2,620	0.50	1,310
30 January 2003	Exercise of options		9,700	0.50	4,850
30 January 2003	Non-cash share issue in consideration for services provided by consultants	(i)	118,101	0.98	115,739
14 February 2003	Exercise of options		499,403	0.50	249,702
20 February 2003	Exercise of options		483,746	0.50	241,873
28 February 2003	Exercise of options		2,530,483	0.50	1,265,242
5 March 2003	Exercise of options		3,107,891	0.50	1,553,945
15 March 2003	Exercise of options		25,000	0.50	12,500
March 2003	Underwriting costs	(ii)	-	-	(144,000)
3 April 2003	Exercise of options		421,314	0.50	210,657
Year ended 30 June 2003	Total		<u>7,574,553</u>		<u>3,739,555</u>
11 August 2003	Exercise of options		50,000	0.50	25,000
13 August 2003	Exercise of options		25,000	0.50	12,500
27 August 2003	Exercise of options		16,000	0.50	8,000
27 August 2003	Non-cash share issue in consideration for services provided by consultants	(i)	70,768	0.70	49,538
29 August 2003	Exercise of options		34,000	0.50	17,000
16 September 2003	Share issue to professional investors for cash		7,102,853	0.70	4,971,997
12 January 2004	Non-cash share issue to directors	(iii)	249,999	0.48	120,000
12 January 2004	Non-cash share issue in consideration for services provided by consultants	(i)	67,955	0.64	43,491
20 February 2004	Non-cash share issue in consideration for services provided by consultants	(i)	155,502	0.55	85,526
8 April 2004	Exercise of options		200,000	0.70	140,000
15 April 2004	Exercise of options		100,000	0.70	70,000
16 April 2004	Exercise of options		200,000	0.50	100,000
16 April 2004	Exercise of options		200,000	0.70	140,000
20 April 2004	Exercise of options		300,000	0.50	150,000
22 April 2004	Exercise of options		200,000	0.50	100,000

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**11 CONTRIBUTED EQUITY (continued)**

Date	Details	Notes	Number	Issue Price	\$
10 May 2004	Non-cash share issue in consideration for services provided by consultants	(i)	825,000	0.83	684,750
1 June 2004	Share issued to US investors for cash		40,000,000	0.72	28,881,609
	Expired options		-		8,000
	Capitalraising costs		-		(2,834,941)
Year ended 30 June 2004	Total		49,797,077		32,772,470

- (i) The Company recognized non-cash compensation expense for shares issued in consideration for services provided by consultants based on the director's valuation of the services rendered.
- (ii) Underwriters subscribed the balance of the listed options with an expiration date of 1 March 2003 that had not been exercised by existing option holders and charged \$144,000 for their services.
- (iii) The base fee for three of the Company's directors was paid by the issue of 83,333 shares each as approved at the 2003 Annual General Meeting.

**(c) Movements in share options**

	Years Ended 30 June					
	2004		2003		2002	
	Number of Options	Comp. Expense	Number of Options	Comp. Expense	Number of Options	Comp. Expense
Beginning of the year	21,085,000	8,000	27,894,310	8,000	28,655,000	8,000
Issued during the year	1,709,167	-	618,274	-	400,000	-
Expired during the year	(200,000)	(8,000)	-	-	-	-
Exercised during the year (Note 11(b))	(1,325,000)	-	(7,427,584)	-	(1,160,690)	-
End of the year	21,269,167	-	21,085,000	8,000	27,894,310	8,000

Details of option issuances are summarized as follows. The Company did not record any compensation expense in connection with the issuance of the options.

2002

- On 23 January 2002, the Company issued 200,000 options to an outside consultant in consideration for services rendered. Such options are exercisable on or before 20 March 2004 at an exercise price of \$0.50 per option.
- On 7 March 2002, the Company issued 200,000 options to outside consultants under the Employee and Consultants Option Plan 2000 (see Note 15(b)) as a reward for services rendered to the Company. Of the 200,000 options, one-third are exercisable beginning May 2001, another third May 2002 and the final third May 2003. Such options are exercisable until 30 June 2005 at an exercise price of \$0.50 per option. These options are forfeited in the event the consultants terminate employment with the Company.

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**11 CONTRIBUTED EQUITY (continued)**

2003

- On 10 July 2002, the Company issued 13,274 options to an employee and 100,000 options to an outside consultant under the Employee and Consultants Option Plan 2000 (see Note 15(b)) as a reward for services rendered to the Company. Of the 100,000 options issued to the consultant, one-third are exercisable beginning May 2001, another third May 2002 and the final third May 2003. The options are exercisable until 30 June 2005 at an exercise price of \$0.50 per option. These options are forfeited in the event the employee or consultant terminate employment with the Company.
- On 31 October 2002, the Company issued 100,000 options to an outside consultant under the Employee and Consultants Option Plan 2000 (see Note 15(b)) as a reward for services rendered to the Company. Such options are exercisable on or before 30 June 2005 at an exercise price of \$0.50 per option. These options are forfeited in the event the consultant terminates employment with the Company.
- On 31 October 2002, the Company issued 200,000 options to an outside consultant in consideration for services rendered. Such options are exercisable on or before 1 October 2005 at an exercise price of \$0.50 per option.
- On 1 March 2003, the Company issued 55,000 options to underwriters in connection with the underwriters' subscription of the remaining balance of the listed options with an expiration date of 1 March 2003 that had not been exercised by existing option holders. Such options were exercisable on the same day at an exercise price of \$0.50 per option.
- On 6 June 2003, the Company issued 5,000 options to an outside consultant in consideration for services rendered. Such options are exercisable beginning 1 March 2005 through 30 June 2005 at an exercise price of \$1.50 per option.
- On 6 June 2003, the Company issued 145,000 options to employees under the Employee and Consultants Option Plan 2000 (see Note 15(b)) as a reward for services rendered to the Company. Of the 145,000 options, 50,000 options are immediately exercisable, 20,000 options are exercisable beginning 1 August 2003, 25,000 options are exercisable beginning 25 December 2003, and 50,000 options are exercisable beginning 31 May 2004. All options have an exercise price of \$0.50 per option and are exercisable until 30 June 2005. These options are forfeited in the event the employees terminate employment with the Company.

2004

- On 8 August 2003, the Company issued 10,000 options to outside consultants under the Employee and Consultants Option Plan 2000 (see Note 15(b)) as a reward for services rendered to the Company. Of the 10,000 options issued to the consultants, half are exercisable beginning 1 December 2003 and the other half are exercisable beginning 1 January 2005. The options are exercisable until 30 June 2005 at an exercise price of \$0.50 per option. These options are forfeited in the event the consultants terminate employment with the Company.
- On 10 September 2003, the Company issued 5,000 options to an outside consultant in consideration for services rendered to the Company. Such options are exercisable between 2 March 2005 and 30 June 2005 at an exercise price of \$1.50 per option.
- On 15 September 2003, the Company issued 244,667 options to employees and 17,500 options to outside consultants under the Employee and Consultants Option Plan 2000 (see Note 15(b)) as a reward for services rendered to the Company. Of the 244,667 options issued to employees, 58,000 are escrowed until 1 August 2004, 166,667 are escrowed until 31 May 2004 and 20,000 are escrowed until 31 August 2004. Of the options issued to the consultants, 2,500 are exercisable beginning 1 July 2004, 7,500 are escrowed until 31 July 2004 and 7,500 are escrowed until 31 August 2004. The options are exercisable until 30 June 2005 at an exercise price of \$0.50 per option. These options are forfeited in the event the employees or consultants terminate employment with the Company.
- On 23 October 2003, the Company issued 500,000 options to an outside consultant in consideration for services rendered to the Company. Such options were exercisable on or before 23 April 2004 at an exercise price of \$0.70 per option. The options were exercised in April 2004.
- On 27 November 2003, the Company issued 500,000 options to an outside consultant under the Employee and Consultants Option Plan 2000 (see Note 15(b)) as a reward for services rendered to the Company. Such options are exercisable on or before 30 June 2004 at an exercise price of \$0.50 per option.

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**11 CONTRIBUTED EQUITY (continued)**

- On 5 December 2003, the Company issued 20,000 options to employees under the Employee and Consultants Option Plan 2000 (see Note 15(b)) as a reward for services rendered to the Company. The options are exercisable between 1 July 2004 and 30 June 2005 at an exercise price of \$0.50 per option. These options are forfeited in the event the employees terminate employment with the Company.
- On 10 May 2004, the Company issued 412,000 options to an outside consultant in consideration for services rendered to the Company. Such options are exercisable on or before 1 February 2007 at an exercise price of \$0.50 per option.

**(d) Warrants**

On 4 June 2004, the Company issued 3,000,000 warrants to US investors as part of the 1 June 2004 US capital raising disclosed in (b) above. These warrants are convertible to 30,000,000 shares (3,000,000 ADRs) at an exercise price of US\$8.00 per warrant on or before 4 June 2009.

**(e) Terms and Conditions of Contributed Equity**

**Ordinary Shares**

Ordinary shares have the right to receive dividends as declared and, in the event of winding up the Company, to participate in the proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held.

Ordinary shares entitle their holder to one vote, either in person or by proxy, at a meeting of the Company.

**Options and Warrants**

Optionholders and Warrantholders do not have the right to receive dividends and are not entitled to vote at a meeting of the Company. Options and warrants may be exercised at any time from the date they vest to the date of their expiry. Share options convert into ordinary shares on a one for one basis on the date they are exercised. Warrants convert into ordinary shares, one warrant for ten ordinary shares on the date they are exercised.

**(f) Shares and options issued after reporting date**

Details of share issuances are as follows:

Date	Details	Number	Issue Price	\$
9 August 2004	Issue of shares in settlement of patent litigation (Note 16)	1,350,000	0.56	756,000
16 September 2004	Issue of shares in lieu of payment to a consultant	49,775	0.82	40,816
		<u>1,399,775</u>		<u>796,816</u>
			<b>30 June</b>	
		<u>2004</u>	<u>2003</u>	<u>2002</u>

Notes

**12 RESERVE AND ACCUMULATED DEFICIT**

Asset revaluation reserve	12(a)	14,661,942	14,661,942	14,661,942
Accumulated deficit during the development stage	12(b)	(25,464,876)	(15,579,262)	(10,994,424)

**(a) Asset revaluation reserve**

**i Nature and purpose of reserve**

The asset revaluation reserve is used to record increments and decrements in the value of non-current assets

**ii Movements in reserve**

Balance at beginning of year	14,661,942	14,661,942	14,661,942
Revaluation of core intellectual property to directors' valuation	-	-	-
Balance at end of year	<u>14,661,942</u>	<u>14,661,942</u>	<u>14,661,942</u>

On 1 July 2000, as allowed by AASB 1041, the directors have deemed the carrying value of the Company's core intellectual property at valuation to be cost. As a result, the asset revaluation reserve is no longer available to absorb any future write-downs of core intellectual property. Subsequent to 1 July 2000, future write-downs of these assets to the recoverable amount must be made through the Statements of Financial Performance.



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**14 EXPENDITURE COMMITMENTS**

In accordance with the terms of the research funding agreement between Neurosciences Victoria Ltd. and Prana, at 30 June 2004 Prana is obliged to spend \$759,375 on research and development activities at the University of Melbourne in the nine months to 31 March 2005. These contracts are currently being renegotiated and the amount may alter but represents the maximum commitment under existing contractual arrangements.

The Company has entered into a ten year contract with Professor Ashley Bush, including payment of US\$100,000 per annum for ten years, the issue of 1,650,000 bonus shares of which 825,000 were issued during the current year and 824,000 options at an exercise price \$0.50 of which 412,000 were issued during the current year.

The Company moved premises in June 2004 and entered into a lease for a three year period totaling \$305,675.

In June 2004, the Company entered into a four year rental agreement for a photocopier, at a total cost over four years of \$11,280.

The CFO Solution provides administrative support at a rate of \$15,000 per month which can be terminated with three months' notice by either party.

	30 June 2004	2003
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**15 EMPLOYEE ENTITLEMENTS AND SUPERANNUATION COMMITMENTS**

Notes

**(a) Employee Entitlements**

The aggregate employee entitlement liability is composed of:

Provisions (current)		42,597	23,831
Provisions (non-current)		8,292	1,175
	10	50,889	25,006

Number of employees: 12 (2003: 6 employees)

**(b) Employee and Consultants Option Plan 2000**

At the Annual General Meeting held on 22 November 2000, shareholders approved the establishment of an Employee and Consultants Option Plan 2000 designed to reward executives, employees and consultants for their contributions to the Company. It is also proposed as a method of retaining key personnel for the growth and development of the Company's intellectual property rights. The options cannot be transferred and are not quoted on the Australian Stock Exchange. At 30 June 2004, there were no Directors, two executives, four employees and five consultants participating in the Scheme. To date, all options have been issued with a \$0.50 exercise price.

Information with respect to the number of options granted under the Employee and Consultants Option Plan 2000 is as follows:

	• Years Ended 30 June					
	2004		2003		2002	
	Number of Options	Exercise Price	Number of Options	Exercise Price	Number of Options	Exercise Price
Beginning of the year	555,000	0.50	210,000	0.50	10,000	0.50
Issued during the year	792,167	0.50	358,274	0.50	200,000	0.50
Exercised during the year	(450,000)	0.50	(13,274)	0.50	-	-
End of the financial year	897,167		555,000		210,000	

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**16 CONTINGENT LIABILITIES**

On 28 July 2004, the Company resolved its patent dispute with P.N. Gerolymatos by the issue of 1,350,000 shares and payment of US\$150,000. This has been fully provided for in the accounts in note 9, resulting in a provision of \$971,764 as of 30 June 2004. Under the settlement agreement the Company could be potentially liable for royalty payments to P.N. Gerolymatos upon the successful commercialization of the Company's research.

The Company has entered into various agreements under which they may be liable to pay royalties upon the successful commercialization of the Company's research. In particular these obligations exist to the University of Melbourne, Massachusetts General Hospital and P.N. Gerolymatos.

The Company is not involved in any legal or arbitration proceedings and, so far as Directors are aware, no such proceedings are pending or threatened against the Company.

**17 SUBSEQUENT EVENTS**

In August 2004, the Company set up a subsidiary in the United States due to the increase in US operations following the appointment of Jonas Alsenas, a US-based Director and Chief Executive Officer, and the increase in US investors in the Company. Also in August 2004, the Company set up a subsidiary in the United Kingdom to allow them to conduct commercial and clinical operations in the UK. Neither of these subsidiaries are currently trading.

See Note 16 with respect to the resolution of the patent dispute with P.N. Gerolymatos.

Other than as disclosed above, no other matters or circumstances have arisen since the end of the financial year which significantly affected or may significantly affect the operations of the Company, the results of those operations, or the state of affairs of the Company in subsequent financial years.

<b>18 LOSS PER SHARE</b>	<b>Years Ended 30 June</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Basic loss per share	(0.13)	(0.08)	(0.10)
Weighted average number of ordinary shares on issue used in the calculation of basic loss per share	75,701,818	61,131,313	57,623,389

The options in place do not have the effect to dilute the loss per share.

**19 DIRECTORS' AND EXECUTIVES' REMUNERATION**

(a) The directors and executive information has been prepared in accordance with the new Accounting Standard AASB 1046: *Directors and Executives Disclosures by Disclosing Entities*.

Specified Directors of Prana Biotechnology Ltd during the year:

Geoffrey Kempler	Executive Chairman	Appointed 11 November 1997
Jonas Alsenas	Executive Director	Appointed 25 March 2004
	CEO	Appointed 9 August 2004
Colin Master	Executive Director	Appointed 9 December 1999
George Mihaly	Non-Executive Director	Appointed 9 December 1999
Brian Meltzer	Non-Executive Director	Appointed 9 December 1999

Specified Executives of Prana Biotechnology Ltd during the year:

Ross Murdoch	COO	Employed May 2002
Dianne Angus	Vice President of IP and Licensing	Employed August 2002

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**19 DIRECTORS' AND EXECUTIVES' REMUNERATION (continued)**

(b) Specified Directors and Specified Executives Remuneration

Consistent with best practice the Directors' sought outside expertise in 2003 from Mercer Human Resources. The remuneration below was determined in accordance with their independent advice.

2004	Primary		Post	Equity	Total
	Base Fee	Consultant	Employment	Options	\$
	\$	Fee	Super	\$	
Specified Directors:		\$			
Geoffrey Kempler	266,818	-	18,182	-	285,000
Jonas Alsenas	32,365	-	-	-	32,365
Colin Master*	40,000	8,333	-	-	48,333
George Mihaly*	40,000	78,858	347	-	119,205
Brian Meltzer*	40,000	50,000	-	-	90,000
	<u>419,183</u>	<u>137,191</u>	<u>18,529</u>	<u>-</u>	<u>574,903</u>

\* The base fee was paid by issue of 83,333 shares each as approved at the 2003 Annual General Meeting.

2004	Primary		Post	Equity	Total
	Base Fee	Consultant	Employment	Options (i)	\$
	\$	Fee	Super	\$	
Specified Executives					
Ross Murdoch	235,417	-	21,188	100,748	357,353
Dianne Angus	151,827	-	13,665	31,751	197,243
	<u>387,244</u>	<u>-</u>	<u>34,853</u>	<u>132,499</u>	<u>554,596</u>

There are only two executive officers of the Company

Mr. R. Murdoch has a contract dated 31 May 2004 which provides for a base annual salary of \$275,000, superannuation at a rate of 9% and options in the Company to the value of 25% of the base salary per annum based on the achievement of performance milestones. The terms and conditions of the issue of options may be subject to change in future years as the Company develops its remuneration policies. The term of the employment contact will last for a period of three years.

Ms D. Angus has a contract dated 21 October 2003 which provides for a base annual salary of \$150,000, superannuation at a rate of 9% and options in the Company to the value of 20% of the base salary per annum based on the achievement of performance milestones. The terms and conditions of the issue of options may be subject to change in future years as the Company develops its remuneration policies. The term of the employment contact will last for a period of three years.

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**19 DIRECTORS' AND EXECUTIVES' REMUNERATION (continued)**

(i) Remuneration Options

Options Granted as Remuneration Specified Executives:	Granted No.	Grant Date	Value per option at Grant Date using Black Scholes (cents)	Exercise Price (cents)	First Exercise Date	Last Exercise Date
Ross Murdoch	50,000	6 June 2003	34.5	0.50	31 May 2004 25 December 2003	30 June 2005
Ross Murdoch	15,000	6 June 2003	34.5	0.50		30 June 2005
Ross Murdoch	166,667	15 Sept 2003	48.3	0.50	31 May 2004	30 June 2005
Dianne Angus	20,000	6 June 2003	34.5	0.50	1 August 2003 25 December 2003	30 June 2005
Dianne Angus	10,000	6 June 2003	34.5	0.50		30 June 2005
Dianne Angus	<u>58,000</u>	15 Sept 2003	48.3	0.50	1 August 2004	30 June 2005
	<u>319,667</u>					

**As of and For the Years Ended 30 June**

**20 AUDITORS' REMUNERATION**

Amounts received or due and receivable for:

	<u>2004</u>	<u>2003</u>	<u>2002</u>
- an audit or review of the financial report of the entity	129,522	126,178	89,078
- audit-related fees	-	-	-
- tax fees	59,580	23,400	36,775
- all other fees	<u>6,900</u>	<u>7,400</u>	<u>10,500</u>
	<u><u>196,002</u></u>	<u><u>156,978</u></u>	<u><u>136,353</u></u>

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**21 RELATED PARTY AND SPECIFIED EXECUTIVE DISCLOSURES**

**Specified Directors' and Specified Executives' Remuneration**

Details of specified directors' and specified executives' remuneration are disclosed in note 19 to the financial statements.

	<b>As of and For the Years Ended 30 June</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
<b>Director-related entity transactions</b>			
Kendle Pty Ltd, a Director-related company to G. Mihaly, provided continuous analysis and reviews of the Company's commercialization and intellectual property management as well as clinical trial management and monitoring (on normal commercial terms and conditions).			
Fees paid to Kendle Pty Ltd during the year were:	379,045	475,289	537,327
Amount owing to Kendle Pty Ltd (included in Payables, inclusive of GST)	53,039	48,968	
Aroma Science Pty Ltd, a Director-related company to G Kempler, provides office, computer administration and meeting facilities (on normal commercial terms and conditions).			
Fees paid to Aroma Science Pty Ltd during the year were:	81,470	114,247	30,000
Amount owing to Aroma Science Pty Ltd (included in Payables, inclusive of GST)	-	492	

**Specified Directors' and Specified Executives' Equity Holdings**

Number of Shares held by Specified Directors' and Specified Executives'

	Balance 1.7.03	Received as Remuneration	Options Exercised	Net Change Other	Balance 30.6.04
<b>Specified Directors</b>					
Geoffrey Kempler	17,055,000	-	-	-	17,055,000
Jonas Alsenas	70,000	-	-	-	70,000
Colin Master	18,000	83,333	-	-	101,333
George Mihaly	60,000	83,333	-	-	143,333
Brian Meltzer	160,000	83,333	-	-	243,333
<b>Specified Executives</b>					
Ross Murdoch	50,000	-	-	-	50,000
Dianne Angus	-	-	-	-	-

"Net change other" refers to shares purchased or sold during the financial year.

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**21. RELATED PARTY AND SPECIFIED EXECUTIVE DISCLOSURES continued**

**Specified Directors' and Specified Executives' Equity Holdings**

Number of Options held by Specified Directors' and Executives'

	Balance 1.7.03 No.	Granted as Remuneration No.	Options Exercised No.	Balance 30.6.04 No.	Total Exercisable 30.6.04 No.	Total Not Exercisable 30.6.04 No.
Specified Directors						
Geoffrey Kempler	9,167,500	-	-	9,167,500	9,167,500	-
Jonas Alsenas	-	-	-	-	-	-
Colin Master	1,000,000	-	-	1,000,000	1,000,000	-
George Mihaly	300,000	-	-	300,000	300,000	-
Brian Meltzer	300,000	-	-	300,000	300,000	-
Specified Executives						
Ross Murdoch	115,000	166,667	-	281,667	281,667	-
Dianne Angus	30,000	58,000	-	88,000	30,000	58,000

**22 SEGMENT INFORMATION**

The Company's activities are predominantly within Australia and cover research into Alzheimer's Disease and other major age-related degenerative disorders.

**23 FINANCIAL INSTRUMENTS**

**(a) Significant accounting policies**

Details of the significant accounting policies and methods adopted, including the criteria for recognition, the basis of measurement and the basis on which revenues and expenses are recognized, in respect of each class of financial asset, financial liability and equity instrument are disclosed in Note 1 to the financial statements.

**(b) Interest rate risk**

The Company has cash on deposit which is professionally managed by external parties to optimize the impact of interest rate fluctuations pursuant to conservative investment guidelines. At 30 June 2004, the Company has \$30,000 in a six month term deposit at a fixed interest rate of 5.20%, \$1,600,000 in 120 day term deposits at fixed interest rates between 5.35% and 5.44%, US\$13,500,000 (A\$19,418,805) in a 27 day term deposit at a fixed interest rate of 0.60%, \$1,299,608 in Australian dollar cheque accounts at variable interest rates ranging from 3.97% to 4.40% and US\$5,027,554 (A\$7,231,785) in a US cheque account at a variable interest rate of 0.05%. The Company also has \$200 in petty cash which does not earn any interest. The weighted average interest rate is 0.89% and apart from usual variances in general rates of interest the Company is not exposed to any significant interest rate risk.

At 30 June 2003, the Company has \$800,000 in 90 day term deposits at fixed interest rates between 4.44% and 4.61%, \$400,000 in a 30 day term deposit at a fixed interest rate of 4.64%, \$2,044,918 in an Australian dollar cheque account at a variable interest rate of 2.80% and \$218,665 (AUS\$ value) in a US dollar cheque account at 30 June 2003. The Company also has \$200 in petty cash which does not earn any interest. The weighted average interest rate is 3.31% and apart from usual variances in general rates of interest the Company is not exposed to any significant interest rate risk.

Receivables and payables are non-interest bearing.

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**23 FINANCIAL INSTRUMENTS (continued)**

The Company's exposure to interest rates and the effective weighted average interest rate for classes of financial assets and liabilities is set out below:

<u>2004</u>	Floating Interest Rate	Fixed Interest Maturing in		Non- Interest bearing	Total	Average Interest Rate
		1 year or less	1-5 years			
FINANCIAL ASSETS	\$	\$	\$	\$	\$	
Cash	8,531,393	21,048,805	-	200	29,580,398	0.89%
Receivables	-	-	-	92,917	92,917	-
	8,531,393	21,048,805	-	93,117	29,673,315	
FINANCIAL LIABILITIES						
Payables	-	-	-	2,661,950	2,661,950	-
Provisions	-	-	-	50,889	50,889	-
	-	-	-	2,712,839	2,712,839	
<u>2003</u>	Floating Interest Rate	Fixed Interest Maturing in		Non-Interest bearing	Total	Average Interest Rate
		1 year or less	1-5 years			
FINANCIAL ASSETS	\$	\$	\$	\$	\$	
Cash	2,044,918	1,200,000	-	218,865	3,463,783	3.31%
Receivables	-	-	-	143,823	143,823	-
	2,044,918	1,200,000	-	362,688	3,607,606	
FINANCIAL LIABILITIES						
Payables	-	-	-	541,217	541,217	-
Provisions	-	-	-	25,006	25,006	-
	-	-	-	566,223	566,223	

**(c) Net fair values**

The carrying amount of financial assets and financial liabilities recorded in the financial statements represents their respective net fair values, determined in accordance with the accounting policies disclosed in Note 1 to the financial statements.

**(d) Credit risk**

Financial assets, which potentially expose the Company to concentrations of credit risk, consist primarily of cash and receivables. The Company's cash and cash equivalents are placed with high credit quality financial institutions and receivables are presented net of any allowances for estimated doubtful receivables. Accordingly, the Directors believe the Company has no significant concentration of credit risk.

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**24            ADDITIONAL COMPANY INFORMATION**

Prana Biotechnology Limited is a listed public company, incorporated and operating in Australia.

Registered Office	Principal Place of Business
Suite 2	Level 2
1233 High Street	369 Royal Parade
Armadale Vic 3148	Parkville Vic 3052

Tel: +61 (03) 9824 8166 Tel: +61 (03) 9349 4906

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**25 RECONCILIATION TO US GAAP**

The financial statements have been prepared in accordance with accounting principles generally accepted in Australia (“A-GAAP”), which differ in certain significant respects from accounting principles generally accepted in the United States of America (“US GAAP”). The following is a summary of the adjustments to net loss and total equity required when reconciling such amounts recorded in the financial statements to the corresponding amounts in accordance with US GAAP, considering the differences between A-GAAP and US GAAP.

Reconciliation of net loss

		<b>Years Ended 30 June</b>		
		<b>2004</b>	<b>2003</b>	<b>2002</b>
Net loss in accordance with A-GAAP		(9,885,614)	(4,584,838)	(5,448,467)
<i>US GAAP adjustments:</i>				
Share-based compensation	(a)			
400,000 options issued to consultants		-	-	(352,000)
Options issued to consultants for services rendered		(429,811)	(81,610)	(656,600)
Options issued to employees for services rendered		(87,768)	(28,108)	-
Options issued to underwriters in connection with subscription of listed options		-	(26,400)	-
Shares issued to consultants and directors for services rendered		(33,023)	(31,004)	(306,485)
Intangible assets	(b)			
Reversal of amortisation expense attributable to costs capitalised under A-GAAP but expensed under US GAAP		60,670	60,670	60,670
Reversal of amortisation expense attributable to upward asset revaluation		977,463	977,463	977,463
Costs capitalised under US GAAP but expensed under A-GAAP		477,390	717,119	1,181,792
Amortisation expense attributable to above		(287,506)	(247,689)	(184,392)
Deferred tax effect of US GAAP adjustments	(c)	-	-	-
Net loss in accordance with US GAAP		(9,208,199)	(3,244,397)	(4,728,019)
Loss per share in accordance with US GAAP:				
Basic and diluted		(0.12)	(0.05)	(0.08)
Weighted average shares – basic and diluted		75,701,818	61,131,313	57,623,389

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**25 RECONCILIATION TO US GAAP continued**

Reconciliation of shareholders' equity

	<b>30 June</b>	
	<b>2004</b>	<b>2003</b>
Total equity in accordance with A-GAAP	38,702,559	15,823,703
<i>US GAAP adjustments:</i>		
Intangible assets	(b)	
Costs capitalised under A-GAAP but expensed under US GAAP	(910,058)	(910,058)
Reversal of amortisation expense attributable to above	276,415	215,745
Reversal of upward asset revaluation	(14,661,942)	(14,661,942)
Reversal of amortisation expense attributable to above	4,453,360	3,475,897
Costs capitalised under US GAAP but expensed under A-GAAP	4,551,285	4,073,895
Amortisation expense attributable to above	(926,663)	(639,157)
Deferred tax effect of US GAAP adjustments	(c) -	-
Total equity in accordance with US GAAP	<u>31,484,956</u>	<u>7,378,083</u>

Rollforward analysis of shareholders' equity under US GAAP

	<b>30 June</b>	
	<b>2004</b>	<b>2003</b>
Balance in accordance with US GAAP, beginning of year	7,378,083	6,715,803
Issuance of shares in connection with private placements, net of issue costs	31,018,665	-
Issuance of shares in connection with exercise of options, net of underwriting costs	762,500	3,569,792
Compensation expense attributable to issuance of options to consultants for services rendered	(a) 429,811	81,610
Compensation expense attributable to issuance of options to employees for services rendered	(a) 87,768	28,108
Compensation expense attributable to issuance of options to underwriters in connection with subscription of listed options	(a) -	26,400
Compensation expense attributable to issuance of shares to consultants and directors for services rendered	(a) 1,016,328	200,767
Net loss in accordance with US GAAP	(9,208,199)	(3,244,397)
Balance in accordance with US GAAP, end of year	<u>31,484,956</u>	<u>7,378,083</u>

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**25 RECONCILIATION TO US GAAP continued**

**a. Share-based compensation**

*400,000 options issued to consultants*

On 6 January 2000, the Company issued 400,000 share options as an incentive for outside consultants. Under A-GAAP, no compensation cost has been recognised in respect of the share options issued by the Company. Under US GAAP, the options issued to the consultants are accounted for under Statements of Financial Accounting Standards ("SFAS") No. 123: *Accounting for Stock-Based Compensation* ("SFAS 123") and Emerging Issues Task Force Issue No. 96-18: *Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ("EITF 96-18"). Under SFAS 123 and EITF 96-18, compensation cost is calculated based on the fair value of options on the date at which the counterparty's performance is complete. The fair value of the options was estimated on the date of grant using the Black-Scholes model with the following weighted average assumptions:

- risk-free interest rate of 5.6%;
- no dividends;
- expected volatility of 21%; and
- expected life of four years.

The compensation cost is charged to earnings over the period from the date of grant (6 January 2000) to the date the consultants' performance was complete (28 March 2002) and adjusted at each statement of financial position date (up to 28 March 2002) for changes in the fair value of the options.

*Options issued to consultants for services rendered*

The Company issued 1,444,500, 405,000 and 400,000 share options to outside consultants during the years ended 30 June 2004, 2003 and 2002, respectively. Certain options were issued under the Employee and Consultants Option Plan 2000 as a reward for services rendered and the remaining options were issued in consideration for services rendered to the Company. Under A-GAAP, no compensation cost has been recognised in respect of the share options issued by the Company. Under US GAAP, the options issued to the outside consultants are accounted for under SFAS 123 and EITF 96-18. Accordingly, the Company has calculated compensation cost based on the estimated fair value of the options measured on the date the services were completed by the respective consultants, using the Black-Scholes model with the following weighted average assumptions:

- risk-free interest rate of 5.50% for 2004, 4.47% for 2003 and 5.48% for 2002;
- no dividends;
- expected volatility of 82% for 2004, 48% for 2003 and 25% for 2002; and
- expected life of two years for 2004, two years for 2003 and three years for 2002.

The compensation cost is charged to operations ratably over the vesting period.

*Options issued to employees for services rendered*

As disclosed in Note 11(c), the Company issued 264,667 and 158,274 share options to employees under the Employee and Consultants Option Plan 2000 as a reward for services rendered to the Company during the years ended 30 June 2004 and 2003 respectively. Under A-GAAP, no compensation cost has been recognised in respect of the share options issued by the Company. Under US GAAP, the Company has elected to account for the issuance of share options to the employees in accordance with Accounting Principles Board Opinion No. 25: *Accounting for Stock Issued to Employees* and related interpretations ("APB 25"). Under APB 25, compensation cost is recognised to the extent that the quoted market price of the stock exceeds the exercise price of the options at the grant date, and is charged to earnings ratably over the vesting period.

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**25 RECONCILIATION TO US GAAP continued**

*Options issued to underwriters in connection with subscription of listed options*

As disclosed in Note 11(c), the Company issued 55,000 share options to underwriters on 1 March 2003 in connection with the underwriters' subscription of the remaining balance of the listed options with an expiration date of 1 March 2003 that had not been exercised by existing option holders. Under A-GAAP, no compensation cost has been recognised in respect of the share options issued by the Company. Under US GAAP, the options issued to the underwriters are accounted for under SFAS 123. Accordingly, the Company has calculated compensation cost based on the estimated fair value of the options measured on 1 March 2003. Because the options are exercisable only on the date of grant, the Company estimated the fair value of the options based on the intrinsic value of the options.

*Shares issued to consultants and directors for services rendered*

As disclosed in Note 11(b), the Company issued 1,119,225, 146,969 and 191,794 shares to outside consultants in consideration for services rendered to the Company during the years ended 30 June 2004, 2003, and 2002, respectively. The Company also issued 249,999 shares to directors in consideration for services rendered to the Company during the year ended 30 June 2004. Under A-GAAP, the Company recognised compensation expense based on the director's valuation of the shares issued. Under US GAAP, the shares issued to the outside consultants and directors are accounted for under SFAS 123 and EITF 96-18. Accordingly, compensation expense is based on the quoted market price of the shares measured on the date the services were completed. The resulting difference between the A-GAAP compensation expense and the US GAAP compensation expense is recognised in the reconciliation.

**b. Intangible assets**

Under A-GAAP, the Company capitalised costs associated with the acquisition and development of core intellectual property (primarily patents) until December 1999. Such costs are amortised on a straight-line basis over the estimated useful lives of 15 years. In December 1999, the directors revalued the intangible assets upwards by \$14,661,942 and recorded the revaluation in the asset revaluation reserve in equity. The increased asset value resulted in additional amortisation for periods subsequent to the revaluation. All costs associated with the acquisition and development of core intellectual property incurred subsequent to the December 1999 revaluation are expensed as incurred under A-GAAP.

For US GAAP purposes, the Company capitalises costs associated with the acquisition of patents and other core intellectual property, legal costs incurred in connection with successful patent defences and costs associated with successful patent applications. Such costs are amortised on a straight-line basis over the estimated useful lives of 15 years. All other costs associated with patents and other core intellectual property are expensed as incurred. Upward revaluations of intangible assets are not allowed under US GAAP (except in connection with a purchase business combination).

**c. Deferred tax effect of US GAAP adjustments**

The deferred tax effect of US GAAP adjustments is nil because it is more likely than not that the net deferred tax asset will not be realized, and accordingly, the Company has recorded a 100% valuation allowance against the net deferred tax asset.

**d. Statement of cash flows**

The presentation of the statements of cash flows in accordance with A-GAAP differs from that required in accordance with SFAS No. 95: *Statement of Cash Flows* ("SFAS 95") under US GAAP. Under A-GAAP, cash held in term deposits with original maturities of less than one year is classified as cash. Under US GAAP, term deposits with original maturities greater than 90 days do not qualify as cash or cash equivalents; rather, such term deposits are classified as current investments. Accordingly, the net change in term deposits with original maturities greater than 90 days is classified as a component of cash flows from investing activities for US GAAP purposes.

The following is a reconciliation of the Statements of Cash Flows had the statement been prepared using the presentation requirements of SFAS 95 (A GAAP measurement principles have been adopted):

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**25 RECONCILIATION TO US GAAP continued**

	<b>Years Ended 30 June</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net cash flows used in operating activities, as reported	<u>(5,347,420)</u>	<u>(3,590,613)</u>	<u>(3,799,515)</u>
Net cash flows used in investing activities, as reported	(134,362)	(87,929)	(50,689)
Less: Term deposits with original maturities greater than 90 days	<u>(1,630,000)</u>	<u>-</u>	<u>-</u>
Net cash outflows used in investing activities, as adjusted	<u>(1,764,362)</u>	<u>(87,929)</u>	<u>(50,689)</u>
Net cash flows from financing activities, as reported	<u>31,781,165</u>	<u>3,569,792</u>	<u>580,345</u>
Net increase/(decrease) in cash held, as adjusted	24,669,383	(108,750)	(3,269,859)
Opening cash brought forward	3,463,783	3,585,014	6,854,873
Exchange rate adjustments on the balance of cash held in foreign currencies	(182,768)	(12,481)	-
Cash at end of year, as reported	29,580,398	3,463,783	3,585,014
Less: Term deposits with original maturities greater than 90 days	<u>(1,630,000)</u>	<u>-</u>	<u>-</u>
Cash at end of year, as adjusted	<u>27,950,398</u>	<u>3,463,783</u>	<u>3,585,014</u>

**e. Other**

Under A-GAAP, cash held in short term deposits with original maturities of less than one year is classified as a component of cash. Under US GAAP, only term deposits with original maturities of 90 days or less qualify as cash equivalents.

Under A-GAAP, interest income is reported as a component of revenue from ordinary activities. Under US GAAP, interest income is reported as a component of non-operating income.

Under A-GAAP, amortisation of intangible assets used in research and development projects is reported in depreciation and amortisation expense. Under US GAAP, amortisation of intangible assets used in research and development projects is reported in research and development expense.

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**25 RECONCILIATION TO US GAAP continued**

Under A-GAAP, other expenses from ordinary activities consist of the following:

	<b>Years Ended 30 June</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Travel	284,105	295,257	78,483
Insurance	53,451	62,403	41,158
Marketing	230,459	198,832	71,690
Office overhead costs	190,488	198,704	139,404
Foreign exchange loss	182,768	12,481	-
Other	269	13,397	5,696
Total	941,540	781,074	336,431

Under US GAAP, travel, insurance, marketing and office overhead costs are classified as general and administrative costs.

## **SIGNATURES**

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Prana Biotechnology Limited

By: /s/Jonas V. Alsenas  
Dr. Jonas V. Alsenas  
Chief Executive Officer

Dated: September 24, 2004

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement No. 333-116232 of Prana Biotechnology Limited on Form F-3 of our report dated September 13, 2004 except for Notes 11(f), 17 and 25 as to which the date is 24 September, 2004, appearing in this Annual Report on Form 20-F of Prana Biotechnology Limited for the year ended June 30, 2004.

/s/ Deloitte Touche Tohmatsu

DELOITTE TOUCHE TOHMATSU

Melbourne, Victoria, Australia

September 24, 2004

**CERTIFICATION PURSUANT TO  
SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002**

I, Jonas V. Alsenas, certify that:

1. I have reviewed this annual report on Form 20-F of Prana Biotechnology Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986]
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 24, 2004

/s/Jonas V. Alsenas\*  
Jonas V. Alsenas  
Chief Executive Officer

\* The originally executed copy of this Certification will be maintained at the Registrant's offices and will be made available for inspection upon request.

**CERTIFICATION PURSUANT TO  
SECTION 302(a) OF THE SARBANES-OXLEY ACT OF 2002**

I, Richard Revelins, certify that:

1. I have reviewed this annual report on Form 20-F of Prana Biotechnology Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986]
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 24, 2004

/s/Richard Revelins\*  
Richard Revelins  
Chief Financial Officer

\* The originally executed copy of this Certification will be maintained at the Registrant's offices and will be made available for inspection upon request.

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Prana Biotechnology Limited (the "Company") on Form 20-F for the period ending June 30, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jonas V. Alsenas, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/Jonas V. Alsenas\*  
Jonas V. Alsenas  
Chief Executive Officer

September 24, 2004

\* The originally executed copy of this Certification will be maintained at the Company's offices and will be made available for inspection upon request.

**18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Prana Biotechnology Limited (the “Company”) on Form 20-F for the period ending June 30, 2004, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Richard Revelins, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/Richard Revelins\*  
Richard Revelins  
Chief Financial Officer

September 24, 2004

\* The originally executed copy of this Certification will be maintained at the Company’s offices and will be made available for inspection upon request.