

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.

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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 products, including our current lead product candidate, PBT2, to market or generate revenues from their commercial application. Our current or any future product candidates, if successfully developed, may not generate sufficient or sustainable revenues to enable us to be profitable.

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. 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; and
- the status and timing of competitive developments.

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. However, such additional financing may not be available from any sources on acceptable terms, or at all, and we may not 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 or cease our operations, including our research and development activities, which would be expected to have a material adverse effect on our business, financial condition and results of operations.

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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, larger or more complex 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.

There is a substantial risk that we may not be able to complete the development of PBT2 or develop other pharmaceutical

products.

We may not be able to progress with the development of our current or any future pharmaceutical product candidates to a stage that will attract a suitable collaborative partner for the development of any current or future pharmaceutical product candidates. The projects initially specified in connection with any such collaboration and any associated funding may change or be discontinued as a result of changing interests of either the collaborator or us, and any such change may change the budget for the projects under the collaboration. Additionally, our research may not lead to the discovery of additional product candidates, and any of our current and future product candidates may not 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. The products we develop may not 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 payers. We cannot predict if or when the development of PBT2 or any future pharmaceutical product will be completed or commercialized, whether funded by us, as part of a collaboration or through a grant.

We may need to prioritize the development of our most promising candidates at the expense of the development of other products.

We may need to prioritize the allocation of development resources and/or funds towards what we believe to be our most promising product or products. The nature of the drug development process is such that there is a constant availability of new information and data which could positively or adversely affect a product in development. We cannot predict how such new information and data may impact in the future the prioritization of the development of our current or future product candidates or that any of our products, regardless of its development stage or the investment of time and funds in its development, will continue to be funded or developed.

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We will not be able to commercialize our PBT2 therapeutic compound for Alzheimer's disease or any future 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 PBT2 product candidate is 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 may not be able to undertake further clinical trials of our PBT2 compound as a therapeutic compound for Alzheimer's disease or other indications and any future product candidate (including one that may emerge from our vaccine program), or to demonstrate the safety and efficacy or superiority of any of these product candidates over existing therapies or other therapies under development, or enter into any collaborative arrangement to commercialize our current or future product candidates on terms acceptable to us, or at all. For example, in April 2005, we ceased clinical trials of our PBT1 compound as a treatment for Alzheimer's disease. 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 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 PBT2. We reported net losses of A\$13,560,678, A\$11,142,320 and A\$11,590,594 during the fiscal years ended June 30, 2008, 2007 and 2006, respectively. As of June 30, 2008, our accumulated deficit was A\$66,043,716. We may never be able to achieve or maintain profitability.

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

Any future success will depend in large part on whether we can:

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

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. Any of the pending or future patent applications filed by us or on our behalf may not be approved, or we may not 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. Licenses required under patents held by third parties may not 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, export, 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.

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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. We may have to defend the validity of our patents in order to protect or enforce our rights against a third party. Third parties 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. While defending our patents, the scope of the claim may be reduced in breadth and inventorship of the claimed subject matter, and proprietary interests in the claimed subject matter may be altered or reduced. 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.

We have limited manufacturing experience with our product candidates. Delays in manufacturing sufficient quantities of such materials to the required standards for pre-clinical and clinical trials may negatively impact our business and operations.

We may not be able to manufacture sufficient quantities of PBT2 or any other development or product candidates in a cost-effective or timely manner. Manufacturing includes the production, formulation and stability testing of an active pharmaceutical ingredient. 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 operations.

We may be required to enter into contracting arrangements with third parties to manufacture PBT2 and any other development or product candidates for large-scale, preclinical and/or clinical trials. We may not be able to make the transition from laboratory-scale to development-scale, or from development-scale 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 may not 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 may not 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 expect that we will be required to design and develop new synthetic pathways for most, if not all, of the products that we currently intend to develop or may develop in the future. We can not predict the success of such efforts, the purity of the products that may be obtained or the nature of the impurities that may result from such efforts. If we are not able to obtain an acceptable purity for any product candidate or an acceptable impurity profile, pre-clinical and clinical trials would be delayed, which could have a material adverse effect on the priority of the development of our product candidates, our business, financial condition and results of operations.

We are dependent upon a sole manufacturer of our lead compound, PBT2, and on a sole manufacturer to encapsulate the compound and could incur significant costs and delays if we are unable to promptly find a replacement for either of them.

We typically rely on a single manufacturer to develop Good Manufacturing Practice (GMP) synthetic processes for our lead compounds. Our lead compound, PBT2, is manufactured by the Institute of Drug Technology Australia Limited. We also rely on a sole manufacturer, Patheon Inc., to encapsulate PBT2. We intend to continue these relationships and this approach, subject to ongoing appraisal of our manufacturing needs and financial position. We may not be able to promptly find a replacement manufacturer, if required, without incurring material additional costs and substantial delays.

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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 and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom, the Medical Products Agency, or MPA, in Sweden and the European Medicines Agency, or EMEA. 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 MHRA 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 may not 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 or consultancy 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 may not 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, MHRA, MPA, EMEA 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 our PBT2 product candidate. 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.

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

Our current or future products may not achieve market acceptance even if they are approved by the TGA, FDA or any other regulatory authority. The degree of market acceptance of such 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. Qualified personnel may not be available in adequate numbers or at a reasonable cost. Further, additional financing may not be available on acceptable terms, or at all, and our sales staff may not 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 may not be able to enter into marketing arrangements with any marketing partner or if such arrangements are established, our marketing partners may not 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 future 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 payers 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 and elsewhere. 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 historically obtained no fault compensation insurance for our clinical trials and intend to obtain similar coverage for future clinical trials. Such coverage may not 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. We may not be able to obtain product liability insurance in the event of the commercialization of a product or such insurance may not 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.

Risks Relating to Our Securities

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. During the last two fiscal years, the market price for our ordinary shares on the Australian Stock Exchange has ranged from as low as A\$0.18 to a high of A\$0.80 and the market price of our American Depositary Shares on the NASDAQ Capital Market has ranged from as low as US\$1.21 to a high of US\$6.73. The market price for our securities 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, patents 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;