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**UNITED STATES  
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, 2016

OR

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

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

OR

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

Date of event requiring this shell company report.....

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)

**Geoffrey Kempler, Chief Executive Officer**

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

**+61 3 9349 4906 (phone) ; +61 3 9348 0377 (fax)**

(Name, telephone, e-mail and/or facsimile number and address of company contact person)

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

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing sixty Ordinary Shares	NASDAQ Capital Market

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

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, 2016.....533,891,470

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes  No

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  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP  International Financial Reporting Standards as issued by the International Accounting Standards Board  Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow:

Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

This Annual Report on Form 20-F is incorporated by reference into our Registration Statement on Form S-8 (File No. 333-153669) and our Registration Statement on Form F-3 (Files No. 333-199783).

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## 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 as the aging process progresses, currently focusing on Alzheimer's disease, Huntington disease, Parkinson's disease and other movement disorders. Other potential applications for our therapies include certain cancers, age-related macular degeneration, Motor Neuron disease, Creutzfeldt-Jakob disease (the human variant of Mad Cow disease) and a variety of orphan neurodegenerative disorders.

The principal listing of our ordinary shares and listed options to purchase our ordinary shares is on the Australian Securities Exchange, or ASX. Since September 5, 2002, our American Depository Shares, or ADSs, have traded on the NASDAQ Capital Market under the symbol "PRAN." The Bank of New York, acting as depository, issues American Depository Receipts, or ADRs, each of which evidences an ADS, which in turn represents sixty of our ordinary shares. As used in this annual report, the terms "we," "us," "our" and "Prana" mean Prana Biotechnology Limited and its subsidiaries, unless otherwise indicated.

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

Our consolidated financial statements appearing in this annual report are prepared in Australian dollars and in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our consolidated financial statements appearing in this annual report comply with both the IFRS and Australian Accounting Standards.

In this annual report, all references to "U.S. dollars" or "US\$" are to the currency of the United States, 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.

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, or the Exchange Act, 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," and similar expressions are intended to identify forward-looking statements. 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.*"

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## PART I

### ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

### ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

### ITEM 3. KEY INFORMATION

#### A. SELECTED CONSOLIDATED FINANCIAL DATA

We prepare our consolidated financial statements in accordance with IFRS, as issued by IASB. Our consolidated financial statements appearing in this annual report comply with both the IFRS as issued by IASB and Australian equivalents to International Financial Reporting Standards, or A-IFRS.

The following table presents our selected consolidated financial data as of the dates and for each of the periods indicated. The following selected consolidated financial data as of June 30, 2016 and 2015 and for the years ended June 30, 2016, 2015 and 2014 have been derived from our audited consolidated financial statements and notes thereto included elsewhere in this annual report. The selected consolidated financial data as of June 30, 2014 and 2013 and for the years ended June 30, 2013 and 2012 have been derived from our audited consolidated financial statements and notes thereto which are not included in this annual report.

The selected consolidated financial data set forth below should be read in conjunction with and are qualified entirely by reference to Item 5. “*Operating and Financial Review and Prospects*” and our consolidated financial statements and notes thereto included elsewhere in this annual report.

#### Statement of Comprehensive Income:

	Year Ended June 30,			
	2016	2015	2014	2013
	(in A\$, except loss per share and number of shares)			
Revenue from continuing operations	142,657	176,842	363,775	150,867
Other income	4,753,697	6,317,438	7,845,396	4,488,526
Research and development expenses	(9,585,371)	(12,298,167)	(14,908,098)	(8,203,822)
General and administration expenses	(3,610,551)	(4,506,122)	(4,925,411)	(3,793,235)
Intellectual property expenses	(241,954)	(257,299)	(477,079)	(294,894)
Other operating expenses	(45,276)	(39,210)	(451,251)	(257,769)
Finance expense – ADDF	-	-	(29,978)	(17,676)
Other gains and losses	857,247	4,721,449	(746,593)	140,761
Net loss	(7,729,551)	(5,885,069)	(13,329,239)	(7,787,242)
Loss per share– basic and diluted	(1.45)	(1.17)	(3.11)	(2.30)
Weighted average number of ordinary shares outstanding - basic and diluted	533,891,470	502,714,982	428,047,123	338,700,006

**Balance Sheet Data**

	As at June 30,			
	2016	2015	2014	2013
	(in A\$)			
Cash and cash equivalents	28,593,538	34,909,574	34,167,018	13,346,760
Working capital	31,299,470	39,025,487	37,597,770	13,883,965
Total assets	33,725,020	41,834,382	41,640,855	17,073,821
Net assets	31,367,213	39,113,264	37,686,287	13,974,713
Issued capital	146,879,214	146,895,714	140,009,415	101,379,111
Share based payment reserves	9,363,181	9,363,181	8,937,434	10,526,925
Accumulated deficit during development stage	(124,875,182)	(117,145,631)	(111,260,562)	(97,931,323)
Total equity	31,367,213	39,113,264	37,686,287	13,974,713

**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 U.S.\$ based on rates quoted on the U.S. Federal Reserve System. Each period end rate is the average ask price for the day. The average rate is the average of all the ask prices for the given time period. The high rate is the highest bid rate for the given time period. The low rate is the lowest bid rate for the given time period.

Year Ended June 30,	At Period End	Average Rate	High	Low
2012	1.0161	1.0327	1.1080	0.9387
2013	0.9146	1.0273	1.0624	0.9112
2014	0.9439	0.9183	0.9757	0.8659
2015	0.7655	0.8369	0.9457	0.7580
2016	0.7432	0.7289	0.7817	0.6855

Month	High	Low
April 2016	0.7817	0.7504
May 2016	0.7641	0.7184
June 2016	0.7598	0.7225
July 2016	0.7632	0.7453
August 2016	0.7717	0.7516
September 2016 (through September 23)	0.7470	0.7675

The exchange rate on September 23, 2016 was U.S.\$ 0.7621 = A\$1.00.

**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 Financial Condition**

**We have a history of significant operating losses since we began operations, we expect to continue to incur operating losses for the foreseeable future and may never achieve or maintain profitability.**

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. We have incurred losses in every period since we began operations in 1997 and reported net losses of A\$7,729,551, A\$5,885,069 and A\$13,329,239 during the fiscal years ended June 30, 2016, 2015 and 2014, respectively. As of June 30, 2016, our accumulated deficit was A\$124,875,182. We expect to continue to incur additional operating losses over at least the next several years as we expand our research and development and pre-clinical activities and commence additional clinical trials of PBT2 and new trials for our product candidate for Parkinson movement disorders, PBT434 and other metal protein attenuating compounds, or MPACs.

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.

If we fail to generate revenue and eventually become and remain profitable, or if we are unable to fund our continuing losses, our shareholders could lose all or part of their investments.

**We will need substantial additional funding to complete our clinical trials and to operate our business; such funding may not be available or, if it is available, such financing is likely to substantially dilute our existing shareholders.**

In the years ended June 30, 2016 and 2015, we raised A\$nil and A\$7,109,583, respectively, from the sale of our ordinary shares pursuant to our at-the-market offering facility. While we have not raised any additional funds since June 30, 2015, we will need to secure additional financing in order to continue to meet our longer term business objectives, including advancement of our research and development programs. We may also require additional funds to pursue regulatory clearances, 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 licensing of our assets or strategic alliances or other arrangements with corporate partners. The global economic climate could adversely impact our ability to obtain such funding, license our assets or enter into alliances or other arrangements with corporate partners.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never achieve, we expect to finance our cash needs primarily through public or private equity offerings, debt financings or through strategic alliances.



We cannot be certain that additional funding will be available on acceptable terms or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials, collaborative development programs or future commercialization initiatives. In addition, any additional funding that we do obtain will dilute the ownership held by our existing security holders. The amount of this dilution may be substantially increased if the trading price of our ADSs is lower at the time of any financing. Regardless, the economic dilution to shareholders will be significant if our stock price does not increase significantly, or if the effective price of any sale is below the price paid by a particular shareholder. Any debt financing could involve substantial restrictions on activities and creditors could seek a pledge of some or all of our assets. We have not identified potential sources for the additional financing that we will require, and we do not have commitments from any third parties to provide any future financing. If we fail to obtain additional funding as needed, we may be forced to cease or scale back operations, and our results, financial condition and stock price would be adversely affected.

**We are a development stage company of pharmaceutical products and our success is uncertain.**

We are a development stage company of our pharmaceutical products which are designed to treat the underlying causes of degeneration of the brain. 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.

**Risks Related To Our Business**

**We are faced with uncertainties related to our research.**

Our research programs are based on scientific hypotheses and experimental approaches that may not lead to desired results. In addition, the timeframe for obtaining proof of principle and other results may be considerably longer than originally anticipated, or may not be possible given time, resource, financial, strategic and collaborator scientific constraints. Success in one stage of testing is not necessarily an indication that the particular program will succeed in later stages of testing and development. It is not possible to predict whether any of the drugs designed for these programs will prove to be safe, effective, and suitable for human use. Each drug will require additional research and development, scale-up, formulation and extensive clinical testing in humans. Unsatisfactory results obtained from a particular study relating to a program may cause us to abandon our commitment to that program or to the lead compound or product candidate being tested. The discovery of toxicities, lack of sufficient efficacy, unacceptable pharmacology, inability to increase scale of manufacture, market attractiveness, regulatory hurdles, competition, as well as other factors, may make our targets, lead therapies or product candidates unattractive for further development or unsuitable for human use, and we may abandon our commitment to that program, target, lead therapy or product candidate.

**Clinical trials are expensive and time consuming, and their outcome is uncertain.**

In order to obtain approvals to market a new drug product, we or our potential partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our potential partners will have to conduct extensive preclinical testing and "adequate and well-controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per trial. Even if we obtain positive results from preclinical or initial clinical trials, we may not achieve the same success in future trials. Clinical trials may not demonstrate statistically sufficient safety and effectiveness to obtain the requisite regulatory approvals for product candidates employing our technology. The failure of clinical trials to demonstrate safety and efficacy for a particular desired indication could harm development of that product candidate for other indications as well as other product candidates.

We expect to commence new clinical trials from time to time in the course of our business as our product development work continues. Any change in, or termination of, our clinical trials could materially harm 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 enrollment;
- our inability to manufacture sufficient quantities of our new proprietary compound or our other product candidates or matching controls;
- unforeseen safety issues; or
- lack of efficacy or unacceptable toxicity during the clinical trials or non-clinical studies.

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 the clinical trials. Moreover, we rely on third parties such as clinical research organizations to assist us in clinical trial management functions including; clinical trial database management, statistical analyses, site management and monitoring. 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.

If we experience delays in testing or approvals or if we need to perform more, larger or more complex clinical trials than planned, our product development costs may increase. Significant delays could adversely affect the commercial prospects of our product candidates and our business, financial condition and results of operations.

**We rely on research institutions to conduct our clinical trials and we may not be able to secure and maintain research institutions to conduct our future trials.**

We rely on research institutions to conduct our clinical trials. Our reliance upon research institutions, including public and private hospitals and clinics, provides us with less control over the timing and cost of clinical trials, clinical study management personnel and the ability to recruit subjects. If we are unable to reach agreements with suitable research institutions on acceptable terms, or if any resulting agreement is terminated, we may be unable to secure, maintain or quickly replace the research institution with another qualified institution on acceptable terms.

**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.

**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. Competition among biotechnology and pharmaceutical companies for qualified employees is intense, including competition from larger companies with greater resources, and we may not be able to continue to attract and retain qualified management, technical and scientific personnel critical to our success. Our success is highly dependent on our ability to develop and maintain important relationships with leading academic institutions and scientists 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 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 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 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.**

Our current or future products may not achieve market acceptance even if they are approved by regulatory authorities. 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 or 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.

**We have limited large scale 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 our product candidates in a cost-effective or timely manner. Manufacturing includes the production, formulation and stability testing of an active pharmaceutical ingredient and its formulation into pharmaceutical products, such as capsules or tablets. Any delays in production would delay our pre-clinical and human clinical trials, which could adversely affect our business, financial condition and operations.

We may be required to enter into contracting arrangements with third parties to manufacture our product candidates for large-scale, pre-clinical 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 product candidates that we currently intend to develop or may develop in the future. We cannot 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 product specification, pre-clinical and clinical trials would be delayed, which could adversely affect the priority of the development of our product candidates, our business, financial condition and results of operations. We also cannot guarantee that the active pharmaceutical ingredient will be suitable for high throughput encapsulation to produce drug products. This may adversely impact the cost of goods or feasibility of market scale manufacture.

Until recently we have depended upon a sole drug substance manufacturer of our lead compound, PBT2, and currently depend on a sole drug product manufacturer to encapsulate the compound. We could incur significant costs and delays if alternative drug substance manufacturers of PBT2 are not suitable or technically capable of producing the PBT2 drug substance to our specifications, or, if we are unable to promptly find a replacement for our current drug product manufacturer.

To date, we have relied on a single manufacturer to develop Good Manufacturing Practice ('GMP'), synthetic processes for our lead compounds. Since 2008, our lead compound in Huntington and Alzheimer's disease, PBT2, has been manufactured by Dr. Reddy's Laboratories Limited, based in Hyderabad, India. This manufacturer enables efficient large scale manufacture of PBT2 to provide drug substance for the current and prospective trials in Alzheimer's patients and Huntington patients. In 2016, we commenced technology transfer of the synthetic process for the PBT2 drug substance to Orgapharm S.A.S. based in Pithiviers, France to facilitate potential process improvements and to establish a second GMP manufacturer of the PBT2 drug substance. In addition, in 2014, Dr. Reddy's manufactured the PBT434 drug substance to service the prospective Phase 1 program for PBT434, our lead compound in Parkinsonian movement disorders.

We currently rely on a sole manufacturer, Patheon Inc., to provide high speed encapsulation capability for PBT2 and placebos. We are actively seeking an additional and back up manufacturer, capable of high speed encapsulation for large scale manufacturing campaigns to service later stage clinical trials, but we may be unsuccessful in our efforts, or may incur material additional costs and substantial delays. In 2015, we appointed the Institute for Drug Technology, Boronia, Australia to undertake development work for the encapsulation of PBT434 drug substance and placebo to commence GMP manufacture in 2016. This campaign does not require high speed encapsulation.

**The failure to establish 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, 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 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 and elsewhere. The adoption of any such legislative or regulatory proposals could adversely affect 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 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.

**Breaches of network or information technology security, natural disasters or terrorist attacks could have an adverse effect on our business.**

Cyber-attacks or other breaches of network or information technology (IT) security, natural disasters, terrorist acts or acts of war may cause equipment failures or disrupt our research and development operations. In particular, both unsuccessful and successful cyber-attacks on companies have increased in frequency, scope and potential harm in recent years. Such an event may result in our inability, or the inability of our partners, to operate the research and development facilities, which even if the event is for a limited period of time, may result in significant expenses and/or significant damage to our experiments and trials. While we maintain insurance coverage for some of these events, the potential liabilities associated with these events could exceed the insurance coverage we maintain. In addition, a failure to protect employee confidential data against breaches of network or IT security could result in damage to our reputation. Any of these occurrences could adversely affect our results of operations and financial condition.

We have been subject, and will likely continue to be subject, to attempts to breach the security of our networks and IT infrastructure through cyber-attack, malware, computer viruses and other means of unauthorized access. However, to date, we have not been subject to cyber-attacks or other cyber incidents which, individually or in the aggregate, resulted in a material impact to our operations or financial condition.

**We expect to expand our drug development, regulatory and business development capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.**

We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of drug development, regulatory affairs and business development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, and have a materially adverse effect on our business.

**Risks Related to Government Regulation**

**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 from such activities will be, subject to regulation by numerous international regulatory authorities. Prior to marketing, any therapeutic product developed must undergo rigorous pre-clinical testing and clinical trials and, to the extent that any of our pharmaceutical products under development are marketed abroad, by the relevant international regulatory authorities. For example in Australia, principally the Therapeutics Goods Administration, or TGA; 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 EMA. These processes can take many years and require the expenditure of substantial resources. Governmental authorities may not grant regulatory approval due to matters arising from pre-clinical animal toxicology, safety pharmacology, drug formulation and purity, clinical side effects or patient risk profiles, or medical contraindications.

In February 2015, the FDA placed PBT2 on Partial Clinical Hold due to particular non-clinical neurotoxicology findings in a dog study. These dog findings limit the dose of PBT2 that we can use in future trials. For more information, you should carefully review "Item 4.B. – Information on the Company – Business Overview – Clinical Trials for Our Lead Compound." We may be unsuccessful in lifting this Partial Clinical Hold or be required to undertake further development work that will adversely impact the timing of commercialization of PBT2. Similarly we may be delayed or prevented from obtaining regulatory approvals for PBT2 to conduct clinical trials by other competent regulatory authorities based on concerns with pre-clinical or clinical safety or clinical trial design. Failure or delay 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 product candidates.

**We will not be able to commercialize any current or 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 product candidates are safe and effective for use in humans for each target indication. Results from early clinical trials may not be predictive of results obtained in large-scale, later-stage clinical testing. 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 current and future product candidates as therapies for Alzheimer's disease, Huntington disease, Parkinsonian movement disorders or other indications 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. Clinical trial results that show insufficient safety and efficacy could adversely affect our business, financial condition and results of operations.

**Positive results in previous clinical trials of PBT2 may not be replicated in future clinical trials of PBT2, which could result in development delays or a failure to obtain marketing approval.**

Positive results in previous clinical trials of PBT2 may not be predictive of similar results in future clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed pre-clinical studies and clinical trials for PBT2 may not be predictive of the results we may obtain in later stage trials. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain FDA or EMA approval for their products.

**Even if approved, any product candidates that we or our subsidiaries may develop and market may be later withdrawn from the market or subject to promotional limitations.**

We may not be able to obtain the labeling claims necessary or desirable for the promotion of our product candidates if approved. We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory or if adverse events or other safety issues arise after approval, the FDA or a comparable regulatory agency in another country may withdraw marketing authorization or may condition continued marketing on commitments from us or our subsidiaries that may be expensive or time consuming to complete. In addition, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our or our subsidiaries' products, additional clinical trials, changes in labeling of our or our subsidiaries' products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of such products if approved.

**Healthcare reform measures and other statutory or regulatory changes could adversely affect our business.**

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our business. For example, the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "ACA"), enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare D program.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations.

The pharmaceutical and biotechnology industries are subject to extensive regulation, and from time to time legislative bodies and governmental agencies consider changes to such regulations that could have significant impact on industry participants. For example, in light of certain highly-publicized safety issues regarding certain drugs that had received marketing approval, the U.S. Congress has considered various proposals regarding drug safety, including some which would require additional safety studies and monitoring and could make drug development more costly. Additional legislation or regulation, if any, relating to safety or other aspects of drug development may be enacted in the future, which could have an adverse effect on our business.

**We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act.**

Our business operations may be subject to anti-corruption laws and regulations, including restrictions imposed by the U.S. Foreign Corrupt Practices Act (the "FCPA"). The FCPA and similar anti-corruption laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. We cannot provide assurance that our internal controls and procedures will always protect us from criminal acts committed by our employees or third parties with whom we work. If we are found to be liable for violations of the FCPA or similar anti-corruption laws in international jurisdictions, either due to our own acts or out of inadvertence, or due to the acts or inadvertence of others, we could suffer from criminal or civil penalties which could have a material and adverse effect on our results of operations, financial condition and cash flows.

**Risks Related to Intellectual Property**

**Our success depends upon our ability to protect our intellectual property and our proprietary technology, to operate without infringing the proprietary rights of third parties and to obtain marketing exclusivity for our products and technologies.**

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

- obtain and maintain patents to protect our own products and technologies;
- obtain orphan designation for our 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, we may not develop additional proprietary products or processes that are patentable, or we may not be able to license any other patentable products or processes.

Our products may be eligible for orphan designation for particular therapeutic indications that are of relatively low prevalence and for which there is no effective treatment. Orphan drug designation affords market exclusivity post marketing authorization for a product for a specified therapeutic utility. The period of orphan protection is dependent on jurisdiction, for example, seven years in the United States and ten years in Europe. The opportunity to gain orphan drug designation depends on a variety of requirements specific to each marketing jurisdiction and can include; a showing of improved benefit relative to marketed products, that the mechanism of action of the product would provide plausible benefit and the nature of the unmet medical need within a therapeutic indication. It is uncertain if our products will be able to obtain orphan drug designation for the appropriate indications and in the jurisdictions sought.



There is a risk that the U.S. Congress, for example, could amend laws to significantly shorten the exclusivity period. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect 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. 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 adversely affect 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. 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. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. 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 adversely affect our business, financial condition and results of operations.

The patents for our product candidates have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. In some of the larger potential market territories, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product's development and regulatory review or by procedural delays before the relevant patent office. However, such an extension may not be granted, or if granted, the applicable time period or the scope of patent protection afforded during any extension period may not be sufficient. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain the exclusive time period. If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U.S. and non-U.S. patents.

**We may face difficulties in certain jurisdictions in protecting our intellectual property rights, which may diminish the value of our intellectual property rights in those jurisdictions.**

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and the European Union, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our collaboration partners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition and results of operations may be adversely affected.

**Intellectual property rights do not address all potential threats to our competitive advantage.**

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to ours but that are not covered by the claims of the patents that we own.
- Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights.
- We or any of our collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license.
- We or any of our collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.
- Compulsory licensing provisions of certain governments to patented technologies that are deemed necessary for the government to access.

**Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products or product candidates.**

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the radiopharmaceutical industry involves both technological complexity and legal complexity. Therefore, obtaining and enforcing radiopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act was recently enacted in the United States, resulting in significant changes to the U.S. patent system. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent with regard to the type of amendments that are allowed during prosecution. These changes could limit our ability to obtain new patents in the future that may be important for our business.

**Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.**

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third-party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

#### **Risks Related to Our Securities**

##### **Our stock price may be volatile and the U.S. trading market for our American Depository Shares (ADSs) 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. On March 4, 2016, our Board of Directors resolved to change the ratio of our Ordinary Shares to ADSs from one (1) ADS representing 10 Ordinary Shares to 1 ADS representing 60 Ordinary Shares, which was effective March 24, 2016. During the last two fiscal years ended June 30, 2016 and subsequently until September 30, 2016, the market price for our ordinary shares on the ASX has, after giving effect to the implementation of the reverse ratio, ranged from as low as A\$0.06 to a high of A\$0.36 and the market price of our ADSs on the NASDAQ Capital Market has ranged from as low as U.S.\$2.70 to a high of U.S.\$17.64. 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;
- 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. Market fluctuations, as well as general political and economic conditions, such as a recession, interest rate or currency rate fluctuations, could adversely affect the market price of our securities.

**Ownership interest in our company may be diluted as a result of additional financings.**

We may seek to raise funds from time to time in public or private issuances of equity, and such financings may take place in the near future or over the longer term. In May 2011, we registered U.S.\$50,000,000 of securities for public sale pursuant to our registration statement on Form F-3. In July 2011, we issued a prospectus under such registration statement providing for the sale of up to 50 million ordinary shares represented by 5 million ADSs pursuant to an "At-The-Market" facility. In August 2013 we issued a prospectus providing for the sale of up to U.S.\$47,184,000 of our ordinary shares under an amended "At-The-Market" facility. On November 26, 2014, we entered into Amendment No. 2 to our At-The-Market Issuance Sales Agreement, to continue the at-the-market equity program under which we may from time to time sell up to an additional aggregate of \$50,000,000 of our ordinary shares represented by ADSs. From November 26, 2014 until June 30, 2015 we sold A\$7.1 million of additional ordinary shares under this program. We made no sales under this facility during the year ended June 30, 2016 and as of October 3, 2016, none of our ordinary shares were sold under this facility. Since the inception of our "At-The-Market" facility in 2011 and through June 30, 2016 we sold an aggregate of 167,113,270 ordinary shares under this facility and raised a total of A\$46.5 million (US\$42.5 million) in gross proceeds.

Without shareholder approval, we may not issue more than 25% of our outstanding ordinary shares in any twelve month period other than by a pro rata rights offering or a share purchase plan offer (of shares with a value at the issue price of up to A\$15,000 per shareholder to a maximum of 30% of our outstanding shares) in each case to the then existing shareholders in accordance with the listing rules of the ASX. Sales of our ADSs offered through our "At-The-Market" facility and future equity offerings may result in substantial dilution to the interests of our current shareholders. The sale of a substantial number of securities to investors, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

**There is a substantial risk that we are a passive foreign investment company, or PFIC, which will subject our U.S. investors to adverse tax rules.**

Holders of our ADSs who are U.S. residents face income tax risks. There is a substantial risk that we are passive foreign investment company, commonly referred to as a PFIC. Our treatment as a PFIC could result in a reduction in the after-tax return to the holders of our ADSs and would likely cause a reduction in the value of such ADSs. 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, cash is considered to be an asset that produces passive income. As a result of our substantial cash position and the decline in the value of our stock, we believe that we became a PFIC during the taxable year ended June 30, 2005, and once again qualified as a PFIC during each of the following fiscal years. We believe that we once again will be classified as a PFIC for the taxable year ended June 30, 2016. Highly complex rules will apply to U.S. holders owning ADSs. Accordingly, you are urged to consult your tax advisors regarding the application of such rules. U.S. residents should carefully read "Item 10.E. Additional Information - Taxation, United States Federal Income Tax Consequences" for a more complete discussion of the U.S. federal income tax risks related to owning and disposing of our ADSs.

**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. The declaration of dividends is subject to the discretion of our Board of Directors and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our ordinary shares, which is uncertain and unpredictable. There is no guarantee that our ordinary shares will appreciate in value or even maintain the price at which you purchased your ordinary shares.

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

Our ordinary shares are quoted in Australian dollars on the ASX and our ADSs have traded on the NASDAQ Capital Market in U.S. dollars. Movements in the Australian dollar/U.S. dollar exchange rate may adversely affect the U.S. dollar price of our ordinary shares. In the past year the Australian dollar has generally depreciated against the U.S. dollar. Any continuation of this trend may negatively affect the U.S. dollar price of our ordinary shares, even if the price of our ordinary shares in Australian dollars decreases or remains unchanged. However, this trend may not continue and may be reversed. If the Australian dollar strengthens against the U.S. dollar, the U.S. dollar price of the ordinary shares could increase, even if the price of our ordinary shares in Australian dollars decreases or remains unchanged.

## **Risks Related to Our Location in Australia**

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

We are incorporated in Australia. All of our executive officers and most of our directors are non-residents 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.

**As a foreign private issuer whose shares are listed on the NASDAQ Capital Market, we may follow certain home country corporate governance practices instead of certain NASDAQ requirements.**

As a foreign private issuer whose shares are listed on the NASDAQ Capital Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of The NASDAQ Stock Market Rules, with regard to, among other things, the composition of the board of directors and its committees, director nomination process, compensation of officers and quorum at shareholders' meetings. In addition, we may choose to follow Australian law instead of the NASDAQ Stock Market Rules that require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. A foreign private issuer that elects to follow a home country practice instead of NASDAQ requirements must submit to NASDAQ in advance a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws. In addition, a foreign private issuer must disclose in its annual reports each such requirement that it does not follow and describe the home country practice followed by the issuer instead of any such requirement. Accordingly, our shareholders may not be afforded the same protection as provided under NASDAQ's corporate governance rules. As of the date of this report, we have not elected to follow any home country practice instead of NASDAQ requirements.

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

We are incorporated in Australia and are subject to the takeovers laws of Australia. Among other things, we are subject to the Australian Corporations Act 2001, or the Corporations Act. Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing from 20% or below to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may deprive or limit our shareholders' strategic opportunities to sell their ordinary shares and may restrict the ability of our shareholders to obtain a premium from such transactions.

**Our Constitution and other Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders.**

As an Australian company we are subject to different corporate requirements than a corporation organized under the laws of the United States. Our Constitution, as well as the Corporations Act, set forth various rights and obligations that are unique to us as an Australian company. These requirements operate differently than from many U.S. companies and may limit or otherwise adversely affect our ability to take actions that could be beneficial to our shareholders. For more information, you should carefully review the summary of these matters set forth under the section entitled, "Item 10.B — Additional Information — Memorandum and Articles of Association" as well as our Constitution.

## Risks Related to Our Compliance with Sarbanes-Oxley

**We may fail to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002, which could adversely affect our operating results, investor confidence in our reported financial information, and the market price of our ordinary shares and ADSs.**

The Sarbanes-Oxley Act of 2002 imposes certain duties on us and our executives and directors. To comply with this statute, we are required to document and test our internal control over financial reporting. Our efforts to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, governing internal control and procedures for financial reporting, have resulted in increased general and administrative expenses and a diversion of management time and attention, and we expect these efforts to require the continued commitment of significant resources. We may identify material weaknesses or significant deficiencies in our assessments of our internal control over financial reporting. Failure to maintain effective internal control over financial reporting could result in investigations or sanctions by regulatory authorities and could adversely affect our operating results, investor confidence in our reported financial information, and the market price of our ordinary shares and ADSs.

**Material weaknesses in our disclosure controls and procedures could negatively affect shareholder and customer confidence.**

Under Sarbanes-Oxley, we are required to assess the effectiveness of our disclosure controls and procedures (as defined in Sarbanes-Oxley) on an annual basis. If we were to conclude that our disclosure controls and procedures were ineffective, shareholder and customer confidence could be negatively affected, which could have a material adverse impact on the market price of our ADSs.

## 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 1, 1233 High Street, Armadale, Victoria, 3143, Australia and our telephone number is 011-61-3-9824-5254. 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 website address is [www.pranabio.com](http://www.pranabio.com). The information in our website is not incorporated by reference into this annual report.

Our mission is to develop therapeutic drugs designed to treat the underlying causes of degeneration of the brain as the aging process progresses, currently focusing on Alzheimer's disease, Huntington disease and Parkinsonian movement disorders. Other potential applications for our therapies include neurodegenerative disorders, certain cancers, age-related macular degeneration, Motor Neuron disease, Creutzfeldt-Jakob disease (the human variant of Mad Cow disease) and a variety of orphan neurodegenerative disorders. 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. In August 2009, a key patent protecting our clinical drug asset PBT2 was granted by the European Patent Office, or the EPO. The patent entitled '8-Hydroxyquinoline derivatives' covers the composition of matter of selected families of 8-Hydroxyquinoline compounds, including PBT2, and the uses of such compounds for the treatment of neurological diseases, including Alzheimer's disease and Huntington disease. The European patent has a 20-year term expiring on July 16, 2023, with a possible extension of the term of up to five additional years under supplementary protection provisions. In November 2009, our key patent protecting our clinical drug asset PBT2 was granted in the United States. The U.S. patent, which is also entitled '8-Hydroxyquinoline derivatives,' covers the composition of matter of selected families of 8-Hydroxyquinoline compounds, including PBT2, and will expire on December 21, 2025. It is possible that the patent may be further extended in the future under the pharmaceutical extension of term provisions that apply in the United States. In March 2015, claims to the use of PBT2 in the treatment of Alzheimer's disease were granted and in October 2015, claims to the use of PBT2 for the treatment of Huntington disease were granted. In April 2011, the Japanese Patent Office granted the same patent, also entitled '8-Hydroxyquinoline derivatives', with the claimed subject matter encompassing compounds and pharmaceutical compositions containing PBT2 and the use of the compounds for the treatment of Alzheimer's disease. The Japanese patent will expire on July 2023 and may be eligible for pharmaceutical extension of patent term for up to a further five years. In December 2011, claims for our key patent protecting our product candidate for Parkinson's disease, PBT434 was granted in the United States. The patent is entitled 'Neurologically Active Compounds' and covers the composition of matter and pharmaceutical compositions of selected families of 8-hydroxyquinazolinone compounds, including PBT434. In March and April 2013, we also received a Notice of Grant from the Canadian Patent Office and European Patent Office, respectively, for our key patent protecting PBT434. The patents, which are entitled, 'Neurologically Active Derivatives' cover the composition of matter of selected quinazolinone compounds, including PBT434. These two cases also included additional granted claims to the use of the compounds for the treatment of neurodegenerative diseases.

The technology has progressed to yield a diversified library of MPACs, of which PBT2 is our lead development compound for Alzheimer's disease and Huntington disease (see "Item 4.B. – Information on the Company – Business Overview – Clinical Trials for Our Lead Compound"). A comprehensive data package for PBT434, our lead compound for prospective development in Parkinsonian movement disorders, has been prepared to support prospective first-in-man studies.

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 which we have relationships. In the three fiscal years ended June 30, 2016, our capital expenditures have totaled A\$54,603.

## **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.

The protein believed to be involved in the toxicity associated with 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. George Glenner sequenced the chemistry of the protein which has since become the dominant focus of Alzheimer's disease research world-wide. In 1987, Professors Masters, Beyreuther and Rudi 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. The intellectual property owned by our company has been developed at several internationally recognized institutional research facilities, listed below, and through a team of scientists employed or engaged by our company who are based at the University of Melbourne.

- The Massachusetts General Hospital, Genetics and Aging Unit in Boston. Massachusetts General Hospital is the largest teaching hospital for Harvard Medical School;
- University of California, San Francisco;
- The University of Melbourne, Department of Pathology; and
- The Florey Institute of Neuroscience and Mental Health in Melbourne.

Work conducted at these institutions demonstrated that clioquinol, codenamed PBT1, had potential efficacy for the treatment of Alzheimer's disease. Since completing our initial public offering and listing process of our ordinary shares on the ASX on March 28, 2000, we have concentrated our resources toward the pursuit of our disease targets and creation of a chemical library of MPACs. Our research efforts led to the development of a novel MPAC, PBT2, a low molecular weight chemical entity that demonstrates a significant pre-clinical improvement over PBT1, and currently a library of over 2,000 MPAC molecules in total (approximately 200 of which are of the same chemical class as PBT2 with the remaining MPACs of other chemical classes).

Our chemistry program is undertaken within laboratories leased from The University of Melbourne's Bio21 Molecular Science and Biotechnology Institute, which is a multidisciplinary research center that specializes in medical, agricultural and environmental biotechnology. Accommodating more than 500 research scientists, students and industry participants, the Bio21 Institute is one of the largest biotechnology research centers in Australia.

#### **Platform Technology, Discovery and Translational Research Programs**

We regard our intellectual property as a "platform technology" since we believe that it addresses the causes of a broad spectrum of neurodegenerative and age-related diseases based on the interrelationship of metals and proteins. Historically, the majority of our research efforts have been directed at research into potential therapeutics for the treatment of Alzheimer's disease, Huntington disease and Parkinsonian movement disorders. Published data together with 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, and we believe that the platform technology may also be applicable for movement disorders, certain cancers, age-related macular degeneration, Motor Neuron disease, Creutzfeldt-Jakob disease and other neurodegenerative diseases. To date, we have performed *in vivo* modeling for our lead compound candidates in mouse animal models for Alzheimer's disease, Huntington disease, Parkinsonian movement disorders, brain cancer and traumatic brain injury.

PBT2, our current Alzheimer's and Huntington disease lead MPAC product candidate, and PBT434, our candidate lead compound for Parkinsonian movement disorders, were selected from the MPAC library on the basis of rational drug design. Both compounds have been built "from the ground up" to fulfill very specific criteria such as oral bioavailability and ability to cross the blood-brain barrier, and have demonstrated significant effectiveness in both pre-clinical *in vitro* and *in vivo* testing.

To increase depth and breadth of our MPAC pipeline into new neurodegenerative indications, we have continued to develop our 'two tier' Translational Research program structure during 2016. The first tier encompasses core new chemical entity design, synthesis and characterization, the 'discovery phase' of the new entities as potential novel MPACs of interest based on their mechanism of action profile. Our discovery research has established Structure Function Relationships ("SAR") within chemical moieties that guide our chemists towards the design of novel therapeutic MPACs. The discovery phase also includes preliminary bioavailability and pharmacokinetic characterization of our MPACs. The second tier comprises 'translational' animal modeling programs to test and validate new candidate MPACs as potential development leads. To date our MPAC library comprises more than 2,000 MPACs. Using SAR that has been developed over years of testing and validation by Prana scientists, new compounds are being generated that retain MPAC functionality across diverse and novel chemical scaffolds. Over the last year, new compounds from ten scaffolds were synthesized with four scaffolds undergoing mechanistic profiling. The compounds are initially screened for differential activities including: (i) the ability to inhibit metal mediated oxidative stress and nitrosative stress; (ii) metal ionophore capability; (iii) the prevention of glutamate induced excitotoxicity, (iv) anti-oligomer aggregation; (v) inhibiting beta-amyloid peptide inhibition of LTP; and (vi) the ability to inhibit the activity of the signaling protein glycogen synthase kinase 3 $\beta$  by inducing its phosphorylation. New screening assays are under development to assess the capability of an MPAC to inhibit aggregation of tau species, to improve mitochondrial function and mechanisms of degradation and clearance. MPACs of interest arising from the Translational Research program may be progressed as back up compounds in Alzheimer's disease and Huntington disease, Parkinsonian movement disorders and/or new indications in neurodegeneration, in particular, orphan indications.



To date, our lead MPAC in Parkinsonian movement disorders, PBT434, which had previously progressed through extensive modelling in Parkinson's disease, has progressed through the Translational Research program and has demonstrated evidence of efficacy in several models of 'Atypical Parkinsonian disorders, including Multiple System Atrophy, Corticobasal Degeneration and Progressive Supranuclear Palsy.

New novel candidate MPACs have been identified in the discovery phase of the research program during 2016 and planning is underway to advance the most promising candidates into the Translational Research program later in calendar 2016.

#### *Alzheimer's disease*

PBT2, our lead MPAC for Alzheimer's disease, is the result of rational drug design and was built "from the ground up" to fulfill very specific criteria. It was designed so that it will be orally bioavailable and cross the blood-brain barrier and to have an improved safety and efficacy profile compared to the prototype MPAC, PBT1. Phase I trials for PBT2 were completed by February 2006 in healthy young and aged volunteers and demonstrated that the drug was well tolerated and suitable for Phase II clinical development.

In 2008, top line results for a Phase IIa clinical study in mild Alzheimer's disease patients were announced, including the primary endpoints of safety and tolerability being met together with several secondary endpoints in biomarker and cognition endpoints also being met. In November 2009, an erratum to the July 2008 edition of *The Lancet Neurology* journal was published that corrected the original results of the neuropsychological test battery, or NTB, arising from the Phase IIa trial. The corrected results show that the overall executive function domain of the NTB, comprising five cognitive tests, was significantly improved for those patients taking 250mg of PBT2 compared to patients on placebo.

In March 2011, we announced that the New York-based Alzheimer's Drug Discovery Foundation would make a \$700,000 project-based investment towards a Phase II imaging biomarker study in 40 patients with prodromal or mild Alzheimer's disease. In March 2014, top line results for the study were announced. The study entailed the use of an amyloid imaging ligand to detect changes in brain beta-amyloid burden after 52 weeks treatment with PBT2 or placebo. For more information, see Item 4.B. "Information on the Company - Business Overview - Clinical Trials for Our Lead Compound."

In July 2008, the results of extensive pre-clinical research findings for PBT2 were published in the journal *Neuron*. The paper by Prana scientist, Associate Professor Paul Adlard was entitled, "Rapid restoration of cognition in Alzheimer's transgenic mice with 8-hydroxyquinoline analogs is associated with decreased interstitial A $\beta$ ". The key findings included the demonstration that PBT2 could rapidly improve cognition in transgenic mice, prevent the formation of toxic soluble Abeta oligomers, lower the Abeta levels in the brain of transgenic mice and protect neurons from the toxic effect of Abeta at the synapses between neurons enabling improved neurotransmission. In March 2009, we published further data on the impact of PBT2 on synapses in transgenic animal models. The findings demonstrated that PBT2 could prevent the loss of synapses in these Alzheimer's disease animal models, indicating that PBT2 has a potent neuroprotective effect on neurons, consistent with the observation that PBT2 can improve cognitive performance in impaired transgenic animals.

During 2009 and 2010, our scientists further examined the apparent link between aging and disease related defects due to metal imbalances in the brain. In February 2010, we reported in *The Journal of Neuroscience* on the loss of synaptic zinc uptake mechanisms in aged animal models and how this correlated with cognitive impairment. Our scientists also investigated the molecular basis for the neuroprotective qualities of PBT2 in animal models of Alzheimer's disease. They found that several important intracellular signaling pathways required for neuronal function were stimulated when animals were treated with PBT2. In March 2011, we reported in the scientific journal PLoS ONE that in the same Alzheimer's animal model where PBT2 is able to significantly improve cognition, it also caused changes in the brain anatomy. Specifically, it was observed that PBT2 treatment had significantly increased the numbers of spines on the branches (or dendrites) of neurons in the hippocampus, a memory centre affected in Alzheimer's disease. Increasing the number of spines permits many more neurons to interconnect with any particular neuron thereby increasing the brain's capacity to carry out learning and memory functions. These findings provide an insight into how PBT2 helps preserve and protect neurons in Alzheimer's disease and also in animal models of Huntington disease.

In September 2011, new data was published on how the ability of PBT2 to transport and deliver zinc and copper in the brain contributes to mechanisms related to its anti-toxic effects of Alzheimer's disease, including inhibition of beta-amyloid aggregation and promotion of the activation of GSK3 protein, an important brain protein suggested to be involved in Alzheimer disease. In addition, one of our research scientists, Dr. Paul Adlard, received an Australian National Health and Medical Research Council, or NHMRC, grant to study the benefits of PBT2 and other compounds in age-related cognitive impairment in a program entitled, "The role of metals in healthy brain aging: identification of novel compounds to prevent age-related cognitive decline." The grant will provide an opportunity to explore the importance of metal distribution imbalances in the brain to both cognitive deficits with ageing and Alzheimer disease. Also in October 2011, our scientist and co-inventor of PBT2, Dr. Kevin Barnham, was awarded a NMHRC grant to explore how PBT2's copper binding and transport activity can inhibit brain excitotoxicity, which is the overstimulation of certain chemical neurotransmitter receptors on neurons (NMDA receptors). Excitotoxicity is a common feature in the brains of patients affected by neurodegenerative disorders such as Alzheimer's disease and Huntington disease. In March 2012, our Chief Scientific Advisor, Professor Rudolph E. Tanzi, published an important body of work on the role of brain metals in the etiology of Alzheimer's disease, supporting Prana's therapeutic strategy. The paper was entitled, 'The Zinc Dyshomeostasis Hypothesis of Alzheimer's disease' published in *PLoS ONE* in March 2012.

In March 2013, Dr. Paul Adlard, presented a paper entitled, "Metal Chaperones are novel therapeutic agents for tauopathy." The findings presented exemplified that the ability of PBT2 to intercede in aberrant metal and target protein interactions and to correct abnormal metal distribution in the brain resulted in PBT2 being able to prevent the formation of 'tangle like' inclusions in neurons in a mouse model. Tau tangles are known to cause neuronal death. This work builds upon the knowledge that PBT2 can prevent the metal mediated toxic gain of function of target proteins such as Abeta and tau to form harmful aggregates in the brain. The data was generated in transgenic mouse model of tauopathy and demonstrated a significant decrease in tau tangle formation, a significant increase in cortical and hippocampal neurons and significant increase in cognitive performance as measured by the Y-maze.

In October 2013, Dr. Adlard also published a paper on the ability of PBT2 to restore learning and memory in old mice. His paper, entitled "A Novel Approach To Rapidly Prevent Age-Related Cognitive Decline" and published in the journal *Aging Cell*, demonstrated that PBT2 could restore the cognition of aged mice to that of young, cognitively normal mice. Age-related cognitive decline is associated with measurable structural and biochemical changes in the brain, which Prana scientists have shown to be significantly improved by PBT2 administration. Importantly, it has been shown that PBT2 up regulated expression of markers of neurogenesis and increased synaptic density which in turn, correlated with improved performance on memory tasks.

The underlying MPAC mechanisms of action of PBT2 work to prevent metal mediated neurodegenerative processes including oxidative stress, formation of toxic amyloid oligomers and compromised neuronal and synaptic function leading to cognitive impairment. In Alzheimer's disease, beta-amyloid aggregates in the synaptic cleft have been associated with impaired synaptic transmission as evidenced by reduced Long Term Potentiation experiments (LTP) in mice. Prana scientists have published that PBT2 is able to inhibit the beta-amyloid induced inhibition of LTP, thus restoring synaptic capability and cognitive function. In February 2015, a new mechanism of action of PBT2 was published in *Neurobiology of Disease* which demonstrated the ability of PBT2 to protect against glutamate-induced (synaptic) excitotoxicity in a metal dependent manner. The paper was entitled, "PBT2 inhibits glutamate-induced excitotoxicity in neurons through metal-mediated preconditioning". The over excitation of NMDA receptors in glutamatergic neurons leads to mitochondrial damage and cell death and has been postulated as one of the pathological events in Alzheimer's disease and Huntington disease. Further elucidation of the protective role of PBT2 is required, however it appears that the zinc ionophore property of PBT2 works to increase intracellular zinc in the post synaptic terminal, triggering the release of calcium which in turn, leads to neuroprotective pathways being activated inside the neuron that prevent excitotoxicity. Over the last two years, the ability of PBT2 to reduce the phosphorylation of the microtubule-associated protein 'tau' has been demonstrated in new *in vitro* screening assays and modelled in transgenic mice. Phosphorylated tau is deposited in cells as fibrillar aggregates in numerous neurodegenerative diseases, notably Alzheimer's disease and also Huntington disease and other neurodegenerative disorders. The functions of tau are regulated by site-specific phosphorylation events, which are dysregulated in the disease state, resulting in tau dysfunction and mislocalization. This can lead to aggregation, neuronal dysfunction and death. Unpublished data show that PBT2 can reduce tau phosphorylation and improve cognitive function in a transgenic tau mouse model.

## *Huntington disease*

Huntington disease is a crippling genetic neurodegenerative disorder of the central nervous system caused by a mutation in a gene which encodes the huntingtin protein. The disease results in progressive deterioration of physical, cognitive and emotional abilities that lead to severe incapacitation and eventually death, generally 15-25 years after the onset of the disease. Huntington disease primarily affects adults, usually between the ages of 30 and 50.

U.S.-based researchers have presented the effects of clioquinol in an animal model of Huntington disease, showing evidence of improved behavior, motor skills and inhibition of the abnormal form of the Huntingtin protein. Based on these findings, we have tested several proprietary MPACs in collaboration with researchers based at the Veterans Affairs Medical Center and the Department of Neurology, University of California, San Francisco, under a collaborative research agreement. PBT2 has shown good efficacy in the R6/2 mouse model of Huntington disease.

In late July 2008, we received the findings from a report commissioned by us from U.S.-based clinical researchers on the suitability of PBT2 for Huntington disease. The report detailed the relevance of animal modeling experiments done with PBT2, its demonstrated mode of action in the brains of Huntington disease model mice and its promising safety and efficacy findings in the earlier Alzheimer's disease Phase IIa study with PBT2. The report recommended that we proceed to clinical trials in Huntington disease research participants.

In July 2010, we presented data emerging from our research and development that the neuroprotective qualities of our lead product candidate PBT2 indicate that it may have clinical application in Huntington disease patients in addition to Alzheimer's disease. At the International Conference on Alzheimer's disease in Hawaii, Dr. Robert Cherny described how PBT2 prolonged survival, increased motor strength and delayed involuntary limb clenching that otherwise presents in the transgenic mouse model of Huntington disease. In addition, PBT2 appears to prevent the aggregation of the hallmark toxic mutant huntingtin protein. Examination of the brains of transgenic mice revealed that PBT2 had a significant impact on preventing the degeneration of neurons, further evidencing the neuroprotective attributes of PBT2 that had been reported earlier in our work on Alzheimer's disease.

In December 2010, our management assembled a team to develop a Phase IIa clinical trial protocol for the treatment of Huntington disease with PBT2. The group comprised leading clinical researchers from Australia and the United States, including members from the Huntington Study Group based in the United States and Australia. The team designed a six month Phase IIa clinical trial testing study most appropriate for PBT2, or the Reach2HD Trial, which included a double blind placebo controlled study of patients with early to mid-stage Huntington disease. For additional details regarding the clinical trial in Huntington disease with PBT2, see Item 4.B. "Information on the Company - Business Overview - Clinical Trials for Our Lead Compound."

In December 2012, we announced the publication of the paper entitled, "PBT2 extends lifespan, reduces striatal atrophy and improves motor performance in a transgenic mouse model of Huntington disease" in the *Journal of Huntington disease*. This paper describes how PBT2 significantly improved functional performance of the mice in the R6/2 model as a consequence of the neuroprotective properties of PBT2 by regulating certain metal mediated events in the brain.

As described in the preceding section, 'Platform Technology, Discovery and Translational Research Programs – Alzheimer's disease', in October 2013 Prana scientist Associate Paul Adlard published a paper in the journal *Aging Cell*, demonstrating that PBT2 could restore the cognition of aged mice to that of young, cognitively normal mice. Age-related cognitive decline is associated with measurable structural and biochemical changes in the brain, which Prana scientists have shown to be significantly improved by PBT2 administration. In particular, this restoration of cognitive function was accompanied by an increase in underlying hippocampal neurons, synaptic density and neuronal proliferation markers around the lateral ventricles, a region susceptible to atrophy in Huntington disease.

Important support for the role of copper in the disease process in Huntington disease came from Tsinghua University in China (Xiao et al PNAS 2013). Using a *Drosophila* model of Huntington disease, bearing an expanded polyQ Htt gene, workers showed that altered expression of genes involved in copper metabolism significantly modulates disease progression. Intervention in dietary copper levels also modified Huntington disease phenotypes in the fly and copper reduction decreased the level of oligomerized and aggregated Htt protein. Critically, substitution of two potential copper-binding residues of Htt, Met8 and His82, completely dissociated the copper-intensifying toxicity of Htt exon1-polyQ. The authors specifically identified copper binding compounds as an ideal therapy for Huntington disease. As mentioned above, in relation to our Alzheimer's disease research, the finding that PBT2 can positively reduce the phosphorylation of tau, supports the emerging profile of PBT2 as an MPAC with neuroprotective characteristics to support neuronal health and function with application in Huntington disease.

#### ***Parkinson's Disease and Movement Disorders***

Parkinson's disease, another crippling disease of the aging population, causes a progressive slowing of movement, tremors and the loss of fine motor control due to the death of *substantia nigral* cells in the brain. The *substantia nigral* cells produce the neurotransmitter dopamine in the brain, which is required for normal motor coordination. Increasingly, dementia is also being recognized as a significant component of Parkinson's disease. Existing therapies, such as dopaminergic agents, may provide some short-term symptomatic relief, but do not address the underlying cause of the disease. We believe that our MPAC technology may affect the aggregation of the proteins concerned in Parkinson's disease and related movement disorders.

During 2005, we entered into a contractual arrangement with the Integrative Neuroscience Facility based at the Florey Institute of Neuroscience and Mental Health in Melbourne, or the Florey Institute, to assist in the examination of the effect of MPACs administered to the 6-hydroxydopamine (PD) mouse model and the alternative MPTP (1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine) mouse model of the disease, which concluded with positive results. These two mouse models mimic the disease by using these toxins to destroy over time the cells of the *substantia nigra*, the area of the brain affected in Parkinson's disease, leading to motor function loss. We began investigating the efficacy of selected MPACs in these two models to screen for possible MPAC candidates as treatment candidates for Parkinson's disease. During 2009 and 2010, our lead Parkinson's disease treatment candidate emerged, PBT434. PBT434 demonstrated significant improvement in models motor function and coordination in both models. As this improvement was observed when the candidate compound was administered after toxins had destroyed significant amounts of *substantia nigra* tissue, the findings indicate that the compound can restore and maintain normal neuronal function. During 2011, further mechanistic characterisation work was undertaken, and it was demonstrated that PBT434 reduces the accumulation of the target protein in Parkinson's disease, alpha-synuclein, and elevates the levels of the neuroprotective protein, DJ-1, which helps to modulate and reduce oxidative stress in neurons.

In August 2011, the New York-based Michael J. Fox Foundation awarded us a \$206,000 grant entitled, 'PBT434, a Novel Neuroprotective Drug For Parkinson's Disease; Completion of Pre-Clinical Studies to Enable Human Clinical Trials.' The research supported by this grant has included various preclinical toxicology studies which were all successful, a clear genotoxicity report and successful safety pharmacology studies - allowing the compound to be positioned for larger scale animal toxicology studies prior to commencing clinical trials.

In November 2012, Prana scientists, Dr. Robert Cherny and Associate Professor David Finkelstein, Head of the Synaptic Neurobiology laboratory at the Florey Institute, received an NHMRC grant to study the benefits of PBT434 in a program entitled, "Identifying the mechanisms of action of a novel 8-hydroxyquinazolinone in models of Parkinson's disease." The program will help elucidate some of the innate mechanisms of action of PBT434.

In June 2013, Prana's science was highlighted at the 17<sup>th</sup> Movement Disorders Congress of Parkinson's Disease and Movement Disorders, in Sydney, Australia. Professor Colin Masters, Director of The Mental Health Research Institute at the Florey Institute and Assoc. Professor David Finkelstein presented data showing that PBT434 is able to prevent the aggregation of alpha synuclein protein target in Parkinson's and other movement disorders. The ability of PBT434 to reduce alpha synuclein has highlighted the opportunity for PBT434 to be investigated in other movement disorders characterized by the over expression alpha synuclein including the orphan indication of Multiple System Atrophy a relatively rare 'atypical parkinsonian' indication.

The MPAC metal binding and chelation properties of PBT434 promote redox silencing of iron, metal homeostasis and intercede in metal induced oxidative modification and aggregation of toxic  $\alpha$ -synuclein species. Part of this mechanistic information was supported in part by Parkinson's UK grant of £150,000 awarded in 2013 to Leeds University in collaboration with Professor David Finkelstein and Associate Professor Robert Cherny of the Florey Institute and Prana's Head of Research on the research.

As described above, PBT434 is neuroprotective having demonstrated significant preservation of the *substantia nigra*, a brain region containing dopaminergic neurons responsible for motor coordination. This has translated into improved motor function, coordination and cognition in the MPTP and 6-OHDA mouse models of Parkinson's disease and over the last two years, in the alpha-synuclein over expressing transgenic mouse model TgA53T. Over the past three years PBT434 has been profiled in mouse models of atypical Parkinsonian conditions including the orphan indications; Multiple System Atrophy (MSA) and Tauopathies such as Corticobasal Degeneration and Progressive Supranuclear Palsy. An outline of results to date includes:-

- ❖ Preservation of motor function in animal models of Parkinson's disease created by administration of the Parkinsonian toxins (MPTP) and 6-OHDA.
- ❖ Significantly improved motor function and coordination as tested by the ability of MSA mice to remain on a rotating rod. Indeed this improvement has been sustained for five months and resulted in a reduction in the accumulation of the insoluble forms of  $\alpha$ -synuclein.
- ❖ In TgA53T, a generic model of synucleinopathy, to investigate Dementia with Lewy Bodies, animals treated with PBT434 exhibited significantly increased numbers of *s.nigra* neurons and a significant reduction in insoluble  $\alpha$ -synuclein and incidence of clapping behavior. Cognition evaluated using the Y-Maze is also significantly improved.
- ❖ In mutant overexpressing tau mice, rTg4510, PBT434 has demonstrated highly significant improvement in the Y-maze cognitive assessment and resulted in a significant reduction in the number of abnormal tau deposits in the hippocampus of 12 month old mice.
- ❖ Significant reduction in the levels of  $\alpha$ -synuclein and tau in the cerebrospinal fluid (CSF) sampled from normal healthy rats within 4 hours and a reduction in  $\alpha$ -synuclein (non-significant) in CSF of dogs over a 28-day period.

A comprehensive ICH compliant IND-enabling non-clinical program has been conducted to evaluate PBT434's pharmacologic and pharmacokinetic profile, including an ICH compliant battery of GLP studies and a series of non GLP preclinical studies. The GLP program included: *in vitro* genotoxicity studies, safety pharmacology studies (the *in vitro* hERG, IRWIN and respiratory studies in rats and a telemetry study in dogs) and two pivotal 28 day toxicokinetic studies with recovery phase conducted in the rat and dog. The preclinical studies included: *in vitro* metabolism, drug interaction and plasma protein binding studies and *in vivo* PK and brain distribution studies in the rat and mouse. Overall PBT434 has been shown to be well tolerated with limited toxicity. It is anticipated that subject to regulatory approval PBT434 will commence its Phase 1 program during 2017 in healthy volunteers to investigate safety, tolerability, pharmacokinetics, pharmacodynamics and putative biomarkers of PBT434.

#### **Clinical Trials for Our Lead Compound**

In November 2005, we successfully completed the first Phase I trial for PBT2, a double blind, placebo-controlled single dose escalation study, conducted on 55 healthy male volunteers between the ages of 18 and 50, which was designed to evaluate the safety, tolerability and pharmacokinetics of PBT2. Data from the study showed that PBT2 was well tolerated with little difference in the incidence of adverse events between those receiving PBT2 and those receiving the placebo. Additionally, the pharmacokinetic analysis demonstrated that the drug exposure increased/decreased predictably and in a linear manner, both of which are desirable characteristics for a central nervous system drug.

In February 2006, we completed the second Phase I safety clinical trial for PBT2. This trial was a multi-dose escalation trial of PBT2 conducted in elderly, healthy male and female volunteers completed in December 2005. Volunteers were dosed at a selected dose for seven days; the dose range was from 200mg to 800mg per day. Both Phase I trials demonstrated that PBT2 was well tolerated and suitable for progression to Phase II trials in patients with Alzheimer's disease.

In February 2008, we reported the top line results of our three month double-blind, placebo-controlled safety and tolerability Phase IIa study of PBT2 in 80 elderly male and female patients with mild forms of Alzheimer's disease. We announced that the trial primary endpoints of safety and tolerability were met and we also announced that with respect to the secondary endpoints, namely biomarker, cognition and behavioral changes, several significant and promising changes were observed. Specifically, that in the cerebrospinal fluid (CSF), PBT2 treatment at a 250mg dose resulted in a significant decrease in the target Abeta 42 protein. In addition, at the 250mg dose, while no significant effect was observed with the ADAS-cog, two of the five NTB tests for improvement in executive function were significantly improved. In July 2008, the results of the Phase IIa trial were published in *The Lancet Neurology* journal.

In November 2009, an erratum to the July 2008 edition of *The Lancet Neurology* journal was published that corrected the original results of the NTB cognitive findings arising from the Phase IIa trial. The corrected results show that in addition to the two measures of executive cognitive function found to be significantly improved, the overall executive function domain of the NTB, comprising five cognitive tests, was significantly improved for those patients taking 250mg of PBT2 compared to patients on placebo. In April 2010, we published an analysis of the responses of individual patients treated with PBT2 in the Phase IIa clinical trial in the *Journal of Alzheimer's Disease*. The analysis demonstrated that there was a significant probability that any patient that showed cognitive executive function improvement in the trial was being treated with 250mg of PBT2. Moreover, 81% of patients on the 250mg dose of PBT2 responded better on the executive function of the NTB score than the best performing patient on placebo. Improvement in ADAS-cog, a measure of memory and cognition, was observed with patients treated with 250mg of PBT2, almost reaching statistical significance by 12 weeks of the Phase IIa trial. The corrected cognitive data from the Phase IIa trial together with the additional analysis provides strong evidence of the ability of PBT2 to improve cognitive executive function as measured by the NTB.

Also in November 2009, Prana presented its pre-clinical and clinical information package on PBT2 to the FDA in accordance with the Pre-Investigational New Drug, or IND, Consultation Program. The meeting provided useful guidance on possible steps to take to open an IND Application with the FDA to undertake clinical trials in the United States in Alzheimer's disease or Huntington disease. The meeting provided us with important information to help form our regulatory strategy for the development of PBT2 in these neurological indications.

In November 2011, we announced the approval from the Austin Health Research Ethics Committee based at the Austin Hospital Melbourne, to commence a 12 month Phase II imaging trial with PBT2 in patients with prodromal or mild Alzheimer disease. The study was supported in part by a grant of U.S.\$700,000 from the New York based Alzheimer's Drug Discovery Foundation, or ADDF. The trial entailed forty patients treated for twelve months with either 250mg PBT2 or a placebo. The trial was designed to investigate the effect of PBT2 on a patient's beta amyloid burden in the brain as measured by Positron Emission Tomography imaging (PET), secondary endpoints included brain metabolic activity as measured by F-18-fluorodeoxyglucose, FDG - PET and brain volume by Magnetic Resonance Imaging, or MRI, and safety. No significant changes in the primary endpoint comparing beta amyloid burden as measured using the imaging agent, Pittsburgh compound B (PiB) in the 27 patients treated with 250mg PBT2 compared to the 15 patients on placebo. Confounding interpretation of the result was the observed overall decline in amyloid burden in the placebo group. No improvement was observed for the secondary endpoints including brain metabolic activity, cognitive and functional measures. However, for patients treated with PBT2 there was a trend towards preserving brain volume in the hippocampus compared to those patients on placebo. A key secondary endpoint was the safety profile of PBT2 after 52 weeks treatment – the longest duration of PBT2 exposure to date in a clinical trial. The adverse event profile of the treatment versus placebo group was equivalent and 40 of the 42 enrolled participants completed the 52 week trial. Participants were provided the option to continue treatment on PBT2 for a further 52 weeks in an open label study, the 'IMAGINE Extension study' and thirty three participants elected to do so with twenty-seven participants completing the IMAGINE Extension study. The independent Data Safety Monitoring Board did not identify any safety concerns related to PBT2 over the combined two year period of the IMAGINE and IMAGINE Extension studies. Unpublished analysis of the IMAGINE Extension data does not distinguish between 12 and 24 months of exposure to PBT2 on any of the measured trial outcomes. However, exploratory post-hoc information from the Extension phase suggest that for the cohort of 27 trial participants that completed all 24 months (11 of the 15 participants that started IMAGINE on placebo together with 16 of the 25 participants that remained on PBT2 for 24 months), the amyloid levels decreased in this cohort compared to an historical control group from the Australian Imaging Biomarker and Lifestyle (AIBL) study.

In late 2012 we finalized the enrolment to a Phase II trial to test PBT2 in patients with Huntington disease over six months. The trial, known as "Reach2HD", was undertaken under an open IND application through the FDA and was conducted in clinical sites across the United States and Australia. The Phase IIa trial design entailed a double blind placebo controlled study of 109 patients with early to mid-stage Huntington disease. The primary objective for the trial was safety and tolerability of PBT2 in this Huntington disease patient population. Secondary endpoints included the effect of PBT2 on cognition, behaviour, functional capacity, motor effects. In addition, a small (n=6) exploratory arm of the study, was undertaken under the guidance of the co-Principal Investigator of the study, Professor Diana Rosas, using MRI brain imaging to undertake iron mapping and volumetric assessment in a patient's brain. Professor Rosas has published that iron and other metals change in concentration and distribution in the brain with increasing severity of the condition. This study was the first clinical trial with PBT2 in this patient population and the results were reported in February 2014. The primary objective of the study was achieved with PBT2 being demonstrated as safe and well tolerated in this first study of PBT2 in Huntington disease.

Cognition was pre-specified as the primary efficacy endpoint and was assessed using three Composite z-scores selected from individual tests; Category Fluency, Trail Making Test Part B, Map Search, Symbol Digit Modalities and Stroop Word Reading. The Main Cognition Composite – comprised of all five tests was not improved with treatment over the six months, nor was the Exploratory Cognition Composite – comprised of all five tests in addition to the Speeded Tapping Test. However, the Executive Function Composite, comprised of the Trail Making Test Part B and Category Fluency Test was significantly improved at 12 weeks (p=0.005) and trended towards improvement at 26 weeks (p=0.069). In the early stage Huntington disease patients, there was a significant improvement in the Executive Function composite (p=0.038). Of particular note, the Trail Making Test Part B of itself was significantly improved at 12 weeks (p=0.001) and at 26 weeks (p=0.042).

There were no significant findings in the other secondary endpoints although there was a small but positive signal in the Total Functional Capacity score. Interestingly, while the MRI did not detect changes in brain iron distribution in the study, the rate of brain cortical tissue thinning was greater in the placebo group compared to the two combined PBT2 treatment groups (100mg and 250mg).

In September 2014, we announced that PBT2 had been granted Orphan Drug designation in the treatment of Huntington disease by the FDA. Orphan Drug designation confers a number of incentives to drug developers including increased facilitation of communication with regulators to achieve concurrence on the development of the Orphan drug towards market approval. To achieve Orphan Drug designation, it must be established that the disease indication is of relatively low prevalence, that there is no existing comparable treatment option for patients and that the drug offers a plausible treatment. In June 2015, the European Commission approved orphan drug designation for PBT2 for the treatment of Huntington disease, stating that we have shown that PBT2 might be of significant benefit for patients with Huntington disease. The approval was based on the recommendation of a positive opinion from the EMA Committee for Orphan Medicinal Products.

During 2015 and 2016, three new PBT2 Phase 1 trials were successfully completed. The data from these trials have provided further safety, pharmacokinetic and pharmacodynamic information on PBT2 and will assist in the design of Phase 3 protocols for PBT2. These Phase 1 studies comprised:

1. A drug to drug interaction study, 'PBT2-104'. Based on in vitro metabolism studies indicating that PBT2 is both a substrate for, and an inhibitor of, CYP1A2, this study was designed to investigate the potential for drug to drug interactions in healthy volunteers when PBT2 is concurrently administered with other agents metabolized by this CYP450 isozyme.
2. A food interaction Study, 'PBT2-103'. Healthy volunteers were randomized into 2 dosing groups; one which was administered 250mg PBT2 after a 12 hour fast, the other which was administered 250mg PBT2 after a prescribed FDA meal. Blood samples were taken over multiple time points over 24 hours to determine the pharmacokinetic profile of PBT2 and its metabolites.
3. Evaluation of the three pharmacokinetic parameters, absorption, metabolism and excretion (ADME) of [C]-PBT2 and to estimate the Absolute Bioavailability of PBT2 in healthy volunteers, 'PBT2-102' to understand the passage of the drug in humans after administration.

Notwithstanding the clinical safety demonstrated to date with PBT2 in our Phase II programs in Alzheimer's disease and Huntington disease, in February 2015 we reported that the FDA had placed PBT2 on Partial Clinical Hold, or PCH, based on particular non-clinical neurotoxicology findings in a dog study. These dog findings limit the dose of PBT2 that we can use in future trials. To have this limitation removed, the FDA required us to establish how the dog study is not relevant to future PBT2 trials in humans or, to describe a strategy to safely proceed with clinically relevant dosages in future clinical trials with PBT2. While our response to the FDA requirements has the proximate goal of removing the PCH, we have used this exercise more broadly to create a strong clinical and non-clinical package of data and its interpretation, to facilitate clinical and commercial development of PBT2, not only in the United States but globally, for both Huntington disease and Alzheimer's disease. The process for assembling this package was facilitated with the appointment of third party specialist pharmacometricians, clinical safety physicians and clinical pharmacologists. They have undertaken extensive safety analyses to characterize the behavior of PBT2 drug exposure in the dog and human and how this translates to the comparative safety profile in the dog relative to humans. Based on the emerging strong safety profile for PBT2, we have prepared a robust safety monitoring plan for future trials in Huntington disease. These plans and a Phase 3 protocol have been submitted to the FDA as part of our response. The combined non-clinical, clinical pharmacology and safety analysis package will be used in part for submissions to European and other regulators in support of our global development plans and prospective marketing approvals.

## **Patents and Licenses**

### ***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 adversely affect 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 grant and 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 of competent jurisdiction 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, 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 adversely affect 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 U.S. 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 adversely affect our business, financial condition and results of operations.

In addition to patent protection, we rely on unpatented trade secrets, know-how and other confidential information as well as proprietary technological innovation and expertise. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisers, third parties may still obtain this information or come upon this same or similar information independently.

#### ***Patent Portfolio***

Over the last year Prana has received further approvals from international patent office's relating to its patent estate. Consequently, the majority of patents covering our lead MPAC's - PBT2, PBT434 and PBT519 have now been Granted. The company continues to pursue 'composition of matter' claims and claims to the use of those drugs for the treatment of neurodegenerative diseases in major jurisdictions, particularly the United States.

Prana also continues to work towards the discovery of new chemical entities that may be effective drugs for various neurodegenerative disorders. Over the last year, Prana chemists have synthesized a large number of different compounds from different chemical classes, with many compounds displaying compelling results in our screening and animal modelling. Our screening paradigm continues to evolve to reflect the latest technology available to our scientists and new mechanisms of action.

A total of six national phase patent case families protect Prana's core MPAC technology. The first case is directed to the 8-hydroxyquinoline chemical class which covers PBT2 and other lead 8-hydroxyquinoline compounds. The other five cases are directed to several 'Follow Up' or next generation MPAC chemical classes, which comprise MPAC scaffolds that are an alternative to the 8-hydroxyquinoline chemical scaffold. The majority of the below patent cases include claims to MPAC compositions of matter and the uses of these compounds in numerous neurological disorders. Notably these cases include composition of matter claims to Prana's lead MPACs for Parkinsonian movement disorders and brain cancer. All six cases have made further successful progress in their examination through the major international patent offices. In particular:

- (i) In October 2015, Prana achieved Allowance of patent claims in the USA covering the use of PBT2 for the treatment of Huntington's disease. These claims provide a second level of protection, in addition to the successfully Granted composition of matter claims to PBT2 in a related application.
- (ii) In August 2015, Prana filed a second Continuation Application in the USA, with claims seeking coverage of the use of 8-hydroxyquinoline compounds, other than PBT2 for the treatment of Huntington disease. This case is currently in active prosecution with the USPTO.
- (iii) In September 2015, Prana received Notice of Grant from the United States patent office in relation to the patent family entitled 'Quinazolinone compounds', which covers selected novel chemical drug candidates related to PBT434.

- (iv) In August 2015, Prana filed a Continuation Application, with claims directed to the use of Quinazolinone compounds for the treatment of neurological diseases. This case is also in active prosecution with the USPTO.
- (v) In December 2015, Prana filed a PCT application directed to 4H-Pyrido(1,2-a) Pyrimidin-4-one compounds, which are novel MPAC compounds for the treatment of neurodegenerative diseases.
- (vi) In March 2016 Prana re-filed two Australian provisional patent applications directed to novel methods of synthesizing compounds including the candidate PBT434 and compounds of similar structure. These patents are titled 'A method of the production of 2-substituted-3H-quinazolin-4-ones-I and 'A method of the production of 2-substituted-3H-quinazolin-4-ones-II'.
- (vii) The patent family cases entitled 'Compounds for Therapy and Diagnosis' continues to be prosecuted Europe, with a case in Canada proceeding to Acceptance. This case includes composition of matter claims to novel non-MPAC metallocomplex compounds that are designed to treat Alzheimer's disease by binding to the metal binding site of Abeta in the brain. The case also covers the use of these metallocomplexes as imaging agents for Alzheimer's disease.
- (viii) An Australian provisional patent application entitled 'Processes for the preparation of an 8-Hydroxyquinoline derivative' has been re-filed in January 2016 to cover alternative synthetic routes to selected 8-Hydroxyquinolines.

**Patent prosecution update**

PATENT	STATUS	INVENTION
"Beta amyloid peptide inhibitors" Filed: July 21, 2000 Applicant: Biomolecular Research Institute and University of Melbourne Assigned to Prana Biotechnology Limited	Patents have been granted in the USA, Canada and Australia.	The invention encompasses claims to specific classes of metallocomplex 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.
"Neurotoxic Oligomers" Filed: June 28, 2000 Applicants: Prana Biotechnology Limited and The General Hospital Corporation	Patents have been Granted in Australia, New Zealand, Canada, China and the USA (2). A case has been granted in Europe and has been validated in separate countries.	The invention is directed to an immunotherapy strategy using or targeting tyrosine cross-linked protein aggregates. The approach may be used in the treatment of Alzheimer's Disease and other amyloid related conditions.
"8-Hydroxyquinoline Derivatives" Filed: July 16, 2003 Applicant: Prana Biotechnology Limited	Patents in Europe, the USA, New Zealand, Canada, Japan, Russia, Singapore, South Korea, Australia, Israel, China, Mexico and South Africa have been Granted. A patent in Hong Kong has been registered. Applications in India and Brazil are under examination. A Continuation Application in the USA is also under examination.	The invention is directed to chemical scaffolds of the 8-Hydroxyquinoline MPAC class and their utility in the treatment of neurological conditions.
"Neurologically-Active Compounds" Filed: October 3, 2003 Applicant: Prana Biotechnology Limited	Patents in the USA, New Zealand, Canada, Japan, Mexico, India, Australia, China, South Korea, Japan, Israel, South Africa and Singapore have been granted. A case has been granted in Europe and has been validated in separate countries. An application in Brazil is under examination. A patent in Hong Kong has been registered.	The invention is directed to alternative MPAC chemical structures and their utility in the treatment of neurological conditions.

<p>"Neurologically- Active Compounds"  Filed: April 1, 2005  Applicant: Prana Biotechnology Limited</p>	<p>Patents have been granted in Singapore, Japan, Mexico, Russia, Australia, the USA, China, Canada, Europe, India, Sth Korea, Israel, New Zealand and South Africa. A case has been Granted in Europe and has been validated in separate countries. An application in Brazil is under examination. A patent in Hong Kong has been registered.</p>	<p>The invention is directed to 'F4' MPAC chemical structures and their utility in the treatment of neurological conditions and includes Parkinson's Disease lead compounds.</p>
<p>"Use of Clioquinol for the treatment of Alzheimer's Disease"  Filed: February 13, 1998  Applicant: Prana Biotechnology Limited</p>	<p>A Patent has been granted in the USA.</p>	<p>This invention is directed to the use of clioquinol for the treatment of Alzheimer's Disease.</p>
<p>"Pharmaceutical compositions of Clioquinol with B12 for therapeutic use"  Filed: February 13, 1998  Applicant: Prana Biotechnology Limited.</p>	<p>A patent has been granted in the USA.</p>	<p>This invention is directed to clioquinol pharmaceutical compositions comprising B12.</p>
<p>"Use of Clioquinol for the treatment of Parkinson's Disease"  Filed: February 13, 1998  Applicant: Prana Biotechnology Limited.</p>	<p>A patent has been granted in the USA.</p>	<p>This invention is directed to the use of clioquinol for the treatment of Parkinson's Disease.</p>
<p>"Method of treatment and prophylaxis and agents useful for same"  Filed: April 13, 2007  Applicant: Prana Biotechnology Limited</p>	<p>Patents have been granted in Australia, Singapore, South Africa, Canada, Japan, Israel, China and New Zealand. A case has been granted in Europe and has been validated in separate countries. Applications are under examination in the USA, India and Brazil.</p>	<p>This invention was originally filed to claim the use of MPAC compounds for the treatment of Age related Macular Degeneration.</p>
<p>"A method of prophylaxis or treatment and agents for same".  Filed: June 22, 2007  Applicant: Prana Biotechnology Limited</p>	<p>A patent has been granted in the USA, China, Australia, Canada and Japan. A case has been granted in Europe and has been validated in separate countries.</p>	<p>This invention is directed to novel MPAC compounds and compounds for treating certain brain cancers.</p>
<p>"Compounds for therapy and diagnosis"  Filed: December 5, 2008  Applicant: Prana Biotechnology Limited</p>	<p>Patents have been granted in New Zealand, Japan, USA and Australia. A remaining application in Europe is under examination. A patent in Canada has been Accepted.</p>	<p>This invention is directed to anti-amyloid angular metallocomplex compounds for the treatment of Alzheimer's Disease.</p>
<p>"Processes for the preparation of 8-Hydroxy quinoline Derivatives"  Filed: 4 January 2016  Applicant: Prana Biotechnology Limited</p>	<p>An Australian provisional application has been refiled.</p>	<p>This invention is directed to synthetic routes for 8-Hydroxyquinoline Derivatives.</p>

<p>“Quinazolinone compounds”  Filed: 24 December 2008  Applicant: Prana Biotechnology Limited</p>	<p>Patents have been granted in Japan and the USA. An application in the USA is undergoing prosecution. Cases in Australia and Europe have been Accepted.</p>	<p>This invention is directed to novel MPAC compounds and to selected MPAC’s used in the treatment of Parkinson’s Disease.</p>
<p>“4H-Pyrido(1,2-a) Pyrimidin-4-one compounds”  Filed: 2 December 2014 (prov)  Applicant: Prana Biotechnology Limited</p>	<p>A PCT patent application has been filed.</p>	<p>This invention is directed to novel MPAC compounds for the treatment of neurodegenerative diseases.</p>
<p>“A method of the production of 2-substituted-3H-quinazolin-4-ones-I”  Filed: 12 March 2016  Applicant: Prana Biotechnology Limited</p>	<p>An Australian provisional application has been refiled.</p>	<p>This invention is directed to synthetic routes for quinazolinone compounds.</p>
<p>“A method of the production of 2-substituted-3H-quinazolin-4-ones-II”  Filed: 12 March 2016  Applicant: Prana Biotechnology Limited</p>	<p>An Australian provisional application has been refiled.</p>	<p>This invention is directed to synthetic routes for quinazolinone compounds.</p>

On January 1, 2001, we entered into a license agreement with the General Hospital Corporation, or GHC, at Massachusetts General Hospital, under which we licensed from GHC certain patents. The agreement was subsequently amended on August 8, 2001 and March 15, 2004. Under the agreement, as amended, the license for a particular patent expires at the end of the term of the patent rights under the respective patent. In general, the anticipated patent expiration date is 20 years from the filing date of the respective patent application. Under the agreement, we agreed to pay GHC a total of U.S.\$166,590 in monthly installments over a 30 month period beginning January 1, 2001 and U.S.\$182,000 in monthly installments over a 30 month period beginning August 1, 2001 for the right to use the results of research under the license agreement. Such obligations have been satisfied by us in full, and we hold the rights under the license. We currently retain a license under the agreement with GHC for the patent ‘Neurotoxic Oligomers.’ This international patent application (PCT application) was filed on June 28, 2000 and matured into national phase prosecution in Canada, China, Europe, Japan and the U.S. Patents have been granted in Europe, Canada, China, Australia and New Zealand to both the active vaccines and the use of antibodies as a passive vaccine for Alzheimer’s disease. A patent has also been granted in the United States containing claims to an active vaccine. A further patent has been granted in the United States that contains claims to antibodies as a passive vaccine for Alzheimer’s disease. The patent is expected to expire on June 28, 2020. The invention is directed to a novel target for an Alzheimer’s disease vaccine. The technologies or products that may arise from this invention include toxic dimerized full length or fragments of beta-amyloid as active vaccines for Alzheimer’s disease or antibodies to these beta-amyloid fragments as passive vaccines for Alzheimer’s disease. The license provides for potential payments to GHC of an aggregate U.S.\$1.5 million, in accordance with the following milestones: (i) U.S.\$500,000 upon the submission of a registration dossier in the United States or Europe; and (ii) U.S.\$1.0 million upon the first approval of a product arising from the invention. The milestones have not been met to date.

#### 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, which are located worldwide, 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, research and screening capabilities, technical resources and manufacturing and marketing capabilities than we do. In addition, many of our competitors may have more experience than we do in non-clinical and human clinical trials of new or improved drugs, as well as in obtaining FDA, EMA, 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 from those activities will be, subject to regulation by human research ethics committees and institutional research boards, as well as numerous governmental authorities in Australia, principally the TGA, the FDA in the United States, the MHRA in the United Kingdom and the EMA in Europe. 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, EMA and MHRA.

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. We cannot 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 and commercially appropriate, 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. Delays in obtaining regulatory approvals could adversely affect the development and commercialization of our pharmaceutical product candidates and could adversely impact our business, financial condition and results of operations.

During the course of clinical trials and non-clinical studies, including 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 human research ethics committees, institutional research boards, the TGA, EMA, FDA or other regulatory authority for any or all targeted indications. Even after being cleared by a regulatory authority, 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 PBT2, PBT434 or any other development or product candidate will be safe or effective when administered to patients.

## Manufacturing and Raw Materials

Our lead compound, PBT2, has since 2008 been manufactured by Dr. Reddy's, based in Hyderabad, India, to provide drug substance for the trials in Alzheimer's patients and Huntington patients. In addition, in 2014, Dr. Reddy's manufactured PBT434 drug substance to service the prospective Phase 1 program for PBT434, our lead compound in Parkinsonian movement disorders. We have investigated other manufacturers as 'back-up' and alternative suppliers of drug substances to facilitate manufacture of pre-registration GMP compounds and investigate the possibility of manufacturing process improvements. In 2016, we commenced technology transfer of the synthetic process for PBT2 drug substance to Orgapharm S.A.S. based in Pithiviers, France to facilitate potential process improvements and to establish a second GMP manufacturer of PBT2 drug substance.

At this time, we rely on a sole manufacturer, Patheon Inc., to provide high speed encapsulation capability for PBT2 and placebos. For smaller scale encapsulation manufacturing campaigns of PBT434 for the prospective Phase 1 program we have engaged the Institute for Drug Technology, Boronia, Australia. We intend to continue using these manufacturers, subject to ongoing appraisal of our manufacturing needs and financial position.

Notwithstanding the appointment of a second manufacturer for PBT2 drug substance, we cannot make any assurances that we will be able to manufacture sufficient quantities of PBT2 or any other development or product candidate in a cost-effective or timely manner. Any delays in production would delay our non-clinical and human clinical trials, which could adversely affect our business, financial condition and results of operations. We also cannot make any assurances that we will be able to enter into collaborative or contracting arrangements on acceptable terms with third party manufacturers 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 cannot 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 product specification, non-clinical and clinical trials would be delayed, which could adversely affect the priority of the development of our product candidates, our business, financial condition and results of operations. We cannot guarantee that it will be possible to scale up new synthetic processes or make the necessary validated process improvements to provide sufficient API for clinical drug trials, which could indefinitely delay the initiation of clinical trials utilizing API. We also cannot guarantee that the API will be suitable for high throughput encapsulation to produce drug product. This may adversely impact the cost of goods or feasibility of market scale manufacture.

#### **C. ORGANIZATIONAL STRUCTURE**

We have two wholly-owned subsidiaries, Prana Biotechnology Inc. and Prana Biotechnology UK Limited, incorporated in the United States and the United Kingdom, respectively.

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

Our executive offices are located at 369 Royal Parade, Parkville, Victoria 3052, Australia, where we occupy approximately 3,800 square feet. The lease for the facility, which expires on September 30, 2017, has an annual rent of A\$123,368.

#### **ITEM 4A. UNRESOLVED STAFF COMMENTS**

Not applicable.

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

*The following discussion and analysis includes certain forward-looking statements with respect to the business, financial condition and results of operations of our company. The words "estimate," "project," "intend," "expect" and similar expressions are intended to identify forward-looking statements within the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated by such forward-looking statements, including those risk factors contained in Item 3.D. of this annual report. You should read the following discussion and analysis in conjunction with our consolidated financial statements and the notes thereto included in this annual report.*

#### **A. OPERATING RESULTS**

##### **Background**

We were incorporated under the laws of the Commonwealth of Australia on November 11, 1997. The principal listing of our ordinary shares and listed options to purchase our ordinary shares is on the ASX. Since September 5, 2002, our ADSs have traded on the NASDAQ Capital Market under the symbol "PRAN."

Our consolidated financial statements appearing in this annual report comply with both IFRS as issued by IASB and A-IFRS. In this annual report, all references to "U.S. dollars" or "US\$" are to the currency of the United States, and all references to "Australian dollars" or "A\$" are to the currency of Australia. All of our revenues are generated in Australian dollars, except for interest earned on foreign currency bank accounts, and the majority of our expenses are incurred in Australian dollars.

## Overview

We are a development stage enterprise at an early to mid-stage in the development of our pharmaceutical products that are designed to treat the underlying causes of neurodegeneration of the brain. 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 discovery phase or early and mid-stage 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 non-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, licensing and research collaborations and interest income.

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 disease targets. We have completed four Phase I studies of PBT2 and a Phase IIa clinical trial for PBT2 in patients with Alzheimer's disease. We have completed the "IMAGINE" Phase II biomarker imaging trial in Alzheimer's disease and a fifty two week open label IMAGINE Extension study and the "Reach2HD" Phase IIa trial in Huntington disease. For details regarding clinical trials for our lead compound PBT2, see Item 4.B. "Information on the Company - Business Overview - Clinical Trials for Our Lead Compound."

## Critical Accounting Policies

We prepare our financial statements in accordance with IFRS as issued by IASB. 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 to the consolidated financial statements that management believes are the most critical to aid in fully understanding and evaluating our financial condition and results of operations under IFRS are discussed below.

*Share-based payments.* Equity-settled share-based payments granted after November 7, 2002 that were invested as of January 1, 2005 are measured at fair value at the date of grant. Fair value is measured by use of the Black-Scholes model (for options without market conditions) or the Barrier Pricing model (for options with market conditions). The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioural considerations. The date used to value share-based payments for non-employees may be different to the grant date used to value employee share-based payments where service conditions apply. The fair value of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period for each tranche of equity, based on our estimate of equity that will eventually vest.

*Research and development payments.* Expenditure during the research phase of a project is recognized as an expense when incurred. Where no internally generated intangible assets can be recognized, development expenditure is recognized as an expense in the period as incurred. Development costs are capitalized if and only if, all of the following are demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

Internally-generated intangible assets, capitalized development costs, are stated at cost less accumulated amortization and impairment, and are amortized on a straight-line basis over their useful lives from the point at which the asset is ready for use.

*Revenue recognition from ordinary activities.* 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. Revenue is made up of interest income which is recognized on a time proportion basis using the effective interest method.

*Grants.* We recognize a grant when there is reasonable assurance that the grant will be received and all grant conditions will be complied with. When the grant relates to an expense item, it is recognised as income over the periods necessary to match the grant on a systematic basis to the costs that it is expected to compensate.

*Recoverable amount of non-current assets.* Each reporting period, our Board of Directors assesses the recoverable amount of all non-current assets to ensure its carrying value does not exceed its recoverable amount. Where the carrying amount of a non-current asset is greater than its recoverable amount, the asset is revalued down to its recoverable amount. Recoverable amount is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted.

*Reclassification of expenses to function in Statement of Profit or Loss and Other Comprehensive Income.* The presentation of our financial results was recently reviewed. The result of this review was to reclassify expenses to function in the Statement of Profit or Loss and Other Comprehensive Income in order to improve the presentation of financial information to the users of the financial statement. This change is in line with the standard industry practice and IFRS. Prior periods' comparatives have been revised to align to the disclosure in the current year. This change in accounting policy had no impact on the total comprehensive loss for the prior periods, or the Statement of Financial Position or Cash Flow Statement.

### **Significant Costs and Expenses**

*Research and development expenses.* Our research and development expenses consist primarily of expenses for contracted research and development activities conducted by third parties on our behalf. Research and development expenses also include costs associated with the acquisition, development of patents and salaries and fees paid to employees and consultants involved in research and development activities.

*General and administration expenses.* Our general and administration expenses consist of (i) personnel expenses such as directors' fees, salaries and benefits paid to employees and officers and equity-based payments awarded to directors, officers and employees; (ii) auditor and accounting expenses which are fees paid to our auditors for services related to annual reports and interim reports filed or submitted in Australia and the United States and fees paid to other accounting firms in respect of tax and other accounting advice; (iii) public relations and marketing expenses which are fees paid to outside consultants for services related to ASX and NASDAQ announcements and presentations; (iv) depreciation expenses; and (v) other administrative and office expenses.

*Intellectual property expenses.* Our intellectual property expenses consist of fees paid to our outside counsel for legal fees associated with patent applications and for the defense of patents.

*Other gains and losses.* Other gains and losses consist of foreign exchange gain (loss) which are the net unrealized gain or loss on cash balances and trade and other payables held in foreign currencies (primarily U.S. dollars, British Pounds and Euros) as well as net realized gains and losses on foreign currency transactions.



## Results of Operations

### Year ended June 30, 2016 compared to year ended June 2015

#### *Revenue from ordinary activities*

Revenue from continuing operations (consisting of interest income only) decreased to A\$142,657 for the year ended June 30, 2016 from A\$176,842 for the year ended June 30, 2015, a decrease of A\$34,185, or 19.33%. The decrease in revenue from continuing operations in the 2016 fiscal year is primarily attributable to lower cash and cash equivalents held in A\$ interest bearing accounts throughout the year and lower prevailing interest rates.

#### *Other Income*

We had other income of A\$4,753,697 for the year ended June 30, 2016, relating to eligible research and development activities, on which we are entitled to a 45% refundable tax offset under an Australian Government tax incentive, introduced on July 1, 2011. We had other income of A\$6,317,438 for the year ended June 30, 2015 relating to eligible research and development activities, on which we were entitled to a 45% refundable tax offset under an Australian Government tax incentive, introduced on July 1, 2011. The decrease in the research and development tax incentive is attributable to reduced eligible expenditure incurred in the 2016 fiscal year as described below.

#### *Research and development expenses*

Our research and development expenses decreased to A\$9,585,371 for the year ended June 30, 2016 from A\$12,298,167 for the year ended June 30, 2015, a decrease of A\$2,712,796, or 22.06%. The decrease in research and development expenses in the year ended June 30, 2016 is primarily attributable to the U.S. Food and Drug Administration's placement of PBT2 on Partial Clinical Hold.

#### *General and administrative expenses*

General and administrative expenses decreased to A\$3,610,551 for the year ended June 30, 2016 from A\$4,506,122 for the year ended June 30, 2015, a decrease of A\$895,571, or 19.87%. The decrease in general and administrative expenses in the fiscal year ended June 30, 2016 is attributable to reduced internal audit and corporate compliance activities.

#### *Intellectual property expenses*

Intellectual property expenses, which include patent portfolio costs and intellectual property related legal costs, decreased to A\$241,954 for the year ended June 30, 2016 from A\$257,299 for the year ended June 30, 2015, a decrease of A\$15,345, or 5.96%. The decrease in intellectual property expenses in the 2016 fiscal year was primarily the result of the maturation of the company IP portfolio.

#### *Foreign exchange gain (loss)*

We recorded a foreign exchange gain of A\$857,247 for the year ended June 30, 2016 compared to a foreign exchange gain of A\$4,721,449 for the year ended June 30, 2015. Foreign exchange gain (loss) reflects the impact of changes in foreign currency exchange rates on cash that we hold in U.S. dollars, British Pounds and Euros. In the 2016 and 2015 fiscal years, the Australian dollar depreciated against the U.S. dollar, which had a favorable impact on the Australian dollar value of our cash held in U.S. dollars. In the 2016 and 2015 fiscal years, the Australian dollar depreciated against the British Pound and Euro, which had a favourable impact on the Australian dollar value of our cash held in British Pounds and Euros. In the 2016 fiscal year, we incurred a foreign exchange gain of A\$951,219 attributable to the cash balances that we held in U.S. dollars, and a foreign exchange loss of A\$93,972 attributable to foreign currency transactions. In the 2015 fiscal year, we incurred a foreign exchange gain of A\$4,950,257 attributable to the cash balances that we held in U.S. dollars, a foreign exchange gain of \$2,995 attributable to the trade payables balances that we held in U.S. dollars, British Pounds and Euros and a foreign exchange loss of A\$231,803 attributable to foreign currency transactions.

## **Year ended June 30, 2015 compared to year ended June 30, 2014**

### *Revenue from ordinary activities*

Revenue from continuing operations (consisting of interest income only) decreased to A\$176,842 for the year ended June 30, 2015 from A\$363,775 for the year ended June 30, 2014, a decrease of A\$186,933, or 51.39%. The decrease in revenue from continuing operations in the 2015 fiscal year is primarily attributable to lower cash and cash equivalents held in A\$ interest bearing accounts throughout the year and lower prevailing interest rates.

### *Other Income*

We had other income of A\$6,317,438 for the year ended June 30, 2015, including A\$6,088,897 relating to eligible research and development activities, on which we are entitled to a 45% refundable tax offset under an Australian Government tax incentive, introduced on July 1, 2011. We had other income of A\$7,845,396 for the year ended June 30, 2014 relating to eligible research and development activities, on which we are entitled to a 45% refundable tax offset under an Australian Government tax incentive, introduced on July 1, 2011. The decrease in the research and development tax incentive is attributable to reduced eligible expenditures incurred in the 2015 fiscal year as described below.

### *Research and development expenses*

Our research and development expenses decreased to A\$12,297,167 for the year ended June 30, 2015 from A\$14,908,098 for the year ended June 30, 2014, a decrease of A\$2,609,931, or 17.51%. The decrease in research and development expenses in the year ended June 30, 2015 is primarily attributable to the majority of the expenses relating to the completion and reporting of both the Alzheimer's disease "IMAGINE" and Huntington Disease "Reach2HD" Phase II studies and pre-Phase III development and manufacturing costs being incurred in the previous year.

### *General and administration expenses*

General and administration expenses decreased to A\$4,506,122 for the year ended June 30, 2015 from A\$4,925,411 for the year ended June 30, 2014, a decrease of A\$419,289, or 8.51%. The decrease in general and administrative expenses in the fiscal year ended June 30, 2015 is attributable to reduced business development activities and external consultation services purchased.

### *Intellectual property expenses*

Intellectual property expenses, which include patent portfolio costs and intellectual property related legal costs, decreased to A\$257,299 for the year ended June 30, 2015 from A\$477,079 for the year ended June 30, 2014, a decrease of A\$219,780, or 46.07%. The decrease in intellectual property expenses in the 2015 fiscal year was primarily the result of the maturation of the company IP portfolio. Specifically, expenditure on local patent attorney services has decreased commensurately with patents Granted and no longer requiring billable prosecution. Due to the majority of patents in the portfolio now being Granted, renewal costs now represent a significant proportion of intellectual property expenses.

### *Foreign exchange gain (loss)*

We recorded a foreign exchange gain of A\$4,721,449 for the year ended June 30, 2015 compared to a foreign exchange loss of A\$746,593 for the year ended June 30, 2014. Foreign exchange gain (loss) reflects the impact of changes in foreign currency exchange rates on cash that we hold in U.S. dollars, British Pounds and Euros. In the 2015 fiscal year, the Australian dollar depreciated against the U.S. dollar, which had a favourable impact on the Australian dollar value of our cash held in U.S. dollars. In the 2014 fiscal year, the Australian dollar appreciated against the U.S. dollar, which had an adverse impact on the Australian dollar value of our cash held in U.S. dollars. In the two fiscal years ended June 30, 2015, the Australian dollar depreciated against the British Pounds and Euros, which had a favourable impact on the Australian dollar value of our cash held in British Pounds and Euros. In the 2015 fiscal year, we incurred a foreign exchange gain of A\$4,950,257 attributable to the cash balances that we held in U.S. dollars, a foreign exchange gain of A\$2,995 attributable to the trade payables balances that we held in U.S. dollars, British Pounds and Euros and a foreign exchange loss of A\$231,803 attributable to foreign currency transactions. In the 2014 fiscal year, we incurred a foreign exchange loss of A\$579,748 attributable to the cash balances that we held in U.S. dollars, a foreign exchange loss of A\$1,487 attributable to the cash balances that were held in Great British Pounds, a foreign exchange gain of A\$28 attributable to cash balances that were held in Euros and a foreign exchange loss of A\$165,330 attributable to foreign currency transactions.

## 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.

## 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. See Item 3.D. "Key Information – Risk Factors – Risks Relating to Our Location in Australia" for a description of factors that could materially affect our operations.

## Recently Issued International Accounting Standards and Pronouncements

### New and amended Accounting Standards and Interpretations Issued and Effective

There are no IFRS or IFRIC interpretations that are effective for the first time for the financial year beginning on or after June 30, 2016 that would be expected to have a material impact on us.

### Accounting Standards issued but not yet effective

Certain new accounting standards and interpretations have been published that are not mandatory for June 30, 2016 reporting periods:

<b>Pronouncement</b>	<b>Title (Issue date)</b>	<b>Effective date</b>	<b>Impact on financial report</b>
IFRS 15	Revenue from contracts with customers	Annual periods beginning on or after January 1, 2017 Earlier application is permitted.	The Company is currently not generating revenue from contracts and thus the impact is expected to be nil.
IFRS 9	Financial instruments	Annual periods beginning on or after January 1, 2018 Earlier application is permitted.	Management is in the process of determining the impact of this standard for subsequent reporting periods.
IFRS 16	Leases	Annual periods beginning on or after January 1, 2019 Earlier application is permitted.	Management is in the process of determining the impact of this standard for subsequent reporting periods.
IFRS 2 (Amendments)	Classification and Measurement of Share-based Payment Transactions	Annual periods beginning on or after January 1, 2018 Earlier application is permitted.	Management is in the process of determining the impact of this standard for subsequent reporting periods.

## B. LIQUIDITY AND CAPITAL RESOURCES

We are a development stage company and have had no sales income to date, and as of June 30, 2016 our accumulated deficit totaled A\$124,875,182. From inception until our initial public offering in March 2000 we financed our operations primarily through borrowings from two of our then 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. During the period from 2001 to 2006, we were awarded government grants in the aggregate amount of A\$3.3 million.

In September 2009, we raised A\$6.0 million before costs in a private placement to one of our institutional shareholders in the United States of 30 million ordinary shares (equivalent to 500,000 ADSs on a post reverse ratio basis) at a price of A\$0.20 per share (A\$12 per ADS on a post reverse ratio basis)). We also agreed to grant the investor, subject to shareholder approval, options to purchase 10 million ordinary shares (equivalent to one million ADSs) at an exercise price of A\$0.30 per share (A\$18 per ADS on a post reverse ratio basis)) that would expire four years after the date of the issuance of the shares in the September 2013 private placement. We also issued to the investor, based on an agreed upon formula, an additional 750,000 ordinary shares pursuant to the approval of our shareholders obtained in November 2009. For additional information, see Item 10.C. "Additional Information - Material Contracts."

In July 2010, we raised A\$1.15 million (US\$1.0 million) before costs in a private placement of 7.065 million of our ordinary shares (equivalent to 117,750 ADSs on a post reverse ratio basis)) to Quintiles, at a price of A\$0.1624 per ordinary share (US\$9.74 per ADS on a post reverse ratio basis). For additional information, see Item 10.C. "Additional Information - Material Contracts."

On February 21, 2011, the ADDF awarded us a grant of US\$700,000, to be provided in two equal instalments over two years. The purpose of the grant was to support a Phase II imaging trial with PBT2 to investigate the effect of PBT2 on the deposition of beta-amyloid in the brains of patients with mild Alzheimer's disease. The ADDF is based in New York and functions on a venture philanthropy model. We issued a convertible promissory note to the ADDF in the principal amount of the grant and a five-year warrant to purchase 612,397 ordinary shares of our company at a price per share of A\$0.17 (equivalent to US\$0.169), being the closing pricing of our ordinary shares on the ASX on the date of our agreement with ADDF. We also agreed to issue an additional five-year warrant to purchase US\$105,000 of our ordinary shares at a price per share equal to the closing price of our ordinary shares on the ASX on the date the second instalment of US\$350,000 was paid. The note was due and payable on February 25, 2014. As at June 30, 2014 both instalments totalling US\$700,000 were repaid in full.

In March 2011, we completed a private placement of our securities to institutional investors for aggregate gross proceeds of approximately A\$6.12 million (US\$6.19 million). Under the terms of the offering, we sold an aggregate of approximately 27.2 million ordinary shares (equivalent to 453,333 ADSs) at a price of A\$0.225 per share (A\$13.5 per ADS on a post reverse ratio basis). We also granted to the investors options to purchase up to an aggregate of approximately 6.8 million ordinary shares (equivalent to 113,333 ADSs) at an exercise price of A\$0.225 per share (A\$13.2 per ADS on a post reverse ratio basis). The options are exercisable for a term of four years, and the exercise price is subject to future adjustment for various events, such as stock splits or dividend distributions.

In June 2011, we completed a private placement of 5.69 million of our ordinary shares to institutional investors and Quintiles Limited, at a price of A\$0.225 per share, for aggregate gross proceeds of approximately A\$1.28 million (US\$1.4 million). We also granted the investors options to purchase 1.42 million ordinary shares at an exercise price of A\$0.225 per share that expired March 24, 2015.

In July 2011, we entered into an At-The-Market Issuance Sales Agreement with McNicoll, Lewis & Vlak LLC, now known as MLV & Co. LLC, or MLV, under which we may sell ADSs, each representing sixty ordinary shares, from time to time through MLV, as our agent for the offer and sale of the ADSs. As of June 30, 2016, we issued a total amount of 2,785,221 million ADSs on a post reverse ratio basis under the At-The-Market Issuance Sales Agreement for gross proceeds of A\$39.4 million (U.S.\$37.0 million).

In October 2012, we raised approximately A\$6.0 million through a private placement of 32.5 million ordinary shares (equivalent to 0.54 million ADSs on a post reverse ratio basis) at a price of A\$0.185 per ordinary share. The capital was raised in order to support our two ongoing Phase II clinical trials, the IMAGINE trial and Reach2HD trial.

In March 2013, we completed a private placement of 36.0 million ordinary shares to Australian institutions and high net worth investors, at a price of A\$0.195 per share, for aggregate gross proceeds of approximately A\$7 million. The proceeds includes A\$2 million as part of an underwritten Share Purchase Plan (SPP) under which eligible shareholders were able to apply for up to A\$15,000 worth of shares (subject to a scale back) at the same price as the private placement (approximately 76,900 ordinary shares at an issue price of A\$0.195 per share, representing a 13.3% discount to the market closing price on the ASX as at the record date). The first A\$2 million under the SPP were underwritten by JM Financial Group Ltd.

On November 26, 2014, we entered into Amendment No. 2 to our At-The-Market Issuance Sales Agreement, to continue the at-the-market equity program under which we from time to time may sell up to an additional aggregate of US\$50,000,000 of ordinary shares represented by ADSs. As of June 30, 2016, we sold 749,242 of our ADSs on a post reverse ratio basis for aggregate gross proceeds of approximately A\$7.11 million (US\$5.54 million) through our ATM facility.

As of June 30, 2016 we had a total of 19.4 million unlisted, unexercised options. The options have exercise prices ranging from A\$0.25 to A\$1.12. If all unlisted options were exercised, we would receive consideration of A\$7.5 million in total.

From inception to June 30, 2016, our capital expenditures have totaled A\$630,298, 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 depreciated on a straight-line basis over the estimated useful lives of three to 20 years, with a net balance at June 30, 2016 of A\$24,225. 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.

We had A\$28,593,538 of cash and cash equivalents at June 30, 2016, compared to A\$34,909,574 at June 30, 2015. For the years ended June 30, 2016 and 2015, we incurred an operating loss of A\$7.7 million and A\$5.9 million, respectively, and an operating cash outflow of A\$7.4 million and A\$10.9 million, respectively. Cash on hand at June 30, 2016 are considered sufficient to meet the Company's forecast cash outflows for, at least 12 months from the date of this report.

We believe that Australian Government tax incentive scheme relating to eligible research and development activities, introduced on July 1, 2011, will provide us with significant benefits in future years. Such eligible R&D activities include but are not limited to:

- Core activities, which are experimental activities whose outcome cannot be known or determined in advance, but can only be determined by applying a systematic progression of work;
- Core activities conducted for the purpose of generating new knowledge (including new knowledge in the form of new or improved processes and materials); or
- Supporting activities that are directly related and designed to support the above).

Under the research and development incentive scheme, entities with an aggregated turnover for the income year of less than A\$20 million will be entitled to a 45% refundable tax incentive. In the year ended June 30, 2016, we recorded A\$4.8 million in other income with respect to funds we will receive in relation to the 2016 financial year under the 2011 research and development incentive scheme.

In the event that we will not be able to raise the required funding for our planned expenditure, we have the ability to further reduce expenses around our current commitments. We retain the ability to curtail other planned, but not committed expenditure, in order to ensure we continue to have adequate funds to pay all liabilities as and when they fall due.

Management remains confident that we will be successful in raising the additional funding required to complete the planned research and development activities and accordingly have prepared the financial statements on a going concern basis.

At this time, our directors are of the opinion that no asset is likely to be realized for an amount less than the amount at which it is recorded in the Statement of Financial Position as of June 30, 2016. Therefore, no adjustments have been made to our consolidated financial statements relating to the recoverability and classification of the asset carrying amounts or the classification of liabilities that might be necessary should we not continue as a going concern.

### Cash Flows

The following table summarizes our cash flows for the periods presented:

	Year ended June 30,		
	2016	2015	2014
	(A\$)		
Net cash used in operating activities	(7,418,526)	(10,871,074)	(13,536,223)
Net cash used in investing activities	(833)	(182,834)	(23,048)
Net cash provided by financing activities	-	6,843,211	34,960,792
Net increase (decrease) in cash and cash equivalents	(7,419,359)	(4,210,697)	21,401,521
Cash and cash equivalents at beginning of period	34,909,574	34,167,018	13,346,760
Redemption of security deposit	152,603	-	-
Exchange rate adjustments on cash held in foreign currencies	950,720	4,953,253	(581,263)
Cash and cash equivalents at end of period	28,593,538	34,909,574	34,167,018

Net cash used in operating activities was A\$7,418,526, A\$10,871,074 and A\$13,536,223 during the years ended June 30, 2016, 2015 and 2014, respectively. Our payments to suppliers and employees during the years ended June 30, 2016, 2015 and 2014 were A\$14,055,879, A\$18,124,103 and A\$18,011,310, respectively. Our operating activity receipts for the years ended June 30, 2016, 2015 and 2014 of A\$6,637,353, A\$7,253,029 and A\$4,475,087 consisted of R&D tax incentive refunds, interest and grants. The A\$4,068,224 decrease in payments to suppliers and employees for the year ended June 30, 2016 when compared to the year ended June 30, 2015 reflects the U.S. Food and Drug Administration's placement of PBT2 on Partial Clinical Hold. The A\$112,793 increase in payments to suppliers and employees for the year ended June 30, 2015 when compared to the year ended June 30, 2014 reflects the timing of payments to complete the 'Reach2HD' Huntington disease trial, the 'IMAGINE' Alzheimer's disease trial and the ongoing IMAGINE - Extension trial together with the initiation of new API (Active Pharmaceutical Ingredient) manufacturing campaigns. During the years ended June 30, 2016, 2015 and 2014, our payments to suppliers and employees was offset by interest received of A\$120,392, A\$216,317 and A\$377,587, respectively.

Net cash used in investing activities was A\$833, A\$182,834 and A\$23,048 during the years ended June 30, 2016, 2015 and 2014, respectively. Cash flows used for investing activities was primarily attributable to payments for the purchase of a payroll account term deposit for the year ended June 30, 2016 and the purchase of property and equipment for the years ended June 30, 2016, 2015 and 2014.

Net cash provided by financing activities was A\$nil, A\$6,843,211 and A\$34,960,792 for the years ended June 30, 2016, 2015 and 2014. There have been no funds raised under our At-The-Market facility during the year ended June 30, 2016. Cash flows provided by financing activities during the year ended June 30, 2015 is primarily attributable to funds raised under our At-The-Market facility of A\$7.11 million (US\$5.54 million). Cash flows provided by financing activities during the year ended June 30, 2014 are attributable to funds raised under our At-The-Market facility of A\$32.37 million (US\$29.74 million).

We realized a foreign exchange gain of A\$950,720 for the year ended June 30, 2016 compared to a foreign exchange gain of A\$4,953,253 for the year ended June 30, 2015 and a foreign exchange loss of A\$581,263 for the year ended June 30, 2014. In 2016, the Australian dollar depreciated against the U.S. dollar by 3%. In 2015, the Australian dollar depreciated against the U.S. dollar by 18%, while in 2014, the Australian dollar appreciated against the U.S. dollar by 3%.

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

In recent years, we have continued our practice of building valuable research collaborations with institutes based in Australia, the United States, the United Kingdom and other countries to enable us to investigate a variety of therapeutic indications including Alzheimer's disease, Huntington disease, Parkinsonian movement disorders and selected cancers. These collaborative arrangements ensure that we work with well-respected laboratories with specific expertise in screening and animal modelling of relevance to the particular indication, without incurring ongoing administrative and personnel costs. We maintain in-house patent counsel and research and development project expertise to coordinate these research collaborations.

When a lead compound is identified as suitable for clinical development, we establish a project team to coordinate all non-clinical and clinical development and manufacturing activities. Typically, we engage a clinical research organization to manage patient enrollment, data management, clinical site coordination and statistical analysis, as was the case with the development of our lead compound PBT2 through Phase I and II development and prospectively for Phase III. We manage our manufacturing campaigns through clinical manufacturing organizations for quality assurance and GMP compliance. All clinical, non-clinical, clinical development and manufacturing of our compounds is performed in compliance with the appropriate governing authorities, regulators and standards (for example, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use).

Research and development expenses amounted to A\$9,585,371, A\$12,298,167 and A\$14,908,098 during the years ended June 30, 2016, 2015 and 2014, respectively. Costs associated with patent applications and defense of patent applications are classified as intellectual property expenses and amounted to A\$241,954, A\$257,299 and A\$477,079 during the years ended June 30, 2016, 2015 and 2014, respectively.

Our research and development expenses consist primarily of expenses for contracted research and development activities conducted by third parties on our behalf, including personnel, testing facilities and other payments in accordance with our research and clinical agreements. Research and development expenses also include costs associated with the acquisition and development of patents. Due to the numerous variables and the uncertain nature of the development of a clinical compound, including obtaining regulatory approvals, we are not able to reasonably estimate the nature, timing and costs of the future expenditures necessary to complete our research and development projects, the anticipated completion dates of each project and when material net cash flows from our research and development programs will commence.

#### D. TREND INFORMATION

We are a development stage company and while we believe that our technology will offer novel therapeutic strategies into an expanding market, we cannot predict with any degree of accuracy the outcome of our research or commercialization efforts.

We have not commercialized any products to date. Accordingly, any trends within the markets in which we operate are expected to have more direct impact on our business in the event that we are successful in commercializing our product candidates, including our current lead product candidates, PBT2 and PBT434.

Over the past few years, there has been increasing pressure to reduce drug prices in the developed markets as a consequence of political initiatives and regulations aiming to curb continuous increases in healthcare spending. Any revenue we earn in the future may be negatively affected by such political initiatives and regulations. The increased burden of healthcare costs in the aging population have led to an increased focus on reducing costs and, therefore, have further increased the pressure to lower drug prices. We expect this trend to continue in the years ahead. However, we believe spending in the healthcare industry, as compared to many other industries, is less linked to economic trends. We expect sales growth to continue at higher levels in emerging markets and also for niche, orphan indications. We also expect that demographic developments, increased treatment penetration, especially in newly established drug markets, and better diagnostic tools to enable the tailoring of drugs to specific needs, will result in continuing growth in overall global drug sales.

We will need substantial additional funding in order to complete the development, testing and commercialization of our product candidates. The commitment to these projects will require additional external funding, at least until we are able to generate sufficient cash flow from sale of one or more of our products to support our continued operations. If adequate funding is not available, we may be required to delay, scale back or eliminate certain aspects of our operations or attempt to obtain funds through unfavorable arrangements with partners or others that may force us to relinquish rights to certain of our technologies, products or potential markets or that could impose onerous financial or other terms. Management is continuing its efforts to obtain additional funds so that we can meet our obligations and sustain operations.

#### 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 as of June 30, 2016. The majority of our contracts for research and development programs have a termination notice period of 30 days. As at June 30, 2016, we had research and development termination commitments approximating A\$1.45 million. No liability has been recognised within our financial statements for this period. In addition, we have the ability to scale down our operations and prioritize our research and development programs in neurology to reduce expenditures as discussed in Item 5B. Liquidity and Capital Resources.

Contractual Obligations	Payments due by period				
	Total	less than 1 year	1-3 years	3-5 Years	more than 5 years
Operating lease obligations	193,940	145,610	48,330	-	-
Total	193,940	145,610	48,330	-	-



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	60	Chairman of the Board of Directors and Chief Executive Officer
Kathryn Andrews	48	Chief Financial Officer
Phillip A. Hains	55	Company Secretary
Dianne M. Angus	55	Chief Operating Officer
Peter A. Marks(1)	59	Director
Brian D. Meltzer(1)(2)(3)	61	Director
George W. Mihaly(1)(2)(3)	62	Director
Lawrence B. Gozlan(3)	36	Director
Ira Shoulson	69	Director

- (1) Member of the Audit Committee  
(2) Member of the Remuneration Committee and Share Plan Committee  
(3) Member of the Nominations Committee

**Mr. Geoffrey Paul Kempler** has served as the Chairman of our Board of Directors since November 1997. Between November 1997 and August 2004 he served as our Chief Executive Officer, and in June 2005 he again assumed the position of Chief Executive Officer. Mr. Kempler is one of the founders of our company. Mr. Kempler is a qualified psychologist. Mr. Kempler, who has extensive experience in investment and business development, has been responsible for the implementation of our strategic plan and the commercialization of our technology. Mr. Kempler holds a B.Sc degree in science from Monash University and a Grad. Dip. App. Soc. Psych. degree from Swinburne University. Mr. Kempler was appointed as a Non-Executive Chairman of Opthea Limited, an ASX listed drug development company developing innovative, biologics-based therapies for the treatment of eye disease, on November 30, 2015.

**Ms. Kathryn Andrews** was appointed as Chief Financial Officer of our company on November 4, 2014. From December 2012 to October 2014 Ms. Andrews held a senior role with The CFO Solution, a firm focused on the listed company and life sciences environments. Between 2007 and 2012 Ms. Andrews provided contract accounting, governance and consulting services to various mining and government organizations. Between 2002 and 2006 Ms. Andrews was the Chief Financial Officer and Company Secretary of Antisense Therapeutics Limited. Between 1999 and 2002 Ms. Andrews provided contract accounting and consulting services to various mining and resources, technology and government organizations. Between 1989 and 1998 Ms. Andrews was employed by Rio Tinto Limited in a variety of accounting, auditing and financial management roles. Between 1985 and 1989 Ms. Andrews was employed by BP Australia Limited in an accounting role. Ms. Andrews is a Certified Practising Accountant and holds a Bachelor of Commerce from the University of Melbourne.

**Mr. Phillip Hains** was appointed as Company Secretary of our company on November 4, 2014. Mr. Hains is a Chartered Accountant operating a specialist public practice, 'The CFO Solution'. The CFO Solution focuses on providing back office support, financial reporting and compliance systems for listed public companies. A specialist in the public company environment, Mr. Hains has served the needs of a number of company boards and their related committees. He has over 20 years' experience in providing businesses with accounting, administration, compliance and general management services. He holds a Master of Business Administration from RMIT and a Public Practice Certificate from the Institute of Chartered Accountants.

**Ms. Dianne Angus** has served as our Chief Operating Office since May 2007. Ms. Angus joined our company in August 2002, initially serving as our Vice President of Intellectual Property and Licensing, she was promoted to Senior Vice President of Business Development, Intellectual Property and Research in July 2004 and served in that position until being promoted to her current position in May 2007. From 1992 to 2000, Ms. Angus managed the intellectual property, licensing and biotechnology product development assets of two Australian companies, AMRAD Corporation Limited and Florigene Limited. At Florigene, Ms. Angus was the joint venture alliance manager with Suntory for three years. From June 2000 to August 2002, Ms. Angus was Director of Dianne Angus and Associates Pty. Ltd. providing strategic business development, technology evaluation and intellectual property consulting services to biotechnology companies. Ms. Angus has worked in the commercial biotechnology sector for over 20 years directing product valuation, acquisition and product licensing. During her career, Ms. Angus has managed large and diverse intellectual property portfolios, contract rights and enforcement. Ms. Angus has negotiated and executed many commercial licenses and research and product development agreements with entities ranging from large pharmaceutical companies to numerous global research institutes. Ms. Angus has also undertaken due diligence assessments on several Australian biotechnology companies for investment brokers. Ms. Angus holds a Bachelor of Science (Education) and Bachelor of Science (Honors) degree from the University of Melbourne, a Master's degree in Biotechnology from Monash University, a Graduate Diploma in Intellectual Property Law from Monash University, a Diploma in Intellectual Property Practice from the Institute of Patent and Trademark Attorneys of Australia and is a registered Australian Patent and Trade Mark Attorney. Ms. Angus is also a member of the Australian Institute of Company Directors.

**Mr. Peter Marks** has served as a director of our company since July 2005. For the period November 21, 2006 to October 20, 2011, Mr. Marks has also served as Executive Chairman of iSonea Ltd, formally KarmelSonix Ltd, a medical devices company listed on the ASX that is focused on developing and commercializing a range of devices in the respiratory and medicine space. For over 13 years until the end of August 2014, Mr. Marks was a Director of Peregrine Corporate Ltd, an Australian based investment bank. Mr. Marks is currently a Director of Armadale Capital Plc (formerly Watermark Global Plc), an AIM listed investment company, focused on natural resources projects based principally in Africa with its current major investments being a gold exploration company in DRC and a coal briquetting operation in South Africa. Mr. Marks is currently a principal of Henslow Pty Ltd (formerly Halcyon Corporate Pty Ltd), a corporate and capital markets advisory firm specializing in advising small to mid-cap companies. Mr. Marks is a non-executive Director of Emeffy Group Limited (formerly Savcor Group Limited), an ASX listed industrial technology business. From September 1998 until March 2001, Mr. Marks was employed by KPMG Corporate Finance Ltd (Australia), where he rose to Director and was responsible for heading up the equity capital markets group in Melbourne. From January 1992 until July 1994, Mr. Marks served as Head of the Melbourne Companies Department at the ASX and was founding Director of Momentum Funds Management Pty Ltd, an Australian venture capital firm. From December 1990 until December 1991, Mr. Marks served as Director of Corporate Finance at Burdett Buckeridge & Young Ltd in their Melbourne offices, from August 1988 until November 1990, he held senior corporate finance position at Barings Securities Ltd, and from July 1985 until July 1988, he served as an Associate Director of McIntosh Securities, now Merrill Lynch Australia. In his roles with these various financial institutions, Mr. Marks was responsible for advising a substantial number of listed and unlisted companies on issues ranging from corporate and company structure, to valuation, business strategies, acquisitions and international opportunities. Mr. Marks holds a Bachelor of Economics degree, a Bachelor of Law degree and Graduate Diploma in Commercial Law from Monash University in Melbourne, Australia, and an MBA degree from the Scottish School of Business at the University of Edinburgh.

**Mr. Brian Derek Meltzer** has served as a director of our company since December 1999. Mr. Meltzer has over 30 years of experience in economics, finance and investment banking. Until December 2013 Mr. Meltzer was 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 board of directors of a number of private companies. Mr. Meltzer is also a director on the board of the Australian-Israel Chamber of Commerce and is Chairman of Independence Australia (previously Paraquad). Mr. Meltzer is Chairman of our Audit Committee and Remuneration Committee. Mr. Meltzer holds a Bachelor of Commerce degree from the University of Auckland and a Master of Economics degree from Monash University.

**Dr. George William Mihaly** has served as director of our company since December 1999. Dr. Mihaly also serves as a director of Waide Pty Ltd., a private company. 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 to the pharmaceutical industry. Synermedica merged with the global consultant research organization Kendle International Inc. in April 2000 and Dr. Mihaly continued as Managing Director of the merged entity in Australia (now called Kendle Pty Ltd) until December 2004. Over the course of the last 35 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 holds a B.Pharm. from Monash University, an M.Sc. degree from Sydney University and a Ph.D. degree from Melbourne University, and he is a fellow of the Australian Institute of Company Directors.

**Mr. Lawrence Gozlan** was appointed as a director of our company on August 8, 2011. Mr. Gozlan, a leading biotechnology investor and advisor, is the Chief Investment Officer and Founder of Scientia Capital, a specialized global investment fund focused exclusively in life sciences. The Company was founded to provide high level expertise and to manage investments for high net worth individuals, family offices and institutional investors wanting exposure to the biotechnology industry. Prior to this, Mr. Gozlan was responsible for the largest biotechnology investment portfolio in Australia as the institutional biotechnology analyst at QIC (“the Queensland Investment Corporation”), an investment fund with over A\$60 billion under management. He previously worked as the senior biotechnology analyst in the equities team at Foster Stockbroking Pty Ltd, and gained senior corporate finance experience advising life sciences companies at Deloitte. During 2014, Mr. Gozlan was a Director of ASX-listed companies OncoSil Medical Limited (ASX:OSL) and Phosphagenics Limited (ASX:POH). He retired from these appointments in May 2015. Mr. Gozlan is currently a non-executive director of AusBiotech, which is the Australian Biotechnology Industry body. He holds a Bachelor of Science with Honors in microbiology and immunology from the University of Melbourne specializing in neurodegenerative diseases.

**Prof. Ira Shoulson** was appointed as a director of our company on May 13, 2014. Professor Shoulson is the Chairman of our Research and Development Advisory Board and has served as a consultant to, and member of, several FDA advisory committees over the past three decades, and has been involved in eight successful new drug applications to the FDA, notably long-acting methylphenidate (Concerta©) for attention deficit disorder, rasagiline (Azilect©) for Parkinson disease, and tetrabenazine (Xenazine©), the first drug approved by the FDA for the treatment of chorea in Huntington disease (HD). Prior to taking up his position with our company, Professor Shoulson concluded his elected term as Chair and President of the Huntington Study Group. Professor Shoulson is Professor of Neurology, Pharmacology and Human Science at Georgetown University, Washington, DC, USA, and Director of the University’s Program for Regulatory Science and Medicine (PRSM). He is also principal investigator of the Georgetown University Center of Excellence in Regulatory Science and Innovation (CERSI), one of four research and education centers currently funded by the FDA.

There are no family relationships among our directors and senior executives.

## B. COMPENSATION

The following table sets forth all compensation we paid for the year ended June 30, 2016 with respect to each of our executive officers and directors during the 2016 fiscal year.

	Salaries, fees, commissions, bonuses and other	Pension, retirement and other similar benefits
Geoffrey P. Kempler (1)	\$ A486,372	--
Dianne M. Angus	\$ A378,658	--
Kathryn Andrews (1)	\$ A136,429	--
Peter A. Marks	\$ A60,000	--
Brian D. Meltzer	\$ A85,000	--
George W. Mihaly	\$ A75,000	--
Lawrence B. Gozlan	\$ A60,000	--
Ira Shoulson (2)	\$ A303,474	--

- (1) Base Fee includes movements in annual leave provision for Mr. Kempler, Ms. Angus and Ms. Andrews accrued in accordance with their employment contracts.  
(2) Prof. Ira Shoulson provides consulting services to our company in a separate capacity to his position as Non-Executive Director. Total cash compensation of \$258,474 was paid to Prof. Ira Shoulson during the 2016 fiscal year in his capacity as a consultant to our company.

In accordance with the approval of our shareholders at our 2004 annual general meeting of shareholders, the aggregate amount available per annum for the remuneration of our non-executive directors for their services (payable in cash, ordinary shares or options) is A\$1,250,000.

As of June 30, 2016, our directors and executive officers as a group, then consisting of nine persons, held options to purchase an aggregate 9,317,819 of our ordinary shares. Of such options, (i) options to purchase 157,819 ordinary shares are exercisable for A\$0.25 consideration on or before March 20, 2017; (ii) options to purchase 8,000,000 ordinary shares are exercisable for A\$0.33 consideration on or before December 13, 2017; (iii) options to purchase 160,000 ordinary shares are exercisable for A\$0.73 consideration on or before November 3, 2018; and (iv) options to purchase 1,000,000 ordinary shares exercisable for A\$0.34 consideration on or before October 2, 2018. All such options were granted under our 2004 Employees', Directors' & Consultants' Share and Option Plan. See Item 6.E. "Directors, Senior Management and Employees - Share Ownership – Stock Option Plans."

*Agreement with Chief Executive Officer.* On September 21, 2007, we entered into an agreement with Mr. Geoffrey Kempler, a director, in connection with his employment as our Chief Executive Officer. Under the agreement, we agreed to pay Mr. Kempler a base salary of A\$386,400 per annum (which may be increased at the discretion of our Board of Directors). Mr. Kempler is entitled to a bonus of A\$6,000 for holding regular meetings (minimum twice a year) of the full Research and Development Advisory Board. Mr. Kempler is entitled to 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-over of two years) and reimbursement of reasonable business expenses incurred in the performance of his duties. Mr. Kempler is also 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. The agreement contains customary confidentiality provisions.

In the event of termination of Mr. Kempler's employment:

- By our company without cause (as defined in the agreement) or by Mr. Kempler with good reason (as defined in the agreement), he will be entitled to: (i) the sum of A\$1 million provided we have sufficient capital requirements to fulfill this obligation within 90 days of termination date; (ii) business expenses that have not been reimbursed and accrued and unused vacation days; and (iii) the acceleration of the vesting of any unvested options to purchase ordinary shares which may be purchased during the remainder of the exercise period of such options.
- By our company with cause (as defined in the agreement) or by Mr. Kempler without good reason (as defined in the agreement), he will be entitled to business expenses that have not been reimbursed and accrued and unused vacation days. Mr. Kempler will only be permitted to exercise unvested options to purchase shares that had been granted to him prior to the employment agreement.
- Due to death or disability (as defined in the agreement), we shall pay Mr. Kempler 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). Mr. Kempler or his estate, as applicable, will be entitled to exercise vested options for ordinary shares.

*Agreement with Chief Operating Officer.* On June 12, 2007, we entered into an amendment to an employment agreement with Ms. Angus in connection with her appointment as our Chief Operating Officer, effective as of May 31, 2007. Under the amended agreement we agreed to pay Ms. Angus a base salary of A\$268,125 per year, plus superannuation equivalent to 9.0% of the base salary (or the percentage stipulated by applicable Australian law). Effective May 1, 2010, Ms. Angus received a salary increase of 8% bringing her annual base salary inclusive of 9% superannuation to A\$344,044. In the 2014 fiscal year, as per changes to Australian law, superannuation increased to 9.25%. In the 2015 fiscal year, as per changes to Australian law, superannuation increased to 9.5%. During the 2013 fiscal year, Ms. Angus also received options to purchase 315,637 ordinary shares, which are exercisable for A\$0.25 on or before March 20, 2017, as remuneration for her services. The options were granted under the 2004 ASX Plan (as defined below). During the 2014 fiscal year, Ms. Angus also received options to purchase 160,000 ordinary shares, which are exercisable for A\$0.73 on or before November 3, 2018, as remuneration for her services. The options were granted under the 2004 ASX Plan. During the 2015 fiscal year, Ms. Angus also received options to purchase 1,000,000 ordinary shares, which are exercisable for A\$0.34 per share on or before October 2, 2018, as remuneration for her services. The options were granted under the 2004 ASX Plan. If we terminate the employment agreement without cause or if Ms. Angus terminates the employment agreement with good reason (as such terms are defined in the agreement) (i) we will pay to Ms. Angus, within 90 days of such termination, the sums she would have been entitled to receive had she continued to provide services for three months following the termination date; and (ii) any unvested options shall be accelerated and will become fully vested and she will be entitled to exercise her options during the remainder of their term.

## **C. BOARD PRACTICES**

### **Introduction**

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.

### **Election 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, rounded down to 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. 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 is our Managing Director. Mr. Brian Meltzer must retire and may stand for re-election at our 2016 annual general meeting of shareholders. Mr. Peter Marks, Mr. Lawrence Gozlan and Prof. Ira Shoulson must retire and may stand for re-election at our 2017 annual general meeting of shareholders. Dr. Mihaly must retire and may stand for re-election at our 2018 annual general meeting of shareholders.

## Non-Executive and Independent Directors

Australian law does not require a company to appoint a certain number of independent directors to its board of directors or audit committee. However, under the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations 3<sup>rd</sup> Edition ("ASX Recommendations"), the ASX recommends, but does not require, that an ASX-listed company have a majority of independent directors on its board of directors and that the audit committee be comprised of independent directors, within the meaning of the rules of the ASX. Our Board of Directors currently has six directors, of which five are non-executive directors within the meaning of the ASX Recommendations, and our audit committee consists of such three non-executive directors. Accordingly, we currently comply with the foregoing recommendations of the ASX Recommendations.

Under the rules of the NASDAQ Stock Market, a majority of our Board of Directors must qualify as independent directors within the meaning of the rules of the NASDAQ Stock Market, each of whom satisfies the respective "independence" requirements of the NASDAQ Stock Market Rules and the Securities and Exchange Commission. Our Board of Directors has determined that each of Messrs. Lawrence Gozlan, Peter Marks and Brian Meltzer and Dr. George Mihaly qualifies as an independent director under the requirements of the ASX, the NASDAQ Stock Market and the Securities and Exchange Commission.

## Committees of the Board of Directors

Our Board of Directors has established the following committees:

**Audit Committee.** The NASDAQ Stock Market rules require us to establish an audit committee comprised of at least three members, each of whom is financially literate and satisfies the respective "independence" requirements of the Securities and Exchange Commission and NASDAQ and one of whom has accounting or related financial management expertise at senior levels within a company.

Our Audit Committee 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. The audit committee meets at least four times per year.

Our Audit Committee currently consists of three board members, each of whom satisfies the "independence" requirements of the Securities and Exchange Commission, the NASDAQ Stock Market Rules and ASX Rules. Our Audit Committee is currently composed of Messrs. Marks and Meltzer and Dr. Mihaly.

**Remuneration Committee.** Our Board of Directors has established a Remuneration Committee, which is comprised solely of independent directors, within the meaning of the NASDAQ Stock Market Rules. The Remuneration Committee is responsible for reviewing the salary, incentives and other benefits of our executive officers and to make recommendations on such matters for approval by our Board of Directors. The Remuneration Committee is also responsible for overseeing and advising our Board of Directors with regard to the adoption of policies that govern our compensation programs, including share and ADS option and employee benefit plans. Additionally, the Remuneration Committee administers our share and ADS option plans and any other employee benefit plans through a sub-committee that it established for this purpose (see Share Plan Committee below). Dr. Mihaly and Mr. Meltzer are the current members of the Remuneration Committee, each of whom qualifies as an "independent director" within the meaning of the NASDAQ Stock Market Rules.

**Share Plan Committee.** Our Remuneration Committee has established a sub-committee, the Share Plan Committee, which administers our share and ADS option plans. Dr. Mihaly and Mr. Meltzer are the current members of the Share Plan Committee, each of whom qualifies as an "independent director" within the meaning of the NASDAQ Stock Market Rules.

**Nominations Committee.** Our Board of Directors has established a Nominations Committee, which is comprised solely of independent directors, within the meaning of the NASDAQ Stock Market Rules. The Nominations Committee is responsible for identifying and recommending to the Board of Directors director nominees for election at the annual meetings of shareholders, as well as candidates to fill any vacancies on the Board of Directors or as an addition to existing directors. Messrs. Gozlan and Meltzer and Dr. Mihaly are the current members of the Nominations Committee, each of whom qualifies as an “independent director” within the meaning of the NASDAQ Stock Market Rules.

**Research and Development Advisory Board.** Our Research and Development Advisory Board oversees and administers our research activities. Our Research and Development Advisory Board is comprised of a number of the leading scientists in the field of age-related degenerative disorders. The members of our Research and Development Advisory Board are as follows:

*Professor Ira Shoulson* is the Chairman of our Research and Development Advisory Board. Professor Shoulson has served as a consultant to, and member of, several FDA advisory committees over the past three decades, and has been involved in eight successful new drug applications to the FDA, notably long-acting methylphenidate (Concerta®) for attention deficit disorder, rasagiline (Azilect®) for Parkinson disease, and tetrabenazine (Xenazine®), the first drug approved by the FDA for the treatment of chorea in Huntington disease (HD). Prior to taking up his position with our company, Professor Shoulson concluded his elected term as Chair and President of the Huntington Study Group. Professor Shoulson is Professor of Neurology, Pharmacology and Human Science at Georgetown University, Washington, D.C., and Director of the University’s Program for Regulatory Science and Medicine (PRSM). He is also principal investigator of the Georgetown University Center of Excellence in Regulatory Science and Innovation (CERSI), one of four research and education centers currently funded by the FDA.

*Professor Craig Ritchie* is the Clinical Research Fellow (Senior), Old Age Psychiatry at Imperial College, London. In 2011 Professor Ritchie was appointed Co-Director of the London (Northwest) Comprehensive Local Research Network. Professor Ritchie is heavily involved, both clinically and academically, in psychiatric disorders of late life, in particular Alzheimer’s disease, delirium and schizophrenia. Professor Ritchie’s interest in conducting and assimilating evidence from clinical trials is based on his clinical background, having worked with elderly patients with dementia for most of his career. In October 2014, Professor Ritchie was appointed Chair of the Psychiatry of Ageing and Director of the Centre for Dementia Prevention at the University of Edinburgh.

*Professor Colin Masters* is the Executive Director of the Mental Health Research Institute (Australia) and a Laureate Professor at The University of Melbourne. He is also the Senior Deputy Director of the Florey Institute of Neuroscience and Mental Health. For more than 30 years, Professor Masters has dedicated his research to the study of the nature of Alzheimer’s disease and other neurodegenerative disorders. Professor Masters and his team are internationally renowned for their work on the disease and he is considered the most eminent neuroscientist in Australia. In addition, Professor Masters is regarded as one of the leading worldwide researchers in the study of Alzheimer’s disease. In 2006, Professor Masters was awarded the Lifetime Achievement Award in Alzheimer’s Disease Research at the 10th International Conference on Alzheimer’s disease (ICAD), the Lennox K. Black International Prize for Excellence in Biomedical Research and the Grand Hamdan International Award for a research breakthrough in the subject of Molecular and Cellular Pathology of Neurological Disorders.

*Professor Rudolph Emile Tanzi* is the Joseph P. and Rose F. Kennedy Professor of Neurology at Harvard Medical School and Director of Genetics and the Aging Research Unit at MGH. Professor Tanzi co-discovered three of the four known Alzheimer’s disease genes and contributed greatly to elucidating the molecular mechanisms by which they cause of Alzheimer’s disease. Professor Tanzi’s laboratory at MGH is one of the leaders in the field. Professor Tanzi conceived the “Metal Hypothesis of Alzheimer’s disease” with Professor Ashley Bush, and over the past 15 years has helped guide the design and development of our platform technology. In January 2012, Professor Tanzi was appointed our Chief Scientific Advisor.

#### **Directors’ Service Contracts**

Except for the agreement with Mr. Kempler in connection with his employment as our Chief Executive Officer, as described above, there are no arrangements or understandings between us and any of our subsidiaries, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their employment or service as directors of our company or any of our subsidiaries.

## 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 (i) any acts, receipts, neglect or defaults of any other director or officer for joining in any receipt or other act for conformity; (ii) 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; (iii) the inefficiency or deficiency of any security in or upon which any of our monies shall be invested; (iv) any loss or damage arising from bankruptcy, insolvency or tortious act of any person with whom any monies, securities or effects shall be deposited; (v) any loss occasioned by any error of judgment, omission, default or oversight on the persons part; or (vi) any 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 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 maintain a directors' and officers' liability insurance policy. 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.

## D. EMPLOYEES

At June 30, 2016, we had twelve employees. Of such employees, 8 persons were employed in research and development and four persons in management. All such employees are located in Australia and one employee is located in the United States.

At June 30, 2015, we had fifteen employees. Of such employees, eleven persons were employed in research and development and four persons in management. All such employees were located in Australia.

At June 30, 2014, we had twelve employees. Of such employees, eight persons were employed in research and development, three persons in management and administration and one person in operations. All such 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.



## A. SHARE OWNERSHIP

### Beneficial Ownership of Executive Officers and Directors

The following table sets forth certain information as of October 3, 2016 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 <sup>(1)</sup>	Percentage of Ownership <sup>(2)</sup>
Geoffrey P. Kempler <sup>(3)</sup>	22,011,000	4.05%
Kathryn Andrews	-	*
Dianne M. Angus <sup>(4)</sup>	1,463,947	*
Peter A. Marks <sup>(5)</sup>	1,043,111	*
Brian D. Meltzer <sup>(6)</sup>	1,326,666	*
George W. Mihaly <sup>(7)</sup>	1,226,666	*
Lawrence B. Gozlan <sup>(8)</sup>	1,000,000	*
Ira Shoulson	-	*
All directors and executive officers as a group (9 persons)	28,071,390	5.17%

\* Less than 1%

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 the above table 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 543,209,289 consisting of 533,891,470 ordinary shares and 9,317,819 unlisted options, issued and outstanding as of October 3, 2016.
3. Includes options to purchase 4,000,000 ordinary shares that are exercisable for A\$0.33 consideration on or before December 13, 2017. Of the 18,011,000 outstanding ordinary shares, 30,000 ordinary shares are held of record by Mr. Kempler, 14,165,000 ordinary shares are held by Baywick Pty Ltd., an Australian corporation owned by Mr. Kempler, 156,000 ordinary shares are held by Sadarajak 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, 600,000 ordinary shares are held of record by Sandhurst Trustees Ltd. Mr. Kempler may be deemed to be the beneficial owner of the ordinary shares held of record by Baywick Pty Ltd., Crystal Triangle Pty Ltd., NRB Developments Pty Ltd. and Sandhurst Trustees Ltd.
4. Includes (i) options to purchase 160,000 ordinary shares that are exercisable for A\$0.73 consideration on or before November 3, 2018; (ii) options to purchase 157,819 ordinary shares that are exercisable for A\$0.25 consideration on or before March 20, 2017; (iii) options to purchase 1,000,000 ordinary shares that are exercisable for A\$0.34 consideration on or before October 2, 2018; and (iv) 146,128 outstanding ordinary shares held of record by Ms. Dianne Angus.
5. Includes options to purchase 1,000,000 ordinary shares that are exercisable for A\$0.33 consideration on or before December 13, 2017. The 43,111 outstanding ordinary shares are held of record by Lampam Pty Ltd., an Australian corporation owned by Mr. Peter Marks.
6. Includes options to purchase 1,000,000 ordinary shares that are exercisable for A\$0.33 consideration on or before December 13, 2017. The 326,666 outstanding ordinary shares are held of record by Navigator Australia Ltd., a superannuation fund of Mr. Meltzer.
7. Includes options to purchase 1,000,000 ordinary shares that are exercisable for A\$0.33 consideration on or before December 13, 2017. Of the 226,666 outstanding ordinary shares, 166,666 ordinary shares are held of record by Dr. Mihaly, 52,000 ordinary shares are held of record by Waide Pty Ltd., an Australian corporation owned by Dr. Mihaly, and 4,000 ordinary shares are held of record by each of Kieren Mihaly and Warwick Mihaly, Dr. Mihaly's sons. Dr. Mihaly disclaims beneficial ownership of the ordinary shares held by his sons, Kieren Mihaly and Warwick Mihaly.
8. Includes options to purchase 1,000,000 ordinary shares that are exercisable for A\$0.33 consideration on or before December 13, 2017.

## Stock Option Plans

In November 2004, we adopted the 2004 Employees', Directors' and Consultants' Share and Option Plan, or the 2004 ASX Plan, and the 2004 American Depository Share (ADS) Option Plan, or the 2004 ADS Plan. For the description below, the 2004 ASX Plan and 2004 ADS Plan are referred to together as the 2004 Plans. Under the 2004 ASX Plan we may issue ordinary shares and under the 2004 ADS Plan we may issue ADSs. We were initially authorized to issue under the 2004 Plans up to an aggregate 12,000,000 ordinary shares or ADSs representing 12,000,000 ordinary shares. Pursuant to subsequent shareholder approvals, the most recent of which was in November 2009, we are entitled to issue up to an aggregate 60,000,000 ordinary shares (or ADSs representing 60,000,000 ordinary shares) under the 2004 Plans. Any increase in such maximum number of ordinary shares or ADSs issuable under the 2004 Plans is subject to shareholder approval.

**2004 ASX Plan.** The purpose of the 2004 ASX Plan is to promote the interest of our company and the interest of the employees, directors and consultants of our company and its subsidiaries. Under the 2004 ASX Plan, we may issue to employees, directors and consultants of our company and its subsidiaries, from time to time, ordinary shares, either by issuance of ordinary shares or under options to purchase ordinary shares granted under the 2004 ASX Plan.

The 2004 ASX Plan is administered by the Share Plan Committee, a sub-committee of the Remuneration Committee. For the purpose of the disclosure below, the term "Remuneration Committee" shall refer to the Remuneration Committee or Share Plan Committee, as applicable. Subject to Board approval where required by applicable law, the Remuneration Committee has the authority, in its sole discretion, to grant options under the 2004 ASX Plan, to interpret the provisions of the 2004 ASX Plan and to prescribe, amend, and rescind rules and regulations relating to the 2004 ASX Plan or any issue or grant thereunder as it may deem necessary or advisable, subject to any other approval if required by applicable law. All decisions made by the Remuneration Committee pursuant to the provisions of the 2004 ASX Plan will be final, conclusive and binding on all persons.

The number of shares issued or options granted, the exercise price and option term or options granted, the vesting schedule and escrow periods of shares issued and options granted, under the 2004 ASX Plan are determined by the Remuneration Committee, in accordance with the provisions of the ASX Plan, and specified in an offer document from our company and accepted by the eligible person, subject to the terms of the 2004 ASX Plan. Options granted under the 2004 ASX Plan will be unlisted and exercisable at an exercise price equal to less than market value of an ordinary share on the ASX at the date of grant, or such other exercise price that the Remuneration Committee determines to be appropriate under the circumstances. The term of an option granted under the 2004 ASX Plan will be determined by the Remuneration Committee; however, no option will be exercisable after the expiration of ten years from the date of its grant. Except as otherwise provided in the 2004 ASX Plan or determined by the Remuneration Committee and set forth in an offer document, the issuance of shares and exercise of options granted under the 2004 ASX Plan will either (i) be subject to an escrow, under which such shares or options cannot be disposed of or exercised, respectively, within six months from the date of issue or grant (or 12 months if issued or granted to a director); or (ii) will vest over a four year period in four equal installments, 25% at the end of each year from the date of grant. Shares issued and options granted under the 2004 ASX Plan may be subject to other performance criteria and hurdles, as determined by the Remuneration Committee.

**2004 ADS Plan.** The purpose of the 2004 ADS Plan is to promote the interests of our company and non-Australian based employees, officers, consultants, independent contractors and directors. Options granted under the 2004 ADS Plan may be incentive stock options, as provided in Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, or non-qualified stock options. Incentive stock options may only be granted to employees of our company and its subsidiaries (including, without limitation, officers and directors who are also employees of our company and its subsidiaries) and may not be granted to any owner of 10% or more of the total combined voting power of all classes of stock of our company and subsidiaries, or a 10% Holder. To the extent that the aggregate fair market value, determined on the date that an option is granted, of ADSs, with respect to which incentive stock options are exercisable for the first time by an optionee during any calendar year exceeds US\$100,000, such option shall be treated as a non-qualified stock option.

Under the 2004 ADS Plan, we may grant to employees, officers, consultants, independent contractors and directors of our company or any of its subsidiaries, from time to time, options to purchase ADSs representing our ordinary shares. The number of ADSs with respect to which options may be granted to any employee under the 2004 ADS Plan in any calendar year shall not exceed 83,333 ADSs (representing 5,000,000 of our ordinary shares). ADSs that are forfeited under the terms of the 2004 ADS Plan and ADSs that are the subject to options that expire unexercised or which are otherwise surrendered by an optionee without receiving any payment or other benefit with respect to such option may again become available for new option grants under the 2004 ADS Plan.

The 2004 ADS Plan is administered by our Share Plan Committee. Subject to Board approval where required by applicable law, the Remuneration Committee has authority, in its sole discretion, to grant options under the 2004 ADS Plan, to interpret the provisions of the 2004 ADS Plan and to prescribe, amend, and rescind rules and regulations relating to the 2004 ADS Plan or any options granted thereunder as it may deem necessary or advisable, subject to any other approval if required by applicable law. All decisions made by the Remuneration Committee pursuant to the provisions of the 2004 ADS Plan shall be final, conclusive and binding on all persons.

The type of option (incentive stock option or non-qualified stock option), exercise price, option term and vesting schedule of options granted under the 2004 ADS Plan are determined by the Remuneration Committee, in accordance with the provisions of the ADS Plan, and specified in an option agreement by and between our company and the optionee, subject to the terms of the 2004 ADS Plan. The exercise price per each ADS will be determined by the Remuneration Committee at the time any option is granted, however the exercise price of an incentive stock option will not be less than 100% of the fair market value of such ADS on the date of the grant and the price of an incentive stock option granted to a 10% Holder will not be less than 110% of the fair market value of such ADS on the date of the grant. Options granted under the 2004 ADS Plan will not be exercisable after the expiration of ten years from the date of grant, and in the case of an incentive stock option granted to a 10% Holder, the term of the option will be five years from the date of grant or such shorter term as may be provided in the option agreement. The options will vest over a four year period in four equal installments, 25% at the end of each year from the date of grant, unless otherwise provided by the Remuneration Committee in an option agreement.

Options granted under the 2004 ADS Plan are not assignable or transferable by the grantee, other than by will or the laws of descent and distribution, and may be exercised during the lifetime of the grantee only by the grantee or his guardian or legal representative.

A summary of the status of the 2004 Plans as of June 30, 2016, 2015 and 2014, and changes during the years ended on those dates, is presented below:

	As of June 30,					
	2016		2015		2014	
	Amount	Weighted average exercise price	Amount	Weighted average exercise price	Amount	Weighted average exercise price
Options outstanding at the beginning of the year...	19,395,582		16,375,582	\$ 0.41	17,031,476	\$ 0.23
Granted			4,400,000	\$ 0.28	3,926,490	\$ 0.69
Exercised			(180,000)	--	(4,582,384)	\$ 0.11
Expired			(1,000,000)	--	--	--
Lapsed			(200,000)	--	--	--
Options outstanding at the end of the year			19,395,582	\$ 0.38	16,375,582	\$ 0.41
Options exercisable at the end of the year	19,395,582		19,395,582	\$ 0.38	16,175,582	\$ 0.40
Options that may be granted as of the end of the year	15,319,202		15,319,202		19,629,202	

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

**A. MAJOR SHAREHOLDERS**

There are no shareholders as of October 3, 2016, known to us who own beneficially more than 5% of our ordinary shares.

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

There have been no significant changes in the ownership of major shareholders during the year.

**Major Shareholders Voting Rights**

A major shareholder would not have different voting rights.

**Record Holders**

As of September 27, 2016, there were 3,277 holders of record of our ordinary shares, of which 20 record holders, holding approximately 0.61% of our ordinary shares, had registered addresses in the United States. These numbers are not representative of the number of beneficial holders of our shares nor are they representative of where such beneficial holders reside, since many of these ordinary shares were held of record by brokers or other nominees. The majority of trading by our U.S. investors is done by means of ADSs that are held of record by National Nominees Ltd., which held 72.66% of our ordinary shares as of such date.

As of August 24 2015, there were 3,470 holders of record of our ordinary shares, of which 20 record holders, holding approximately 0.58% of our ordinary shares, had registered addresses in the United States. These numbers are not representative of the number of beneficial holders of our shares nor are they representative of where such beneficial holders reside, since many of these ordinary shares were held of record by brokers or other nominees. The majority of trading by our U.S. investors is done by means of ADSs that are held of record by National Nominees Ltd., which held 73.19% of our ordinary shares as of such date.

**B. RELATED PARTY TRANSACTIONS**

Prof. Ira Shoulson provides consulting services to Prana Biotechnology in a separate capacity to his position as Non-Executive Director. Prof. Ira Shoulson was appointed as Non-Executive Director on May 13, 2014. Total cash compensation of \$258,474 was paid to Prof. Ira Shoulson for the period July 1, 2015 to June 30, 2016 in his capacity as a consultant to the Company.

There were no other related party transactions other than those related to Director and Key Management Personnel remuneration and equity and transactions by the parent with its subsidiaries.

**A. INTERESTS OF EXPERTS AND COUNSEL**

Not applicable.

## ITEM 8. FINANCIAL INFORMATION

### A. FINANCIAL STATEMENTS AND OTHER FINANCIAL INFORMATION

See our consolidated financial statements, including the notes thereto, in Item 18.

#### Legal Proceedings

We are not involved in any legal proceedings nor are we subject to any threatened litigation that is material to our business or financial condition.

#### 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 various factors, including our results of operations, financial condition, current and anticipated cash needs, future prospects, contractual restrictions and other factors as the Board of Directors may deem relevant.

### B. SIGNIFICANT CHANGES

There have been no significant changes in the operation or financial condition of our company since June 30, 2016.

## ITEM 9. THE OFFER AND LISTING

### A. OFFER AND LISTING DETAILS

#### Australian Securities 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.

	Per Ordinary Share (A\$)	
	High	Low
<u>Fiscal Year Ended June 30,</u>		
2012	0.22	0.14
2013	0.31	0.14
2014	1.37	0.16
2015	0.36	0.14
2016	0.17	0.06
<u>Fiscal Year Ended June 30, 2014:</u>		
First Quarter	0.74	0.24
Second Quarter	0.85	0.38
Third Quarter	1.37	0.62
Fourth Quarter	0.30	0.16
<u>Fiscal Year Ended June 30, 2015:</u>		
First Quarter	0.36	0.22
Second Quarter	0.25	0.17
Third Quarter	0.22	0.14
Fourth Quarter	0.26	0.14
<u>Fiscal Year Ended June 30, 2016:</u>		
First Quarter	0.18	0.13
Second Quarter	0.14	0.10
Third Quarter	0.11	0.06
Fourth Quarter	0.12	0.06
<u>Month Ended:</u>		
April 2016	0.09	0.06
May 2016	0.09	0.08
June 2016	0.12	0.08
July 2016	0.11	0.10
August 2016	0.15	0.09
September 2016	0.12	0.09

## NASDAQ Capital Market

Since September 5, 2002 our ADSs have traded on the NASDAQ Capital Market under the symbol "PRAN." The following table sets forth, for the periods indicated, the high ask and low bid prices of our ADSs on the NASDAQ Capital Market as adjusted to give effect to the reverse ordinary share to ADS ratio implemented on March 24, 2016.

	Per ADS (U.S. \$)	
	High <sup>1</sup>	Low <sup>1</sup>
<b><u>Fiscal Year Ended June 30,</u></b>		
2012	13.86	8.40
2013	18.36	9.00
2014	79.74	8.82
2015	17.64	6.42
2016	7.68	2.70
<b><u>Fiscal Year Ended June 30, 2014:</u></b>		
First Quarter	39.00	13.86
Second Quarter	47.22	21.72
Third Quarter	79.74	16.68
Fourth Quarter	16.26	8.82
<b><u>Fiscal Year Ended June 30, 2015:</u></b>		
First Quarter	17.64	11.58
Second Quarter	13.74	8.40
Third Quarter	10.26	6.42
Fourth Quarter	11.10	6.48
<b><u>Fiscal Year Ended June 30, 2016:</u></b>		
First Quarter	7.68	4.20
Second Quarter	6.42	4.08
Third Quarter	4.50	2.70
Fourth Quarter	5.14	2.79
<b><u>Month Ended:</u></b>		
April 2016	4.01	2.79
May 2016	3.99	3.60
June 2016	5.14	3.65
July 2016	5.04	4.25
August 2016	6.69	4.30
September 2016	5.39	4.38

<sup>1</sup> On March 9, 2016, the company effected a ratio change from 1 ADS representing 10 ordinary shares to 1 ADS representing 60 ordinary shares (representing a 6-for-1 reverse split). The above prices have been adjusted to reflect the new ratio.

**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 ADSs were eligible to trade on the NASDAQ Capital OTC Bulletin Board in the United States and since September 5, 2002, our ADSs have traded on the NASDAQ Capital 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 depositary, issues ADRs, each of which evidences an ADS, which in turn represented ten of our ordinary shares. On March 24, 2016, the company effected a ratio change from 1 ADS representing 10 ordinary shares to 1 ADS representing 60 ordinary shares (representing a 6-for-1 reverse split).

**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**

We were registered on November 11, 1997 as Prana Pty Ltd and on November 26, 1999 we converted to a public company and changed our name to Prana Corporation Ltd. On January 1, 2000, we changed our name to Prana Biotechnology Limited. Our registration number is ACN 080699065.

**Prana's Purposes and Objects**

As a public company we have all the rights, powers and privileges of a natural person. Our Constitution does not specify any purposes or objects.

## **The Powers of the Directors**

Under the provisions of our Constitution our directors may exercise all of the powers of our company, other than those that are required by our Constitution or the Corporations Law of Australia to be exercised at a general meeting of shareholders. A director may participate in a meeting and vote on a proposal, arrangement or contract in which he or she is materially interested, so long as the director's interest is declared in accordance with the Corporations Law. The authority of our directors to enter into borrowing arrangements on our behalf is not limited, except in the same manner as any other transaction by us.

## **Rights Attached to Our Ordinary Shares**

The concept of authorized share capital no longer exists in Australia and as a result, our authorized share capital is unlimited. All our outstanding ordinary shares are validly issued, fully paid and non-assessable. The rights attached to our ordinary shares are as follows:

*Dividend rights.* If our board of directors recommends a dividend, registered holders of our ordinary shares may declare a dividend by ordinary resolution in a general meeting. The dividend, however, cannot exceed the amount recommended by our board of directors. Our board of directors may declare an interim dividend.

*Voting rights.* Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders. Such voting rights may be affected by the grant of any special voting rights to the holders of a class of shares with preferential rights that may be authorized in the future.

The quorum required for an ordinary meeting of shareholders consists of at least two shareholders represented in person or by proxy who hold or represent, in the aggregate, at least one third of the voting rights of the issued share capital. A meeting adjourned for lack of a quorum generally is adjourned to the same day in the following week at the same time and place or any time and place as the directors designate in a notice to the shareholders. At the reconvened meeting, the required quorum consists of any two members present in person or by proxy.

An ordinary resolution, such as a resolution for the declaration of dividends, requires approval by the holders of a majority of the voting rights represented at the meeting, in person, by proxy or by written ballot and voting thereon. Under our Constitution, a special resolution, such as amending our Constitution, approving any change in capitalization, winding-up, authorization of a class of shares with special rights, or other changes as specified in our Constitution, requires approval of a special majority, representing the holders of no less than 75% of the voting rights represented at the meeting in person, by proxy or by written ballot, and voting thereon.

Pursuant to our Constitution, our directors are elected at our annual general meeting of shareholders by a vote of the holders of a majority of the voting power represented and voting at such meeting.

*Rights in our profits.* Our shareholders have the right to share in our profits distributed as a dividend and any other permitted distribution.

*Rights in the event of liquidation.* In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of ordinary shares in proportion to the nominal value of their holdings. This right may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

## **Changing Rights Attached to Shares**

According to our Constitution, in order to change the rights attached to any class of shares, unless otherwise provided by the terms of the class, such change must be adopted by a general meeting of the shareholders and by a separate general meeting of the holders of the affected class with a majority of 75% of the voting power participating in such meeting.



## Annual and Extraordinary Meetings

Our Board of Directors must convene an annual meeting of shareholders at least once every calendar year, within five months of our last fiscal year-end balance sheet data. Notice of at least 28 days prior to the date of the meeting is required. An extraordinary meeting may be convened by the board of directors, it decides or upon a demand of any directors, or of one or more shareholders holding in the aggregate at least five percent of our issued capital. An extraordinary meeting must be called not more than 21 days after the request is made. The meeting must be held not later than two months after the request is given.

## Limitations on the Rights to Own Securities in Our Company

Neither our Constitution nor the laws of the Commonwealth of Australia restrict in any way the ownership or voting of our shares. However, (i) there are certain limitations on the percentage of shares a person may hold in our company as described under Item 3.D. "Risk Factors – "Risks Relating to our Location in Australia" above; and (ii) acquisitions and proposed acquisitions of securities in Australian companies may be subject to review and approval by the Australian Federal Treasurer under the Takeovers Act as described under Item 10.E. "Additional Information – Exchange Controls" above.

## Changes in Our Capital

Pursuant to the Listing Rules of the ASX, our directors may in their discretion issue securities equal to not more than 25% of our issued capital within a 12-month period. Issuances of securities in excess of such amount require the approval of our shareholders by an ordinary resolution.

## C. MATERIAL CONTRACTS

On December 1, 2000, we entered into a research funding and intellectual property assignment agreement with the University of Melbourne, under which the University of Melbourne agreed to conduct certain research projects on our behalf. Such projects include structure-based drug design involving the design of various metal-based compounds as potential diagnostics and therapeutics, drug screening and development involving the characterization of our compounds in vitro and in vivo models of neurodegenerative disorders, and cell-based drug discovery involving the screening and assessment of our compounds in cell-based systems to measure toxicity and cellular dysfunction and to develop new screens for our company. In consideration of such services, we agreed to pay the University of Melbourne a sum of A\$591,000 (inclusive of goods and services tax). In consideration for the assignment of rights to intellectual property developed by the University of Melbourne during the research period, we agreed to pay to the University of Melbourne royalties equal to 1.5% of the net invoice price of all products incorporating such intellectual property sold by us or on our behalf, or, the lesser of 1.5% of the net invoice price of such products sold by a licensee or assignee and 10% of gross revenues received from licensees or assignees relating to the exploitation of such intellectual property. The parties extended the term of this agreement by entering into consecutive agreements on December 1, 2003, December 1, 2006 and December 1, 2009. The recent research funding and intellectual property assignment agreement is deemed to have commenced as of the expiration date of the previous agreement on December 1, 2009 and expired on December 1, 2012. The parties entered into a new research funding and intellectual property assignment agreement with the same key terms which expired on December 31, 2013. The University of Melbourne subcontracted substantial parts of the research to the Florey Institute of Neuroscience and Mental Health. Following the novation of the agreements with the Florey Institute on November 7, 2014, we entered into a sixth research funding and intellectual property assignment agreement.

In December 2008, we entered into a process development and manufacturing agreement with Dr. Reddy's to enable the transfer of existing manufacturing methods for PBT2 to Dr. Reddy's to work on improving the route of manufacture, optimization and scale up manufacture of PBT2. The agreement is comprised of a series of independent sub-projects, each of which is subject to our prior authorization to be initiated and funded, at our sole discretion. The work is completed, including the large scale manufacture of approximately 50kg of PBT2 API. Ongoing work includes stability studies of the API and storage of chemical precursors. The term of the agreement is for 90 days post the receipt by us of a written report or manufacturing deliverables under the last approved sub-project under the agreement. Early termination is available to either party under specified conditions, including material breach and voluntary termination by either party upon 30 days written notice. On August 19, 2013, we entered into a new manufacturing service agreement to produce 20kg with an option for a further 40kg of PBT2 to service prospective Phase III trials. The option was exercised as of May 2014 and manufacturing of the 40kg PBT2 API is complete. We paid Dr. Reddy's US\$389,520, US\$264,000, and US\$137,500 for the fiscal years 2016, 2015 and 2014, respectively, for services provided under the agreement.

On March 24, 2014, we entered into a manufacturing services agreement with Dr. Reddy's for PBT434 API supply. We paid Dr. Reddy's US\$66,500, US\$22,000 and US\$336,000 for the fiscal years 2016, 2015 and 2014, respectively, for services provided under the agreement.

On March 24, 2014, we entered into a manufacturing services agreement with Dr. Reddy's for PBT434 API supply. We paid Dr. Reddy's US\$66,500, US\$22,000 and US\$336,000 for the fiscal years 2016, 2015 and 2014, respectively, for services provided under the agreement.

On September 21 2015, we entered into a master services agreement with Orgapharm S.A.S for the manufacture of PBT2 API. We paid Orgapharm S.A.S €186,012 during the fiscal year 2016 for services provided under this agreement.

On July 13, 2011, we entered into an At-The-Market Issuance Sales Agreement with MLV, under which we may sell ADSs, each representing ten ordinary shares, from time to time through MLV, as our agent for the offer and sale of the ADSs. This agreement was amended on August 30, 2013 and on November 26, 2014. On March 24, 2016 we completed a ratio change of our ADSs from 1 ADS representing 10 ordinary shares to 1 ADS representing 60 ordinary shares. We agreed to pay MLV a commission equal to 3% of the gross proceeds of the sales price of all ADSs sold through it as sales agent under the sales agreement. Because there is no minimum offering amount required as a condition to closing this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. The offering of our ADSs pursuant to the sales agreement will terminate on the earliest of (1) the sale of all of the ordinary shares subject to the sales agreement, or (2) termination of the sales agreement by us or MLV. We and MLV may terminate the sales agreement at any time in our sole discretion upon five days prior notice. MLV may terminate the sales agreement at any time in certain circumstances, including the occurrence of a material adverse change that, in the sales agent's judgment, may make it impracticable or inadvisable to market or sell our ADSs or a suspension or limitation of trading of our ADSs on The NASDAQ Capital Market. The aggregate offering price for the ordinary shares represented by ADSs may not exceed the aggregate amount that can be sold under the registration statement that we filed on November 3, 2014, an aggregate of US\$50,000,000 in addition to any ordinary shares. As of June 30, 2016, we issued a total amount of 4.5 million ADSs under this At-The-Market Issuance Sales Agreement for gross proceeds of A\$7.11 million (US\$5.54 million).

On January 22, 2015 we entered into a Master Services Agreement with Certara Portugal to undertake pharmacokinetic, pharmacosafety and pharmacodynamic modelling and analyses from non-clinical and clinical studies with PBT2. No payments were made to Certara Portugal in the fiscal year 2015. We paid Certara Portugal US\$421,651 in fiscal year 2016 for services provided under this agreement.

On March 17, 2015 we entered into a Master Services Agreement with d3 Medicine LLC to provide clinical pharmacology, clinical safety, safety pharmacology and regulatory consulting services in relation to non-clinical and clinical studies with PBT2. We paid d3 Medicine LLC US \$1,363,930 and US\$700,057 in fiscal years 2016 and 2015 respectively for services provided under this agreement.

On September 1, 2015 we entered into a Master Services Agreement with the Institute of Drug Technology (IDT) Australia Limited to provide manufacturing services, in particular process development for the encapsulation of PBT434 and its manufacture into drug product. We paid IDT A\$17,724 in fiscal year 2016 for services provided under the agreement.

#### **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, in certain circumstances foreign persons are prohibited from acquiring more than a limited percentage of the shares in an Australian company without notification to or approval from the Australian Treasurer. 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 the shares in any company having total assets exceeding A\$252 million or more. In addition, a foreign person may not acquire shares in a company having total assets of A\$252 million or more if, as a result of that acquisition, the total holdings of all foreign persons and their associates will exceed 40% in aggregate without the approval of the Australian Treasurer. However, for "U.S. Investors" and investors from certain other countries, a threshold of A\$1,094 million applies (except in certain circumstances) to each of the previous acquisitions. A "U.S. Investor" is defined by the Takeovers Act as a U.S. national or a U.S. enterprise.

If the necessary approvals are not obtained, the Treasurer may make an order requiring the acquirer to dispose of the shares it has acquired within a specified period of 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 ADSs. At present, we do not have total assets of A\$252 million.

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\$252million; 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 ADSs.

## E. TAXATION

The following is a discussion of Australian and U.S. tax consequences material to our shareholders. To the extent that the discussion is based on tax legislation which has not been subject to judicial or administrative interpretation, the views expressed in the discussion might not be accepted by the tax authorities in question or by court. The discussion is not intended, and should not be construed, as legal or professional tax advice and does not exhaust all possible tax considerations.

**Holders of our ADSs should consult their own tax advisors as to the United States, Australian or other tax consequences of the purchase, ownership and disposition of ADSs, including, in particular, the effect of any foreign, state or local taxes.**

## 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 of the absolute beneficial ownership 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 ADSs for Australian Taxation Purposes

Holders of our ADSs are treated as the owners of the underlying ordinary shares for Australian income tax and capital gains tax purposes. Therefore, dividends paid on the underlying ordinary shares will be treated for Australian tax purposes as if they were paid directly to the owners of ADSs, and the disposal of ADSs will be treated for Australian tax purposes as the disposal of the underlying ordinary shares. In the following analysis we discuss the application of the Australian income tax and capital gains tax rules to non-Australian resident 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 that are not franked or are partly franked and are paid to non-Australian resident shareholders are subject to dividend withholding tax, but only to the extent the dividends are not franked.

Unfranked dividends paid to a non-resident shareholder are subject to withholding tax at 30%, unless the shareholder is a resident of a country with which Australia has a double taxation agreement. In accordance with the provisions of the Double Taxation Convention between Australia and the United States, the maximum rate of Australian tax on unfranked dividends to which a resident of the United States is beneficially entitled is 15%, where the U.S. resident holds less than 10% of the voting rights in our company, or 5% where the U.S. resident holds 10% or more of the voting rights in our company. The Double Taxation Convention between Australia and the United States does not apply to limit the tax rate on dividends where the ADSs are effectively connected to a permanent establishment or a fixed base carried on by the owner of the ADSs in Australia through which the shareholder carries on business or provides independent personal services, respectively.

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

Australian capital gains derived by non-Australian residents in respect of the disposal of capital assets that are not taxable Australian property will be disregarded. Non-Australian resident shareholders will not be subject to Australian capital gains tax on the capital gain made on a disposal of our shares, unless they, together with associates, hold 10% or more of our issued capital, tested either at the time of disposal or over any continuous 12 month period in the 24 months prior to disposal, and the value of our shares at the time of disposal are wholly or principally attributable to Australian real property assets.

Australian capital gains tax applies to net capital gains at a taxpayer's marginal tax rate. Previously, certain shareholders, such as individuals were entitled to a discount of 50% for capital gains on shares held for greater than 12 months. However, as part of the 2012-2013 Federal Budget measures, the Australian Government announced changes to the application of the CGT discount for foreign resident individuals on taxable Australian assets, including shares. These changes became effective on 29 June 2013.

The effect of the change is to:

- Retain access to the full CGT discount for discount capital gains of foreign resident individuals in respect of the increase in the value of a CGT asset that occurred before 9 May 2013; and
- Remove the CGT discount for discount capital gains for foreign resident individuals that arise after 8 May 2013.

Foreign residents will still have access to a discount on discount capital gains accrued prior to 8 May 2013 provided they choose to obtain a market valuation for their assets as at that date.

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 - Shareholders Holding Shares on Revenue Account*

Some non-Australian resident shareholders may hold shares on revenue rather than on capital account, for example, share traders. These shareholders 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 shareholders 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 32.5% for non-Australian resident individuals. Some relief from the Australian income tax may be available to such non-Australian resident shareholders under the Double Taxation Convention between the United States and Australia, for example, because the shareholder does not have a permanent establishment in Australia.

To the extent an amount would be included in a non-Australian resident shareholder'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 shareholder would not be subject to double tax on any part of the income gain or capital gain.

#### **Dual Residency**

If a shareholder were a resident of both Australia and the United States under those countries' domestic taxation laws, that shareholder may be subject to tax as an Australian resident. If, however, the shareholder 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 applicable would be limited by the Double Taxation Convention. Shareholders should obtain specialist taxation advice in these circumstances.

#### **Stamp Duty**

A transfer of shares of a company listed on the ASX is not subject to Australian stamp duty except in some circumstances where one person, or associated persons, acquires 90% or more of the shares.

#### **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.

## 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 (as defined below) who hold ADSs 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, and the bilateral taxation convention between Australia and the U.S., 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 discuss all the tax consequences that may be relevant to an investment in ADSs by 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 U.S. or taxpayers whose functional currency is not the U.S. dollar, persons who hold the ADSs through partnerships or other pass-through entities, persons who acquired their ADSs 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 shares by vote or value, and investors holding ADSs as part of a straddle or appreciated financial position or as part of a hedging or conversion transaction.

If a partnership or an entity treated as a partnership for U.S. federal income tax purposes owns ADSs, the U.S. federal income tax treatment of a partner in such a partnership will generally depend upon the status of the partner and the activities of the partnership. A partnership that owns ADSs and the partners in such partnership should consult their own tax advisors about the U.S. federal income tax consequences of holding and disposing of ADSs.

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 U.S. federal estate and gift tax, 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 ADSs.

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 ADSs will be treated as owning the underlying ordinary shares represented by the ADSs held by them. Subject to the passive foreign investment company, or PFIC rules discussed below, the gross amount of any distributions received with respect to the underlying ordinary shares represented by the ADSs, including the amount of any Australian taxes withheld therefrom, will constitute dividends for U.S. federal income tax purposes, to the extent of our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. You will be required to include this amount of dividends in gross income as ordinary income. 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 ADSs, and any amount in excess of your tax basis will be treated as gain from the sale of ADSs. See "Disposition of ADSs" 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 in Australian dollars, including the amount of any Australian taxes withheld therefrom, 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 Australian dollars and converts Australian dollars into U.S. dollars at an exchange rate other than the rate in effect on such day will likely have a foreign currency exchange gain or loss, which would be treated as U.S.-source ordinary income or loss for purposes of U.S. foreign tax credit.

Subject to complex limitations, any Australian withholding tax imposed on our dividends will be a foreign income tax eligible for credit against a U.S. Holder's U.S. federal income tax liability (or, alternatively, for deduction against income in determining such tax liability). The limitations set forth 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. Dividends generally will be treated as foreign-source passive category income or general category income for U.S. foreign tax credit purposes, depending upon the holder's circumstances. 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 ADSs to the extent such U.S. Holder has not held the ADSs for at least 16 days of the 31-day period beginning on the date that 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 ADSs 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. You should consult with your own tax advisors to determine whether and to what extent you would be entitled to this credit.

Subject to certain limitations, "qualified dividend income" received by a non-corporate U.S. Holder will be subject to tax at a reduced maximum tax rate of 20 percent. Distributions taxable as dividends generally qualify for the 20 percent rate provided that either: (i) the issuer is entitled to benefits under the Tax Treaty or (ii) the ADSs are readily tradable on an established securities market in the United States and certain other requirements are met. We believe that we are entitled to benefits under the Tax Treaty and that the ADSs currently are readily tradable on an established securities market in the United States. However, no assurance can be given that the ADSs will remain readily tradable. Furthermore, the reduced rate does not apply to dividends received from PFICs. The amount of foreign tax credit is limited in the case of foreign qualified dividend income. U.S. Holders of ADSs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

#### **Disposition of ADSs**

If you sell or otherwise dispose of ADSs, 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 ADSs. Subject to the PFIC rules discussed below, 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 ADSs 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 ADSs 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 Australian dollars in connection with the sale or disposition of ADSs, the amount realized will be based on the U.S. dollar value of the Australian dollars received with respect to the ADSs as determined on the settlement date of such exchange. A U.S. Holder who receives payment in Australian dollars and converts them 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 of foreign currency gain or loss required of cash basis taxpayers with respect to a sale or disposition of ADSs, 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 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 Australian dollars 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 other disposition of such ADSs.

#### **Passive Foreign Investment Companies**

We believe that we are a PFIC, for U.S. federal income tax purposes. Our treatment as a PFIC could result in a reduction in the after-tax return to the U.S. Holders of our ADSs and may cause a reduction in the value of such securities.

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, cash is considered to be an asset that produces passive income. Passive income generally includes dividends, interest, royalties, rents, annuities and the excess of gains over losses from the disposition of assets that produce passive income. As a result of our substantial cash position and the decline in the value of our stock, we believe that we became a PFIC during the taxable year ended June 30, 2005. We believe that we continued to be classified as a PFIC during the taxable year ended June 30, 2016 and may continue to be a PFIC for each of the subsequent fiscal years.

As a PFIC, our dividends (if any are paid) will not qualify for the reduced maximum tax rate, discussed above, and, unless you timely elect to “mark-to-market” your ADSs, as described below:

- you will be required to allocate “excess distributions” or gain recognized upon the disposition of ADRs ratably over your holding period for the ADSs. An “excess distribution” is the amount by which distributions during a taxable year in respect of an ADS exceed 125% of the average annual distributions during the three preceding taxable years (or, if shorter, your holding period for the ADSs).
- the amount allocated to each year during which we are considered a PFIC, other than the year of the distribution or disposition, will 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 will 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 will be taxable as ordinary income in the current year, and
- you will be required to file an annual return on IRS Form 8621.

The PFIC provisions discussed above apply to U.S. persons who directly or indirectly hold stock in a PFIC. Generally, a U.S. person is considered an indirect shareholder of a PFIC if it is:

- a direct or indirect owner of a pass-through entity, including a trust or estate, that is a direct or indirect shareholder of a PFIC,
- a shareholder of a PFIC that is a shareholder of another PFIC, or
- a 50%-or-more shareholder of a foreign corporation that is not a PFIC and that directly or indirectly owns stock of a PFIC.

An indirect shareholder may be taxed on a distribution paid to the direct owner of the PFIC and on a disposition of the stock indirectly owned. Indirect shareholders are strongly urged to consult their tax advisors regarding the application of these rules.

If we cease to be a PFIC in a future year, a U.S. Holder may avoid the continued application of the tax treatment described above by electing to be treated as if it sold its ADSs on the last day of the last taxable year in which we were a PFIC. Any gain would be recognized and subject to tax under the rules described above. Loss would not be recognized. A U.S. Holder’s basis in its ADSs would be increased by the amount of gain, if any, recognized on the sale. Solely for purposes of the PFIC rules, a U.S. Holder would be required to treat its holding period for its ADSs as beginning on the day following the last day of the last taxable year in which we were a PFIC.

If the ADSs are considered “marketable stock” and if you elect to “mark-to-market” your ADSs, you would not be subject to the rules described above. Instead, you will generally include in income any excess of the fair market value of the ADSs at the close of each tax year over your adjusted basis in the ADSs. If the fair market value of the ADSs 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 ADSs 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 ADSs 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 ADSs with respect to which the mark-to-market election is made, is treated as ordinary income or loss (except that loss is treated as capital loss to the extent the loss exceeds the net mark-to-market gains, if any, that a U.S. Holder included in income with respect to such ADSs in prior years). However, gain or loss from the disposition of ADSs (as to which a “mark-to-market” election was made) in a year in which we are no longer a PFIC, will be capital gain or loss. Our ADSs should be considered “marketable stock” if they traded at least 15 days during each calendar quarter of the relevant calendar year in more than *de-minimis* quantities.



A U.S. Holder of ADSs will not be able to avoid the tax consequences described above by electing to treat us as a qualified electing fund, or QEF, because we do not intend to prepare the information that U.S. Holders would need to make a QEF election.

#### **Additional Tax on Investment Income**

U.S. Holders that are individuals, estates, or trusts and whose income exceeds certain thresholds will be subject to a 3.8% Medicare contribution tax on net investment income, which will include dividends on and capital gains from the sale or other taxable disposition of ADSs, subject to certain limitations and exceptions.

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

Payments in respect of ADSs may be subject to information reporting to the IRS 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. 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, which is generally an annual income tax return.

U.S. individuals who hold certain specified foreign financial assets, including stock in a foreign corporation, with values in excess of certain thresholds are required to file IRS Form 8938 with their U.S. federal income tax return. Such form requires disclosure of information concerning such foreign assets, including their value. Failure to file the form when required is subject to penalties. An exemption from reporting applies to foreign assets held through a U.S. financial institution, generally including a non-U.S. branch or subsidiary of a U.S. institution and a U.S. branch of a non-US institution. Investors are encouraged to consult with their own tax advisors regarding the possible application of this disclosure requirement to their investment in our ADSs.

#### **F. DIVIDENDS AND PAYING AGENTS**

Not applicable.

#### **G. STATEMENT BY EXPERTS**

Not applicable.

#### **H. DOCUMENTS ON DISPLAY**

We are subject to the reporting requirements of the Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 thereunder. 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. In addition, we are not required 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 file with the Securities and Exchange Commission an annual report on Form 20-F containing financial statements that have been examined and reported on, with an opinion expressed by, an independent registered public accounting firm, and we submit reports to the Securities and Exchange Commission on Form 6-K containing (among other things) press releases and unaudited financial information for the first six months of each fiscal year. We post our annual report on Form 20-F on our website ([www.pranabio.com](http://www.pranabio.com)) promptly following the filing of our annual report with the Securities and Exchange Commission. The information on our website is not incorporated by reference into this annual report.

This annual report and the exhibits thereto and any other document we 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 100 F Street, N.E., Room 1580, Washington, D.C. 20549. 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. The Exchange Act file number for our Securities and Exchange Commission filings is 000-49843.

The Securities and Exchange Commission maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the Securities and Exchange Commission using its EDGAR (Electronic Data Gathering, Analysis, and Retrieval) system.

The documents concerning our company referred to in this annual report may also be inspected at our offices located at Suite 1, 1233 High Street, Armadale, Victoria, Australia, 3143.

#### **I. SUBSIDIARY INFORMATION**

Not applicable.

#### **ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We invest our excess cash and cash equivalents in interest-bearing accounts and term deposits with banks in Australia. Our management believes that the financial institutions that hold our investments are financially sound and accordingly, minimal credit risk exists with respect to these investments. 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 had approximately A\$21,890,509, A\$27,100,354 and A\$26,398,943 in cash held in U.S. dollars, GBP and Euro as of June 30, 2016, 2015 and 2014, respectively. A hypothetical 3%, 3% and 12% adverse movement in end-of-period exchange rates for U.S. dollars, GBP and Euro, respectively, would reduce the cash balance at the end of each year by approximately A\$656,715, A\$838,149 and A\$815,288, respectively.

We conduct our activities almost exclusively in Australia. We are required to make certain payments in U.S. dollars and other currencies, however such payments are not significant to our operations and we believe an adverse movement in end-of-period exchange rates would not have a material impact on our operating results. In the twelve months ended June 30, 2016, the Australian dollar depreciated against the U.S. dollar by 3%. In the financial years 2015 and 2014, the Australian dollar depreciated by 18% and appreciated by 3% against the U.S. dollar, respectively. As of June 30, 2016, payables in U.S. dollars and other currencies were immaterial. A hypothetical 3% adverse movement in the U.S. dollar, 0.5% adverse movement in the Euro and 6% adverse movement in the Great British Pound exchange rates would increase the cost of these payables by approximately A\$2,622.

We do not currently utilize derivative financial instruments or other financial instruments subject to market risk.

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

**Fees and Charges Payable by ADS Holders**

The table below summarizes the fees and charges that a holder of our ADSs may have to pay, directly or indirectly, to our depository, The Bank of New York Mellon, or BoNY, pursuant to the Deposit Agreement, which was filed as Exhibit 2.1 to our Registration Statement on Form F-6 filed with the SEC on December 21, 2007, and the types of services and the amount of the fees or charges paid for such services. The disclosure under this heading "Fees and Charges Payable by ADS Holders" is subject to and qualified in its entirety by reference to the full text of the Deposit Agreement. The holder of an ADS may have to pay the following fees and charges to BoNY in connection with ownership of the ADS:

**Persons Depositing or Withdrawing Shares Must Pay:**

**For:**

- |   |  |
|---|--|
| <ul style="list-style-type: none"><li>• US\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)</li><br/><li>• US\$0.005 (or less) per ADS</li><li>• A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs</li><li>• US\$1.50 (or less) per ADS</li><li>• Expenses of the depository</li><br/><li>• Taxes and other governmental charges the depository or the custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes</li><li>• Any charges incurred by the depository or its agents for servicing the deposited securities</li></ul> | <ul style="list-style-type: none"><li>• Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property</li><li>• Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates</li><li>• Any cash distribution to you</li><li>• Distribution of securities distributed to holders of deposited securities which are distributed by the depository to ADS holders</li><li>• Transfers, combination and split-up of ADSs</li><li>• Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)</li><li>• Converting foreign currency to U.S. dollars</li><li>• As necessary</li><br/><li>• As necessary</li></ul> |
|---|--|

The depository collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depository collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depository may collect its annual fee for depository services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depository may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The depository may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depository may make payments to us to reimburse and/or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the deposit agreement, the depository may use brokers, dealers or other service providers that are affiliates of the depository and that may earn or share fees or commissions.

**Fees and Payments Made by the Depositary to the Company**

We incurred expenses in relation to services for our annual general meeting and special general meeting of shareholders. For the year ended June 30, 2016, we paid BoNY a total of US\$26,281 (comprised of payments for the distribution and printing of meeting material and proxy vote tabulation). For the year ended June 30, 2015, we paid BoNY a total of US\$33,523 (comprised of payments for the distribution and printing of meeting material and proxy vote tabulation). We also paid BoNY US\$22,479 in the year ended June 30, 2015 in connection with the conversion of ordinary shares into ADSs for issuance under our "At-The-Market" facility. The conversion charge of US\$0.005 per ADS was applied plus international wire charges.

## 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

#### Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our chief executive officer and chief financial officer to allow timely decisions regarding required disclosure. Our management, including our chief executive officer and chief financial officer, conducted an evaluation of our disclosure controls and procedures, as defined under Exchange Act Rule 13a-15(e), as of the end of the period covered by this Annual Report on Form 20-F. Based upon that evaluation, our chief executive officer and chief financial officer concluded that, as of June 30, 2016, our disclosure controls and procedures were effective.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework* (2013). Based on that assessment, our management concluded that as of June 30, 2016, our internal control over financial reporting is effective.

## Changes in Internal Control over Financial Reporting

During the year ended June 30, 2016, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### 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 by rules of the Securities and Exchange Commission. For a brief listing of Mr. Meltzer's relevant experience, see Item 6.A. "Directors, Senior Management and Employees - Directors and Senior Management."

### ITEM 16B. CODE OF ETHICS

We have adopted a code of ethics that applies to all senior financial officers of our company, including our chief executive officer, 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 Independent Public Accountants

The following table sets forth, for each of the years indicated, the fees billed by PricewaterhouseCoopers, which has served as our principal independent registered public accounting firm since November 30, 2006.

Services Rendered	Year Ended June 30,	
	2016	2015
Audit (1)	\$ A166,479	\$ A160,158
Audit-Related (2)	\$ A38,297	\$ A256,113
Other (3)	-	\$ A83,640
Total	\$ A204,776	\$ A499,911

(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 services provided in connection with the auditor's review of our internal controls.

(3) Other fees relate to services provided in connection with other public filings for the Securities and Exchange Commission.

#### 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. 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. All of the fees described above were pre-approved by our Audit Committee.

**ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

**Issuer Purchase of Equity Securities**

Neither we, nor any affiliated purchaser of our company, has purchased any of our securities during the year ended June 30, 2016.

**ITEM 16F. CHANGES IN REGISTRANT'S CERTIFYING ACCOUNTANT**

None.

**ITEM 16G. CORPORATE GOVERNANCE**

Under NASDAQ Stock Market Rule 5615(a)(3), foreign private issuers, such as our company, are permitted to follow certain home country corporate governance practices instead of certain provisions of the NASDAQ Stock Market Rules. A foreign private issuer that elects to follow a home country practice instead of any NASDAQ rule must submit to NASDAQ, in advance, a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws. As of the date of this annual report, we have not submitted notice to NASDAQ informing them of that we elect to follow home country practice instead of a NASDAQ rule.

**ITEM 16H. MINE SAFETY DISCLOSURE**

Not applicable.

**ITEM 17. FINANCIAL STATEMENTS**

Our company has elected to furnish financial statements and related information specified in Item 18.

**ITEM 18. FINANCIAL STATEMENTS**

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ITEM 19. EXHIBITS

Index to Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference		Filing Date/ Period End Date
		Form	Exhibit	
1	Constitution of Registrant.	20-F	1.1	6/30/09
2.1	Deposit Agreement dated March 23, 2001, as amended and restated as of December 21, 2007, among the Registrant, the Bank of New York, as Depository, and owners and holders from time to time of ADRs issued thereunder, including the Form of American Depositary Receipts.	F-6 POS	1	12/21/07
4.1	License Agreement dated January 1, 2001, between the Registrant and The General Hospital Corporation.	20-F		5/29/02
4.2	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.	20-F		5/29/02
4.3	Agreement to Provide Accounting, Administration, Corporate Advice and Company Secretarial Services dated February 23, 2000, between the Registrant and Malvern Administrative Services (now The CFO solution).	20-F		5/29/02
4.4	Second Amendment to Exclusive License Agreement dated January 1, 2001, between the Registrant and The General Hospital Corporation dated March 15, 2004.	20-F	4.6	6/30/04
4.5	Settlement Agreement dated July 28, 2004, among the Registrant, P.N. Gerolymatos S.A, or PNG, Mr. Gerolymatos, 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.	20-F	4.21	6/30/04
4.6	Prana Biotechnology Limited, 2004 American Depositary Share (ADS) Option Plan.	6-K	Annexure A to Item 1	11/3/04
4.7	Prana Biotechnology Limited, 2004 Employees', Directors' and Consultants' Share and Option Plan.	6-K	Annexure B to Item 1	11/3/04
4.8	Fourth Research Funding and Intellectual Property Assignment Agreement dated December 1, 2009.	20-F	4.9	6/30/12
4.9	Fifth Research Funding and Intellectual Property Assignment Agreement dated December 1, 2012.	20-F	4.9	6/30/13
4.10*	Sixth Research Funding and Intellectual Property Assignment Agreement dated November 7, 2014.			
4.11	Employment Agreement dated September 21, 2007, among the Registrant and Mr. Kempler.	20-F	4.19	6/30/07



4.12	Letter Agreements effective as of June 12, 2007 between the Registrant and Ms. Dianne Angus.	20-F	4.21	6/30/07
4.13	Placement Confirmation Letter dated September 8, 2009, between the Registrant and BAM Capital LLC.	20-F	4.25	6/30/07
4.14	Manufacturing Services Agreement for PBT2 HCI Supply dated August 19, 2013 between the Registrant and Dr. Reddy's Laboratories Limited.	20-F	4.30	6/30/13
4.15	Amendments to Manufacturing Services Agreement for PBT2 HCI Supply dated August 19, 2013 between the Registrant and Dr. Reddy's Laboratories Limited, as amended: Amendment No. 1 effective September 26, 2013; and Amendment No. 2 effective August 31, 2013.	20-F	4.35	6/30/14
4.16	Manufacturing Services Agreement for PBT434 API supply dated March 28, 2014	20-F	4.36	6/30/14
4.17	Master Service Agreement between the Registrant and Certara Portugal dated January 22, 2015	20-F	4.17	6/30/15
4.18	Master Service Agreement between the Registrant and d3 Medicine LLC dated March 17, 2015	20-F	4.18	6/30/15
4.19*	Master Service Agreement between the Registrant and Orgapharm S.A.S. dated September 21, 2015.			
4.20*	Master Service Agreement between the Registrant and IDT Australia Limited dated September 1, 2015			
8.1*	List of Subsidiaries of the Registrant.			
12.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act, as amended.			
12.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act, as amended.			
13.1*	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.			
13.2*	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.			
15.1*	Consent of PricewaterhouseCoopers.			

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\* Filed herewith.

**PRANA BIOTECHNOLOGY LIMITED**  
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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of Prana Biotechnology Limited

In our opinion, the accompanying consolidated statements of financial position and the related consolidated statements of profit or loss and other comprehensive income, consolidated statements of changes in of shareholders' equity and consolidated cash flow statements present fairly, in all material respects, the financial position of Prana Biotechnology Limited and its subsidiaries at June 30, 2016 and June 30, 2015, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2016 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. 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 of these statements in accordance with the 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers  
Melbourne, Australia  
October 3, 2016

**PRANA BIOTECHNOLOGY LIMITED**  
**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**  
(in Australian dollars, except number of shares)

	Notes	June 30,	
		2016	2015
<b>Assets</b>			
<b>Current Assets</b>			
Cash and cash equivalents		28,593,538	34,909,574
Trade and other receivables	5	4,786,765	6,521,154
Other current assets	6	276,504	313,465
<b>Total Current Assets</b>		<b>33,656,807</b>	<b>41,744,193</b>
<b>Non-Current Assets</b>			
Property and equipment, net of accumulated depreciation of A\$329,541 and \$322,342, respectively	7	24,225	44,727
Other non-current assets	6	43,988	45,462
<b>Total Non-Current Assets</b>		<b>68,213</b>	<b>90,189</b>
<b>Total Assets</b>		<b>33,725,020</b>	<b>41,834,382</b>
<b>Liabilities</b>			
<b>Current Liabilities</b>			
Trade and other payables	8	1,748,566	2,152,015
Other financial liabilities	9	-	12,076
Provisions	10	608,771	554,615
<b>Total Current Liabilities</b>		<b>2,357,337</b>	<b>2,718,706</b>
<b>Non-Current Liabilities</b>			
Provisions	10	470	2,412
<b>Total Non-Current Liabilities</b>		<b>470</b>	<b>2,412</b>
<b>Total Liabilities</b>		<b>2,357,807</b>	<b>2,721,118</b>
<b>Net Assets</b>		<b>31,367,213</b>	<b>39,113,264</b>
<b>Equity</b>			
Issued capital			
2016: 533,891,470 fully paid ordinary shares			
Nil options over fully paid ordinary shares			
2015: 533,891,470 fully paid ordinary shares			
Nil options over fully paid ordinary shares			
	12	146,879,214	146,895,714
Reserves	13	9,363,181	9,363,181
Accumulated deficit during the development stage	14	(124,875,182)	(117,145,631)
<b>Total Equity</b>		<b>31,367,213</b>	<b>39,113,264</b>

*The accompanying notes are an integral part of the consolidated financial statements.*

PRANA BIOTECHNOLOGY LIMITED

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME  
(in Australian dollars, except number of shares)

	Notes	Years ended June 30,		
		2016	2015	2014
Revenues from ordinary activities	2	142,657	176,842	363,775
Other income	2	4,753,697	6,317,438	7,845,396
Intellectual property expenses		(241,954)	(257,299)	(477,079)
General and administration expenses	3	(3,610,551)	(4,506,122)	(4,925,411)
Research and development expenses	3	(9,585,371)	(12,298,167)	(14,908,098)
Finance expenses		-	-	(29,978)
Other operating expenses		(45,276)	(39,210)	(451,251)
Other gains and losses	3	857,247	4,721,449	(746,593)
<b>Loss before income tax expense</b>		<b>(7,729,551)</b>	<b>(5,885,069)</b>	<b>(13,329,239)</b>
Income tax expense	4	-	-	-
<b>Loss for the year</b>		<b>(7,729,551)</b>	<b>(5,885,069)</b>	<b>(13,329,239)</b>
<b>Other comprehensive loss</b>			-	-
<b>Total comprehensive loss for the year</b>	15 (a)	<b>(7,729,551)</b>	<b>(5,885,069)</b>	<b>(13,329,239)</b>
<b>Loss per share (basic and diluted - cents per share)</b>	19	<b>(1.45)</b>	<b>(1.17)</b>	<b>(3.11)</b>
Weighted average number of ordinary shares used in computing basic and diluted net loss per share		533,891,470	502,714,982	428,047,123

The accompanying notes are an integral part of the consolidated financial statements.

**PRANA BIOTECHNOLOGY LIMITED**  
**CONSOLIDATED CASH FLOW STATEMENTS**  
(in Australian dollars)

	Notes	Years Ended June 30,		
		2016	2015	2014
<b>Cash Flows from Operating Activities</b>				
Payments to suppliers and employees		(14,055,879)	(18,124,102)	(18,011,310)
Interest received		120,392	216,317	377,587
Grants received		-	228,541	2,500
R&D tax refund		6,516,961	6,808,170	4,095,000
Net cash flows used in operating activities	15(a)	(7,418,526)	(10,871,074)	(13,536,223)
<b>Cash Flows from Investing Activities</b>				
Payment for payroll and rental security deposits		1,474	(154,077)	-
Payments for purchase of plant and equipment		(2,307)	(28,757)	(23,048)
Net cash flows used in investing activities		(833)	(182,834)	(23,048)
<b>Cash Flows from Financing Activities</b>				
Proceeds from exercise of options and issue of securities		-	7,128,142	37,110,325
Payment of share issue costs		-	(284,931)	(1,339,369)
Repayment of borrowings		-	-	(810,164)
Net cash flows provided by financing activities		-	6,843,211	34,960,792
Net (decrease) increase in cash and cash equivalents		(7,419,359)	(4,210,697)	21,401,521
Opening cash and cash equivalents brought forward		34,909,574	34,167,018	13,346,760
Redemption of security deposit		152,603	-	-
Exchange rate adjustments on cash and cash equivalents held in foreign currencies		950,720	4,953,253	(581,263)
<b>Closing cash and cash equivalents carried forward</b>	15(b)	<b>28,593,538</b>	<b>34,909,574</b>	<b>34,167,018</b>

*The accompanying notes are an integral part of the consolidated financial statements.*

PRANA BIOTECHNOLOGY LIMITED

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY  
(in Australian dollars, except for number of shares)

	Notes	Number of Shares	Issued Capital	Reserves	Accumulated Deficit During Development Stage	Total Equity
<b>Balance, June 30, 2013</b>		381,610,426	101,379,111	10,526,925	(97,931,323)	13,974,713
<b>Transactions with owners in their capacity as owners:</b>						
Issuance of shares in connection with At-The-Market facility, net of costs	12(b)	85,108,500	30,818,030	-	-	30,818,030
Issuance of shares in connection with share purchase plan, net of costs	12(c)	1,000,000	276,950	-	-	276,950
Non-cash issuance of options to employees	13(b)	-	-	33,824	-	33,824
Non-cash issuance of options to consultants	13(b)	-	-	959,084	-	959,084
Issuance of shares in connection with exercise of options, net of costs	12(b) &(b)(b)	20,928,034	7,535,324	(2,582,399)	-	4,952,925
		107,036,534	38,630,304	(1,589,491)	-	37,040,813
Net loss		-	-	-	(13,329,239)	(13,329,239)
<b>Total comprehensive loss for the year</b>		-	-	-	(13,329,239)	(13,329,239)
<b>Balance, June 30, 2014</b>		488,646,960	140,009,415	8,937,434	(111,260,562)	37,686,287
<b>Transactions with owners in their capacity as owners:</b>						
Issuance of shares in connection with At-The-Market facility, net of costs	12(b)	44,954,510	6,844,311	-	-	6,844,311
Issuance of shares in connection with share purchase plan, net of costs	12(c)	110,000	16,500	-	-	16,500
Non-cash issuance of options to employees	13(b)	-	-	170,397	-	170,397
Non-cash issuance of options to consultants	13(b)	-	-	280,838	-	280,838
Issuance of shares in connection with exercise of options, net of costs	12(b) &(b)(b)	180,000	25,488	(25,488)	-	-
		45,244,510	6,886,299	425,747	-	7,312,046
Net loss		-	-	-	(5,885,069)	(5,885,069)
<b>Total comprehensive loss for the year</b>		-	-	-	(5,885,069)	(5,885,069)
<b>Balance, June 30, 2015</b>		533,891,470	146,895,714	9,363,181	(117,145,631)	39,113,264
<b>Transactions with owners in their capacity as owners:</b>						
Issuance of shares in connection with At-The-Market facility, net of costs	12(b)	-	-	-	-	-
Issuance of shares in connection with share purchase plan, net of costs	12(c)	-	(16,500)	-	-	(16,500)
Non-cash issuance of options to employees	13(b)	-	-	-	-	-
Non-cash issuance of options to consultants	13(b)	-	-	-	-	-
Issuance of shares in connection with exercise of options, net of costs	12(b) &(b)(b)	-	-	-	-	-
		-	(16,500)	-	-	(16,500)
Net loss		-	-	-	(7,729,551)	(7,729,551)
<b>Total comprehensive loss for the year</b>		-	-	-	(7,729,551)	(7,729,551)
<b>Balance, June 30, 2016</b>		533,891,470	146,879,214	9,363,181	(124,875,182)	31,367,213

The accompanying notes are an integral part of the consolidated financial statements.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

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

**Background**

Prana Biotechnology Limited and its controlled subsidiaries, Prana Biotechnology Inc. and Prana Biotechnology UK Limited (referred to collectively as “Prana” or the “Company”), 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 focusing on Alzheimer’s disease, Huntington disease, Parkinson’s disease and other neurological disorders. Prana Biotechnology Limited, the parent entity, was incorporated on November 11, 1997 in Melbourne, Australia and the UK and U.S. subsidiaries were incorporated in August 2004.

**Financial Reporting Framework**

The financial report of Prana Biotechnology Limited for the year ended June 30, 2016 was authorized for issue in accordance with a resolution of the Board of Directors on September 29, 2016.

Prana Biotechnology Limited is a for-profit entity for the purpose of preparing the financial statements.

The consolidated financial statements of the Company comply with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board (IASB).

These financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial liabilities at fair value through profit or losses.

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 accounting policies set out below have been applied in preparing the financial statements for the year ended June 30, 2016 and the comparative information presented in these financial statements for the years ended June 30, 2015 and 2014.

**Critical accounting estimates, judgments and assumptions**

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

The Company makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

(a) Critical judgments in applying the entity’s accounting policies - use of volatility period in valuing warrant liabilities

Warrants and options exercisable into American Depositary Receipts (“ADRs”) recorded as financial liabilities under IAS 32 *Financial Instruments: Presentation* (see Note 9) are measured at fair value using a Black-Scholes valuation model. At each reporting date any options and warrants for ADRs are recorded at fair value with the corresponding difference being recorded in the income statement as a gain or loss.

Warrants that were exercisable for ADRs expired without being exercised on June 4, 2009. On June 30, 2011, the Company granted warrants to purchase 612,397 ordinary shares to Alzheimer’s Drug Discovery Foundation (“ADDF”). The warrants were exercisable at A\$0.17 consideration and expired without being exercised on 25 February 2016.

**Share-based Payments**

The value attributed to share options and remuneration shares issued is an estimate calculated using an appropriate mathematical formula based on an option pricing model. The choice of models and the resultant option value require assumptions to be made in relation to the likelihood and timing of the conversion of the options to shares and the value and volatility of the price of the underlying shares.

**R&D Tax Incentives**

The Australian Government replaced the research and development tax concession with the research and development tax incentive from July 1, 2011. The provisions provide refundable or non-refundable tax offsets. The research and development tax incentive applies to expenditure incurred and the use of depreciating assets in an income year commencing on or after July 1, 2011. A 45% refundable tax offset, equivalent to a deduction of 150%, will be available to eligible small companies with an annual aggregate turnover of less than \$20 million. Eligible companies can receive a refundable tax offset of 45% of their research and development spending.



**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

The Company's research and development activities are eligible under an Australian Government tax incentive for eligible expenditure from July 1, 2011. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. For the period to June 30, 2016 the Company has recorded an item in other income of A\$4.8 million (2015: A\$6.1 million) to recognize this amount which relates to this period.

**Going Concern Basis**

The Company is a development stage medical biotechnology company and as such expects to be utilizing cash until its research activities have become marketable. For the year ended June 30, 2016, the Company incurred an operating loss of A\$7.7 million (2015: Loss: A\$5.9 million) and an operating cash outflow of A\$7.4 million (2015: A\$10.9 million). As at year end the net assets of the Company stood at A\$31.4 million (2015: A\$39.1 million) and the cash position has decreased to A\$28.6 million from A\$34.9 million at 30 June 2015.

Cash on hand at June 30, 2016 are considered sufficient to meet the Company's forecast cash outflows for, at least 12 months from the date of this report. While there is uncertainty in the Company's cash flow forecast in relation to the phasing of proposed expenditure on research and development which may impact the forecast cash position, the Directors believe the Company will be able to maintain sufficient cash reserves through a range of options, including:

- The Company continues to pursue raising additional funds through alternative funding structures and has a strong history of raising capital. The Company had an "at the market" (ATM) facility through which it could raise additional funds of up to US\$44.5 million by the sale of American Depositary Receipts ("ADRs"). This facility, which was established through the filing of a shelf registration statement on Form F-3 with the United States Securities and Exchange Commission in November, 2014 has been a successful source of raising funds. In prior reporting periods, the Company has raised A\$46.5 million (US\$42.5 million) under this and a previous ATM facility.
- The Company has on issue a total of 19.4 million unlisted, unexercised options. The options have exercise prices ranging from A\$0.25 to A\$1.12. If all unlisted options were exercised, the Company would receive consideration of A\$7.5 million in total. Although the exercise of options may be available, it is not in the Company's control to receive this consideration.
- Notwithstanding, in the event that the Company will not have sufficient funds to effect its current plans through the above mentioned methods, the Company has the ability to scale down its operations and prioritize its research and development programs.

In addition to these options, the Company has recorded a Trade Receivable at June 30, 2016 in the amount of A\$4.8 million from the Australian Tax Office in respect of its 2016 research and development tax incentive claim. The Company expects to receive this amount during the 12 months ended 30 June 2017.

On this basis, the Directors are satisfied that the Company is a going concern and at this time and are of the opinion that no asset is likely to be realized for an amount less than the amount at which it is recorded in the Consolidated Statement of Financial Position as at June 30, 2016.

Therefore, no adjustments have been made to the financial report relating to the recoverability and classification of the asset carrying amounts or the classification of liabilities that might be necessary should the Company not continue as a going concern.

**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.

The Company cannot be certain that it will be able to raise any required funding or capital, on favorable terms or at all, or that it 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, it may be required to reduce the scope of its development plans.

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

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

**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.

**(a) Principles of Consolidation**

The consolidated financial statements are prepared by combining the financial statements of all the entities that comprise the Company, being Prana Biotechnology Limited and its subsidiaries as defined in Accounting Standard IAS 27: *Consolidated and Separate Financial Statements*. Consistent accounting policies are employed in the preparation and presentation of the consolidated financial statements.

Subsidiaries are all those entities (including special purpose entities) over which the Company has the power to govern the financial and operating policies, generally accompanying a shareholder of more than one-half of the voting rights. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether the Company controls another entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are de-consolidated from the date that control ceases.

In preparing the consolidated financial statements, all inter-company balances and transactions, and unrealized profits/losses arising within the Company are eliminated in full. Investments in subsidiaries are accounted for at cost in the individual financial statements of Prana Biotechnology Limited.

**(b) Segment Reporting**

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Chief Executive Officer of Prana Biotechnology Limited. For the current and previous reporting periods, the Company operated in one segment, being research into Alzheimer's disease, Huntington disease, Parkinson's disease and other neurodegenerative disorders.

**(c) Income Tax**

Current tax

Current tax is calculated by reference to the amount of income taxes payable or recoverable in respect of the taxable profit or loss for the period. It is calculated using tax rates and tax laws that have been enacted or substantively enacted by reporting date. Current tax for current and prior periods is recognized as a liability (or asset) to the extent that it is unpaid (or refundable).

Deferred tax

Deferred tax is accounted for using the liability method in respect of temporary differences arising from differences between the carrying amount of assets and liabilities in the financial statements and the corresponding tax base of those items.

In principle, deferred tax assets and liabilities are recognized for all taxable temporary differences. Deferred tax assets are recognized to the extent that it is probable that sufficient taxable amounts will be available against which deductible temporary differences or unused tax losses and tax offsets can be utilized. However, deferred tax assets and liabilities are not recognized if the temporary differences giving rise to them arise from the initial recognition of assets and liabilities (other than as a result of a business combination) which affects neither taxable income nor accounting profit or loss.

Deferred tax liabilities are recognized for taxable temporary differences arising on investments in subsidiaries except where the Company is able to control the reversal of the temporary differences and it is probable that the temporary differences will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with these investments are only recognized to the extent that it is probable that there will be sufficient taxable profits against which to utilize the benefits of the temporary differences and they are expected to reverse in the foreseeable future.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period(s) when the asset and liability giving rise to them are realized or settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by reporting date. The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Company expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset when the entity has a legally enforceable right to offset and intends either to settle on a net basis or to realize the asset and settle the liability simultaneously.

Current and deferred tax for the period

Current and deferred tax is recognized as an expense or income in the Statement of Profit or Loss, except when it relates to items credited or debited directly to equity, in which case the deferred tax is also recognized directly in equity, or where it arises from the initial accounting for a business combination, in which case it is taken into account in the determination of goodwill.

The Company has significant unused tax losses and as such a significant deferred tax asset; however, the deferred tax asset has not been recognized, as it is not probable that future taxable profit will be available against which the unused losses and unused tax credits can be utilized, given the nature of the Company's business (research and development) and its history of losses.

**(d) Property and Equipment**

Property and equipment is measured at historical cost less accumulated depreciation and impairment and consists of laboratory equipment, computer equipment, furniture and fittings and leasehold improvements attributable to the Company's premises at Parkville, Victoria, Australia.

Historical cost includes expenditure that is directly attributable to the acquisition of the item.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Company and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to the income statement during the reporting period in which they are incurred.

Depreciation

Depreciation is provided on property and equipment. Depreciation is calculated on a straight-line method to allocate their cost, net of their residual values, over their estimated useful lives.

The following estimated useful lives, ranging from three to 20 years are used in the calculation of depreciation:

<u>Class of Fixed Asset</u>	<u>Depreciation Rate</u>
Furniture and fittings	5-33%
Computer equipment	33%
Plant and equipment	10-33%
Leasehold improvements	33%

Leasehold improvements are depreciated over the shorter of the lease term and useful life.

The depreciation method, residual values and useful lives are reviewed, and adjusted if appropriate, at each annual reporting period.

**(e) Leases**

Leases in which a significant proportion of the risks and rewards of ownership are not transferred to the Company as lessee are classified as operating leases.

Operating lease payments are recognized as an expense on a straight-line basis over the lease term, except where another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

**(f) Financial Instruments**

Loans and Receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for those with maturities greater than 12 months after the reporting date which are classified as non-current assets. Loans and receivables are included in trade and other receivables in the balance sheet. Trade receivables, loans, and other receivables are recorded at amortized cost less impairment.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Warrants and Options

Under IAS 32, options and warrants issued other than for goods or services that are exercisable in a currency other than the functional currency of the Company and meet the definition of a liability, are recorded as financial liabilities rather than equity. See accounting policy (r) share-based payments for the accounting policy for warrants and options issued as share-based payments for goods or services.

Warrants and options recorded as financial liabilities under IAS 32 are valued at fair value using the Black-Scholes model. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioural considerations. At each reporting date, the options and warrants are revalued to their current fair value, with the difference in fair value recorded in the Statement of Profit or Loss and Other Comprehensive Income.

**(g) Impairment of Assets**

At each reporting date, the Company reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have been impaired. If any such indication exists, the recoverable amount of the asset is estimated to determine the extent of the impairment loss (if any).

Where the asset does not generate cash flows that are independent from other assets, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Intangible assets not yet available for use are tested for impairment annually and whenever there is an indication that the asset may be impaired.

The recoverable amount for the asset (or cash-generating unit) is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or cash-generating unit) is reduced to its recoverable amount and an impairment loss is recognized in profit or loss immediately.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit) is increased to the revised estimate of its recoverable amount, but only to the extent that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or cash-generating unit) in prior years. A reversal of an impairment loss is recognized in profit or loss immediately.

No impairment charges were incurred during the three years ended June 30, 2016.

**(h) Intangible Assets - Research and Development**

Expenditure during the research phase of a project is recognized as an expense when incurred. Where no internally generated intangible assets can be recognized, development expenditure is recognized as an expense in the period as incurred. Development costs are capitalized if and only if, all of the following are demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

Internally-generated intangible assets (capitalized development costs) are stated at cost less accumulated amortization and impairment, and are amortized on a straight-line basis over their useful lives over a maximum of five years.

At June 30, 2016, 2015 and 2014, Prana had no capitalized research and development costs.

**(i) Foreign Currency Transactions and Balances**

Functional and Presentation Currency

Items included in the financial statements of each of the Company's entities are measured using Australian dollars, which is the currency of the primary economic environment in which the Company operates (the functional currency).

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Foreign currency transactions

All foreign currency transactions during the financial year are brought to account using the exchange rate in effect at the date of the transaction. Foreign currency monetary items at each reporting date are translated at the exchange rate existing at each reporting date. Non-monetary assets and liabilities carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when the fair value was determined.

Exchange differences are recognized in profit or loss in the period in which they arise except for exchange differences on monetary items receivable from or payable to a foreign operation for which settlement is neither planned or likely to occur, which form part of the net investment in a foreign operation, are recognized in the foreign currency translation reserve and recognized in profit or loss on disposal of the net investment.

Company entities The results and financial position of all the Company's entities that have a functional currency difference from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet, and
- income and expenses for each income statement are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions), and
- all resulting exchange differences are recognized as a separate component of equity.

On consolidation, the assets and liabilities of the Company's overseas operations are translated at exchange rates prevailing at the reporting date. Income and expense items are translated at the average exchange rates for the period unless exchange rates fluctuate significantly. Exchange differences arising, if any, are recognized in the foreign currency translation reserve, and recognized in profit or loss on disposal of the foreign operations.

**(j) Employee Benefits**

Short-term obligations

Short-term employee benefits are benefits (other than termination benefits) that are expected to be settled wholly before 12 months after the end of the annual reporting period in which the employees render the related service, including wages, and salaries. Short-term employee benefits are measured at the (undiscounted) amounts expected to be paid when the obligation is settled. The Company's obligations for short-term employee benefits such as wages and salaries are recognized as a part of current trade and other payables in the statement of financial position.

The Company's obligations for annual leave are presented as part of provisions in the Statement of Financial Position. The obligations are presented as current liabilities in the Statement of Financial Position if the Company does not have an unconditional right to defer settlement for at least twelve months after the reporting period regardless of when the actual settlement is expected to occur.

Other long-term obligations

The liability for long service leave is not expected to be settled wholly within twelve months after the end of the period in which the employees render the related service. The liability is therefore recognized in the provision for employee benefits and measured as the present value of expected future payments to be made in respect of services provided by employees up to the end of the reporting period using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the end of the reporting period of government bonds with terms and currencies that match, as closely as possible, the estimated future cash outflows. Re-measurements as a result of experience adjustments and changes in actuarial assumptions are recognized in profit or loss.

The obligations are presented as current liabilities in the balance sheet if the entity does not have an unconditional right to defer settlement for at least twelve months after the reporting period, regardless of when the actual settlement is expected to occur.

**(k) Provisions**

Provisions are recognized when the Company has a present obligation, the future sacrifice of economic benefits is probable, and the amount of the provision can be measured reliably.

The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at reporting date, taking into account the risks and uncertainties surrounding the obligation. Where a provision is measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows.

When some or all of the economic benefits required to settle a provision are expected to be recovered from a third party, the receivable is recognized as an asset if it is virtually certain that recovery will be received and the amount of the receivable can be measured reliably.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

**(l) Cash and Cash Equivalents**

Cash and cash equivalents includes cash on hand, deposits held at call with banks and other short-term highly liquid investments with original maturities of three months or less.

**(m) Revenue from ordinary activities**

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. Revenue is made up of interest income which is recognized on a time proportion basis using the effective interest method.

**(n) Grants**

Grants are recognized when there is reasonable assurance that the grant will be received and all grant conditions will be complied with.

When the grant relates to an expense item, it is recognized as income over the periods necessary to match the grant on a systematic basis to the costs that it is expected to compensate.

**(o) Goods and Services Tax (“GST”)**

Revenues, expenses and assets are recognized net of the amount of GST, except where the amount of GST incurred is not recoverable from the taxation authority. In these circumstances the GST is recognized as part of the cost of acquisition of the asset or as part of an item of expense. Receivables and payables in the Balance Sheet are shown inclusive of GST.

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

Cash flows are included in the Cash Flow Statement on a gross basis. The GST component of cash flows arising from investing and financing activities which is recoverable from, or payable to, the taxation authority is classified as operating cash flows.

**(p) Trade and Other Payables**

These amounts represent liabilities for goods and services provided to the Company prior to the end of financial year which are unpaid. The amounts are unsecured and are usually paid within 30 days of recognition.

**(q) Borrowings**

Loans and borrowings are initially recognized at the fair value of the consideration received, net of transaction costs. They are subsequently measured at amortized cost using the effective interest method.

Where there is an unconditional right to defer settlement of the liability for at least 12 months after the reporting date, the loans or borrowings are classified as non-current.

**(r) Share-Based Payments**

Equity-settled share-based payments granted after November 7, 2002 that were unvested as of January 1, 2005 are measured at fair value. The measurement date is determined for share-based payments issued to directors, employees and consultants as follows:

Directors

The issuance of share-based payments to directors is subject to approval by shareholders as per ASX Listing Rule 10.11. The measurement date for share-based payments issued to directors is the grant date, being the date at which the share-based payments are approved by shareholders.

Employees

The issuance of share-based payments to employees may be subject to shareholder approval per ASX Listing Rule 7.1 which prohibits the issuance of more than 15% of the Company's shares in a 12 month period without shareholder approval. The measurement date for share-based payments issued to employees is the grant date, being the date at which a shared understanding of the terms and conditions of the arrangement is reached. However, if an issuance to an employee is subject to shareholder approval because it exceeds the 15% threshold per ASX Listing Rule 7.1, then the measurement date of these share-based payments is the date at which the share-based payments are approved by shareholders.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

Consultants

The issuance of share-based payments to consultants may be subject to shareholder approval per ASX Listing Rule 7.1 which prohibits the issuance of more than 15% of the Company's shares in a 12 month period without shareholder approval. The measurement date for share-based payments issued to consultants who provide services considered to be similar to employees is deemed to be the date at which a shared understanding of the terms and conditions of the arrangement is reached. The measurement date for share-based payments issued to consultants who provide services considered to be differentiated from those provided by employees is deemed to be the date at which the entity obtains the goods or the counterparty renders the service. If a service period applies and the work is continually provided over the service period, and if the share price of the Company does not change significantly during the service period, then the average share price, volatility and risk-free rate over the service period are used in calculating the value of the share-based payments issued. However, if the underlying share price of the Company does change significantly during the service period, then the value of share-based payments are calculated at each individual date that goods and services are provided, using the actual valuation inputs at that date. Shares issued to consultants for services are recorded as non-cash compensation and are recognized at either the fair value of the services rendered, or if this cannot be reasonably estimated, the fair value of the underlying equity instruments issued.

Equity-based compensation benefits are provided to directors, employees and consultants under the 2004 ASX Plan (the "2004 ASX Plan") and the 2004 American Depository Share (ADS) Option Plan (the "2004 ADS Plan"). Information relating to this plan is set out in Note 18.

The fair value of options granted under the 2004 ASX Plan is recognized as an expense with a corresponding increase in equity. The fair value is measured at grant date and recognized over the period during which the recipients become unconditionally entitled to the options.

The fair value at grant date is independently determined using a Black-Scholes (for options without market condition) and Barrier Pricing (for options with market conditions) model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk free interest rate for the term of the option. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioral considerations.

The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Company's estimate of shares that will eventually vest.

**(s) Loss Per Share**

Basic loss per share is determined by dividing the net loss after income tax expense by the weighted average number of ordinary shares outstanding during the financial 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.

**(t) Share Capital**

Ordinary share capital is recognized as the fair value of the consideration received by the Company. Any transaction costs arising on the issue of ordinary shares are recognized directly in equity as a reduction of the share proceeds received.

**(u) Trade and Other Receivables**

Trade and other receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest rate method less provision for impairment.

**(v) Comparative Figures**

Comparative figures, are, where appropriate, reclassified to be comparable with figures presented in the current financial year.

*Impact of Re-classification of Expenses on Comparative Amounts*

The re-classification of expenses to function in Statement of Profit or Loss and Other Comprehensive Income has recently been completed to conform to standard industry practice and IFRS. The impact of the reclassification is shown in the table below.

Prior periods' comparatives have been revised to align to disclosure in the Financial Statements as shown below. This change in accounting policy has no impact on the total comprehensive loss for the prior periods, or the Statement of Financial Position and cash flow statement.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

	Years ended June 30, 2015		
	Unadjusted	Adjustment	Adjusted
Revenues from ordinary activities	176,842		176,842
Other income	6,317,438		6,317,438
Research and development expenses	(12,298,167)		(12,298,167)
Corporate personnel expenses	(2,344,337)	2,344,337	-
General and administrative expenses	-	(4,506,122)	(4,506,122)
Intellectual property expenses	(257,299)		(257,299)
Auditor and accounting expenses	(416,271)	416,271	-
Travel expenses	(125,532)	125,532	-
Public relations and marketing expenses	(87,851)	87,851	-
Depreciation expenses	(31,587)	31,587	-
Other expenses	(1,626,076)	1,626,076	-
Other operating expenses	-	(39,210)	(39,210)
Other gains & losses	-	4,721,449	4,721,449
Foreign exchange gain (loss)	4,721,449	(4,721,449)	-
Gain (loss) on fair valuation of financial liabilities	86,322	(86,322)	-
<b>Loss before income tax expense</b>	<b>(5,885,069)</b>		<b>(5,885,069)</b>
Income tax expense	-		-
<b>Loss for the year</b>	<b>(5,885,069)</b>		<b>(5,885,069)</b>
<b>Other comprehensive loss</b>	<b>-</b>		<b>-</b>
<b>Total comprehensive loss for the year</b>	<b>(5,885,069)</b>		<b>(5,885,069)</b>
<b>Loss per share (basic and diluted - cents per share)</b>	<b>(1.17)</b>		<b>(1.17)</b>
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	502,714,982		502,714,982

	Years ended June 30, 2014		
	Unadjusted	Adjustment	Adjusted
Revenues from ordinary activities	363,775		363,775
Other income	7,845,396		7,845,396
Research and development expenses	(14,908,098)		(14,908,098)
General and administrative expenses	-	(4,925,411)	(4,925,411)
Corporate personnel expenses	(2,059,642)	2,059,642	-
Intellectual property expenses	(477,079)		(477,079)
Auditor and accounting expenses	(342,609)	342,609	-
Travel expenses	(421,013)	421,013	-
Public relations and marketing expenses	(358,597)	358,597	-
Depreciation expenses	(22,384)	22,384	-
Other expenses	(2,142,179)	2,142,179	-
Finance expenses	-	(29,978)	(29,978)
Other operating expenses	-	(451,251)	(451,251)
Other gains & losses	-	(746,593)	(746,593)
Interest expense - ADDF	(29,978)	29,978	-
Foreign exchange gain (loss)	(746,593)	746,593	-
Gain (loss) on fair valuation of financial liabilities	(30,238)	30,238	-
<b>Loss before income tax expense</b>	<b>(13,329,239)</b>		<b>(13,329,239)</b>
Income tax expense	-		-
<b>Loss for the year</b>	<b>(13,329,239)</b>		<b>(13,329,239)</b>
<b>Other comprehensive loss</b>	<b>-</b>		<b>-</b>
<b>Total comprehensive loss for the year</b>	<b>(13,329,239)</b>		<b>(13,329,239)</b>
<b>Loss per share (basic and diluted - cents per share)</b>	<b>(3.11)</b>		<b>(3.11)</b>
Weighted average number of ordinary shares used in computing basic and diluted net loss per share	428,047,123		428,047,123



**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**1. BACKGROUND AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

**(w) Parent Information**

The financial information for the parent entity, Prana Biotechnology Limited, has been prepared on the same basis as the consolidated statements, except as set out below:

Investments in Subsidiaries

Investments in subsidiaries are accounted for at cost in the financial statements of Prana Biotechnology Limited.

**(x) New Accounting Standards And Interpretations**

New and amended Accounting Standards and Interpretations issued and effective

There are no IFRS or IFRIC interpretations that are effective for the first time for the financial year beginning on or after June 30, 2016 that would be expected to have a material impact on the Company.

Accounting Standards issued by not yet effective

Certain new accounting standards and interpretations have been published that are not mandatory for June 30, 2016 reporting periods. Initial application of the following Standards and Interpretations are not expected to affect any of the amounts recognized in the financial report, but may change the disclosures presently made in relation to the Company.

<b>Pronouncement</b>	<b>Title (Issue date)</b>	<b>Effective date</b>	<b>Impact on financial report</b>
IFRS 15	Revenue from contracts with customers	Annual periods beginning on or after January 1, 2017 Earlier application is permitted.	The Company is currently not generating revenue from contracts and thus the impact is expected to be nil.
IFRS 9	Financial instruments	Annual periods beginning on or after January 1, 2018 Earlier application is permitted.	Management is in the process of determining the impact of this standard for subsequent reporting periods.
IFRS 16	Leases	Annual periods beginning on or after January 1, 2019 Earlier application is permitted.	Management is in the process of determining the impact of this standard for subsequent reporting periods.
IFRS 2 (Amendments)	Classification and Measurement of Share-based Payment Transactions	Annual periods beginning on or after January 1, 2018 Earlier application is permitted.	Management is in the process of determining the impact of this standard for subsequent reporting periods.

There are no other standards that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

	Years Ended June 30,		
	2016	2015	2014
<b>2. REVENUE AND OTHER INCOME FROM CONTINUING OPERATIONS</b>			
<b>Other revenue</b>			
Interest	142,657	176,842	363,775
Total other revenue	142,657	176,842	363,775
<b>Other income</b>			
R&D Tax Incentive	4,753,697	6,088,897	7,802,947
Michael J Fox Foundation Grant	-	-	39,949
Other Grants	-	228,541	2,500
Total other income	4,753,697	6,317,438	7,845,396
Total revenue and other income from continuing operations	4,896,354	6,494,280	8,209,171
<b>3. EXPENSES FROM ORDINARY ACTIVITIES</b>			
<b>Research and Development Expenses (1)</b>			
Employee expenses	1,821,717	1,866,915	1,827,934
Other research and development expenses	7,763,654	10,431,252	13,080,164
<b>General and Administration Expenses</b>			
Depreciation on fixed assets	22,810	31,587	22,384
Employee expenses (non R&D related)	992,751	937,348	807,502
Consultant and director expenses	750,158	1,227,731	1,212,240
Audit, internal control and other assurance expenses	204,776	499,911	420,519
Corporate compliance expenses	358,096	421,958	493,362
Office rental	195,561	161,175	163,583
Other administrative and office expenses	1,086,400	1,226,412	1,805,821
<b>Other gains and losses</b>			
Foreign exchange (gain)/loss	(857,247)	(4,721,449)	746,593

(1) Research and development expenses consist of expenses paid for contracted research and development activities conducted by third parties on behalf of the Company.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

	<b>Years Ended June 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>4. INCOME TAX</b>			
(a) Income tax expense:			
Current tax	-	-	-
Adjustment for current tax of prior periods	-	-	-
Deferred tax	-	-	-
(b) Numerical reconciliation of income tax expense to prima facie tax payable:			
Prima facie tax on net loss before income tax at 30% (2016, 2015 & 2014: 30%)	(2,318,865)	(1,765,431)	(3,998,686)
Effect of lower tax rates of tax on overseas income	(11,111)	(41)	(43)
Add tax effect of:			
(Over)/Under provision of income tax in previous year relating to a revision of estimates	4,582,839	3,071,631	2,214,342
Equity issued for nil consideration	-	140,651	1,269,857
Research and development expenditure (net of tax incentive)	1,743,004	(2,153,737)	(7,180,486)
Gain/(loss) on fair value of financial liabilities	-	25,897	(30,238)
Other	54,222	1,549	5,761
Deferred tax asset not recognized	(4,050,088)	679,571	7,719,579
Income tax expense attributable to loss before income tax	-	-	-
(c) Potential deferred tax asset at June 30, 2016, 2015 and 2014 in respect of: tax losses not brought to account is			
(1):	35,687,127	38,463,614	39,143,186
Temporary differences	(1,655,223)	3,934,146	(37,806)

(1) Tax losses can be carried forward indefinitely subject to continuity of ownership and same business test rules.

	<b>Years Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>5. TRADE AND OTHER RECEIVABLES</b>		
Grant receivable		55,699
Accrued interest income		4,255
R&D tax incentive receivable	4,753,646	6,461,212
Goods and services tax receivable	7,836	(12)
Total Trade and Other Receivables	4,786,765	6,521,154

	<b>Years Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>6. OTHER ASSETS</b>		
<u>Current</u>		
Prepayments	276,504	159,963
Payroll term deposit	-	152,603
Other receivables	-	899
Total	276,504	313,465
<u>Non-current</u>		
Rental term deposit	43,988	45,462
Total	43,988	45,462

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

7. PROPERTY AND EQUIPMENT	Notes	Years Ended June 30,	
		2016	2015
Gross carrying amount			
Balance at beginning of year		367,069	392,795
Additions		2,799	28,757
Disposals		(16,102)	(54,483)
Balance at end of year		353,766	367,069
Accumulated depreciation			
Balance at beginning of year		(322,342)	(345,238)
Disposals		15,611	54,483
Depreciation expense	3	(22,810)	(31,587)
Balance at end of year		(329,541)	(322,342)
Net book value at end of year		24,225	44,727

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

	Years Ended June 30,	
	2016	2015
Laboratory equipment, at cost	112,631	112,631
Less accumulated depreciation	(111,839)	(110,964)
Total laboratory equipment	792	1,667
Computer equipment, at cost	127,078	140,382
Less accumulated depreciation	(107,583)	(103,771)
Total computer equipment	19,495	36,611
Furniture and fittings, at cost	38,398	38,398
Less accumulated depreciation	(34,460)	(31,949)
Total furniture and fittings	3,938	6,449
Leasehold improvements, at cost	75,659	75,659
Less accumulated depreciation	(75,659)	(75,659)
Total leasehold improvements	-	-
Total	24,225	44,727

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

	Years Ended June 30,	
	2016	2015
<b>8. TRADE AND OTHER PAYABLES</b>		
Trade creditors	311,719	362,493
Accrued research and development expenses	1,178,656	1,299,492
Accrued intellectual property expenses	10,910	-
Accrued corporate personnel expenses	7,421	535
Accrued audit and accounting fees	143,776	415,911
Accrued travel expenses	1,650	-
Other accrued expenses	94,434	73,584
<b>Total</b>	<b>1,748,566</b>	<b>2,152,015</b>

	Years Ended June 30,			
	2016	2015	2016	2015
	No.	No.	A\$	A\$
<b>9. FINANCIAL LIABILITIES</b>				
<u>Current</u>				
Warrants over ordinary shares (a)	-	612,397	-	12,076
<b>Total</b>			<b>-</b>	<b>12,076</b>

(a) Warrants over ordinary shares

As per the agreement with the ADDF, the Company issued warrants to purchase 612,397 ordinary shares to the ADDF representing 30% of the value of the first tranche of the US\$350,000 grant received during the financial year end June 30, 2011. The warrants were convertible to ordinary shares on or before February 25, 2016, when they expired without being exercised, at an exercise price of A\$ 0.17 per warrant.

Under IAS 32 paragraph 11, the warrants associated with this transaction are required to be classified as a financial liability, as opposed to issued capital. On initial recognition the warrants are measured at fair value on the Statement of Financial Position. At each reporting date the financial liability representing the warrants are required to be re-valued to fair value with the movement in the fair value recorded in the Statement of Profit or Loss and Other Comprehensive Income.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

	Years Ended June 30,	
	2016	2015
<b>10. PROVISIONS</b>		
<b>Current</b>		
Annual leave (1)	288,122	261,823
Long service leave (1)(2)	320,649	292,792
<b>Total</b>	608,771	554,615
<b>Non-Current</b>		
Long service leave (2)	470	2,412

A provision has been recognized for employee entitlements relating to long service leave. In calculating the present value of future cash flows in respect of long service leave, the probability of long service leave being taken is based on historical data. The measurement and recognition criteria relating to employee benefits have been included in Note 1 to this report.

**(1) Movements in provisions**

Movements in each class of provision during the financial year are set out below:

	Years Ended June 30,	
	2016	2015
<b>Annual leave</b>		
Carrying amount at start of year	261,823	217,646
Charged/(credited) to profit or loss		
-additional provisions recognized	165,384	199,667
-unused amounts reversed	-	-
Amounts used during the year	(139,085)	(155,490)
Carrying amount at end of year	288,122	261,823
<b>Long service leave</b>		
Carrying amount at start of year	295,204	280,166
Charged/(credited) to profit or loss		
-additional provisions recognized	25,915	15,038
-unused amounts reversed	-	-
Amounts used during the year	-	-
Carrying amount at end of year	321,119	295,204
<b>TOTAL</b>	<b>609,241</b>	<b>557,027</b>

**(2) Amounts not expected to be settled within the next 12 months**

The current provision for long service leave includes all unconditional entitlements where employees have completed the required period of service and also those where employees are entitled to pro-rata payments in certain circumstances.

The entire amount is presented as current, since the Company does not have an unconditional right to defer settlement. However, based on past experience, the Company does not expect all employees to take the full amount of accrued long service leave or require payment within the next 12 months. The following amounts reflect leave that is not expected to be taken or paid within the next 12 months.

	Years Ended June 30,	
	2016	2015
Long service leave obligation expected to be settled after 12 months	320,649	292,792

**11. COMMITMENTS AND CONTINGENCIES**

There are no contingent assets or liabilities at the date of this report. The Company is not involved in any legal or arbitration proceedings and, so far as management is aware, no such proceedings are pending or threatened against the Company.

In respect of expenditure commitments, refer to Note 16.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

	Notes	Years Ended June 30,		
		2016	2015	2014
<b>12. ISSUED CAPITAL</b>				
<b>(a) Issued Capital</b>				
533,891,470 (2015: 533,891,470) fully paid ordinary shares	12(b)	144,177,570	144,194,070	137,307,771
Nil (2015: Nil) options for fully paid ordinary shares	12(c)	2,701,644	2,701,644	2,701,644
		<u>146,879,214</u>	<u>146,895,714</u>	<u>140,009,415</u>

**(b) Movements in Issued Shares**

	June 30,					
	2016		2015		2014	
	No.	A\$	No.	A\$	No.	A\$
Beginning of the year	533,891,470	144,194,070	488,646,960	137,307,771	381,610,426	98,677,467
Movement during the year	-	(16,500)	45,244,510	6,886,299	107,036,534	38,630,304
End of the year	<u>533,891,470</u>	<u>144,177,570</u>	<u>533,891,470</u>	<u>144,194,070</u>	<u>488,646,960</u>	<u>137,307,771</u>

Details of share issuances are as follows:

Date	Details	Notes	Number	Issue Price	A\$
Year ended June 30, 2013			<u>83,629,608</u>		<u>15,245,034</u>
August 2, 2013	Shares to investors as part of at-the-market facility		1,469,780	0.40	588,216
August 5, 2013	Shares to investors as part of at-the-market facility		465,980	0.38	176,592
August 6, 2013	Shares to investors as part of at-the-market facility		3,601,550	0.39	1,413,617
August 7, 2013	Shares to investors as part of at-the-market facility		2,517,590	0.38	956,832
August 30, 2013	Exercise of options – consultants		150,000	0.35	52,140
August 30, 2013	Exercise of options – consultants		100,000	0.12	11,700
August 30, 2013	Exercise of options – consultants		86,625	0.14	12,266
August 30, 2013	Exercise of options – consultants		100,000	0.12	11,700
August 30, 2013	Exercise of options – investors		10,000,000	0.39	3,857,143
August 30, 2013	Shares to investors as part of at-the-market facility		1,167,610	0.57	662,809
September 9, 2013	Shares to investors as part of at-the-market facility		2,160,950	0.58	1,261,265
September 10, 2013	Shares to investors as part of at-the-market facility		1,395,610	0.56	786,494
September 11, 2013	Shares to investors as part of at-the-market facility		523,120	0.55	288,606
September 12, 2013	Shares to investors as part of at-the-market facility		2,056,760	0.52	1,071,557
October 3, 2013	Exercise of options – employees		97,418	0.18	17,577
October 3, 2013	Exercise of options – employees		625,000	0.45	282,828
October 25, 2013	Exercise of options – consultants		60,000	0.14	8,496
October 25, 2013	Exercise of options – employees		217,478	0.14	30,795
November 4, 2013	Shares to investors as part of at-the-market facility		6,745,750	0.48	3,209,209
November 5, 2013	Shares to investors as part of at-the-market facility		143,700	0.48	69,054
November 4, 2013	Exercise of options – employees		722,419	0.42	300,405
November 6, 2013	Shares to investors as part of at-the-market facility		8,380	0.49	4,070
November 25, 2013	Exercise of options – consultants		200,000	0.40	80,786

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**12. ISSUED CAPITAL (continued)**

<b>Date</b>	<b>Details</b>	<b>Notes</b>	<b>Number</b>	<b>Issue Price</b>	<b>A\$</b>
December 13, 2013	Exercise of options – employees		73,200	0.35	25,444
December 20, 2013	Exercise of options – employees		81,750	0.14	11,576
December 20, 2013	Exercise of options – consultants		100,000	0.40	40,393
January 3, 2014	Exercise of options – investors		1,700,000	0.35	593,622
January 28, 2014	Exercise of options – investors		500,000	0.35	174,595
February 6, 2014	Exercise of options – investors		3,928,900	0.35	1,371,931
February 6, 2014	Exercise of options – employees		50,000	0.35	17,380
February 21, 2014	Exercise of options – employees		60,000	0.28	16,800.00
February 21, 2014	Exercise of options – employees		146,128	0.25	36,532
February 21, 2014	Exercise of options – employees		157,818	0.35	54,858
February 26, 2014	Exercise of options – employees		34,220	0.51	17,298
February 26, 2014	Exercise of options – employees		47,700	0.35	16,581
March 11, 2014	Exercise of options – consultants		200,000	0.40	80,786
March 11, 2014	Exercise of options – employees		60,000	0.35	20,856
March 11, 2014	Exercise of options – employees		66,500	0.28	18,620
March 11, 2014	Exercise of options – consultants		1,000,000	0.26	260,000
March 11, 2014	Exercise of options – employees		146,128	0.25	36,532
March 11, 2014	Shares to investors as part of at-the-market facility		980,130	1.23	1,202,928
March 12, 2014	Shares to investors as part of at-the-market facility		41,760	1.18	49,339
March 14, 2014	Shares to investors as part of at-the-market facility		1,594,220	1.11	1,767,019
March 17, 2014	Shares to investors as part of at-the-market facility		2,280,750	1.05	2,405,397
April 3, 2014	Exercise of options – investors		216,750	0.35	75,687
April 3, 2014	Shares to investors as part of at-the-market facility		22,339,170	0.31	6,963,613
April 4, 2014	Shares to investors as part of at-the-market facility		17,290,080	0.27	4,607,964
April 7, 2014	Shares to investors as part of at-the-market facility		18,325,610	0.25	4,672,819
April 7, 2014	Non cash share issue in consideration for services provided by consultants	(i)	1,000,000	0.25	252,750
June 30, 2014	Non cash share issue in consideration for services provided by consultants		-	-	24,200
	Security issuance costs		-	-	(1,339,369)
Year ended June 30, 2014			<u>107,036,534</u>		<u>38,630,304</u>
July 1, 2014	Reverse proposed issue to a consultant		-	-	(24,200)
July 21, 2014	Non cash share issue in consideration for services provided by consultants	(i)	110,000	0.23	25,300
July 21, 2014	Exercise of options – employees		180,000	-	25,488
February 23, 2015	Shares to investors as part of at-the-market facility		35,631,690	0.15	5,304,319
February 24, 2015	Shares to investors as part of at-the-market facility		2,538,820	0.14	357,270
June 2, 2015	Shares to investors as part of at-the-market facility		6,784,000	0.22	1,466,553
June 30, 2015	Non cash share issue in consideration for services provided by consultants		-	-	16,500
	Security issuance costs		-	-	(284,931)
Year ended June 30, 2015			<u>45,244,510</u>		<u>6,886,299</u>
July 1, 2015	Reverse proposed issue to a consultant		-	-	(16,500)
Year ended June 30, 2016			<u>-</u>		<u>(16,500)</u>



**PRANA BIOTECHNOLOGY LIMITED**  
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**12. ISSUED CAPITAL (continued)**

(i) Shares issued to consultants for services are recorded as non-cash compensation and are recognized at either the fair value of the services rendered, or if this cannot be reasonably estimated, the fair value of the underlying equity instruments issued. Shares issued to consultants have been valued as outlined below:

The services provided by these consultants were documented in consultancy agreements which outlined remuneration in the form of an annual fee and share-based compensation in the form of shares. The equity-based compensation is not linked to any particular milestone or element of the services to be provided under the terms of the agreements.

Given the extended period of consultants' involvement and associated milestones, the Company determined there were no comparable service examples against which to benchmark the value of the consultants' services. Additionally, there was no distinction between the portion of the services which gave rise to the cash entitlements and the portion that gave rise to share entitlements. As the Company could not reliably estimate the fair value of the services received, the Company determined that it was appropriate to measure the services at the fair value of the underlying equity instruments issued.

**(c) Movements in Options**

	June 30,					
	2016		2015		2014	
	Number of Options	A\$	Number of Options	A\$	Number of Options	A\$
Beginning of the year	-	2,701,644	-	2,701,644	-	2,701,644
End of the year*	-	2,701,644	-	2,701,644	-	2,701,644

\*There was no movement in options during the financial years ended June 30, 2016, 2015 and 2014.

**(d) Terms and Conditions of Issued Capital**

Ordinary shares

Ordinary shares have the right to receive dividends as declared and, in the event of a winding up of 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 vote, either in person or by proxy, at a meeting of the Company's shareholders.

Options

Option holders do not have the right to receive dividends and are not entitled to vote at a meeting of the Company's shareholders. Options may be exercised at any time from the date they vest to the date of their expiration. Share options convert into ordinary shares on a one for one basis on the date they are exercised.

**(e) Shares Issued after Reporting Date**

No equity issues have occurred after reporting date.

**13. RESERVES**

	Notes	Years Ended June 30,		
		2016	2015	2014
<b>(a) Share Based Payments</b>				
19,395,582 (2015: 19,395,582) options for fully paid ordinary shares	13(b)	7,394,184	7,394,184	6,968,437
Nil (2015: Nil) options for ADRs	13(c)	1,515,434	1,515,434	1,515,434
Nil (2015: 612,397) warrants for ADRs	13(d)	453,563	453,563	453,563
		9,363,181	9,363,181	8,937,434

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**13. RESERVES (continued)**

The share-based payment reserve is used to recognize the fair value of options and warrants issued to directors, executives, employees and consultants but not exercised. Amounts are transferred out of the reserve and into issued capital when the options or warrants are exercised.

**(b) Movements in Options for Fully Paid Ordinary Shares**

	Years Ended June 30,					
	2016		2015		2014	
	Number of Options	Comp. Expense (A\$)	Number of Options	Comp. Expense (A\$)	Number of Options	Comp. Expense (A\$)
Beginning of the year	19,395,582	7,394,184	18,542,577	6,968,437	35,544,121	8,557,928
Issued during the year	-	-	4,400,000	451,235	3,926,490	992,908
Expired during the year	-	-	(3,166,995)	-	-	-
Forfeited during the year	-	-	(200,000)	-	-	-
Exercised during the year	-	-	(180,000)	(25,488)	(20,928,034)	(2,582,399)
End of the year	19,395,582	7,394,184	19,395,582	7,394,184	18,542,577	6,968,437

Details of option grants are summarized as follows.

**Year ended June 30, 2014:**

- On October 25, 2013, the Company granted options to purchase 200,000 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.61 consideration and expire on October 24, 2018. The fair value of the options is A\$0.17.
- On November 4, 2013, the Company granted options to purchase 200,000 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.73 consideration and expire on November 3, 2018. The fair value of the options is A\$0.21.
- On November 4, 2013, the Company granted options to purchase 160,000 ordinary shares to key management personnel under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.73 consideration and expire on November 3, 2018. The fair value of the options is A\$0.21.
- On December 13, 2013, the Company granted options to purchase 1,200,000 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$1.04 consideration and expire on December 11, 2018. The fair value of the options is A\$0.36.
- On February 7, 2014, the Company granted options to purchase 300,000 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$1.12 consideration and expire on February 5, 2019. The fair value of the options is A\$0.64.
- On April 7, 2014, the Company granted options to purchase 1,200,000 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.25 consideration and expire on April 6, 2018. The fair value of the options is A\$0.23.
- On August 5, 2014, the Company granted options to purchase 306,490 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.66 consideration and expire on August 4, 2018. The fair value of the options is A\$0.18.
- On October 2, 2013, the Company granted options to purchase 360,000 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.66 consideration and expire on October 1, 2018. The fair value of the options is A\$0.17.

**Year ended June 30, 2015:**

- On October 3, 2014, the Company granted options to purchase 1,000,000 ordinary shares to key management personnel under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.34 consideration and expire on October 2, 2018. The fair value of the options is A\$0.17.
- On February 19, 2015, the Company granted options to purchase 2,000,000 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.26 consideration and expire on February 18, 2020. The fair value of the options is A\$0.08.
- On May 27, 2015, the Company granted options to purchase 1,400,000 ordinary shares to consultants under the 2004 Plan (see Note 17) in recognition of services rendered to the Company. The options are exercisable at A\$0.27 consideration and expire on May 25, 2020. The fair value of the options is A\$0.08.

**Year ended June 30, 2016:**

None

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**13. RESERVES (continued)**

**(c) Movements in Options for ADRs**

	Years Ended June 30,					
	2016		2015		2014	
	Number of Options	Comp. Expense (A\$)	Number of Options	Comp. Expense (A\$)	Number of Options	Comp. Expense (A\$)
Beginning of the year	-	1,515,434	-	1,515,434	-	1,515,434
Expiration of options (1)	-	-	-	-	-	-
End of the year	-	1,515,434	-	1,515,434	-	1,515,434

(1) Options exercisable at US\$5.00 on or before December 17, 2012. These options are convertible to ADRs, 1 ADR = 60 ordinary shares. At time of issue, 1 ADR = 10 ordinary shares. These options expired without being exercised on December 17, 2012.

**(d) Movement in Warrants for ADRs**

	Years Ended June 30,					
	2016		2015		2014	
	Number of Warrants	Comp. Expense (A\$)	Number of Warrants	Comp. Expense (A\$)	Number of Warrants	Comp. Expense (A\$)
Beginning of the year (1)	-	453,563	-	453,563	-	453,563
Beginning of the year (2)	612,397	-	612,397	-	612,397	-
Expired	(612,397)	-	-	-	-	-
End of the year	-	453,563	612,397	453,563	612,397	453,563

(1) Warrants exercisable at US\$8.00 on or before June 4, 2009. These warrants are convertible to ADRs; one ADR represents ten ordinary shares. Warrants expired without being exercised on June 4, 2009.

(2) Warrants exercisable at A\$0.17 on or before February 25, 2016. These warrants expired without being exercised on February 25, 2016.

**(e) Terms and Conditions of Reserves**

Options and warrants

Option holders and warrant holders do not have the right to receive dividends and are not entitled to vote at a meeting of the Company's shareholders. Options and warrants may be exercised at any time from the date they vest to the date of their expiration. Share options are exercisable into ordinary shares on a one for one basis on the date they are exercised. Options granted under the 2004 ADS Plan are exercisable into ADRs, being one option for one ADR, which equals ten ordinary shares, on the date they are exercised.

In Australia, there is not a set number of authorized shares, shares are not reserved for the exercise of options, and shares do not have a par value.

**(f) Options and Warrants Issued after Reporting Date**

No option issues have occurred after reporting date. There have been no warrants granted after reporting date.

	Years Ended June 30,	
	2016	2015
<b>14. ACCUMULATED DEFICIT DURING DEVELOPMENT STAGE</b>		
Balance at beginning of year	(117,145,631)	(111,260,562)
Net loss for the year	(7,729,551)	(5,885,069)
Balance at end of year	(124,875,182)	(117,145,631)

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

	Years Ended June 30,		
	2016	2015	2014
<b>15. CASH FLOW INFORMATION</b>			
<b>(a) Reconciliation of Net Loss to Net Cash Flows From Operations</b>			
Net loss	(7,729,551)	(5,885,069)	(13,329,239)
<b>Non-cash items</b>			
Depreciation of property and equipment	22,810	31,587	22,384
Non-cash issue of equity in consideration of operating expenses	(16,500)	468,835	1,269,857
Foreign exchange (gain) loss	(950,720)	(4,953,253)	581,263
(Gain) loss on fair value of financial liabilities	-	(86,322)	37,473
<b>Changes in assets and liabilities</b>			
Decrease (increase) in trade and other receivables	1,734,389	764,255	(3,761,471)
Decrease (increase) in other current assets	(115,643)	(63,979)	15,359
(Decrease) increase in trade and other payables	(403,449)	(1,206,343)	1,582,980
(Decrease) in other current liabilities	(12,076)	-	(33,332)
Increase in provision for employee entitlements	52,214	59,215	78,503
Net cash flows used in operating activities	(7,418,526)	(10,871,074)	(13,536,223)
<b>(b) Reconciliation of Cash and Cash Equivalents</b>			
Cash and cash equivalents balance comprises:			
- cash and cash equivalents on hand	28,593,538	34,909,574	34,167,018
Closing cash and cash equivalents balance	28,593,538	34,909,574	34,167,018
<b>(c) Non-Cash Financing and Investing Activities</b>			

During the years ended June 30, 2015 and 2014, the Company issued shares and granted options in connection with non-cash transactions. See Notes 12(b) and 13(b).

**16. EXPENDITURE COMMITMENTS**

The Company has non-cancelable operating leases contracted for but not capitalized in the financial statements. The Company has commitments under these contracts within one year of A\$145,610 and greater than one year but less than three years of A\$48,330. The property lease is a non-cancellable lease with an 18 month term, with rent payable monthly in advance. The property lease commenced April 1, 2015 and expires on September 30, 2017.

The majority of our contracts for research and development programs have a termination notice period of 30 days. As at June 30, 2016, we had research and development termination commitments approximating A\$1.45 million. No liability has been recognized within our financial statements for this period. In addition, we have the ability to scale down our operations and prioritize our research and development programs in neurology to reduce expenditures.

Details in relation to commitments under employee service agreements with Directors and Key Management Personnel are outlined in Note 20.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**17. SHARE BASED PAYMENTS**

**(a) Employee and Consultant Plans**

At the Annual General Meeting held on November 17, 2004, the shareholders approved the establishment of employee and consultant plans designed to reward directors, employees and consultants for their contributions to the Company. The plans are to be used as a method of retaining key personnel for the growth and development of the Company. Due to Prana's U.S. presence, a U.S. plan (the 2004 ADS Plan) and an Australian plan (the 2004 ASX Plan) were developed.

At 30 June 2016 equity had been issued to 1 previous Director, while a Director, under the US plan and 6 Directors, 2 Key Management Personnel, 12 employees and 19 consultants under the Australian Plan. At June 30, 2015, equity had been issued to one former Director under the 2004 ADS Plan and six Directors, three key management personnel, 16 employees and 19 consultants under the 2004 ASX Plan. At June 30, 2014, equity had been issued to one former Director under the 2004 ADS Plan and six Directors, three key management personnel, 16 employees and 19 consultants under the 2004 ASX Plan.

At the 2004 Annual General Meeting, shareholders authorized the Company to issue in the aggregate up to 12 million ordinary shares under the two plans. This was increased to 22 million ordinary shares at the 2005 Annual General Meeting and further increased to 30 million ordinary shares at the 2007 Annual General Meeting, 45 million ordinary shares at the 2008 Annual General Meeting and 60 million ordinary shares at the 2009 Annual General Meeting. The Share Plan Committee, a sub-committee of the Remuneration Committee administers the two plans and is able to change the terms of the equity issued under them from the default terms.

Under the 2004 ADS Plan, the exercise price must equal or exceed the fair value of the ADS on the date the options are awarded. The option expiration date cannot exceed ten years from the date the options were awarded. The default vesting conditions are 25% per year on the date the options were awarded.

Under the 2004 ASX Plan, the exercise price must be equal or be less than the market value of the ordinary shares on ASX on the date of grant. The option expiration date cannot exceed ten years from the date the options were granted. The default vesting conditions are 25% per year on the date the options were granted.

Information with respect to the number of options granted under the 2004 ASX Plan as follows:

	Years Ended June 30,					
	2016		2015		2014	
	Number of Options	Weighted Average Exercise Price (A\$)	Number of Options	Weighted Average Exercise Price (A\$)	Number of Options	Weighted Average Exercise Price (A\$)
Beginning of the year	19,395,582	0.38	16,375,582	0.41	17,031,476	0.23
Issued during the year	-	-	4,400,000	0.28	3,926,490	0.69
Exercised during the year	-	-	(180,000)	-	(4,582,384)	0.11
Expired during the year	-	-	(1,000,000)	0.25	-	-
Lapsed during the year	-	-	(200,000)	1.12	-	-
Forfeited during the year	-	-	-	-	-	-
Outstanding at year end	<u>19,395,582</u>	0.38	<u>19,395,582</u>	0.38	<u>16,375,582</u>	0.41
Exercisable at year end	<u>19,395,582</u>	0.38	<u>19,395,582</u>	0.38	<u>16,175,582</u>	0.40

**PRANA BIOTECHNOLOGY LIMITED**  
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**17. SHARE BASED PAYMENTS (continued)**

Options outstanding at the end of the year have the following expiry date and exercise prices:

Series	Grant Date	Expiry Date	Exercise Price	Share options	
			\$A	2016	2015
PBTAA	October 25, 2013	October 24, 2018	0.61	200,000	200,000
PBTAB	October 3, 2014	October 2, 2018	0.34	1,000,000	1,000,000
PBTAC	June 26, 2013	June 25, 2018	0.37	1,649,573	1,649,573
PBTAD	November 4, 2013	November 3, 2018	0.73	360,000	360,000
PBTAE	December 13, 2013	December 11, 2018	1.04	1,200,000	1,200,000
PBTAF	February 7, 2014	February 5, 2019	1.12	100,000	100,000
PBTAG	April 7, 2014	April 6, 2018	0.25	1,200,000	1,200,000
PBTAH	February 19, 2015	February 18, 2020	0.26	2,000,000	2,000,000
PBTAQ	December 12, 2012	December 13, 2017	0.33	8,500,000	8,500,000
PBTAR	May 27, 2015	May 25, 2020	0.27	1,400,000	1,400,000
PBTAW	March 21, 2012	March 20, 2017	0.25	1,119,519	1,119,519
PBTAY	August 5, 2013	August 4, 2018	0.66	306,490	306,490
PBTAZ	October 2, 2013	October 1, 2018	0.66	360,000	360,000
			<b>Total</b>	<b>19,395,582</b>	<b>19,395,582</b>
Weighted average remaining contractual life of options outstanding at end of period				2.04 years	3.04 years

*Risk free interest rate* – This is the government bond rate (having a term that most closely resembles the expected life of the option) in effect at the grant date. The Australian government bond rate has been used for options which are exercisable for fully paid ordinary shares and the U.S. government bond rate has been used for options which are exercisable for ADRs.

*Dividend yield* – Prana has never declared or paid dividends on its ordinary shares and does not anticipate paying any dividends in the foreseeable future.

*Expected volatility* – Prana estimates expected volatility based on historical volatility over the estimated life of the option and other factors. Historical volatility has been the basis for determining expected share price volatility as it is assumed that this is indicative of future movements. The life of the options is based on historical exercise patterns, which may not eventuate in the future.

*Expected life* – This is the period of time that the options granted are expected to remain outstanding. This estimate is based primarily on historical trend of option holders to exercise their option near the date of expiry. As a result the expected life is considered to equal the period from grant date to expiry date.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**17. SHARE BASED PAYMENTS (continued)**

*Model inputs –*

The model inputs for the valuations of options approved and issued during the current and previous financial years are as follows:

Series	Grant Date	Exercise Price per Share A\$	Share Price at Grant Date A\$	Expected Share Price Volatility	Years to Expiry	Dividend Yield	Risk-free Interest Rate
PBTAY	August 5, 2013	0.66	0.38	62.00%	5.00	0%	3.05%
PBTAZ	October 2, 2013	0.66	0.41	61.00%	5.00	0%	3.24%
PBTAA	October 25, 2013	0.61	0.38	63.60%	5.00	0%	3.31%
PBTAD	November 4, 2013	0.73	0.44	68.80%	5.00	0%	3.46%
PBTAE	December 13, 2013	1.04	0.69	70.70%	5.00	0%	3.45%
PBTAF	February 7, 2014	1.12	1.18	58.50%	5.00	0%	3.44%
PBTAG	April 7, 2014	0.25	0.23	289.40%	4.00	0%	3.02%
PBTAB	October 3, 2014	0.34	0.22	130.50%	4.00	0%	2.71%
PBTAH	February 19, 2015	0.26	0.16	74.80%	5.00	0%	2.00%
PBTAR	May 27, 2015	0.27	0.17	69.40%	5.00	0%	2.25%

Information with respect to the number of shares issued under the 2004 ASX Plan as follows:

	<b>Years Ended June 30,</b>		
	<b>2016</b>	<b>2015</b>	<b>2014</b>
	<b>Number of Shares</b>	<b>Number of Shares</b>	<b>Number of Shares</b>
Beginning of the year	13,277,715	12,987,715	7,405,331
Issued during the year (1)	-	290,000	5,582,384
End of the financial year	<u>13,277,715</u>	<u>13,277,715</u>	<u>12,987,715</u>

(1) In the years ended June 30, 2015 and 2014 this includes options to purchase 180,000 and 4,582,384 ordinary shares, respectively granted under the 2004 ASX Plan that were exercised.

The weighted average fair value of the shares granted during the year ended June 30, 2015 and 2014 was \$0.23 and \$0.25. No shares were granted during the year ended June 30, 2016.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**18. SUBSEQUENT EVENTS**

No matters or circumstances have arisen since the end of the reporting period, not otherwise disclosed in this report, which significantly affected or may significantly affect the operations of the Company, the result of those operations or the state of affairs of the Company in subsequent financial years.

**19. LOSS PER SHARE**

	Years Ended June 30,		
	2016	2015	2014
Basic and diluted loss per share (cents per share)	(1.45)	(1.17)	(3.11)
Weighted average number of ordinary shares on issue used in the calculation of basic and diluted loss per share	533,891,470	502,714,982	428,047,123

The options and warrants in place do not have the effect of diluting the loss per share.

**20. KEY MANAGEMENT PERSONNEL COMPENSATION**

	Years Ended June 30,		
	2016	2015	2014
Short-term employee benefits	1,476,000	1,554,843	1,139,860
Post-employment benefits	95,117	96,324	77,775
Long-term benefits	13,817	2,733	17,615
Share-based payments	-	170,397	33,824
	<b>1,584,934</b>	<b>1,824,297</b>	<b>1,269,074</b>

**21. AUDITORS' REMUNERATION**

	Years Ended June 30,		
	2016	2015	2014
- audit and review fees: current year financial reports	166,479	160,158	145,187
- audit and review fees: internal controls	38,297	256,113	187,422
- audit and review fees: other assurance services	-	83,640	65,000
	<b>204,776</b>	<b>499,911</b>	<b>397,609</b>

PricewaterhouseCoopers was appointed as the Company's principal independent registered public accounting firm on November 30, 2006. Australian law does not require the Company's Auditors to be appointed at the Company's annual general meeting of shareholders. There is an annual engagement letter which is signed, subject to the Company's audit committee approval, with PricewaterhouseCoopers for audit and review work. No non-audit services were provided by PricewaterhouseCoopers during the 2016, 2015 and 2014 fiscal years.



**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**22. RELATED PARTY TRANSACTIONS**

**a. Equity Interests in Subsidiaries**

Prana Biotechnology Limited owns 100% of its subsidiaries, Prana Biotechnology Inc. and Prana Biotechnology UK Ltd.

**b. Key Management Personnel Remuneration**

The Directors of Prana during the year:

Geoffrey Kempler	Executive Chairman and Chief Executive Officer
Brian Meltzer	Non-Executive Independent Director
George Mihaly	Non-Executive Independent Director
Peter Marks	Non-Executive Independent Director
Lawrence Gozlan	Non-Executive Independent Director
Ira Shoulson	Non-Executive Director

The Key Management Personnel of the Company during the year:

Dianne Angus	Chief Operating Officer
Kathryn Andrews	Chief Financial Officer

Remuneration of all key management personnel of the Company is determined by the Board of Directors following recommendation by the Remuneration Committee.

The Company is committed to remunerating senior executives in a manner that is market competitive and consistent with 'best practice' including the interests of shareholders. Remuneration packages are based on fixed and variable components, determined by the executive's position, experience and performance, and may be satisfied via cash or equity.

Non-executive Directors are remunerated out of the aggregate amount approved by shareholders and at a level that is consistent with industry standards. Non-executive Directors do not receive performance based bonuses and prior shareholder approval is required to participate in any issuance of equity. No retirement benefits are payable other than statutory superannuation, if applicable.

The Company's remuneration policy is not solely based on the Company's performance, but also on industry practice.

The Company's primary focus is research activities with a long term objective of developing and commercializing its research and development results.

The Company envisages its performance in terms of earnings will remain negative whilst the Company continues in the research and clinical trials. Shareholder wealth reflects this speculative and volatile market sector. This pattern is indicative of the Company's performance over the past four years.

The purpose of a performance bonus is to reward individual performance in line with Company objectives. Consequently, performance based remuneration is paid to an individual where the individual's performance clearly contributes to a successful outcome for the Company. This is regularly measured in respect of performance against key performance indicators ("KPI's").

The Company uses a variety of KPI's to determine achievement, depending on the role of the executive being assessed. These include:

- successful contract negotiations;
- Company share price reaching a targeted rate on the ASX or applicable market over a period of time; or
- achievement of research project milestones within scheduled time and/or budget.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**22. RELATED PARTY TRANSACTIONS (continued)**

	Short Term Benefits		Post-Employment	Long Term Benefits	Equity	Total
	Base Fee A\$	Bonus A\$	Superannuation Contribution A\$	Long-service Leave A\$	Options A\$	
2016						
Directors' remuneration						
Geoffrey Kempler (1)	448,617	-	29,990	7,766	-	486,373
Brian Meltzer	50,000	-	35,000	-	-	85,000
George Mihaly	75,000	-	-	-	-	75,000
Peter Marks	60,000	-	-	-	-	60,000
Lawrence Gozlan	60,000	-	-	-	-	60,000
Ira Shoulson (2)	303,474	-	-	-	-	303,474
	997,091	-	64,990	7,766	-	1,069,847

(1) Base Fee includes movements in annual leave provision for Mr. Kempler accrued in accordance with his employment contract.

(2) Includes consulting fees paid to Prof. Ira Shoulson in the amount of \$258,474.

	Short Term Benefits		Post-Employment	Long Term Benefits	Equity	Total
	Base Fee A\$	Bonus A\$	Superannuation Contribution A\$	Long-service Leave A\$	Options A\$	
2015						
Directors' remuneration						
Geoffrey Kempler (1)	421,689	100,000	35,000	(224)	-	556,465
Brian Meltzer	50,000	-	35,000	-	-	85,000
George Mihaly	75,000	-	-	-	-	75,000
Peter Marks	60,000	-	-	-	-	60,000
Lawrence Gozlan	50,000	-	-	-	-	50,000
Ira Shoulson (2)	250,648	-	-	-	-	250,648
	1,007,337	-	70,000	(224)	-	1,077,113

(1) Base Fee includes movements in annual leave provision for Mr. Kempler accrued in accordance with his employment contract. During the 2015 fiscal year, Mr. Kempler received A\$100,000 incentive bonus which he was awarded in 2012.

(2) Includes consulting fees paid to Prof. Ira Shoulson in the amount of A\$205,426.

	Short Term Benefits		Post-Employment	Long Term Benefits	Equity	Total
	Base Fee A\$	Bonus A\$	Superannuation Contribution A\$	Long-service Leave A\$	Options A\$	
2014						
Directors' remuneration						
Geoffrey Kempler (1)	444,389	-	25,000	8,601	-	477,990
Brian Meltzer	50,000	-	35,000	-	-	85,000
George Mihaly	75,000	-	-	-	-	75,000
Peter Marks	60,000	-	-	-	-	60,000
Lawrence Gozlan	50,000	-	-	-	-	50,000
Ira Shoulson (2)	5,625	-	-	-	-	5,625
	685,014	-	60,000	8,601	-	753,615

(1) Base Fee includes movements in annual leave provision for Mr. Kempler accrued in accordance with his employment contract.

(2) Prof. Ira Shoulson was appointed to the Board on May 13, 2014;

**PRANA BIOTECHNOLOGY LIMITED**  
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**22. RELATED PARTY TRANSACTIONS (continued)**

	Short Term Benefits		Post-Employment	Long Term Benefits	Equity	Total
	Base Fee A\$	Other A\$	Superannuation Contribution A\$	Long-service Leave A\$	Options A\$	
2016						
Executives' Remuneration						
Dianne Angus (1) (2)	353,300	-	19,307	6,051	-	378,658
Kathryn Andrews (1)	125,609	-	10,820	-	-	136,429
	478,909	-	30,127	6,051	-	515,087

(1) Base Fee includes movements in annual leave provision for Ms Dianne Angus and Ms Kathryn Andrews accrued in accordance with their employment contracts.

	Short Term Benefits		Post-Employment	Long Term Benefits	Equity	Total
	Base Fee A\$	Other A\$	Superannuation Contribution A\$	Long-service Leave A\$	Options A\$	
2015						
Executives' Remuneration						
Phillip Hains (2)	100,000	-	-	-	-	100,000
Dianne Angus (1)	326,346	-	18,783	2,874	170,397	518,401
Kathryn Andrews (3)	81,233	-	7,541	82	-	88,857
Richard Revelins (4)	39,926	-	-	-	-	39,926
	547,506	-	26,324	2,957	170,397	747,184

(1) Base Fee includes movements in annual leave provision for Ms Dianne Angus and Ms Kathryn Andrews accrued in accordance with their employment contracts.

(2) Mr. Hains retired from his appointment as Acting Chief Financial Officer on November 4, 2014;

(3) Ms Andrews was appointment as Chief Financial Officer on November 4, 2014;

(4) Mr. Richard Revelins retired from his appointment as Company Secretary and Chief Financial Officer on November 4, 2014.

	Short Term Benefits		Post-Employment	Long Term Benefits	Equity	Total
	Base Fee A\$	Other A\$	Superannuation Contribution A\$	Long-service Leave A\$	Options A\$	
2014						
Executives' Remuneration						
Richard Revelins	80,013	-	-	-	-	80,013
Dianne Angus (1) (2)	324,833	-	17,775	9,015	33,824	385,447
Phillip Hains (3)	50,000	-	-	-	-	50,000
	454,846	-	17,775	9,015	33,824	515,460

(1) Base Fee includes movements in annual leave provision for Ms, Dianne Angus accrued in accordance with his employment contract.

(2) Ms. Angus received unlisted options during the year ended June 30, 2014. The option prices were calculated using the Black-Scholes Model applying the following inputs:

Grant Date: November 4, 2013	Volatility: 68.80%
Exercise Price: A\$0.73	Risk-free Interest Rate: 3.46%
Stock Price: A\$0.44	Dividend Yield: 0%
Years to Expiry: 5.00	Option Price: A\$0.2114

(3) Mr. Hains was appointed as Acting Chief Financial Officer on May 1, 2014.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**22. RELATED PARTY TRANSACTIONS (continued)**

The following Director was under contract during the year ended June 30, 2016:

<u>Directors</u>	<u>Duration</u>	<u>Notice Requirements</u>	<u>Termination</u>
Mr. Geoffrey Kempler	Until termination by either party Signed September 21, 2007	For Good Reason Mr. Kempler may terminate with 30 days' notice Or Without Cause the Company may terminate with 90 days' notice Without Good Reason Mr. Kempler may terminate with 90 days' notice Or With Cause the Company may terminate with 30 days' notice	<ul style="list-style-type: none"> <li>• Pay Mr. Kempler within ninety (90) days of the termination date A\$1,000,000 provided the Company has sufficient capital requirements to fulfill this clause</li> <li>• Accrued entitlements including all unreimbursed business expenses</li> <li>• Accelerate the vesting of any unvested options</li> <li>• Bonus pro-rate only if termination occurs in 1<sup>st</sup> year</li> </ul>

The following Senior Executives were under contract during the year ended June 30, 2016:

<u>Key Management Personnel</u>	<u>Duration</u>	<u>Notice Requirements</u>	<u>Termination</u>
Ms Dianne Angus	Until termination by either party Signed October 2, 2006 Letter Agreement signed June 12, 2007	For Good Reason Ms. Angus may terminate with 30 days' notice Or Without Cause the Company may terminate with 120 days' notice Without Good Reason Ms Angus may terminate with 120 days' notice Or With Cause the Company may terminate without notice	<ul style="list-style-type: none"> <li>• Pay remuneration entitlements three months from the time of termination (less any payout made for the notice period). The Company can elect to pay such sum as cash, equity in the Company or as a combination of both cash and equity</li> <li>• Accrued entitlements including all unreimbursed business expenses</li> <li>• Accelerate the vesting of any unvested options</li> <li>• Permitted to keep and/or exercise options that have vested at the time of termination</li> <li>• Accrued entitlements including all unreimbursed business expenses</li> </ul>
Ms Kathryn Andrews	Until termination by either party Signed November 11, 2014	Ms Andrews may terminate with 30 days' notice Or Without Cause the Company may terminate with 30 days' notice Or With Cause the Company may terminate without notice	<ul style="list-style-type: none"> <li>• Permitted to keep and/or exercise options that have vested at the time of termination</li> <li>• Accrued entitlements including all unreimbursed business expenses</li> </ul>

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**22. RELATED PARTY TRANSACTIONS (continued)**

**c. Key Management Personnel Equity Holdings**

Fully Paid Ordinary Shares of the Company	Balance July 1, 2015	Received as Remuneration	Received on Exercise of Options	Net Change Other (1)	Balance June 30, 2016
	No.	No.	No.	No.	No.
Geoffrey Kempler	18,011,000	-	-	-	18,011,000
Brian Meltzer	326,666	-	-	-	326,666
George Mihaly	226,666	-	-	-	226,666
Peter Marks	43,111	-	-	-	43,111
Lawrence Gozlan	-	-	-	-	-
Ira Shoulson	-	-	-	-	-
Richard Revelins (5)	-	-	-	-	-
Dianne Angus	146,128	-	-	-	146,128
Phillip Hains (5)	-	-	-	-	-
Kathryn Andrews (6)	-	-	-	-	-
	<u>18,753,571</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>18,753,571</u>
Fully Paid Ordinary Shares of the Company	Balance July 1, 2014	Received as Remuneration	Received on Exercise of Options	Net Change Other (1)	Balance June 30, 2015
	No.	No.	No.	No.	No.
Geoffrey Kempler	17,811,000	-	-	200,000	18,011,000
Brian Meltzer	326,666	-	-	-	326,666
George Mihaly	226,666	-	-	-	226,666
Peter Marks	43,111	-	-	-	43,111
Lawrence Gozlan	-	-	-	-	-
Ira Shoulson	-	-	-	-	-
Richard Revelins (5)	20,308	-	-	(20,308)	-
Dianne Angus	146,128	-	-	-	146,128
Phillip Hains (5)	211,800	-	-	(211,800)	-
Kathryn Andrews (6)	-	-	-	-	-
	<u>18,785,679</u>	<u>-</u>	<u>-</u>	<u>(32,108)</u>	<u>18,753,571</u>
Fully Paid Ordinary Shares of the Company	Balance July 1, 2013	Received as Remuneration	Received on Exercise of Options	Net Change Other (1)	Balance June 30, 2014
	No.	No.	No.	No.	No.
Geoffrey Kempler	17,811,000	-	-	-	17,811,000
Brian Meltzer	326,666	-	-	-	326,666
George Mihaly	226,666	-	-	-	226,666
Peter Marks	43,111	-	-	-	43,111
Lawrence Gozlan	-	-	-	-	-
Ira Shoulson (3)	-	-	-	-	-
Richard Revelins	20,308	-	500,000	(500,000)	20,308
Dianne Angus	-	-	868,547	(722,419)	146,128
Phillip Hains (4)	211,800	-	-	-	211,800
	<u>18,639,551</u>	<u>-</u>	<u>1,368,547</u>	<u>(1,222,419)</u>	<u>18,785,679</u>

(1) Net change other refers to shares purchased or sold during the financial year.

(2) Balance at date of appointment, August 8, 2011.

(3) Balance at date of appointment, May 13, 2014.

(4) Balance at date of appointment, May 1, 2014.

(5) Balance at date of retirement, November 4, 2014.

(6) Balance at date of appointment, November 4, 2014.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**22. RELATED PARTY TRANSACTIONS (continued)**

**c. Key Management Personnel Equity Holdings (continued)**

Share Options of the Company	Balance July 1, 2015 No.	Granted as Remuneration No.	Options Exercised No.	Options Forfeited No.	Net Change Other	Options Vested During 2016 fiscal year	Balance June 30, 2016 No.	Total Vested and Exercisable June 30, 2016 No.	Total Unvested June 30, 2016 No.
Geoffrey Kempler	4,000,000	-	-	-	-	-	4,000,000	4,000,000	-
Brian Meltzer	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
George Mihaly	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Peter Marks	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Lawrence Gozlan	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Ira Shoulson	-	-	-	-	-	-	-	-	-
Dianne Angus	1,317,819	-	-	-	-	-	1,317,819	1,317,819	-
Kathryn Andrews (6)	-	-	-	-	-	-	-	-	-
	9,317,819	-	-	-	-	-	9,317,819	9,317,819	-
Share Options of the Company	Balance July 1, 2014 No.	Granted as Remuneration No.	Options Exercised No.	Options Forfeited No.	Net Change Other	Options Vested During 2015 fiscal year	Balance June 30, 2015 No.	Total Vested and Exercisable June 30, 2015 No.	Total Unvested June 30, 2015 No.
Geoffrey Kempler	4,000,000	-	-	-	-	-	4,000,000	4,000,000	-
Brian Meltzer	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
George Mihaly	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Peter Marks	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Lawrence Gozlan	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Ira Shoulson	-	-	-	-	-	-	-	-	-
Richard Revelins (5)	500,000	-	-	-	(500,000)	-	-	-	-
Dianne Angus	317,819	1,000,000	-	-	-	-	1,317,819	1,317,819	-
Phillip Hains (5)	-	-	-	-	-	-	-	-	-
Kathryn Andrews (6)	-	-	-	-	-	-	-	-	-
	8,817,819	1,000,000	-	-	(500,000)	-	9,317,819	9,317,819	-
Share Options of the Company	Balance July 1, 2013 No.	Granted as Remuneration No.	Options Exercised No.	Options Forfeited No.	Net Change Other (1)	Options Vested During 2014 fiscal year	Balance June 30, 2014 No.	Total Vested and Exercisable June 30, 2014 No.	Total Unvested June 30, 2014 No.
Geoffrey Kempler	4,000,000	-	-	-	-	-	4,000,000	4,000,000	-
Brian Meltzer	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
George Mihaly	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Peter Marks	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Lawrence Gozlan	1,000,000	-	-	-	-	-	1,000,000	1,000,000	-
Ira Shoulson (3)	-	-	-	-	-	-	-	-	-
Richard Revelins	1,000,000	-	(500,000)	-	-	-	500,000	500,000	-
Dianne Angus	2,052,730	160,000	(868,547)	-	(1,026,364)	-	317,819	317,819	-
Phillip Hains (4)	-	-	-	-	-	-	-	-	-
	11,052,730	160,000	(1,368,547)	-	(1,026,364)	-	8,817,819	8,817,819	-

(1) Net change other refers to shares purchased or sold during the financial year.

(2) Balance at date of appointment, August 8, 2011.

(3) Balance at date of appointment, May 13, 2014.

(4) Balance at date of appointment, May 1, 2014.

(5) Balance at date of retirement, November 4, 2014.

(6) Balance at date of appointment, November 4, 2014.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**23. SEGMENT INFORMATION**

The Company's Chief Executive Officer (Chief Operating Decision Maker) examines internal reports to assess the Company's performance and determine the allocation of resources. The Company's activities are predominantly within Australia and cover research into Alzheimer's disease, Huntington disease, Parkinson's disease and other neurodegenerative disorders. Accordingly, the Company has identified one reportable segment.

**24. FINANCIAL INSTRUMENTS**

The Company's activities expose it to a variety of financial risks including market risk, credit risk and liquidity risk. The Company's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the financial performance of the Company. Risk management is carried out under policies approved by the Board of Directors and overseen by the Audit, Risk and Compliance Committee.

**(a) Market Risk**

**(i) Foreign Currency Risk**

The Company engages in international purchase transactions and is exposed to foreign currency risk arising from various currency exposures, primarily with respect to the Australian dollar. The parent entity also has exposure to foreign exchange risk in the currency cash reserves it holds to meet its foreign currency payments. The Company does not make use of derivative financial instruments to hedge foreign exchange risk.

The following financial assets and liabilities are subject to foreign currency risk, the currency of the original amounts are displayed in brackets, all the amounts in the table below are displayed in A\$ at year-end spot rates:

	<b>Consolidated Entity</b>	
	<b>2016</b>	<b>2015</b>
	<b>A\$</b>	<b>A\$</b>
Cash and cash equivalents (USD)	21,890,509	27,100,354
Cash and cash equivalents (€EUR)	-	-
Cash and cash equivalents (£GBP)	-	-
Trade and other payables (USD)	(36,348)	(79,490)
Trade and other payables (€EUR)	(10,176)	(25,617)
Trade and other payables (£GBP)	(2,437)	(4,926)
<b>Total exposure</b>	<b>21,841,548</b>	<b>26,990,321</b>

The Company has conducted a sensitivity analysis of its exposure to foreign currency risk. The Company is currently exposed to the US dollar (USD), Euro (EUR) and British Pound (GBP). The sensitivity analysis below is conducted on a currency by currency basis using the sensitivity analysis variable, which has been based on the average annual movement in the AUD/USD, AUD/GBP and AUD/EUR exchange rates over the past 5 years based on the year-end spot rates. The variables for USD, GBP and EUR being 3%, 12% and 3% respectively. All the amounts in the table below are displayed in Australian Dollars (A\$).

Based on the financial instruments held at June 30, 2016, had the Australian dollar weakened/strengthened by 3% against the US dollar, 12% against the GBP and 3% against the EURO with all other variables held constant, the Company's post-tax loss for the year would have been A\$634,419 lower/A\$673,431 higher (2015: A\$786,576 lower/A\$835,247 higher), mainly as a result of foreign exchange gains/losses on translation of US dollar denominated financial instruments as detailed in the above table. The Company's exposure to other foreign exchange movements is not material.

We realized a foreign exchange gain of A\$950,720 for the year ended June 30, 2016 compared to a foreign exchange loss of A\$4,953,253 for the year ended June 30, 2015 and a foreign exchange gain of A\$581,263 for the year ended June 30, 2014. In 2016, the Australian dollar depreciated against the U.S. dollar by 3%. In 2015, the Australian dollar depreciated against the U.S. dollar by 18%, while in 2014, the Australian dollar appreciated against the U.S. dollar by 3%.

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**24. FINANCIAL INSTRUMENTS (continued)**

(ii) Interest Rate Risk

The Company has an exposure to interest rate risk, which is the risk that a financial instrument's value will fluctuate as a result of changes in market interest rates and the effective weighted average interest rates on classes of financial assets and financial liabilities.

The Company's exposure to interest rate risk has not changed since the prior year.

At June 30, 2016, the Company had the following cash accounts:

- A\$95,890 in an Australian dollar transaction account at an interest rate of 0.05% as of June 2016;
- A\$36,361 in an Australian dollar transaction account at an interest rate of 0.00% as of June 2016;
- A\$419,324 in an Australian Business Cash High Interest account at an interest rate of 1.50% as of June 2016;
- A\$154 in an Australian Trust account at an interest rate of 0% as of June 2015;
- US\$16,267,416 (A\$21,888,345) in U.S. checking accounts at an interest rate of 0.03% as of June 30, 2016;
- A\$6,000,000 in a three month term deposit at a fixed interest rate of 3.00% which matures on August 11, 2016;
- A\$150,000 in a six month term deposit at a fixed interest rate of 2.92% which matures on September 11, 2016;
- A\$43,988 in a twelve month term deposit at a fixed interest rate of 2.85% which matures on March 7, 2017;
- A\$1,300 in petty cash which does not earn any interest;
- US\$1,608 (A\$2,164) in petty cash which does not earn any interest.

The weighted average interest rate is 0.68% for cash and cash equivalents and 2.87% for terms deposits over three months and apart from usual variances in general rates of interest the Company is not exposed to any significant interest rate risk.

At June 30, 2015, the Company had the following cash accounts:

- A\$98,442 in an Australian dollar transaction account at an interest rate of 0.05% as of June 2015;
- A\$2,507 in an Australian dollar transaction account at an interest rate of 0.00% as of June 2015;
- A\$1,707,493 in an Australian Business Cash High Interest account at an interest rate of 1.50% as of June 2015;
- A\$47 in an Australian Trust account at an interest rate of 0% as of June 2015;
- US\$20,750,646 (A\$27,098,476) in U.S. checking accounts at an interest rate of 0.03% as of June 30, 2015;
- A\$6,000,000 in a three month term deposit at a fixed interest rate of 2.92% which matures on September 24, 2015;
- A\$152,603 in a six month term deposit at a fixed interest rate of 2.90% which matures on October 13, 2015;
- A\$45,462 in a twelve month term deposit at a fixed interest rate of 3.10% which matures on March 7, 2016;
- A\$500 in petty cash which does not earn any interest;
- CAD\$219 (A\$231) in petty cash which does not earn any interest; and
- US\$1,438 (A\$1,878) in petty cash which does not earn any interest.

The weighted average interest rate is 0.59% for cash and cash equivalents and 0.41% for terms deposits over three months and apart from usual variances in general rates of interest the Company is not exposed to any significant interest rate risk.



**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**24. FINANCIAL INSTRUMENTS (continued)**

Receivables and payables are non-interest bearing.

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:

June 30, 2016	Floating Interest Rate (A\$)	Fixed Interest Maturing in (A\$)		Non-Interest bearing (A\$)	Total (A\$)	Average Interest Rate
		1 year or less	1-5 years			
<b>Financial Assets</b>						
Cash and cash equivalents	22,440,074	6,150,000	-	3,464	28,593,538	0.68%
Trade and other receivables	-	-	-	4,786,765	4,786,765	
Other current assets	-	-	-	276,504	276,504	
Other non-current assets	-	-	43,988	-	43,988	2.85%
<b>Total Financial Assets</b>	<u>22,440,074</u>	<u>6,150,000</u>	<u>43,988</u>	<u>5,066,733</u>	<u>33,700,795</u>	
<b>Financial Liabilities</b>						
Trade and other payables	-	-	-	1,748,566	1,748,566	
<b>Total Financial Liabilities</b>	<u>-</u>	<u>-</u>	<u>-</u>	<u>1,748,566</u>	<u>1,748,566</u>	
<b>June 30, 2015</b>						
	Floating Interest Rate (A\$)	Fixed Interest Maturing in (A\$)		Non-Interest bearing (A\$)	Total (A\$)	Average Interest Rate
		1 year or less	1-5 years			
<b>Financial Assets</b>						
Cash and cash equivalents	34,906,965	-	-	2,609	34,909,574	0.59%
Trade and other receivables	-	-	-	6,521,154	6,521,154	
Other current assets	-	152,603	-	160,862	313,465	2.90%
Other non-current assets	-	-	45,462	-	45,462	3.10%
<b>Total Financial Assets</b>	<u>34,906,965</u>	<u>152,603</u>	<u>45,462</u>	<u>6,684,625</u>	<u>41,789,655</u>	
<b>Financial Liabilities</b>						
Trade and other payables	-	-	-	2,152,015	2,152,015	
Other financial liabilities	-	-	-	12,076	12,076	
<b>Total Financial Liabilities</b>	<u>-</u>	<u>-</u>	<u>-</u>	<u>2,164,091</u>	<u>2,164,091</u>	

**PRANA BIOTECHNOLOGY LIMITED**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – in Australian dollars (unless otherwise noted)**

**24. FINANCIAL INSTRUMENTS (continued)**

**(b) Credit Risk**

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Company. The Company has no significant concentration of credit risk and it is not the Company's policy to hedge credit risk.

The Company ensures that surplus cash is invested with financial institutions of appropriate credit worthiness and limits the amount of credit exposure to any one counter party.

There has been no significant change in the Company's exposure to credit risk since the previous year. The carrying amount of the Company's financial assets represents the maximum credit exposure.

**(c) Liquidity Risk**

Prudent liquidity risk management implies maintaining sufficient cash and the availability of funding through an adequate amount of committed credit facilities. The Company manages liquidity risk by maintaining sufficient bank balances to fund its operations and the availability of funding through committed credit facilities.

Management monitors rolling forecasts of the Company's liquidity reserve on the basis of expected cash flows.

	<b>Maturities of Financial Liabilities</b>				<b>Total contracted cash flows</b>	<b>Carrying amounts</b>
	<b>Less than 6 months</b>	<b>6-12 months</b>	<b>Greater than 12 months and less than 5 years</b>			
<b>2016</b>						
Trade and other payables	1,748,566	-	-	1,748,566	1,748,566	
Total	1,748,566	-	-	1,748,566	1,748,566	
<b>2015</b>						
Trade and other payables	2,152,015	-	-	2,152,015	2,152,015	
Total	2,152,015	-	-	2,152,015	2,152,015	

**(d) Capital Risk Management**

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern and to maintain an optimal capital structure so as to maximize shareholder value. In order to maintain or achieve an optimal capital structure, the Company may issue new shares or reduce its capital, subject to the provisions of the Company's constitution. The capital structure of the Company consists of equity attributed to equity holders of the Company, comprising contributed equity, reserves and accumulated losses disclosed in Notes 12, 13 and 14. By monitoring undiscounted cash flow forecasts and actual cash flows provided to the Board by the Company's Management the Board monitors the need to raise additional equity from the equity markets.

**(e) Fair Value Estimation**

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

**Financial Instruments measured at Fair Value**

The financial instruments recognized at fair value in the Statement of Financial Position have been analyzed and classified using a fair value hierarchy reflecting the significance of the inputs used in making the measurements. The fair value hierarchy consists of the following levels:

- quoted prices in active markets for identical assets or liabilities (Level 1);
- inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (derived from prices) (Level 2); and
- inputs for the asset or liability that are not based on observable market data (unobservable inputs) (Level 3).

In 2016 and 2015, none of the Company's assets and liabilities except for the other financial liabilities had their fair value determined using the fair value hierarchy. The other financial liabilities are classified as level 2 instruments. No transfers between the levels of the fair value hierarchy occurred during the current or previous years.

**25. ADDITIONAL COMPANY INFORMATION**

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

<u>Registered Office</u>	<u>Principal Place of Business</u>
Suite 1 Level 2 1233 High Street Armadale Vic 3143 Australia Tel: +61 (03) 9824 5254	369 Royal Parade Parkville Vic 3052 Australia Tel: +61 (03) 9349 4906

**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 report on its behalf.

Prana Biotechnology Limited

By: /s/ Geoffrey P. Kempler  
Geoffrey P. Kempler  
Chief Executive Officer

Dated October 3, 2016



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**Master Services Agreement**

**Date** September, 2015

**Parties** **Orgapharm S.A.S.**  
of Rue du Moulin de la Canne, Pithiviers France 45 300  
*(Orgapharm)*

**Prana Biotechnology Ltd** ACN 080 699 065  
of Level 2, 369 Royal Parade, Parkville Victoria Australia 3052  
*(Prana)*

(each a **party** and collectively, the **parties**)

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**Introduction**

- A Prana is in the business of developing drug candidates for the treatment of neurodegenerative diseases.
- B Orgapharm is in the business of manufacturing fine chemicals.
- C Prana has sought the assistance of Orgapharm to manufacture PBT2 API. There may also be occasions in future where Prana may call on Orgapharm to provide other pharmaceutical manufacturing and related services.
- D This Agreement contains the terms and conditions upon which Orgapharm will provide services to Prana.

**Agreement**

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**1 Definitions and Interpretation**

**Definitions**

1.1 In this Agreement:

*Agreement* means this agreement including any schedule or annexure to it.

*Agreement IP* means, for each Project, the following:

- (a) the Deliverables; and
- (b) the Results,

and all Intellectual Property Rights throughout the world subsisting in them, excluding any Existing IP.

*API* means an active pharmaceutical ingredient.

*Approved Purposes* means:

- (a) the performance of the Services and production of the Deliverables by Orgapharm;
-

- (b) Prana's input in pursuance of this Agreement to facilitate the performance of the Services by Orgapharm; and
- (c) the use of the Agreement IP by Prana for its business purposes.

**Business Day** means a day other than Saturday, Sunday or a public holiday or bank holiday in the place where an act is to be performed or a payment is to be made.

**Cause Event** means:

- (a) a material breach by Orgapharm of its obligations under this Agreement or the Quality Agreement;
- (b) receipt by Orgapharm of an FDA Form 483 or Warning Letter or other like document from the EMA or any other regulatory authority;
- (c) any audit, inspection or product, documentation or information request by the FDA, TGA or other regulatory authority which is specific to Prana's Compounds.

**cGMP** or **GMP** means all applicable Laws of any country, region or Governmental Agency having jurisdiction over the manufacture of Products having regard to the purpose for which they are to be used, which Laws relate to current good manufacturing practices and includes ICH Q7 'Guidance for Industry Q7 Good Manufacturing Practice for Active Pharmaceutical Ingredients', the EU Code of GMP (as amended or replaced) and other codes of practice, regulations, rules, principles and guidelines which are obligatory in relation to any Product under any such Laws.

**Change Order** means a change in respect of the work to be performed by Orgapharm under a given Work Order.

**EU Code of GMP** means:

- (a) the principles and guidelines of good manufacturing practice stated in Commission Directive 2003/94/EC; and
- (b) the guidelines published by the European Commission in EudraLex Volume 4,

as amended or replaced from time to time.

**Commencement Date** means the date of this Agreement.

**Compounds** means Prana's proprietary compounds (current and future), including the compounds known as PBT2 and PBT 434 and any APIs of them.

**Confidential Information** means Orgapharm Confidential Information or Prana Confidential Information as the context allows.

**Corporations Law** means the *Corporations Act 2001* (Cth).

**Deliverables** means data, results, information, advice, reports, analyses, documents, materials, APIs, compounds, products, procedures, processes, techniques and other items or things prepared, obtained, generated by Orgapharm as part of the Services, and to be delivered to Prana, all in accordance with the requirements specified in the relevant Work Order and this Agreement.

**EMA** means the European Medicines Agency, and any successor agency having substantially the same functions.

**Existing IP** of a party means the Technology owned, developed or obtained by or on behalf of that party:

- (a) prior to the Commencement Date; or
- (b) independent of this Agreement and without the use of the other party's Confidential Information,

and includes all Intellectual Property Rights throughout the world subsisting in such Technology.

**FDA** means the United States Food and Drug Administration, and any successor agency having substantially the same functions.

**Force Majeure** means an act of God, strike, lock-out or other labour dispute, war declared or undeclared, blockade, riot, insurrection, lightning, fire, earthquake, storm, flood, explosion, restraint of government or government agency, prohibition or any other cause whether or not of the kind listed above which is beyond the control of the party affected.

**Governmental Agency** means any court, administrative agency or commission or other governmental agency, body or instrumentality, domestic or foreign, and includes, without limitation, the EMA, FDA and TGA.

**Initial Project** means PBT2 synthesis and manufacturing development work and subsequent pilot and large scale cGMP manufacture of PBT2 API for use in a Phase 3 clinical trial to be conducted in one or more of Australia, Europe and the USA.

**Insolvency Event** means the happening of any of the following:

- (a) an application is made to a court for an order that a party be wound-up or that a provisional liquidator be appointed (unless the application is withdrawn, struck out or dismissed within 45 days of it being made);
- (b) a liquidator is appointed in respect of a party;
- (c) an administrator, receiver or receiver and manager is appointed in relation to a party or in respect of any of its assets;
- (d) except to reconstruct or amalgamate while solvent on terms approved by the other party, a party enters into, or resolves to enter into, an arrangement or composition with, or assignment for the benefit of, all or any of its creditors, or it, or anyone on its behalf, proposes a reorganisation, moratorium, deed of company arrangement or other administration involving any of them or the winding up or dissolution of the party;
- (e) a party is, states that it is or is presumed under any applicable law to be, insolvent; and
- (f) anything having a substantially similar effect to any of the events specified above happens under the law of any jurisdiction.

**Intellectual Property Rights** means all intellectual and industrial property rights throughout the world (whether registered or unregistered) including rights and interests (including applications for and any right to apply for registrations of such rights) in respect of or in connection with designs, discoveries, inventions (including patents), copyright (including future copyright and rights in the nature of or analogous to copyright), trade marks, database rights, confidential information, know how and trade secrets.

**Laws** means the common law and any statute, regulation, order, rule, subordinate legislation, code of practice or other document enforceable under any statute, regulation, order, rule or subordinate legislation.

**Material Form** in relation to information, includes any form (whether visible or not) of storage from which the information can be reproduced, and any form in which the information is embodied or encoded and in relation to Prana's Compounds means whatever form they are present in the possession of Orgapharm or their Representatives.

**Orgapharm Confidential Information** means:

- (a) Proposals; and
- (b) all:
  - (i) Existing IP of Orgapharm;
  - (ii) information concerning Orgapharm's affairs, assets or property or any business, property or transaction in which it may be or may have been concerned or interested;
  - (iii) information which, by its nature or by the circumstances of its disclosure, is or could reasonably be expected to be regarded as confidential to Orgapharm, which is or has been disclosed by Orgapharm to Prana (whether orally, electronically or in writing) or is otherwise obtained by Prana but does not include Public Information.

**Prana Confidential Information** means:

- (a) the Compounds;
- (b) RFPs;
- (c) Agreement IP; and
- (d) all:
  - (i) Existing IP of Prana;
  - (ii) data, results, information, analyses, papers, materials, records, notes, documents and reports concerning:
    - (A) the Compounds;
    - (B) the synthesis or commercial manufacture of the Compounds;
    - (C) research, tests, trials and studies planned or conducted in relation to the Compounds;
    - (D) Prana's dealings with regulatory authorities around the world in relation to any Compound;
  - (iii) information concerning Prana's affairs, assets or property or any business, property or transaction in which it may be or may have been concerned or interested;
  - (iii) information which, by its nature or by the circumstances of its disclosure, is or could reasonably be expected to be regarded as confidential to Prana, which is or has been disclosed by Prana to Orgapharm (whether orally, electronically or in writing) or is otherwise obtained by Orgapharm but does not include Public Information

**Products** means PBT2 API and such other products to be manufactured by Orgapharm pursuant to this Agreement.

**Projects** means:

- (a) the Initial Project; and
- (b) any subsequent project for the delivery of agreed Services by Orgapharm to Prana under this Agreement.

**Proposal** means a proposal for the provision of Services submitted to Prana by Orgapharm.

**Public Information** means:

- (a) information which, at the time of disclosure, was published, known publicly or otherwise in the public domain;
- (b) information which, after disclosure, is published, becomes known publicly, or otherwise becomes part of the public domain through no fault of the receiving party;
- (c) information which, prior to the time of disclosure, is known to the receiving party as evidenced by its written records or other tangible evidence;
- (d) information which is made available to the receiving party in good faith by a third party who is under no obligation of confidence to the disclosing party;
- (e) information which the receiving party is required to disclose by law, provided the receiving party has given the disclosing party prompt prior notice and assistance in any reasonable effort to obtain confidential treatment with respect to such disclosure; or
- (f) information which is independently developed by or for the receiving party without use of, reliance upon, or with reference to the disclosing party's Confidential Information.

**Quality Agreement** means the quality agreement to be entered by the parties pursuant to clause 5.7.

**Representative** in relation to a party means a director, officer, employee or contractor (approved by Prana under clause 14.4 in the case of an Orgapharm contractor) of that party.

**Results** means:

- (a) all results, data, information, processes, procedures, methodologies, techniques, concepts, ideas, compounds, formulations, materials, reports, analyses, documents, items or things; and
- (b) all discoveries, inventions, developments, modifications, innovations, enhancements or improvements,

that are made, generated, brought into existence, conceived, discovered, invented, developed, created, derived, modified, improved, enhanced, adapted or reduced to practice by either party or their Representatives (whether alone or jointly with the other party) under or in connection with or as a consequence of a Project.

**RFP** means a request submitted by Prana to Orgapharm for a proposal for the provision of Services under this Agreement.

**Services** means for a given Project, the services to be provided by Orgapharm under this Agreement, as agreed and specified in a Work Order for the Project.

**Specification** means an agreed specification for a Deliverable which may be either:

- (a) annexed to a Work Order or incorporated therein by reference; or



- (b) prepared and agreed by the parties during the course of a Project.

**Sub-Project** in relation to a Project, means a sub-project or discrete pieces of work (if any) described in the corresponding Work Order for performance by Orgapharm, subject in each case to Orgapharm receiving prior written approval from Prana and the parties agreeing on the Specification/s for the Deliverable/s for the sub-project or discrete piece of work..

**Technology** means:

- (a) proprietary compounds, samples, prototypes, formulations, ideas, knowledge, concepts, methods, techniques, processes, procedures, trade secrets, technology, discoveries, inventions, know-how, data, technical and scientific information, research and development results, development plans, test results, procedures for experiments and tests and manufacturing scale-ups, methods or schemes for synthesising chemicals and compounds, isolation and purification methods, hardware and software;
- (b) patents, patentable inventions, designs, trade marks, works of copyright and rights in confidential information;
- (c) all other intellectual property of any kind, whether or not protectable under patent, trade mark, copyright, design or other intellectual property laws.

**TGA** means the Australian Therapeutic Goods Administration, and any successor agency having substantially the same functions.

**Work Order** means one or more written Work Orders referencing this Agreement or otherwise attached to this Agreement and executed by both parties pertaining to the Services to be supplied by Orgapharm under this Agreement. A template Work Order is set out in Schedule 1.

## **Interpretation**

1.2 In this Agreement, unless the context requires another meaning:

- (a) a reference to:
  - (i) the singular includes the plural and vice versa;
  - (ii) a document (including this Agreement) is a reference to that document (including any Schedules and Annexures) as amended, consolidated, supplemented, novated or replaced;
  - (iii) an item, Recital, clause, Schedule or Annexure is to an item, Recital, clause, Schedule or Annexure of or to this Agreement;
  - (iv) a notice means a notice, approval, demand, request, nomination or other communication given by one party to another under or in connection with this Agreement;
  - (v) a person (including a party) includes an individual, company, other body corporate, association, partnership, firm, joint venture, trust or government agency; and
  - (vi) the words "including" or "includes" means "including, but not limited to", or "includes, without limitation" respectively;
- (b) where a word or phrase is defined, its other grammatical forms have a corresponding meaning; and

(c) headings are for convenience only and do not affect interpretation of this Agreement.

1.3 This Agreement may not be construed adversely to a party only because that party was responsible for preparing it.

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## **2 Term**

2.1 This Agreement commences on the Commencement Date and continues for five (5) years or until the completion of any then current Work Order by Orgapharm, unless terminated earlier in accordance with this Agreement. This Agreement may be extended by mutual agreement of the parties in writing.

## **3 Services and Work Orders**

3.1 If at any time during the Term Prana wishes to engage Orgapharm to provide Services to it, then subject to the parties entering a Work Order in respect of the Services, Orgapharm agrees to provide the Services on the terms and conditions contained in this Agreement.

3.2 Each Work Order:

- (a) is incorporated herein by reference;
- (b) shall be in a form similar to the sample Work Order attached to this Agreement as Annexure A;
- (c) shall include a description of the specific services to be performed by Orgapharm, the deliverables, timelines, protocols, specifications, fees and charges payable by Prana and such other details and terms as are agreed to by the parties;
- (d) is taken to include the Quality Agreement and all applicable Specifications.

3.3 In the event of any conflict between the terms and conditions of a Work Order and a provision of this Agreement, the terms and conditions of this Agreement shall prevail unless the Work Order expressly specifies that the particular term of the Work Order takes precedence.

3.4 Any change to a Work Order must be mutually agreed and documented by Orgapharm in a written amendment to the Work Order (a “**Change Order**”). When a signed Change Order is received from Prana, the Change Order shall constitute an amendment to the applicable Work Order and shall be considered part of this Agreement. No changes to a Work Order will take effect and Orgapharm must not commence any new or changed Services unless and until it has received a signed Change Order from Prana.

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## **4 Orgapharm’s Obligations and Warranties**

4.1 Orgapharm will perform each Project and the associated Services:

- (a) using suitably qualified Representatives;
  - (b) in a timely manner in accordance with the Work Order;
  - (c) with due care and skill and to the best of Orgapharm’s knowledge and expertise;
  - (d) in accordance with relevant local industry standards, best practice and guidelines or where none apply, relevant international industry standards, best practice and guidelines;
  - (e) in accordance with cGMP, the Work Order and all applicable Laws;
-

- (f) in accordance with any reasonable direction given by Prana; and
- (g) otherwise in accordance with the provisions of this Agreement.

4.2 Orgapharm represents and warrants that:

- (a) it has the right to enter into this Agreement;
- (b) it has and will maintain the requisite licences from the EMA, FDA, TGA and all other applicable governmental, municipal and public agencies, bodies and authorities for the conduct of its business at each of its premises;
- (c) it has and will maintain all rights, title, licences, interests, property, equipment and resources necessary to fully and lawfully perform each Project and the associated Services;
- (d) it and its Representatives have the necessary experience, skill, knowledge and competence to perform each Project and the associated Services;
- (e) each Deliverable will meet the Specification and be:
  - (i) complete, accurate, free from errors and fit for the purpose/s for which it is required by Prana;
  - (ii) compliant with all requirements specified in this Agreement and the relevant Work Order;
  - (iii) cGMP compliant and otherwise compliant with all other applicable Laws;
  - (iv) provided at the time and in the manner and form prescribed in the relevant Work Order.

4.3 Orgapharm will:

- (a) permit all relevant inspections by the EMA, FDA, TGA or other regulatory authorities of its premises, procedures and documentation;
- (b) notify Prana:
  - (i) within five (5) Business Days of receiving any notice of inspection from the EMA, FDA, TGA or other regulatory authority;
  - (ii) within three (3) Business Days of receiving any request from the EMA, FDA, TGA or other regulatory authority for Prana's Compounds, products or samples or related batch or other documentation or information;
  - (iii) within one (1) Business Day of receiving any FDA Form 483 or Warning Letter or other like document from the EMA, TGA or any other regulatory authority which relates to Prana's Compounds or which may impact on Orgapharm's ability to supply such products (in accordance with a Work Order) or the facilities used to produce, test or package them,

and provide Prana with copies of all such letters, notices or documents and Orgapharm's response to them (in each case redacted, where appropriate, to exclude text not relevant to Prana or the Services, Results or Compounds).

4.4 Orgapharm must:

- (a) take out and maintain during the term of this Agreement and for 12 months thereafter, appropriate public and product liability insurance policies with a reputable insurer which give coverage against all usual risks and for an amount of at least \$ €10,000,000 per occurrence.
- (b) at Prana's request provide Prana with certificates of currency for those policies.

## 5 Project Obligations

5.1 For each Project:

- (a) Orgapharm will designate a project leader to liaise with Prana in relation to Orgapharm's performance of the Services and the provision of the Deliverables (the "Project Leader"); and
- (b) Prana will designate a contact who will be the point of contact for the Project Leader (the "Prana Contact").

5.2 The parties must agree the Specifications for each Deliverable and Orgapharm must receive written authority from the Prana Contact or Prana's Chief Operating Officer before commencing any Sub-Project. Without such agreement and authority for a given Sub-Project, Orgapharm must not undertake and may not charge Prana its fee for the Sub-Project or any other amount. If in relation to a given Sub-Project, Prana provides written authority to undertake the Sub-Project after the relevant commencement date specified in the Work Order, then Orgapharm shall commence the Sub-Project as soon as is reasonably practicable thereafter, and in any event, not later than 14 days after Prana provides written authority to undertake the Sub-Project.

5.3 Orgapharm must provide the following updates and reports to the Prana Contact for each Project:

- (a) prompt email notification of any material technical or operational problems or issues encountered by Orgapharm;
- (b) fortnightly written updates (in a format acceptable to Prana) of the work undertaken and the Results obtained for the fortnight, problems encountered by Orgapharm, the stage of each Project or Sub-Project, as applicable that Orgapharm is up to and any other information that would be relevant to Prana in relation to the Project; and
- (c) such reports specified in the applicable Work Order for the Project.

5.4 Orgapharm must create a separate project folder in the applicable department directory in its computer system:

- (a) which is dedicated to Prana Projects; and
- (b) accessible only by those Orgapharm Representatives working on such projects.

5.5 Copies of all letters, reports, memos, notes, documents and other written materials created or brought into existence by Orgapharm in relation to each Project shall be saved electronically and stored by Orgapharm on the Prana drive.

5.6 All Results arising out of the Project must be recorded in a written format. The results captured in a written format must:

- (a) be maintained and signed in accordance with best industry practice; and
- (b) be made available for inspection by Prana upon request by Prana in writing.

5.7 If they have not already done so, the parties agree to put a quality agreement in place for the purpose of the Services to be undertaken by Orgapharm under this Agreement.

5.8 On 30 days prior written notice, Orgapharm (or such shorter period of notice as may be agreed in good faith by the parties) must allow Prana to undertake an audit of its premises, procedures actions and documentation in relation to Prana's Projects, Compounds and Agreement IP and Orgapharm's observance of obligations under this Agreement and the Quality Agreement. Prana audits shall be limited to one audit with a maximum of two (2) auditors for two (2) days (or otherwise as may be negotiated in advance and agreed by the parties) per calendar year except if Prana reasonably believes that a Cause Event has occurred, in which case Prana may conduct an additional audit with 48 hrs prior written notice.

- 5.9 At any time during the conduct of a Project on prior notice by Prana, Orgapharm must allow Prana or any Representative of it to attend any premises at which a Project is being conducted for the purpose of assessing the progress of the Project.
- 5.10 If at any time during or after the termination of this Agreement, Prana requires a third party to perform any work relating to a Compound, including its manufacture, then Orgapharm must, at the request of Prana, co-operate with Prana and the third party and provide such assistance, advice, documentation and information (including the relevant Results) as is necessary to enable the third party to perform the work requested by Prana. Prana agrees to pay all out-of-pocket expenses reasonably incurred by Orgapharm, provided that any anticipated expenses in excess of US\$1,000 are approved by Prana in writing before they are incurred.
- 5.11 It is agreed in relation to any Deliverables supplied by Orgapharm pursuant to this Agreement that Prana shall have fifteen (15) days (“**Testing Period**”) from the date they are delivered to perform acceptance testing on the Deliverables in order to confirm that they comply with the Specifications (“**Acceptance Testing**”). If Prana is satisfied that the Deliverables meet Specification, then it will confirm this in writing to Orgapharm and pay the applicable payment. If Prana finds that any Deliverables supplied by Orgapharm do not meet specification, then Prana will immediately notify Orgapharm in writing of any non-compliance. If the non-compliance relates to:
- (a) Product supplied to Prana, then Prana may by written notice:
    - (i) require that Orgapharm (at Orgapharm’s cost) manufacture and supply the applicable quantity of Product again based on:
      - (A) a manufacture start as soon as practicable after the date of Prana’s notice, and as agreed in good faith by both parties, given the understanding that delay in delivery of acceptable Product will adversely impact Prana;
      - (B) a manufacturing period less than or equal to the period of time originally allocated for the activity in the Work Order; or
    - (ii) terminate the Project in whole or in part, in which case Prana will not be liable to pay for, and Orgapharm must immediately refund any moneys paid by Prana (if any) on account of, the Project or the terminated part of it;
  - (b) services or documents or Results supplied, then Prana may by written notice:
    - (i) require that Orgapharm (at Orgapharm’s cost) immediately repeat the services or re-write the documents to rectify the non-compliance as soon as practicable thereafter;; or
    - (ii) terminate the Project in whole or in part, in which case Prana will not be liable to pay for, and Orgapharm must immediately refund any moneys paid by Prana (if any) on account of, the Project or the terminated part of it.
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## 6 Fees and Charges

- 6.1 Orgapharm shall invoice Prana in a manner consistent with the payment schedule and other terms and conditions set out in the relevant Work Order. Payment of invoices shall be due thirty (30) days after the date of each invoice unless any milestone or Deliverable or Service referable to the invoiced Services has not been satisfied or supplied in accordance with the Work Order or this Agreement in which case payment shall be due on the later of thirty (30) days after the date of the invoice or the date when the milestone is satisfied or the Deliverable or Service is supplied in accordance with the Work Order or this Agreement.

**7 Risk and Property**

7.1 Property in any Product produced by Orgapharm pursuant to a Work Order will pass to Prana upon payment for it in full. Risk in the Product will remain with Orgapharm while in storage at Orgapharm's premises but will otherwise pass to Prana on despatch from its premises to Prana or Prana's nominee.

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**8 Intellectual Property**

8.1 The parties acknowledge and agree that all Agreement IP will vest in and be solely owned by Prana. Orgapharm hereby assigns all of Orgapharm's right, title and interest (if any) in the Agreement IP to Prana with effect from the time it is generated or comes into existence.

8.2 Orgapharm and its Representatives must give Prana all assistance and advice and execute all documents as may be required by Prana from time to time in relation to:

- (a) any assignment that may be required to transfer Agreement IP to Prana;
- (b) any applications by Prana for patents or other registrable Intellectual Property Rights in respect of the Agreement IP;
- (c) any applications, submissions or other documents that Prana seeks to file with a regulatory authority or other government department, agency or body to obtain an approval or consent in relation to its proprietary compounds;
- (d) any other purpose reasonably arising from or incidental to this Agreement.

8.3 This Agreement will not affect the ownership of a party's Existing IP which is, and will continue to be, solely owned by that party. In particular, it is expressly agreed Orgapharm will remain the sole owner of any and all of its Existing IP (including its Existing IP used in connection with any given Project or Work Order).

8.4 Orgapharm grants Prana a non-exclusive, perpetual, worldwide, royalty-free licence (with the right to grant sublicences) to use and reproduce its Existing IP to the extent necessary to enable Prana to use the Agreement IP for the sole purpose of manufacturing and marketing PBT2 or any other PBT2 pharmacophore Compound.

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**9 Confidentiality**

9.1 Each party:

- (a) acknowledges and agrees that the Confidential Information of the other party will at all times remain the exclusive property of that other party; and
- (b) undertakes to keep the Confidential Information of the other party secret and to protect and preserve the confidential nature and secrecy of that Confidential Information.

9.2 Prana agrees and acknowledges in relation to Orgapharm Confidential Information, and Orgapharm agrees and acknowledges in relation to Prana Confidential Information, that it:

- (a) may only use or reproduce the other party's Confidential Information for the Approved Purposes;
- (b) must not disclose the other party's Confidential Information to any person except as permitted by this Agreement;

- (c) must not permit unauthorised persons to have access to the other party's Confidential Information;
  - (d) must not make, or assist or permit any person (including its Representatives) to make any unauthorised use, disclosure or reproduction of the other Party's Confidential Information;
  - (e) must ensure that any person who has access to the other party's Confidential Information does not make any unauthorised use, reproduction or disclosure of that information;
  - (f) must enforce the confidentiality obligations imposed or required to be imposed by this Agreement, including diligently prosecuting at its cost any breach or threatened breach of those confidentiality obligations by a person to whom that party has disclosed the other Party's Confidential Information and, where appropriate, making applications for interim or interlocutory relief; and
  - (g) must provide assistance reasonably requested by the other party, in relation to any proceedings the other party may take against any person for unauthorised use, copying or disclosure of the other Party's Confidential Information.
- 9.3 A party may disclose the other party's Confidential Information to a Representative on a need to know basis but in each case, only to the extent necessary for the Approved Purposes, and provided the Representative is placed under confidentiality obligations no less onerous than those set out in this Agreement.
- 9.4 Each party must:
- (a) establish and maintain effective security measures to safeguard the other party's Confidential Information from access or use not authorised under this Agreement;
  - (b) keep the other party's Confidential Information under its own control;
  - (c) immediately notify the other party of any suspected or actual unauthorised use, copying or disclosure of the other party's Confidential Information;
- 9.5 Either party may at any time by notice in writing to the other party request the return, deletion or destruction of all Material Forms of its Confidential Information in the possession, power or control of the other party or any of its Representatives (whether or not those Material Forms were created by the other party or its Representatives) and the other party must immediately comply with such request. In the case of Prana Compounds to be returned by Orgapharm, the parties acknowledge and agree that Orgapharm may retain samples of any Compounds manufactured by it so that it may comply with its cGMP obligations.
- 9.6 The return, deletion or destruction, as applicable, of the Material Forms of Confidential Information under clause 9.5 does not release a Party from its obligations under this clause 10.
- 9.7 Each party acknowledges and agrees that:
- (a) its breach of this Agreement would be harmful to the business interests of the other party;
  - (b) monetary damages alone would not be a sufficient remedy for a breach of this Agreement; and
  - (c) in addition to any other remedy which may be available in law or equity, a party is entitled to interim, interlocutory and permanent injunctions or any of them, to prevent breach of this Agreement and to compel specific performance of it.

## 10 Liability

- 10.1 Except as expressly provided to the contrary in this Agreement, all terms, conditions, warranties, guarantees, undertakings or representations of any kind made by or on behalf of a party, prescribed by statute or implied in relation to the subject matter of this Agreement are, to the fullest extent permitted by law, excluded.
- 10.2 Subject to clause 10.4 and except to the extent that liability may not be lawfully excluded, Orgapharm's liability in respect of all and any claims arising under this Agreement in relation to a Work Order, including any breach of this Agreement by Orgapharm or any negligence of Orgapharm or its Representatives, cannot exceed three times the agreed aggregate contract price for all works specified in the Work Order.
- 10.3 Notwithstanding any other provision of this Agreement, neither party shall have any liability to the other for any consequential loss suffered or incurred by the other party, however arising.
- 10.4 Clauses 10.2 and 10.3 shall have no application to any claim arising from a breach by either party of clause 9.
- 10.5 Prana shall indemnify and hold harmless Orgapharm in respect of any and all claims or demands by any third party against Orgapharm alleging loss, damage, personal injury or death arising out of the Deliverables provided by Orgapharm save and except for claims for loss, damage, injury or death arising directly or indirectly from any negligence or recklessness on the part of Orgapharm or any intentionally harmful act or omission by Orgapharm or any Representative of it or any infringement by Orgapharm of the third party's intellectual property rights.
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## 11 Termination

- 11.1 Either party may terminate this Agreement and/or any Work Order by written notice to the other party with immediate effect from the date of the notice or any later date that it may nominate if:
- (a) the other party materially breaches this Agreement and fails to remedy such breach within 30 days of receipt of notice from the first party specifying the breach and requiring it to be remedied;
  - (b) the other party materially breaches this Agreement and the breach is incapable of remedy; or
  - (c) an Insolvency Event happens to the other party.
- 11.2 Prana may terminate this Agreement and/or or any Work Order (or any part of a Work Order) by giving Orgapharm 30 days written notice. For any incomplete Work Order, Orgapharm must, unless otherwise directed by Prana, cease work immediately and use its commercially reasonable efforts to mitigate any reimbursable expenses or non-cancellable commitments properly incurred in accordance with this Agreement or the applicable Work Order.
- 11.3 Upon the termination of this Agreement or any Work Order pursuant to clauses 11.1, 11.2 or 11.2, Orgapharm may invoice Prana for Services and reimbursable expenses and non-cancellable commitments properly performed or incurred in accordance with this Agreement and the applicable Work Order through to the date of termination (**Final Invoice**). In the absence of any offsetting claim, Prana agrees to immediately pay all outstanding invoices and otherwise pay the Final Invoice (or so much thereof as may be due having regard to any up-front fees already paid) within 30 days of the date of the invoice. If after raising the Final Invoice, Prana's account is in credit, then Orgapharm shall immediately refund the credit balance.
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11.4 The expiry or termination of this Agreement will not affect or limit any accrued rights of the parties.

11.5 Clauses 1, 4.2, 4.4, 5.10, 7, 8, 9, 10, 11, 14.15 and 14.16 shall survive the termination of this Agreement.

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## 12 Force Majeure

12.1 If any party to this Agreement is unable to carry out any obligation (other than to pay money), by reason of Force Majeure, then that obligation will be suspended so far as it is affected by the Force Majeure for the duration of the Force Majeure. The party affected must promptly give written notice to the other party of the Force Majeure with full particulars thereof and so far as is known, the probable extent to which that party will be unable to perform or will be delayed in performing the obligation.

12.2 If:

- (a) performance of an obligation is prevented by Force Majeure; or
- (b) a delay caused by Force Majeure exceeds 90 days,

then either party may terminate this Agreement by written notice to the other party.

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## 13 Notices

### Requirements

13.1 All notices must be:

- (a) in legible writing and in English;
- (b) addressed to the recipient at the address or facsimile number set out below or to any other address or facsimile number that a party may notify to the other:

#### to Orgapharm:

Address: Rue du Moulin de la Canne,  
Pithiviers France 45 300

Attention: Rabiaâ Berkous  
Facsimile no: 33(0)2 38 30 24 2 4

to Prana:

Address: Level 2, 369 Royal Parade  
Parkville Victoria 3052  
Australia

Attention: Dianne Angus

Facsimile no: 9348 0377

- (c) signed by the party or, where the sender is a company, by an authorised representative of the sender; and

(d) sent to the recipient by hand, prepaid post or facsimile.

13.2 Without limiting any other means by which a party may be able to prove that a notice has been received by the other party, a notice will be considered to have been received:

(a) if sent by hand, when left at the address of the recipient;

(b) if sent by prepaid post, 2 days after the date of posting; or

(c) if sent by facsimile, on receipt by the sender of an acknowledgment or transmission report generated by the sender's machine indicating that the whole facsimile was sent to the recipient's facsimile number;

but if a notice is served by hand, or is received by the recipient's facsimile, on a day that is not a Business Day, or after 5:00 pm (recipient's local time) on a Business Day, the notice will be considered to have been received by the recipient at 9.00 am (recipient's local time) on the next Business Day.

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## **14 General provisions**

### **Entire agreement**

14.1 This Agreement and any other documents referred to in this Agreement or executed in connection with this Agreement is the entire agreement of the parties about the subject matter of this Agreement and supersedes all other representations, negotiations, arrangements, understandings or agreements and all other communications. No party has entered into this Agreement relying on any representations made by or on behalf of the other, other than those expressly made in this Agreement.

### **Further assurances**

14.2 Each party must, at its own expense, whenever reasonably requested by the other party, promptly do or arrange for others to do, everything reasonably necessary or desirable to give full effect to this Agreement and the transactions contemplated by this Agreement.

### **Costs**

14.3 Each party must pay its own costs in respect of this Agreement and the documents and transactions contemplated by this Agreement.

### **Subcontracting and Assignment**

14.4 Orgapharm must not subcontract the Services or assign or otherwise transfer, create any charge, trust or other interest in, or otherwise deal in any other way with any of its rights under this Agreement without the prior written consent of Prana. Orgapharm shall remain responsible for any Services performed by any subcontractors to the same extent as if such Services were being performed by Orgapharm itself.

### **Invalid or unenforceable provisions**

14.5 If a provision of this Agreement is invalid or unenforceable in a jurisdiction:

(a) it is to be read down or severed to the extent of the invalidity or unenforceability; and

(b) that fact does not affect the validity or enforceability of the remaining provisions.

### **Waiver and exercise of rights**

14.6 A waiver by a party of a provision of or of a right under this Agreement is binding on the party granting the waiver only if it is given in writing and is signed by the party or an authorised representative of the party granting the waiver.

14.7 A waiver is effective only in the specific instance and for the specific purpose for which it is given.

14.8 A single or partial exercise of a right by a party does not preclude another exercise of that right or the exercise of another right.

14.9 Failure by a party to exercise or delay in exercising a right does not prevent its exercise or operate as a waiver.

**Amendment**

14.10 This Agreement may be amended only by a document signed by all parties.

**Counterparts**

14.11 This Agreement may be signed in counterparts, both of which shall be deemed to be an original but when taken together shall constitute one and the same agreement and shall become effective when a counterpart has been signed by each of the parties hereto and delivered to the other (by facsimile, pdf or otherwise).

**Rights cumulative**

14.12 The rights, remedies and powers of the parties under this Agreement are cumulative and do not exclude any other rights, remedies or powers.

**Consents and approvals**

14.13 A party may give its approval or consent conditionally or unconditionally or withhold its approval or consent in its absolute discretion unless this Agreement expressly provides otherwise.

**Successors and assigns**

14.14 This Agreement is binding on, and has effect for the benefit of, the parties and their respective successors and permitted assigns.

**Governing law**

14.15 This Agreement is governed by the laws of Victoria, Australia.

14.16 Each party irrevocably and unconditionally:

- (a) submits to the non-exclusive jurisdiction of the courts of Victoria in relation to any dispute or claim arising out of or in connection with the subject matter of this agreement;
- (b) waives, without limitation, any claim or objection based on absence of jurisdiction or inconvenient forum.

**Executed as an agreement**

**Signed** for and on behalf of

**Orgapharm S.A.S.**

by its authorised representative:

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Signature of authorised representative

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Name (please print)

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Title (please print)

**Signed** for and on behalf of

**Prana Biotechnology Ltd**

ACN 080 699 065

by its authorised representative:

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Signature of authorised representative

---

Name (please print)

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Title (please print)

**ANNEXURE A**

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**WORK ORDER NO. [#]**

This Work Order No. [#] is issued pursuant to the Master Services Agreement dated [insert date of MSA] (the “MSA”) between Prana Biotechnology Ltd ACN 080 699 065 of Level 2, 369 Royal Parade, Parkville Victoria 3052 Australia (“Prana”) and Orgapharm S.A.S. of Rue du Moulin de la Canne, Pithiviers France 45 300 (“Orgapharm”).

Once executed by both parties, this Work Order will be incorporated into the MSA. Capitalized terms not defined in this Work Order shall have the meanings ascribed to them in the MSA.

**[Work Orders will contain the following, as applicable:]**

1. Background
2. Description of Services and Deliverables
3. Responsibilities
4. Project Timeline
5. Fees, Reimbursable Expenses and Payment Schedule
6. Any other applicable terms and conditions not covered in the MSA
7. Exhibits to the Work Order (e.g. specifications, Quality Agreement)

**WORK ORDER AGREED TO AND ACCEPTED BY:**

**Orgapharm S.A.S**

**Prana Biotechnology Ltd**

By:

By:

Name:

Name:

Title:

Title:

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**Master Services Agreement**

**Commencement Date** 1 September, 2015

**Parties** **IDT Australia Limited** ACN 066 522 970  
of 45 Wadhurst Drive, Boronia Victoria 3155  
(*IDT*)

**Prana Biotechnology Ltd** ACN 080 699 065  
of Level 2, 369 Royal Parade, Parkville Victoria Australia 3052  
(*Prana*)

(each a **party** and collectively, the **parties**)

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**Introduction**

- A Prana is in the business of developing drug candidates for the treatment of neurodegenerative diseases.
- B IDT is in the business of formulating, developing and manufacturing API and finished dosage forms, analytical testing (including stability and microbiological testing), clinical packaging and distribution of pharmaceutical products from its facilities in Boronia, Victoria.
- C Prana has sought the assistance of IDT to formulate, develop and manufacture API and finished dosage forms, analytical testing (including stability and microbiological testing), clinical packaging and distribution of clinical trial materials for Prana's proprietary product/s such as PBT434 and PBT2 and matching placebo for clinical trials. There may also be occasions in future where Prana may call on IDT to provide other pharmaceutical manufacturing and related services.
- D This Agreement contains the terms and conditions upon which IDT will provide services to Prana.

**Agreement**

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**1 Definitions and Interpretation**

**Definitions**

1.1 In this Agreement:

*Agreement* means this agreement including any schedule or annexure to it.

*Agreement IP* means the following:

(a) the Deliverables; and

(b) the Results,

and all Intellectual Property Rights throughout the world subsisting in them.

*API* means an active pharmaceutical ingredient.

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**Approved Purposes** means:

- (a) the performance of the Services and production of the Deliverables by IDT;
- (b) Prana's input in pursuance of this Agreement to facilitate the performance of the Services by IDT; and
- (c) the use of the Agreement IP by Prana for its business purposes.

**Business Day** means a day other than Saturday, Sunday or a public holiday or bank holiday in the place where an act is to be performed or a payment is to be made.

**Cause Event** means:

- (a) a material breach by IDT of its obligations under this Agreement or the Quality Agreement;
- (b) receipt by IDT of an FDA Form 483 of the type specified in clause 4.3(b)(iii) or Warning Letter or other like document from the TGA or any other regulatory authority;
- (c) any audit, inspection or product, documentation or information request by the FDA, TGA or other regulatory authority which is specific to Prana's Products.

**cGMP** or **GMP** means current Good Manufacturing Practices applicable to the Products, as established and interpreted by the relevant Governmental Agencies from time to time.

**Change Order** means a change in respect of the work to be performed by IDT under a given Work Order.

**Commencement Date** means the date of this Agreement first written above.

**Compounds** means Prana's proprietary compounds, including the compounds known as PBT2 and PBT 434 and any APIs of them.

**Confidential Information** means IDT Confidential Information or Prana Confidential Information as the context allows.

**Corporations Law** means the *Corporations Act 2001* (Cth).

**Deliverables** means data, results, information, advice, reports, analyses, documents, materials, APIs, compounds, Investigational Medicinal Product, formulations, procedures, techniques, batch records and Product specifications, test methods and specifications and other items or things prepared, obtained, generated or derived by IDT as part of the Services, and to be delivered to Prana, all in accordance with the requirements specified in the relevant Work Order and this Agreement.

**EMA** means the European Medicines Agency, and any successor agency having substantially the same functions.

**Existing IP** of a party means the Technology owned, developed or obtained by or on behalf of that party:

- (a) prior to the Commencement Date; or
- (b) independent of this Agreement and without the use of the other party's Confidential Information,

and includes all Intellectual Property Rights throughout the world subsisting in such Technology.

**FDA** means the United States Food and Drug Administration, and any successor agency having substantially the same functions.

**Force Majeure** means an act of God, strike, lock-out or other labour dispute, war declared or undeclared, blockade, riot, insurrection, lightning, fire, earthquake, storm, flood, explosion, restraint of government or government agency, prohibition or any other cause whether or not of the kind listed above which is beyond the control of the party affected.

**Governmental Agency** means any court, administrative agency or commission or other governmental agency, body or instrumentality, domestic or foreign, and includes, without limitation, the FDA, EMA and TGA.

**GST** means goods and services tax under the GST Law.

**GST Law** has the same meaning as in *A New Tax System (Goods and Services Tax) Act 1999* (Cth).

**IDT Confidential Information** means:

- (a) Proposals; and
- (b) all:
  - (i) Existing IP of IDT;
  - (ii) information concerning IDT's affairs, assets or property or any business, property or transaction in which it may be or may have been concerned or interested;
  - (iii) information which, by its nature or by the circumstances of its disclosure, is or could reasonably be expected to be regarded as confidential to IDT,which is or has been disclosed by IDT to Prana (whether orally, electronically or in writing) or is otherwise obtained by Prana but does not include Public Information.

**Initial Project** means the cGMP manufacture of PBT434 capsules and matching placebo capsules for a Phase 1 clinical trial to be conducted in one or more of Australia, Europe and the USA.

**Insolvency Event** means the happening of any of the following:

- (a) an application is made to a court for an order that a party be wound-up or that a provisional liquidator be appointed (unless the application is withdrawn, struck out or dismissed within 45 days of it being made);
- (b) a liquidator is appointed in respect of a party;
- (c) a resolution is passed or a decision taken to appoint an administrator, receiver or receiver and manager in respect of a party or there is a Controller (as defined in the Corporations Law) appointed in relation to a party or in respect of any of its assets;
- (d) except to reconstruct or amalgamate while solvent on terms approved by the other party, a party enters into, or resolves to enter into, an arrangement or composition with, or assignment for the benefit of, all or any of its creditors, or it, or anyone on its behalf, proposes a reorganisation, moratorium, deed of company arrangement or other administration involving any of them or the winding up or dissolution of the party;
- (e) a party is, states that it is or is presumed under any applicable law to be, insolvent; and



(f) anything having a substantially similar effect to any of the events specified above happens under the law of any jurisdiction.

**Intellectual Property Rights** means all intellectual and industrial property rights throughout the world (whether registered or unregistered) including rights and interests (including applications for and any right to apply for registrations of such rights) in respect of or in connection with designs, discoveries, inventions (including patents), copyright (including future copyright and rights in the nature of or analogous to copyright), trade marks, database rights, confidential information, know how and trade secrets.

**Investigational Medicinal Product or IMP** means active and/or placebo capsule, produced, packaged and labelled in accordance with a Work Order.

**Laws** means the common law and any statute, regulation, order, rule, subordinate legislation, code of practice or other document enforceable under any statute, regulation, order, rule or subordinate legislation.

**Material Form** in relation to information, includes any form (whether visible or not) of storage from which the information can be reproduced, and any form in which the information is embodied or encoded and in relation to Prana's Compounds means whatever form they are present in the possession of IDT or their Representatives.

**Prana Confidential Information** means:

- (a) the Compounds;
- (b) RFPs;
- (c) Agreement IP; and
- (d) all:
  - (i) Existing IP of Prana, including all data, results, information, analyses, papers, materials, records, notes, documents and reports concerning:
    - (A) the Compounds;
    - (B) the synthesis or commercial manufacture of the Compounds;
    - (C) research, tests, trials and studies planned or conducted in relation to the Compounds;
  - (ii) information concerning Prana's affairs, assets or property or any business, property or transaction in which it may be or may have been concerned or interested;
  - (iii) information which, by its nature or by the circumstances of its disclosure, is or could reasonably be expected to be regarded as confidential to Prana, which is or has been disclosed by Prana to IDT (whether orally, electronically or in writing) or is otherwise obtained by IDT but does not include Public Information

**Premises** means IDT's facilities in Boronia, Victoria or such other facilities agreed by Prana in writing.

**Products** means IMPs (for PBT434), Compounds and such other products to be manufactured by IDT pursuant to this Agreement.

**Projects** means:

- (a) the Initial Project; and
- (b) any subsequent project for the delivery of agreed Services by IDT to Prana under this Agreement.

**Proposal** means a proposal for the provision of Services submitted to Prana by IDT.

**Public Information** means:

- (a) information which, at the time of disclosure, was published, known publicly or otherwise in the public domain;
- (b) information which, after disclosure, is published, becomes known publicly, or otherwise becomes part of the public domain through no fault of the receiving party;
- (c) information which, prior to the time of disclosure, is known to the receiving party as evidenced by its written records or other tangible evidence;
- (d) information which is made available to the receiving party in good faith by a third party who is under no obligation of confidence to the disclosing party;
- (e) information which the receiving party is required to disclose by law, provided the receiving party has given the disclosing party prompt prior notice and assistance in any reasonable effort to obtain confidential treatment with respect to such disclosure; or
- (f) information which is independently developed by or for the receiving party without use of, reliance upon, or with reference to the disclosing party's Confidential Information.

**Quality Agreement** means the quality agreement to be entered by the parties pursuant to clause 5.7.

**Representative** in relation to a party means a director, officer, employee or contractor (approved by Prana under clause 15.4 in the case of an IDT contractor) of that party.

**Results** means:

- (a) all results, data, information, processes, procedures, methodologies, techniques, concepts, ideas, compounds, formulations, materials, reports, analyses, documents, items or things; and
- (b) all discoveries, inventions, developments, modifications, innovations, enhancements or improvements,

that are made, generated, brought into existence, conceived, discovered, invented, developed, created, derived, modified, improved, enhanced, adapted or reduced to practice by either party or their Representatives (whether alone or jointly with the other party) under or in connection with or as a consequence of a Project.

**RFP** means a request submitted by Prana to IDT for a proposal for the provision of Services under this Agreement.

**Services** means for a given Project, the services to be provided by IDT under this Agreement, as agreed and specified in a Work Order for the Project.

**Specification** means a specification agreed by the parties in writing for a Deliverable which may be either:

- (a) recorded in or annexed to a Work Order or incorporated therein by reference; or
- (b) prepared and agreed by the parties during the course of a Project.

**Sub-Project** in relation to a Project, means a sub-project or discrete piece of work (if any) described in the corresponding Work Order for performance by IDT, subject in each case to IDT receiving prior written approval from Prana and the parties agreeing in writing on the Specification/s for the Deliverable/s for the sub-project or discrete piece of work.

**Technology** means:

- (a) proprietary compounds, samples, prototypes, formulations, ideas, knowledge, concepts, methods, techniques, processes, procedures, trade secrets, technology, discoveries, inventions, know-how, data, technical and scientific information, research and development results, development plans, test results, procedures for experiments and tests and manufacturing scale-ups, methods or schemes for synthesising chemicals and compounds, isolation and purification methods, hardware and software;
- (b) patents, patentable inventions, designs, trade marks, works of copyright and rights in confidential information;
- (c) all other intellectual property of any kind, whether or not protectable under patent, trade mark, copyright, design or other intellectual property laws.

**TGA** means the Australian Therapeutic Goods Administration, and any successor agency having substantially the same functions.

**Work Order** means one or more written Work Orders referencing this Agreement or otherwise attached to this Agreement and executed by both parties pertaining to the Services to be supplied by IDT under this Agreement. A template Work Order is set out in Schedule 1.

## Interpretation

1.2 In this Agreement, unless the context requires another meaning:

- (a) a reference to:
  - (i) the singular includes the plural and vice versa;
  - (ii) a document (including this Agreement) is a reference to that document (including any Schedules and Annexures) as amended, consolidated, supplemented, novated or replaced;
  - (iii) an item, Recital, clause, Schedule or Annexure is to an item, Recital, clause, Schedule or Annexure of or to this Agreement;
  - (iv) a notice means a notice, approval, demand, request, nomination or other communication given by one party to another under or in connection with this Agreement;
  - (v) a person (including a party) includes an individual, company, other body corporate, association, partnership, firm, joint venture, trust or government agency; and
  - (vi) the words "including" or "includes" means "including, but not limited to", or "includes, without limitation" respectively;
- (b) where a word or phrase is defined, its other grammatical forms have a corresponding meaning; and
- (c) headings are for convenience only and do not affect interpretation of this Agreement.

1.3 This Agreement may not be construed adversely to a party only because that party was responsible for preparing it.

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## **2 Term**

2.1 This Agreement commences on the Commencement Date and continues for five (5) years or until the completion of any then current Work Order by IDT, unless terminated earlier in accordance with this Agreement. This Agreement may be extended by mutual agreement of the parties in writing.

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## **3 Services and Work Orders**

3.1 If at any time during the Term Prana wishes to engage IDT to provide Services to it, then subject to the parties entering a Work Order in respect of the Services, IDT agrees to provide the Services on the terms and conditions contained in this Agreement.

3.2 Each Work Order:

- (a) is incorporated herein by reference;
- (b) shall be in written form similar to the sample Work Order attached to this Agreement as Annexure A;
- (c) shall include a description of the specific services to be performed by IDT, the Deliverables, timelines, protocols, Specifications, fees and charges payable by Prana and such other details and terms as are agreed to by the parties; and
- (d) is taken to include the Quality Agreement and all applicable Specifications.

3.3 In the event of any conflict between the terms and conditions of a Work Order and a provision of this Agreement, the terms and conditions of this Agreement shall prevail unless the Work Order expressly specifies that the particular term of the Work Order takes precedence.

3.4 Any change to a Work Order must be mutually agreed and documented by IDT in a written amendment to the Work Order (a "**Change Order**"). When a signed Change Order is received from Prana, the Change Order shall constitute an amendment to the applicable Work Order and shall be considered part of this Agreement. No changes to a Work Order will take effect and IDT must not commence any new or changed Services unless and until it has received a signed Change Order from Prana.

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## **4 IDT's Obligations and Warranties**

4.1 IDT will perform each Project and the associated Services at the Premises:

- (a) using suitably qualified Representatives;
- (b) using commercially reasonable endeavours to perform each Project and the associated Services in a timely manner in accordance with the Work Order;
- (c) with due care and skill and to the best of IDT's knowledge and expertise;
- (d) in accordance with relevant local industry standards, best practice and guidelines or where none apply, relevant international industry standards, best practice and guidelines;

- (e) in accordance with cGMP, the Work Order and all Laws applicable to the operation of the Premises;
- (f) in accordance with any reasonable direction given by Prana; and
- (g) otherwise in accordance with the provisions of this Agreement.

4.2 IDT represents and warrants that:

- (a) it has the right to enter into this Agreement;
- (b) it has and will maintain the requisite licences from the FDA, TGA and all other applicable governmental, municipal and public agencies, bodies and authorities for the conduct of its business at each of its premises;
- (c) it has and will maintain all:
  - (i) rights, title, licences and interests in its Existing IP;
  - (ii) property, equipment and resources,necessary to perform each Project and the associated Services;
- (d) it and its Representatives have the necessary experience, skill, knowledge and competence to perform each Project and the associated Services.

4.3 IDT will:

- (a) permit all relevant inspections by the FDA, TGA or other regulatory authorities of its premises, procedures and documentation;
- (b) notify Prana:
  - (i) within three (3) Business Days of receiving any notice of inspection from the FDA, TGA or other regulatory authority only to the extent such an inspection relates to Prana's IMP/Compounds or may impact on IDT's ability to supply such products;
  - (ii) within one (1) Business Day of receiving any request from the FDA, TGA or other regulatory authority for Prana's IMP, Compounds, products or samples or related batch or other documentation or information;
  - (iii) within one (1) Business Day of receiving any FDA Form 483 or Warning Letter or other like document from the TGA or any other regulatory authority which relates to Prana's IMP/Compounds or which may impact on IDT's ability to supply such products (in accordance with a Work Order) or the facilities used to produce, test or package them,

and provide Prana with copies of all such letters, notices or documents and IDT's response to them (in each case redacted, where appropriate, to exclude text not relevant to Prana or its IMP/Compounds).

4.4 IDT must:

- (a) take out and maintain during the term of this Agreement and for 12 months thereafter, appropriate public and product liability insurance policies with a reputable insurer which give coverage against all usual risks and for an amount of at least \$10,000,000 per occurrence.
- (b) at Prana's request provide Prana with certificates of currency for those policies.

5 **Project Obligations**

- 5.1 For each Project:
- (a) IDT will designate a project leader to liaise with Prana in relation to IDT's performance of the Services and the provision of the Deliverables (the "**Project Leader**"); and
  - (b) Prana will designate a contact who will be the point of contact for the Project Leader (the "**Prana Contact**").
- 5.2 The parties must agree in writing on the Specifications for each Deliverable and IDT must receive written authority from the Prana Contact or Prana's Chief Operating Officer before commencing any Sub-Project. Without such agreement and authority for a given Sub-Project, IDT must not undertake and may not charge Prana its fee for the Sub-Project or any other amount. If in relation to a given Sub-Project, Prana provides written authority to undertake the Sub-Project after the relevant commencement date specified in the Work Order, then IDT shall commence the Sub-Project as soon as is reasonably practicable thereafter.
- 5.3 IDT must provide the following updates and reports to the Prana Contact for each Project:
- (a) prompt email notification of any material technical or operational problems or issues encountered by IDT;
  - (b) fortnightly email updates (in a format acceptable to Prana) of the work undertaken and the Results obtained for the fortnight, problems encountered by IDT, the stage of each Project or Sub-Project, as applicable that IDT is up to and any other information that would be relevant to Prana in relation to the Project; and
  - (c) such reports specified in the applicable Work Order for the Project.
- 5.4 IDT must create a separate project folder in the applicable department directory in its computer system:
- (a) which is dedicated to Prana Projects; and
  - (b) accessible only by those IDT Representatives working on such projects.
- 5.5 Copies of all letters, reports, memos, notes, documents and other written materials created or brought into existence by IDT in relation to each Project shall be saved electronically and stored by IDT in the Prana project folder.
- 5.6 All Results arising out of the Project must be recorded in a written format. The results captured in a written format must:
- (a) be maintained and signed in accordance with IDT's information retention policies and practices; and
  - (b) be made available for inspection by Prana upon request by Prana in writing.
- 5.7 If they have not already done so, the parties agree to put a quality agreement in place for the purpose of the Services to be undertaken by IDT under this Agreement.
- 5.8 On 14 days prior written notice, IDT must allow Prana to undertake an audit of its Premises, procedures actions and documentation in relation to Prana's Projects, IMPs, Compounds and Agreement IP and IDT's observance of obligations under this Agreement and the Quality Agreement. Prana audits shall be limited to one audit with a maximum of two (2) auditors for two (2) days (or otherwise as may be negotiated in advance and agreed by the parties) per calendar year except if Prana reasonably believes that a Cause Event has occurred or may occur in which case Prana may conduct an additional audit with 5 days prior written notice (or such shorter period of notice agreed by the parties in good faith having regard to the urgency of the situation).

- 5.9 If at any time during or after the termination of this Agreement, Prana requires a third party to perform any work relating to a Compound, including its manufacture, then IDT must, at the request of Prana, co-operate with Prana and the third party and provide such assistance, advice, documentation and information (including the relevant Results) as is necessary to enable the third party to perform the work requested by Prana. Prana agrees to pay all out-of-pocket expenses reasonably incurred by IDT, provided that any anticipated expenses in excess of USD\$1,000 are approved by Prana in writing before they are incurred.
- 5.10 If any Deliverable is not produced by IDT to Specification in accordance with this Agreement as a direct result of the negligence of, or breach of GMP or any IDT Standard Operating Procedure by, IDT or any Representative of it, then Prana may reject the Deliverable and:
- (a) require that IDT promptly repeat the applicable Service/s; or
  - (b) terminate the applicable Work Order in whole or in part, in which case Prana will not be liable to pay for, and IDT must immediately refund any moneys paid by Prana (if any) on account of, the Work Order or the terminated part of it, as applicable.
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## 6 Fees and Charges

- 6.1 IDT shall invoice Prana in a manner consistent with the payment schedule and other terms and conditions set out in the relevant Work Order. Payment of invoices shall be due thirty (30) days after the date of each invoice.
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## 7 GST

- 7.1 Except where express provision is made to the contrary, and subject to this clause, any amount that may be payable under this Agreement is exclusive of any GST. If GST is or becomes payable on a supply made under or in connection with this Agreement, an additional amount (**Additional Amount**) is payable by the party providing consideration for the supply (**Recipient**) equal to the amount of GST payable on that supply as calculated by the party making the supply (**Supplier**) in accordance with the GST Law.
- 7.2 The Additional Amount payable under clause 7.1 must be paid at the same time and in the same manner as the consideration for the supply, subject to receipt by the Recipient of a valid tax invoice.
- 7.3 If the rate of GST payable in respect of supplies made (or deemed to be made) in connection with this Agreement changes, the amount payable must be adjusted so that the economic benefit of this Agreement to the party receiving each payment remains the same, irrespective of the rate of GST which applies.
- 7.4 Notwithstanding any other provision of this Agreement, if either party is required to reimburse or indemnify the other party for any cost, expense or other amount, the amount to be reimbursed or indemnified must be reduced by any part which is recoverable as an input tax credit by the party which incurred it (or representative member of that party's GST group).
- 7.5 Terms used in this clause 7 (including "supply", "consideration", "representative member", "tax invoice" and "GST group") have the same meaning as defined in the GST Law.
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## **8 Risk and Property**

- 8.1 Property in any Products produced by IDT pursuant to a Work Order will pass to Prana upon payment for them in full. Risk in the Products will remain with IDT while in storage at IDT's premises but will otherwise pass to Prana on despatch from its premises to Prana or Prana's nominee.
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## **9 Intellectual Property**

- 9.1 The parties acknowledge and agree that all Agreement IP will vest in and be solely owned by Prana. IDT hereby assigns all of IDT's right, title and interest (if any) in the Agreement IP to Prana with effect from the time it is generated or comes into existence.
- 9.2 IDT and its Representatives must give Prana all reasonable assistance and advice and execute all documents as may be required by Prana from time to time in relation to:
- (a) any assignment that may be required to transfer Agreement IP to Prana;
  - (b) any applications by Prana for patents or other registrable Intellectual Property Rights in respect of the Agreement IP;
  - (c) any applications, submissions or other documents that Prana seeks to file with a regulatory authority or other government department, agency or body to obtain an approval or consent in relation to its proprietary compounds;
  - (d) any other purpose reasonably arising from or incidental to this Agreement.
- 9.3 This Agreement will not affect the ownership of a party's Existing IP which is, and will continue to be, solely owned by that party.
- 9.4 IDT grants Prana a non-exclusive, perpetual, worldwide, royalty-free licence (with the right to grant sublicenses) to use, reproduce and adapt its Existing IP only to the extent necessary to enable Prana to use the Agreement IP for its business purposes.
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## **10 Confidentiality**

- 10.1 Each party:
- (a) acknowledges and agrees that the Confidential Information of the other party will at all times remain the exclusive property of that other party; and
  - (b) undertakes to keep the Confidential Information of the other party secret and to protect and preserve the confidential nature and secrecy of that Confidential Information.
- 10.2 Prana agrees and acknowledges in relation to IDT Confidential Information, and IDT agrees and acknowledges in relation to Prana Confidential Information, that it:
- (a) may only use or reproduce the other party's Confidential Information for the Approved Purposes;
  - (b) must not disclose the other party's Confidential Information to any person except as permitted by this Agreement;
  - (c) must not permit unauthorised persons to have access to the other party's Confidential Information;



- (d) must not make, or assist or permit any person (including its Representatives) to make any unauthorised use, disclosure or reproduction of the other Party's Confidential Information;
  - (e) must ensure that any person who has access to the other party's Confidential Information does not make any unauthorised use, reproduction or disclosure of that information;
  - (f) must enforce the confidentiality obligations imposed or required to be imposed by this Agreement, including diligently prosecuting at its cost any breach or threatened breach of those confidentiality obligations by a person to whom that party has disclosed the other Party's Confidential Information and, where appropriate, making applications for interim or interlocutory relief; and
  - (g) must provide assistance reasonably requested by the other party, in relation to any proceedings the other party may take against any person for unauthorised use, copying or disclosure of the other Party's Confidential Information.
- 10.3 A party may disclose the other party's Confidential Information to a Representative on a need to know basis but in each case, only to the extent necessary for the Approved Purposes, and provided the Representatives are placed under confidentiality obligations no less onerous than those set out in this Agreement.
- 10.4 Each party must:
- (a) establish and maintain effective security measures to safeguard the other party's Confidential Information from access or use not authorised under this Agreement;
  - (b) keep the other party's Confidential Information under its own control;
  - (c) immediately notify the other party of any suspected or actual unauthorised use, copying or disclosure of the other party's Confidential Information;
- 10.5 Either party may at any time by notice in writing to the other party request the return, deletion or destruction of all Material Forms of its Confidential Information in the possession, power or control of the other party or any of its Representatives (whether or not those Material Forms were created by the other party or its Representatives) and the other party must immediately comply with such request. In the case of Prana Compounds to be returned by IDT, the parties acknowledge and agree that IDT may retain samples of any Compounds manufactured by it so that it may comply with its cGMP obligations.
- 10.6 The return, deletion or destruction, as applicable, of the Material Forms of Confidential Information under clause 10.5 does not release a Party from its obligations under this clause 10.
- 10.7 Each party acknowledges and agrees that:
- (a) its breach of this Agreement would be harmful to the business interests of the other party;
  - (b) monetary damages alone would not be a sufficient remedy for a breach of this Agreement; and
  - (c) in addition to any other remedy which may be available in law or equity, a party is entitled to interim, interlocutory and permanent injunctions or any of them, to prevent breach of this Agreement and to compel specific performance of it.
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## **11 Liability**

- 11.1 Except as expressly provided to the contrary in this Agreement, all terms, conditions, warranties, guarantees, undertakings or representations of any kind made by or on behalf of a party, prescribed by statute or implied in relation to the subject matter of this Agreement are, to the fullest extent permitted by law, excluded.

- 11.2 Subject to clause 11.4, IDT's liability in respect of all and any claims arising under this Agreement in relation to a Work Order, including any breach of this Agreement by IDT or any negligence of IDT or its Representatives, cannot exceed the agreed aggregate contract price for all works specified in the Work Order.
- 11.3 Notwithstanding any other provision of this Agreement, neither party shall have any liability to the other for any consequential loss suffered or incurred by the other party, however arising.
- 11.4 Clauses 11.2 and 11.3 shall have no application to any claim arising from a breach by either party of clause 10.
- 11.5 Prana shall indemnify and hold harmless IDT in respect of any and all claims or demands by any third party against IDT alleging loss, damage, personal injury or death arising out of the Deliverables provided by IDT save and except for claims for loss, damage, injury or death arising directly or indirectly from any gross negligence or recklessness on the part of IDT or any intentionally harmful act or omission by IDT or any Representative of it.
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## 12 Termination

- 12.1 Either party may terminate this Agreement and/or any Work Order by written notice to the other party with immediate effect from that or any later date that it may nominate if:
- (a) the other party materially breaches this Agreement and fails to remedy such breach within 30 days of receipt of notice from the first party specifying the breach and requiring it to be remedied;
  - (b) the other party materially breaches this Agreement and the breach is incapable of remedy; or
  - (c) an Insolvency Event happens to the other party.
- 12.2 Prana may terminate this Agreement and/or any Work Order (or any part of a Work Order) by giving IDT 30 days written notice. For any incomplete Work Order, IDT must, unless otherwise directed by Prana, cease work immediately and use its commercially reasonable efforts to mitigate any reimbursable expenses or non-cancellable commitments properly incurred in accordance with this Agreement or the applicable Work Order.
- 12.3 Upon the termination of this Agreement or any Work Order pursuant to clauses 12.1, 12.2 or 13.2, IDT may invoice Prana for Services and reimbursable expenses and non-cancellable commitments properly performed or incurred in accordance with this Agreement and the applicable Work Order through to the date of termination (**Final Invoice**). In the absence of any offsetting claim, Prana agrees to immediately pay all outstanding invoices and otherwise pay the Final Invoice (or so much thereof as may be due having regard to any up-front fees already paid) within 30 days of the date of the invoice. If after raising the Final Invoice, Prana's account is in credit, then IDT shall immediately refund the credit balance.
- 12.4 The expiry or termination of this Agreement will not affect or limit any accrued rights of the parties.
- 12.5 Clauses 1, 4.2, 4.4, 5.9, 7, 8, 9, 10, 11, 12, 15.15 and 15.16 shall survive the termination of this Agreement.

### 13 Force Majeure

- 13.1 If any party to this Agreement is unable to carry out any obligation (other than to pay money), by reason of Force Majeure, then that obligation will be suspended so far as it is affected by the Force Majeure for the duration of the Force Majeure. The party affected must promptly give written notice to the other party of the Force Majeure with full particulars thereof and so far as is known, the probable extent to which that party will be unable to perform or will be delayed in performing the obligation.
- 13.2 If:
- (a) performance of an obligation is prevented by Force Majeure; or
  - (b) a delay caused by Force Majeure exceeds 90 days,
- then either party may terminate this Agreement by written notice to the other party.
- 

### 14 Notices

#### Requirements

- 14.1 All notices must be:
- (a) in legible writing and in English;
  - (b) addressed to the recipient at the address or facsimile number set out below or to any other address or facsimile number that a party may notify to the other:  
  
**to IDT:**  
  
Address: 45 Wadhurst Drive  
Boronia Victoria 3155  
  
Attention: Managing Director  
Facsimile no: (03) 9801 8773  
  
to Prana:  
  
Address: Level 2, 369 Royal Parade  
Parkville Victoria 3052  
Australia  
  
Attention: Dianne Angus  
  
Facsimile no: 9348 0377
- (c) signed by the party or, where the sender is a company, by an authorised representative of the sender; and
  - (d) sent to the recipient by hand, prepaid post or facsimile.
- 14.2 Without limiting any other means by which a party may be able to prove that a notice has been received by the other party, a notice will be considered to have been received:
- (a) if sent by hand, when left at the address of the recipient;

- (b) if sent by prepaid post, 2 days after the date of posting; or
- (c) if sent by facsimile, on receipt by the sender of an acknowledgment or transmission report generated by the sender's machine indicating that the whole facsimile was sent to the recipient's facsimile number;

but if a notice is served by hand, or is received by the recipient's facsimile, on a day that is not a Business Day, or after 5:00 pm (recipient's local time) on a Business Day, the notice will be considered to have been received by the recipient at 9.00 am (recipient's local time) on the next Business Day.

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**15 General provisions**

**Entire agreement**

- 15.1 This Agreement and any other documents referred to in this Agreement or executed in connection with this Agreement is the entire agreement of the parties about the subject matter of this Agreement and supersedes all other representations, negotiations, arrangements, understandings or agreements and all other communications. No party has entered into this Agreement relying on any representations made by or on behalf of the other, other than those expressly made in this Agreement. For the avoidance of doubt, IDT's terms and conditions for consulting/project work will have no application,

**Further assurances**

- 15.2 Each party must, at its own expense, whenever reasonably requested by the other party, promptly do or arrange for others to do, everything reasonably necessary or desirable to give full effect to this Agreement and the transactions contemplated by this Agreement.

**Costs**

- 15.3 Each party must pay its own costs in respect of this Agreement and the documents and transactions contemplated by this Agreement.

**Subcontracting and Assignment**

- 15.4 IDT must not subcontract the Services or assign or otherwise transfer, create any charge, trust or other interest in, or otherwise deal in any other way with any of its rights under this Agreement without the prior written consent of Prana. IDT shall remain responsible for any Services performed by any subcontractors to the same extent as if such Services were being performed by IDT itself.

**Invalid or unenforceable provisions**

- 15.5 If a provision of this Agreement is invalid or unenforceable in a jurisdiction:
- (a) it is to be read down or severed to the extent of the invalidity or unenforceability; and
  - (b) that fact does not affect the validity or enforceability of the remaining provisions.

**Waiver and exercise of rights**

- 15.6 A waiver by a party of a provision of or of a right under this Agreement is binding on the party granting the waiver only if it is given in writing and is signed by the party or an authorised representative of the party granting the waiver.
- 15.7 A waiver is effective only in the specific instance and for the specific purpose for which it is given.

15.8 A single or partial exercise of a right by a party does not preclude another exercise of that right or the exercise of another right.

15.9 Failure by a party to exercise or delay in exercising a right does not prevent its exercise or operate as a waiver.

**Amendment**

15.10 This Agreement may be amended only by a document signed by all parties.

**Counterparts**

15.11 This Agreement may be signed in counterparts, both of which shall be deemed to be an original but when taken together shall constitute one and the same agreement and shall become effective when a counterpart has been signed by each of the parties hereto and delivered to the other (by facsimile, pdf or otherwise).

**Rights cumulative**

15.12 The rights, remedies and powers of the parties under this Agreement are cumulative and do not exclude any other rights, remedies or powers.

**Consents and approvals**

15.13 A party may give its approval or consent conditionally or unconditionally or withhold its approval or consent in its absolute discretion unless this Agreement expressly provides otherwise.

**Successors and assigns**

15.14 This Agreement is binding on, and has effect for the benefit of, the parties and their respective successors and permitted assigns.

**Governing law**

15.15 This Agreement is governed by the laws of Victoria.

15.16 Each party irrevocably and unconditionally:

- (a) submits to the non-exclusive jurisdiction of the courts of Victoria in relation to any dispute or claim arising out of or in connection with the subject matter of this agreement;
- (b) waives, without limitation, any claim or objection based on absence of jurisdiction or inconvenient forum.

**Executed as an agreement**

**Signed** for and on behalf of

**IDT Australia Limited**

**ACN 066 522 970**

by its authorised representative:

\_\_\_\_\_  
Signature of authorised representative

**Dr Paul D R MacLeman**

\_\_\_\_\_  
Name (please print)

**Managing Director**

\_\_\_\_\_  
Title (please print)

**Signed** for and on behalf of

**Prana Biotechnology Ltd**

**ACN 080 699 065**

by its authorised representative:

\_\_\_\_\_  
Signature of authorised representative

**Dianne Angus**

\_\_\_\_\_  
Name (please print)

**Chief Operating Officer**

\_\_\_\_\_  
Title (please print)

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ANNEXURE A

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**WORK ORDER NO. [#]**

This Work Order No. [#] is issued pursuant to the Master Services Agreement dated [insert date of MSA] (the “MSA”) between Prana Biotechnology Ltd ACN 080 699 065 of Level 2, 369 Royal Parade, Parkville Victoria 3052 Australia (“Prana”) and IDT Australia Limited ACN 080 699 065 of 45 Wadhurst Drive, Boronia Victoria 3155 (“IDT”).

Once executed by both parties, this Work Order will be incorporated into the MSA. Capitalized terms not defined in this Work Order shall have the meanings ascribed to them in the MSA.

*[Work Orders will contain the following, as applicable:]*

1. Background
2. Description of Services and Deliverables
3. Responsibilities
4. Project Timeline
5. Fees, Reimbursable Expenses and Payment Schedule
6. Any other applicable terms and conditions not covered in the MSA
7. Exhibits to the Work Order (e.g. specifications, Quality Agreement)

**WORK ORDER AGREED TO AND ACCEPTED BY:**

**IDT Australia Limited**

**Prana Biotechnology Ltd**

By:

By:

Name:

Name:

Title:

Title:

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**LIST OF SUBSIDIARIES**

We have the following wholly-owned subsidiaries:

Prana Biotechnology Inc., incorporated in the U.S.

Prana Biotechnology UK plc, incorporated in the United Kingdom.

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended**

I, Geoffrey P. Kempler, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (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 period covered by the 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: October 3, 2016

/s/ Geoffrey P. Kempler \*  
Geoffrey P. Kempler  
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 OF CHIEF FINANCIAL OFFICER  
Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended**

I, Kathryn Andrews, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (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 period covered by the 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: October 3, 2016

/s/ Kathryn Andrews \*  
Kathryn Andrews  
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 ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Geoffrey P. Kempler, 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.

October 3, 2016

/s/ Geoffrey P. Kempler \*

Geoffrey P. Kempler

Chief Executive Officer

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

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**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 ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kathryn Andrews, 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/ Kathryn Andrews \*  
Kathryn Andrews  
Chief Financial Officer

October 3, 2016

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

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-153669) and Form F-3 (No. 333-199783) of Prana Biotechnology Limited of our report dated October 3, 2016 relating to the financial statements, which appears in this Form 20 F.

/s/ PricewaterhouseCoopers  
Melbourne, Australia  
October 3, 2016

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