# 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
$\boxtimes$	OR ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended June 30, 2014
	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)

Name of each exchange on which registered NASDAQ Capital Market

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

Title of each class American Depositary Shares, each representing ten Ordinary Shares

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

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 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 Other 🗆 by the International Accounting Standards Board 🗵 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 Statements on Form F-3 (Files No. 333-173375 and 333-174278).

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

1934.

No 🗵

Yes 🗆

# **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's 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 Receipts, or ADRs, have traded on the NASDAQ Capital Market under the symbol "PRAN." The Bank of New York, acting as depositary, issues our ADRs, each of which evidences an American Depositary Share, or ADS, which in turn represents ten of our ordinary shares. As used in this annual report, the terms "we," "us," "our" and "Prana" mean Prana Biotechnology Limited 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 of America, and all references to "Australian dollars" or "A\$" are to the currency of Australia.

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

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 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 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, 2014 and 2013 and for the years ended June 30, 2014, 2013 and 2012 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, 2012, 2011 and 2010 and for the years ended June 30, 2011 and 2010 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,				
—	2014	2013	2012	2011	2010
		(in A\$, except los	s per share and number	of shares)	
Revenue from continuing operations	363,775	150,867	186,664	156,135	215,008
Other income	7,845,396	4,488,526	2,340,851	6,785	-
Research and development expenses	(14,908,098)	(8,203,822)	(4,252,002)	(3,498,035)	(1,716,583)
Corporate personnel expenses	(2,059,642)	(2,298,426)	(1,835,279)	(1,225,754)	(1,458,643)
Intellectual property expenses	(477,079)	(294,894)	(261,706)	(399,237)	(431,082)
Auditor and accounting expenses	(342,609)	(166,086)	(153,597)	(157,436)	(168,909)
Travel expenses	(421,013)	(131,710)	(91,624)	(159,971)	(234,555)
Public relations and marketing expenses	(358,597)	(136,186)	(124,970)	(110,646)	(130,090)
Depreciation expenses	(22,384)	(23,130)	(19,621)	(31,577)	(35,290)
Other expenses	(2,142,179)	(1,169,407)	(1,095,739)	(853,523)	(940,699)
Interest expense - ADDF	(29,978)	(17,676)	(11,544)	(3,758)	-
Foreign exchange gain (loss)	(746,593)	140,761	45,959	(145,377)	(6,079)
Gain (loss) on fair value of financial liabilities	(30,238)	(126,059)	33,139	(8,791)	-
Net loss	(13,329,239)	(7,787,242)	(5,239,469)	(6,431,185)	(4,906,922)
Loss per share (cents per share) – basic and diluted	(3.11)	(2.30)	(1.82)	(2.60)	(2.16)
Weighted average number of ordinary shares outstanding - basic and diluted	428,047,123	338,700,006	287,765,812	247,578,570	227,527,388

# **Balance Sheet Data**

	As at June 30,				
	2014	2013	2012	2011	2010
			(in A\$ )		
Cash and cash equivalents	34,167,018	13,346,760	5,636,469	8,838,245	5,227,298
Working capital	37,597,770	13,883,965	5,544,497	6,856,842	5,207,235
Total assets	41,640,855	17,073,821	7,341,868	9,010,952	6,801,417
Net assets	37,686,287	13,974,713	5,623,447	6,931,202	5,229,316
Issued capital	140,009,415	101,379,111	86,134,077	82,340,819	75,120,164
Share based payment reserves	8,937,434	10,526,925	9,633,451	9,494,995	8,582,579
Accumulated deficit during development stage	(111,260,562)	(97,931,323)	(90,144,081)	(84,904,612)	(78,473,427)
Total equity	37,686,287	13,974,713	5,623,447	6,931,202	5,229,316

# **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 US\$ based on rates quoted on OANDA. 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
2010	0.8567	0.8822	0.9405	0.7723
2011	1.0597	0.9894	1.1011	0.8323
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
Month		High	Low	
April 2014		0.9460	0.9205	
May 2014		0.9409	0.9196	
June 2014		0.9445	0.9225	
July 2014		0.9505	0.9301	
August 2014		0.9374	0.9227	
September 2014		0.9401	0.8682	
October 2014 (through October 31)		0.8898	0.8642	

The noon buying rate on October 31, 2014 was US\$0.88 = 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 Business**

#### We have incurred operating losses and may not be profitable in the future; our plans to maintain and increase liquidity may not be successful.

We have been unprofitable to date and expect to incur losses over the next several years as we expand our drug discovery, development programs, pre-clinical testing and as we conduct clinical trials of our product candidates. Our actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including:

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

In the years ended June 30, 2014 and 2013, we raised A\$32,373,336 and A\$3,210,069, respectively, from the sale of our ordinary shares pursuant to our at-the-market offering facility. We have not raised any additional funds since June 30, 2014. In addition, in the year ended June 30, 2014, we raised A\$4,952,925, through the exercise of previously issued unlisted options. However, to continue to meet our longer term business objectives, which would include advancement of our research and development programs, we will need to secure additional financing. 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. Any shortfall in funding could result in our having to curtail or cease our operations, including our research and development activities, which would be expected to adversely affect our business, financial condition and results of operations.

We have incurred losses in every period since we began operations in 1997 and reported net losses of A\$13,329,239, A\$7,787,242 and A\$5,239,469 during the fiscal years ended June 30, 2014, 2013 and 2012, respectively. As of June 30, 2014, our accumulated deficit was A\$111,260,562. 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 PBT434 and other MPACs. We may never be able to achieve or maintain profitability.

### 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 as the aging process progresses. We have not sufficiently advanced the development of any of our products, including our current lead product candidate, PBT2, to market or generate revenues from their commercial application. Our current or any future product candidates, if successfully developed, may not generate sufficient or sustainable revenues to enable us to be profitable.

#### We 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.

Clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for any of our 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. The failure of clinical trials to demonstrate safety and effectiveness for our desired indications could harm the development of that product candidate as well as other product candidates. 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 recruitment;

- 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.

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 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.

# 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 EMEA. 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. 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. Conducting pre-clinical testing and clinical studies is an expensive, protracted and time-consuming process. Likewise, results from early clinical trials may not be predictive of results obtained in large-scale, later-stage clinical testing. In addition, even though a potential drug product shows promising results in clinical trials, regulatory authorities may not grant the necessary approvals without sufficient safety and efficacy data.

We may not be able to undertake further clinical trials of our current and future product candidates as therapies for Alzheimer's disease, Huntington's disease, Parkinson's disease 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 trials have nonetheless failed to obtain FDA or EMA/EC approval for their products.

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

We know that competitors are developing or manufacturing various technologies or products for the treatment of diseases that we have targeted for product development. Some of these competitive products use therapeutic approaches that compete directly with our 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 including, the TGA, FDA, EMA or any other regulatory authority. The degree of market acceptance of such products will depend on a number of factors, including:

- the receipt and timing of regulatory approvals for the uses that we are studying;
- the establishment and demonstration to the medical community of the safety, clinical efficacy 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.

# Our success depends upon our ability to protect our intellectual property and our proprietary technology and to operate without infringing the proprietary rights of third parties.

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

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

protect our trade secrets, know-how and other confidential information.

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

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

# The patent protection for our product candidates may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

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. 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. 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 U.S. and the EU, 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 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.

# 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 biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and exploiting patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and exploiting biopharmaceutical patents is costly, time-consuming and inherently uncertain. 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. Such examples include:

• Nautilus, Inc. v. Biosig Instruments, Inc. (2014), where the Court imposed a stricter requirement for clarity of claim language than previously applied by the Federal Circuit, thereby making it easier to invalidate patents for insufficiently apprising the public of the scope of the invention.

• Limelight Networks, Inc. v. Akamai Technologies, Inc. (2014), where the Court articulated a standard for inducement of infringement that makes it more difficult to establish liability for inducing infringement of a multi-step method claim that is performed by multiple parties.

• Association for Molecular Pathology v. Myriad Genetics, Inc. (2013), where the Court held that isolated naturally-occurring DNA is patent ineligible subject matter.

• KSR v. Teleflex (2007), where the Court decided unanimously that the Federal Circuit Court had been wrong in taking a narrow view of when an invention is "obvious" and thus cannot be patented.

• EBay Inc. v. MercExchange, LLC (2006), where the Court heightened the standard for an injunction after a finding of patent infringement.

• Merck KGgA v. Integra Lifesciences (2004), where the Court adopted an expansive interpretation of the activities associated with regulatory approval exempt from patent infringement.

In addition, the America Invents Act, or AIA, has been recently enacted in the United States, resulting in significant changes to the U.S. patent system. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, the combination of the U.S. Supreme Court decisions and AIA has created uncertainty with respect to the value of patents, once obtained. A few highlights of changes to U.S. patent law under the AIA are:

• Under the AIA, a patent is awarded to the "first-inventor-to-file" rather than the first to invent.

• There is a new definition of prior art which removes geographic and language boundaries found in the pre-AIA law. At the same time, certain categories of "secret" prior art have been eliminated.

• The AIA introduced new procedures for challenging the validity of issued patents: post-grant review and inter partes review.

• Patent owners under the AIA may now request supplemental examination of a patent to consider, reconsider, or correct information believed to be relevant to the patent.

• The AIA allows third parties to submit any patent, published application, or publication relevant to examination of a pending patent application with a concise explanation for inclusion during prosecution of the patent application.

The "first-inventor-to-file" system and the new definitions of prior art apply to U.S. patent applications with claims having an effective filing date on or after March 16, 2013. Until at least 2034, patent practice will involve both pre-AIA and AIA laws.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to exploit 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 in the type of amendments that are allowed during prosecution. Changes in patent law or patent jurisprudence 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.

# 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.

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

At this time, we typically rely on a single manufacturer to develop Good Manufacturing Practice, synthetic processes for our lead compounds. Since 2008, our lead compound, 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's patients. We also rely on a sole manufacturer, Patheon Inc., to encapsulate PBT2. We may seek to find an alternative or back up manufacturer but may not be able to promptly find an alternative or replacement manufacturer without incurring material additional costs and substantial delays.

### 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.

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

In both the U.S. 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 changes 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.

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.

#### 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.

# 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 ADRs.

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 ADRs.

### **Risks Relating to Our Securities**

#### Our stock price may be volatile and the U.S. trading market for our 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. During the last two fiscal years ended June 30, 2014 and subsequently until October 30, 2014, the market price for our ordinary shares on the ASX has ranged from as low as A\$0.14 to a high of A\$1.37 and the market price of our ADSs on the NASDAQ Capital Market has ranged from as low as US\$1.47 to a high of US\$13.29. 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 March 2011, we issued 27,200,000 ordinary shares and options to purchase an additional 6,800,000 ordinary shares in a private placement. In May 2011, we registered US\$50,000,000 of securities for public sale pursuant to our registration statement on Form F-3 filed on May 17, 2011. 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 US\$47,184,000 of our ordinary shares under an amended "At-The-Market" facility. From its inception and through October 27, 2014, we issued a total of 122,158,760 ordinary shares through our "at-the-market" facility. In October 2012 and April 2013, we issued 32,500,000 and 25,641,030 ordinary shares, respectively, in private placements and in May 2013, we issued 10,370,488 ordinary shares in a share purchase plan offer. Without shareholder approval, we may not issue more than 15% 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 future 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 ADRs. 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, 2014. If we are classified as a PFIC for U.S. federal income tax purposes, highly complex rules will apply to U.S. holders owning ADRs. Accordingly, you are urged to consult your tax advisors regarding the application of such rules. United States 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 United States 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 appreciated against the U.S. dollar. Any continuation of this trend may positively affect the U.S. dollar price of our ordinary shares, even if the price of our ordinary shares in Australian dollars increases or remains unchanged. However, this trend may not continue and may be reversed. If the Australian dollar weakens against the U.S. dollar, the U.S. dollar price of the ordinary shares could decline, even if the price of our ordinary shares in Australian dollars increases or remains unchanged.



### **Risks Relating 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 other than a public offering 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.

### ITEM 4. INFORMATION ON THE COMPANY

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

Our legal and commercial name is Prana Biotechnology Limited. We were incorporated under the laws of the Commonwealth of Australia on November 11, 1997 and began limited operations shortly thereafter. Our registered office is located at Suite 2, 1233 High Street, Armadale, Victoria, 3143, Australia and our telephone number is 011-61-3-9824-5254. 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 <u>www.pranabio.com</u>. 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's disease and Parkinson's disease and other movement disorders. Other potential applications for our therapies include neurodegenerative disorders, certain cancers, agerelated 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's 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. Also in August 2009, we received a notice of allowance from the United States Patent and Trade Mark Office, or USPTO, for our key patent protecting our clinical drug asset PBT2. The patent was granted in November 2009. 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 April 2011, the Japanese Patent Office had 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 November 2011, we received a notice of allowance from the USPTO, for our key patent protecting our product candidate for Parkinson's disease, PBT434. The patent is entitled 'Neurologically Active Compounds' and covers the composition of matter and pharmaceutical compositions of selected families of 8hydroxy quinazolinone 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 metal protein attenuating compounds ('MPACs') of which PBT2 is our lead development compound for Alzheimer's Disease and Huntington's disease. We reported on the results of two Phase II trials in both indications in first quarter 2014 (see Item 4.B. "Information on the Company – Business Overview – Clinical Trials for Our Lead Compound"). PBT434, our lead compound identified for prospective development in various movement disorders, is progressing well in toxicology studies ahead of 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, 2014, our capital expenditures have totaled A\$71,783.



# 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 worldwide. 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;
- · 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 metal protein attenuating compounds, or 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 1,500 novel 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's disease and Parkinson's disease. 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 for Alzheimer's disease with transgenic mice expressing a similar phenotype to human Alzheimer's disease. Similarly, a transgenic mouse carrying a mutated Huntingtin gene is used to model Huntington's disease, and mice treated with neuronal toxins to produce the Parkinson's phenotype are used to model Parkinson's disease.

PBT2, our current Alzheimer's and Huntington's disease lead MPAC product candidate, and PBT434, our candidate lead compound for Parkinson's disease and 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.

During the financial year 2014, our research strategy has evolved to a two tier program. 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. Our discovery research has established Structure Function Relationships (SAR) within chemical moieties that guide our chemists towards novel therapeutic MPAC based treatments for neurodegenerative disorders. The discovery phase also includes preliminary bioavailability and pharmacokinetic characterization of our MPCS. The second tier comprises a set of dedicated proof of concept animal modelling to establish dose relationships relative to tolerability and efficacy, our 'Translational Research' program. MPACs of interest arising from the discovery phase may be progressed as back up compounds in Alzheimer's disease and Huntington's disease, movement disorders and/or new indications in neurodegeneration, in particular, orphan indications.

To date, our lead MPAC in 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 stage of the research program during 2014 and planning is underway to advance the most promising candidates into the Translational Research program in later this year and in 2015.

#### Alzheimer's disease

PBT2 was announced as Prana's lead MPAC for Alzheimer's disease in early August 2003. PBT2 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. PBT2 was selected from over 300 MPAC compounds that had been developed by us at such time on the basis of its significant effectiveness in pre-clinical testing, both *in vitro* and *in vivo*. It was designed 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 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 2014, top line results for the Phase II Imaging study were announced. This biomarker trial entailed the use of an amyloid imaging ligand to detect changes in brain beta-amyloid burden after 52 weeks treatment with PBT2 or placebo, 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 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.

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 (NHMRC) grant to study the benefits of PBT2 and other compounds in age-related cognitive impairment in a program entitled, "The role of metal in healthy brain aging: identification of novel compounds to prevent age-related cognitive deficits." 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's 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.

Our research into the interaction of metals with Abeta protein has resulted in the identification of agents which can block the metal binding site on Abeta thereby preventing the downstream toxicity of Abeta protein on neurons. This therapeutic approach to Alzheimer's disease is an alternative and complimentary drug strategy to our MPACs, which directly compete with Abeta protein by binding metals such as copper and zinc. Results from several proof-of-concept compounds were published in the Proceedings of the *National Academy of Sciences Journal* in May 2008. In addition to their use as Alzheimer's disease therapeutics, these amyloid binding compounds may also have potential as novel imaging agents, binding Abeta in the brain. Our discovery program is generating novel forms of this alternative anti-amyloid class of compounds for testing in animal models as either therapeutic or diagnostic agents.

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 study in 40 patients with prodromal or mild Alzheimer's disease. The primary outcome measure for this trial is the burden of amyloid in the brain as measured by brain imaging techniques and an update on the progress of this trial is provided in Item 4. B. "Information on the Company - Business Overview - Clinical Trials for Our Lead Compound."

On November 29, 2012, Dr. Robert Cherny, our company's Head of Research, presented at the symposium of the New York Academy of Sciences entitled, "Targeting Metals in Alzheimer's and Other Neurodegenerative Disease." The symposium provided an in depth review of the role metals play in the causative events leading to the neuropathology that drives Alzheimer's disease, Parkinson's disease and Huntington's disease. Dr. Cherny discussed our potentially disease modifying therapeutic strategy involving the design of small molecules to restore the balance of transition metals in the brain (that are critical for neuronal function) and reduce the accumulation of aggregated target proteins.

In March 2013, Prana scientist, Associate Professor 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.

#### Huntington's Disease

Huntington's 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's 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's 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's 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's disease. The report detailed the relevance of animal modeling experiments done with PBT2, its demonstrated mode of action in the brains of Huntington's 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's 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's disease patients in addition to Alzheimer's disease. At the International Conference on Alzheimer's Disease in Hawaii, our Head of Research, Associate Professor 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's 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's 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 includes a double blind placebo controlled study of 100 patients with early to mid-stage Huntington's Disease. On April 30, 2012, we announced that the first patient had been dosed in the Reach2HD Trial. For additional details regarding the clinical trial in Huntington's disease with PBT2, see Item 4.8. "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's disease" in the Journal of Huntington's 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. The work underpins the ongoing Reach2HD trial in Huntington's disease patients.

As described in the preceding section, 'Platform Technology and 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's disease.

Important support for the role of copper in the disease process in Huntington's disease came from Tsinghua University in China (Xiao et al PNAS 2013). Using a Drosophila model of Huntington's 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's 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's 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 platform 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 Howard Florey Institute in Melbourne to assist in the examination of the effect of MPACs administered to the 6-hydroxydopamine (PD) mouse model of the disease, which concluded with positive results. In addition, groups unrelated to us have published data that demonstrates the usefulness of clioquinol in treating the symptoms of Parkinson's disease generated in the alternative MPTP (1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine) mouse model of the disease. 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 and identified six potential compound leads. During 2009 and 2010, a 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 indicates that the compound can restore and maintain normal neuronal function.

In September 2010, we selected PBT434 as a new novel lead drug candidate with potential to be developed as a disease modifying treatment for Parkinson's disease. 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 and 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, Associate Professor Robert Cherny, Prana's Head of Research and Associate Professor David Finkelstein, Head of the Synaptic Neurobiology laboratory at the Florey Institute of Neuroscience and Mental Health, received an Australian National Health and Medical Research Council (NHMRC) grant to study the benefits of PBT434 in a program entitled, "Identifying the mechanisms of action of a novel 8-hydroxy quinazolinone 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 of Neuroscience and Assoc. Professor David Finkelstein, Head of the Parkinson's Disease Laboratory also at the Florey 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.

During 2014, PBT434 has progressed into larger scale toxicology studies in animals to identify the maximum tolerated dose, followed by longer term dosing to assess the suitable and tolerable dosage levels for Phase I, first-in-man clinical trials in 2015. The toxicology trials have progressed well with results expected by the end of the 2014 calendar year. As described in the above section, 'Platform Technology, Discovery and Translational Research Programs', PBT434 has benefitted from the investment in animal modelling and mechanistic experiments to yield information that may enable PBT434 to progress into clinical development for atypical parkinsonian orphan indications including Multiple System Atrophy, Corticobasal Degeneration and Progressive Supranuclear Palsy in addition to development opportunities in Parkinson's disease.

# Brain Cancer

We have initiated a program of research into the potential use of selected MPACs from our library for use in the treatment of brain cancer, in particular the most prevalent and deadly form of the disease, Glioblastoma Multiforme, or GBM. Patients with GBM have a very poor prognosis upon diagnosis with an estimated median survival of approximately 12 months. The most commonly prescribed treatments are chemotoxic agents together with radiation therapy, which confer a median survival increase of several months. There is an increasing body of published evidence that there are elevated levels of copper in tumors leading to increased cellular oxidative stress. Several of our MPACs that demonstrate potent toxicity against human gliomablastoma cell lines and yet remain untoxic to normal brain cells are being tested in mouse models of GBM. We believe that MPACs with a strong ability to deliver copper into tumor cells will promote their death, and we are currently investigating this *in vivo*.

In September 2009, we received a report on a study conducted on PBT519, our lead brain cancer MPAC, by the Royal Melbourne Hospital. The report showed that PBT519 was able to significantly prevent the growth of the tumors of the deadly GBM form of brain cancer in mouse models of the disease. Moreover, PBT519 appeared to be very well tolerated and was at least as efficacious as the current leading form of chemotherapy, temozolomide. The data indicates that PBT519 may work synergistically with temozolomide in reducing the growth of such brain tumors. Our researchers are generating mechanistic information on the behaviour of this compound and generating other structurally related MPACs with potential anti-cancer activity. During 2012 and 2013, prospective candidate compounds were submitted to the National Institutes for Cancer in the National Institutes of Health and the Department of Health and Human Services based in Bethesda, Maryland.

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

In February 2005, we were awarded a research and development START grant of A\$1.35 million to take PBT2 through safety testing and Phase I clinical trials for Alzheimer's disease. Formal pre-clinical toxicology testing for PBT2 was completed and in March 2005, we commenced a series of Phase I clinical trials at a facility associated with the Utrecht University Hospital in Utrecht, the Netherlands. 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's disease. The meeting provided us with important information to help form our regulatory strategy for the development of PBT2 in these neurological indications.

During the first half of 2010, we developed a Phase IIb trial protocol to test PBT2 in a Phase II trial in patients with Alzheimer's disease under the guidance of an international protocol steering committee. The protocol provided for a substantial trial measuring the effects of PBT2 on cognition and functional abilities in patients with mild to moderate Alzheimer's disease. At that time, the trial was not progressed in favour of other clinical development strategic options. 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 US\$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. The first patient was enrolled in the "IMAGINE" study in March 2012 and we completed enrolment by the end of the calendar year 2012 with top line results published March 2014. 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 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 p

In addition to the current activities to initiate an imaging trial in Alzheimer's patients, in late 2012 we finalized the enrolment to a Phase II trial to test PBT2 in patients with Huntington's disease. 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 II a trial design entailed a double blind placebo controlled study of 109 patients with early to mid-stage Huntington's disease. The primary objective for the trial was safety and tolerability of PBT2 in this Huntington's 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's 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, 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's disease patients, there was a significant improvement in the Executive Function composite (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, whilst 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).

Based on these findings, Prana has recruited an international panel of experts in Huntington's disease to advise on the protocol design for a Phase 3 study. The protocol and the supporting package of clinical and pre-clinical data on PBT2 is being assembled to present to regulators over 2014/2015. In September 2014, we announced that PBT2 had been granted Orphan Drug designation in the treatment of Huntington's 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 and that there is no existing comparable treatment option for patients and that the drug offers a plausible treatment. Currently, we are preparing a submission to the European Medicines Agency (EMA) for Orphan designation and we are also considering submissions to other territories.

Both the Reach2HD and the IMAGINE clinical trials were conducted under the governance of independent Data Safety Monitoring Boards, or DSMBs. A DSMB is an independent group of experts who review the accumulated safety data in ongoing clinical trials, in order to safeguard the interests and safety of participating patients. During the conduct of the trials to date, the respective DSMB's have met and maintained their recommendation to continue the protocols as planned.

# 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 invention. 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 obvicus 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 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 United States Patent and Trademark Office, to determine the priority of invention for patent applications filed by competitors. Any such litigation, interference or opposition proceeding, regardless of outcome, could be expensive and time consuming, and adverse determinations in any such proceedings could prevent us from developing, manufacturing or commercializing our products and could 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 that are protected in part by confidentiality and invention assignment agreements with our employees, advisors and consultants.

#### Patent Portfolio

Prana continues its intellectual property strategy of seeking the broadest possible protection over its drug assets, in the form of 'composition of matter' claims and claims to the use of those drugs for the treatment of neurodegenerative diseases. Over the last year Prana has received numerous further approvals from international patent office's relating to its MPAC patent estate, in particular: our lead MPAC for Parkinson's disease and movement disorders, PBT434 and; our lead brain MPAC cancer drug candidate, PBT519. The majority of patents covering our lead Alzheimer's and Huntington's disease MPAC PBT2 have now been granted.

Prana is working towards the discovery of new chemical entities that may be effective drugs for the same diseases, with the objective of filing new patents according to those developments.

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 these 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 Parkinson's disease/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 February 2014, Prana filed a 'Track One' application with the USPTO for the patent containing claims to the use of PBT2 for the treatment of Alzheimer's disease in the USA. A Track One application receives prioritized and accelerated examination of the patent case, potentially allowing faster allowance of the claims.
- (ii) In April 2014, Prana received Notice of Grant from the Israeli Patent Office for its key patent protecting PBT434. The patent, which is entitled, 'Neurologically Active Derivatives' covers the composition of matter of selected quinazolinone compounds, including PBT434. This case also included additional granted claims to the use of the compounds for the treatment of neurodegenerative diseases. Prana has validated the European patent in 16 major jurisdictions.
- (iii) In May 2014, Prana received Notice of Grant from the Canadian Patent Office for its key patent protecting PBT519 and related pyridopyrimidine compounds in composition of matter claims. Prana has validated the European patent in 16 major jurisdictions.
- (iv) Over the course of 2014, Prana received Grant notices from each of the Canadian, Australian, Chinese, European and Japanese Patent Offices for the patent protecting methods of treatment of glioma brain tumours with PBT519 and related pyridopyrimidine compounds. This case is entitled 'Use of pyridopyrimidine compounds in the treatment of gliomas'

#### Patent prosecution update

The national phase patent family entitled 'Quinazolinone compounds', which covers selected novel chemical drug candidates related to PBT434 and their uses for neurological conditions, particularly Parkinson's disease, continues to be in prosecution in Australia, Europe, Japan and the United States.

The patent family of cases filed with co-applicant The General Hospital Corporation and entitled 'Neurotoxic Oligomers' has also progressed in major jurisdictions. Prana received a Notice of Grant from the Canadian patent office during March 2013 for both active and passive immunotherapy treatment claims. All patents within this family have now been granted.

The patent family cases entitled 'Compounds for Therapy and Diagnosis' continues to be prosecuted in Canada and Europe. Prana received a notice of Grant from the Japanese patent office in June 2014. 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.

An Australian provisional patent application entitled 'Processes for the preparation of an 8-Hydroxyquinoline derivative' has been re-filed in January 2014 to cover alternative synthetic routes to selected 8-Hydroxyquinolines.

The following table presents our portfolio of patent and patents applications, including their status and a brief description of the respective inventions.

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

Patent	Status	Invention
"Neurologically- Active Compounds"	Patents have been granted in Singapore, Japan, Mexico, Russia, Australia, the USA, China, Canada, Europe, India, Sth Korea,	The invention is directed to 'F4' MPAC chemical structures and their utility in the treatment of neurological conditions and
Filed: April 1, 2005	Israel, New Zealand and South Africa. An application in Brazil is under examination. A patent in Hong Kong has been registered.	includes Parkinson's disease lead compounds.
Applicant: Prana Biotechnology Limited		
"Use of Clioquinol for the treatment of Alzheimer's Disease"	A Patent has been granted in the USA.	This invention is directed to the use of clioquinol for the treatment of Alzheimer's disease.
Filed: February 13, 1998		
Applicant: Prana Biotechnology Limited		
"Pharmaceutical compositions of Clioquinol with B12 for therapeutic use"	A patent has been granted in the USA.	This invention is directed to clioquinol pharmaceutical compositions comprising B12.
Filed: February 13, 1998		
Applicant: Prana Biotechnology Limited.		
"Use of Clioquinol for the treatment of Parkinson's Disease"	A patent has been granted in the USA.	This invention is directed to the use of clioquinol for the treatment of Parkinson's Disease.
Filed: February 13, 1998		
Applicant: Prana Biotechnology Limited.		

Patent	Status	Invention		
"Method of treatment and prophylaxis and agents useful for same" Filed: April 13, 2007 Applicant: Prana Biotechnology Limited	Patents have been granted in Australia, Singapore, South Africa, Canada, Europe, Japan, China and New Zealand. Applications are under examination in Israel, the USA, India and Brazil. Patents only directed to F4 type chemical structures have been allowed to lapse.			
"A method of prophylaxis or treatment and agents for same." Filed: June 22, 2007 Applicant: Prana Biotechnology Limited	A patent has been granted in the USA, China, Australia, Canada, Europe and Japan.	This invention is directed to novel MPAC compounds and compounds for treating certain brain cancers.		
"Compounds for therapy and diagnosis" Filed: December 5, 2008 Applicant: Prana Biotechnology Limited		This invention is directed to anti-amyloid angular metallocomplex compounds for the treatment of Alzheimer's disease.		
"Processes for the preparation of 8-Hydroxy quinoline Derivatives" Filed: 4 January 2013 Applicant: Prana Biotechnology Limited	An Australian provisional application has been refiled.	This invention is directed to synthetic routes for 8- Hydroxyquinoline Derivatives.		
"Quinazolinone compounds" Filed: 24 December 2008 Applicant: Prana Biotechnology Limited	88-F	This invention is directed to novel MPAC compounds and to selected MPAC's used in the treatment of Parkinson's disease.		
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On February 8, 2000, we entered into a patent assignment and intellectual property licensing agreement with The Biomolecular Research Institute, or BRI, under which two patent applications were assigned to us. One is an international patent application (PCT application) entitled 'Beta-Amyloid Peptide Inhibitors' which is granted in Australia, Canada and in the United States and in prosecution in Europe and Japan. The invention is directed to compounds which block the metal binding site on Beta-Amyloid. The technologies or products that may arise from this invention include metallo-based compounds as therapeutics or preventative treatments for Alzheimer's disease. The other patent entitled 'Method of Screening for inhibitors of Alzheimer's Disease,' an Australian provisional application that matured into a patent application in the United States, was allowed to lapse in the second half of 2009. In consideration of the assignment of the patents, we are required to pay BRI a royalty of 1.5% on the net invoiced price of products sold utilizing such patents. In addition, we must also pay the lesser of 1.5% of the net invoice price of products sold or 10% of royalties received from any licensee or sub-licensee we appoint to utilize such patents, or a minimum of A\$2,000 a year. If the patent rights are assigned before a total of A\$20,000 has been paid as royalties, the difference between the royalties paid and A\$20,000 must be paid to BRI. To date, we paid a total of \$350,000 under the agreement, all of which amount was paid in 2000. On September 10, 2007, we, BRI and the Commonwealth Scientific and Industrial Research Organization, or CSIRO, executed an Assignment and Novation Deed under which BRI assigned to CSIRO all of its rights and obligations under the patent assignment agreement, including entitlement to royalties.

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 United States. 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 albo 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 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. The patent'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 Unite

# 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 have much more experience than we do in pre-clinical testing and human clinical trials of new or improved drugs, as well as in obtaining FDA, TGA and other regulatory approvals.

#### **Regulatory Considerations**

Our ongoing research and development activities are, and the production and marketing of our pharmaceutical product candidates derived 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 EMEA. Prior to marketing, any therapeutic product developed must undergo rigorous pre-clinical testing and clinical trials, as well as an extensive regulatory approval process mandated by the TGA and, to the extent that any of our pharmaceutical products under development are marketed abroad, by foreign regulatory agencies, including the FDA.

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 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, EMEA, 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, is manufactured by Dr. Reddy's, based in Hyderabad, India. At this time, we are relying on this manufacturer to enable future and efficient large scale manufacture of PBT2 to provide drug substance for the current and prospective trials in Alzheimer's patients and Huntington's patients. However, we are investigating other manufacturers as a 'back-up' suppliers to the campaigns at Dr. Reddy's and to facilitate manufacture of pre-registration GMP compound. At this time, we also rely on a sole manufacturer, Patheon, to encapsulate PBT2. We intend to continue this approach, subject to ongoing appraisal of our manufacturing needs and financial position.

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 pre-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 pocification, 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 cannot guarantee that it will be possible to scale up new synthetic processes 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, both of which are currently inactive.

# 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 October 31, 2014, has an annual rent of A\$140,994. We have the option to renew the lease for an additional five year term.

# 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 ADRs 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 of America, 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 stage in the development of our pharmaceutical products that are designed to treat the underlying causes of degeneration of the brain as aging progresses. We have incurred net losses since inception and expect to incur substantial and increasing losses for the next several years as we expand our research and development activities and move our product candidates into later stages of development. All of our product candidates are in early stages of development and we face the risks of failure inherent in developing drugs based on new technologies. The process of carrying out the development of our products to later stages of development may require significant additional research and development expenditures, including pre-clinical testing and clinical trials, as well as for obtaining regulatory approval. To date, we have funded our operations primarily through the sale of equipt 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. In early August 2003, our PBT2 compound was announced as a new lead MPAC molecule for Alzheimer's disease. We have completed two 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 imaging trial in Alzheimer's disease and the "Reach2HD" Phase IIa trial in Huntington's 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 unvested 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.

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.

## 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.



Corporate personnel expenses. Our personnel expenses consist of directors' fees, salaries and benefits paid to employees and officers and equity-based payments awarded to directors, officers and employees.

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.

Auditor and accounting expenses. Our auditor and accounting expenses consist of the 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.

Travel expenses. Our travel expenses consist primarily of expenses associated with air travel, accommodation and associated consumables both locally and overseas by directors, employees and consultants.

Public relations and marketing expenses. Our public relations and marketing expenses consist of fees paid to outside consultants for services related to ASX and NASDAQ announcements and presentations.

Depreciation expense. Depreciation of property and equipment is provided on a straight-line basis over the estimated useful lives of three to 20 years.

•	Furniture and fittings:	5-33%
٠	Computer equipment:	33%
•	Laboratory equipment:	10-33%
٠	Leasehold improvements:	33%

Other expenses. Other expenses consist of corporate compliance, insurance, computer and overhead expenses.

Foreign exchange gain (loss). Foreign exchange gain (loss) includes 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.

Gain (loss) on fair value of financial liabilities. Each reporting period we are required to revalue financial liabilities. We recorded financial liabilities attributable to warrants that were issued to the investors in our private placement in the United States in June 2004 and with respect to options issued in a private placement to investors in February 2011. The warrants which were issued in 2004 expired on June 4, 2009, permitted the investors to purchase an aggregate 3,000,000 ADRs at an exercise price of US\$8.00 per ADR. Because the warrants were exercisable in a currency that is not the functional currency of our company, they were required to be classified as a financial liability. These warrants expired without being exercised. The 2011 options, which expire on February 25, 2016, permit the investors to purchase an aggregate 612,397 ordinary shares at an exercise price of A\$0.17 per share. When the fair value of the outstanding 2011 options increase or decrease, the difference is recorded as a gain or loss, as applicable, on the fair value of financial liabilities.

# **Results of Operations**

# Year ended June 30, 2014 compared to year ended June 30, 2013

#### Revenue from ordinary activities

Revenue from continuing operations (consisting of interest income only) increased to A\$363,775 for the year ended June 30, 2014 from A\$150,867 for the year ended June 30, 2013, an increase of A\$212,908, or 141.12%. The increase in revenue from continuing operations in the 2014 fiscal year is primarily attributable to higher cash and cash equivalents held throughout the year.



# Other Income

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. We had other income of A\$4,488,526 for the year ended June 30, 2013 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.

### Research and development expenses

Our research and development expenses (including research and development expenses paid to related parties) increased to A\$14,908,098 for the year ended June 30, 2014 from A\$8,203,822 for the year ended June 30, 2013, an increase of A\$6,704,276, or 81.72%. The increase in research and development expenses in the year ended June 30, 2014 is primarily attributable to remaining expenditure for the conduct of the 'Reach2HD' Huntington's 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.

### Corporate personnel expenses

Corporate personnel expenses decreased to A\$2,059,642 for the year ended June 30, 2014 from A\$2,298,426 for the year ended June 30, 2013, a decrease of A\$238,784, or 10.39%. The decrease in corporate personnel expenses in the 2014 fiscal year is primarily attributable to a decrease in equity-based compensation in the form of options and shares issued to directors, employees and consultants. In the 2014 fiscal year, we expensed A\$472,463 in respect of equity-based payments to directors, consultants and employees compared to A\$819,085 in the 2013 fiscal year.

#### Intellectual property expenses

Intellectual property expenses, which include patent portfolio costs and intellectual property related legal costs, increased to A\$477,079 for the year ended June 30, 2014 from A\$294,894 for the year ended June 30, 2013, an increase of A\$182,185, or 61.78%. The increase in intellectual property expenses in the 2014 fiscal year was primarily the result of the maturing patent portfolio into the granted phase giving rise to indexed annual renewal fees for these granted patents.

#### Auditor and accounting expenses

Auditor and accounting expenses increased to A\$342,609 for the year ended June 30, 2014 from A\$166,086 for the year ended June 30, 2013, an increase of A\$176,523, or 106.28%. The increase in auditor and accounting expenses in the 2014 fiscal year is primarily attributable to increased costs for services provided in connection with filings made with the Securities and Exchange Commission and compliance with section 404 of the Sarbanes Oxley Act of 2002 (SOX 404) regulations.

# Travel expenses

Travel expenses increased to A\$421,013 for the year ended June 30, 2014 from A\$131,710 for the year ended June 30, 2013, an increase of A\$289,303, or 219.65%. The increase in travel expenses in the 2014 fiscal year is primarily attributable to a higher amount of overseas travel by executives and consultants for company business meetings and travel to overseas manufacturing, non-clinical and clinical study sites.

#### Public relations and marketing expenses

Public relations and marketing expenses increased to A\$358,597 for the year ended June 30, 2014 from A\$136,186 for the year ended June 30, 2013, an increase of A\$222,411 or 163.31%. Our public relations and marketing expenses consist primarily of costs relating to our U.S.-based investor relations consultants. The increase in public relations and marketing expenses in the 2014 fiscal year is primarily attributable to increased communications regarding our active clinical trial programs and investment opportunities.



## Depreciation expenses

Depreciation expenses decreased to A\$22,384 for the year ended June 30, 2014 from A\$23,130 for the year ended June 30, 2013, a decrease of A\$746 or 3.23%.

#### Other expenses

Other expenses from ordinary activities increased to A\$2,142,179 for the year ended June 30, 2014 from A\$1,169,407 for the year ended June 30, 2013, an increase of A\$972,772, or 83.19%. The increase in other expenses in the 2014 fiscal year is primarily attributable to an increase in business development expenses associated with the appointment of business development personnel into our company.

#### Foreign exchange gain (loss)

We recorded a foreign exchange loss of A\$746,593 for the year ended June 30, 2014 compared to a foreign exchange gain of A\$140,761 for the year ended June 30, 2013. Foreign exchange gain (loss) reflects the impact of changes in foreign currency exchange rates on cash that we hold in U.S. dollars, Great British Pounds and Euros. 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 2013 fiscal year, 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 two fiscal years ended June 30, 2014, the Australian dollar depreciated against the Great British Pounds and Euros, which had a favorable impact on the Australian dollar value of our cash held in Great British Pounds and Euros, which had a favorable impact on the Australian dollar value of our cash held in Great British Pounds and Euros, which had a favorable impact on the Australian dollar value of our cash held in Great British Pounds and Euros, and 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\$165,330 attributable to foreign currency transactions. In the 2013 fiscal year, we incurred a foreign exchange gain of A\$102,280 attributable to the cash balances that we held in U.S. dollars, a foreign exchange gain of A\$159 attributable to the cash balances that we held in U.S. dollars, a foreign exchange gain of A\$33,097 attributable to foreign currency transactions.

# Gain (loss) on fair value of financial liabilities

We recorded a loss on fair value of financial liabilities of A\$30,238 for the year ended June 30, 2014 compared to a loss on fair value of financial liabilities of A\$126,059 for the year ended June 30, 2013. The loss in both 2014 and 2013 is attributable to the change in value of warrants that were issued in connection with an agreement signed with the ADDF. The loss on fair value of financial liabilities is also attributable to the changes in the market price of our ADRs and the volatility of the ADR market price.

## Year ended June 30, 2013 compared to year ended June 30, 2012

#### Revenue from ordinary activities

Revenue from continuing operations (consisting of interest income only) decreased to A\$150,867 for the year ended June 30, 2013 from A\$186,664 for the year ended June 30, 2012, a decrease of A\$35,797, or 19.18%. The decrease in revenue from continuing operations in the 2013 fiscal year is primarily attributable to interest on an R&D tax refund we received in the previous financial year from the Australian Taxation Office, relating to the 2010 financial year.

# Other Income

We had other income of A\$4,488,526 for the year ended June 30, 2013 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\$2,340,851 for the year ended June 30, 2012 relating to eligible research and development activities.

#### Research and development expenses

Our research and development expenses (including research and development expenses paid to related parties) increased to A\$8,203,822 for the year ended June 30, 2013 from A\$4,252,002 for the year ended June 30, 2012, an increase of A\$3,951,820, or 92.94%. The increase in research and development expenses in the year ended June 30, 2013 is primarily attributable to the initiation of patient enrolment into the Phase II "Reach2HD" Huntington's Disease clinical trial in April 2012 with full recruitment achieved by the end of the 2012 calendar year. Accordingly, during the year ending June 30, 2013 Prana incurred substantial patient fees, clinical research organisation milestones and associated running costs of a fully recruited trial. In addition, during the year ending June 30, 2013 recruitment for the Phase II Alzheimer's' Disease "IMAGINE" trial was completed and similarly Prana incurred increasing patient, clinical research organisation and running costs.

# Corporate personnel expenses

Corporate personnel expenses increased to A\$2,298,426 for the year ended June 30, 2013 from A\$1,835,279 for the year ended June 30, 2012, an increase of A\$463,147, or 25.24%. The increase in corporate personnel expenses in the 2013 fiscal year is primarily attributable to an increase in equity-based compensation in the form of options and shares issued to directors, employees and consultants. In the 2013 fiscal year, we expensed A\$819,085 in respect of equity-based payments to directors, consultants and employees compared to A\$120,191 in the 2012 fiscal year.

## Intellectual property expenses

Intellectual property expenses, which include patent portfolio costs and intellectual property related legal costs, increased to A\$294,894 for the year ended June 30, 2013 from A\$261,706 for the year ended June 30, 2012, an increase of A\$33,188, or 12.68%. The increase in intellectual property expenses in the 2013 fiscal year was primarily due to the completion of substantial prosecution of a key international patent application.

#### Auditor and accounting expenses

Auditor and accounting expenses increased to A\$166,086 for the year ended June 30, 2013 from A\$153,597 for the year ended June 30, 2012, an increase of A\$12,489, or 8.13%. The increase in auditor and accounting expenses in the 2013 fiscal year is primarily attributable to increased costs for services provided in connection with filings made with the Securities and Exchange Commission.

#### Travel expenses

Travel expenses increased to A\$131,710 for the year ended June 30, 2013 from A\$91,624 for the year ended June 30, 2012, an increase of A\$40,086, or 43.75%. The increase in travel expenses in the 2013 fiscal year is primarily attributable to a higher amount of overseas travel by executives and consultants for company business meetings.

#### Public relations and marketing expenses

Public relations and marketing expenses increased to A\$136,186 for the year ended June 30, 2013 from A\$124,970 for the year ended June 30, 2012, an increase of A\$11,216 or 8.97%. Our public relations and marketing expenses consist primarily of costs relating to our U.S.-based investor relations consultants. The increase in public relations and marketing expenses in the 2013 fiscal year is primarily attributable to increased announcements relating to the successful progression of PBT2 into two clinical trials. The increase in public relations and marketing expenses was also attributable to the depreciation of the Australian dollar against the U.S. dollar during the twelve months ended June 30, 2013, which increased the Australian dollar cost of such U.S. dollar denominated expenses.

# Depreciation expenses

Depreciation expenses increased to A\$23,130 for the year ended June 30, 2013 from A\$19,621 for the year ended June 30, 2012, an increase of A\$3,509 or 17.88%. The increase in depreciation expenses in the 2013 fiscal year is primarily attributable to additional computer equipment and furniture and fittings in the aggregate amount of A\$21,972 was purchased during the 2013 fiscal year.

### Other expenses

Other expenses from ordinary activities increased to A\$1,187,083 for the year ended June 30, 2013 from A\$1,107,283 for the year ended June 30, 2012, an increase of A\$79,800, or 7.21%. The increase in other expenses in the 2013 fiscal year is primarily attributable to an increase in business development expenses associated with the commercial assessment for PBT2 for Huntington's Disease.

# Foreign exchange gain (loss)

We recorded a foreign exchange gain of A\$140,761 for the year ended June 30, 2013 compared to a foreign exchange gain of A\$45,959 for the year ended June 30, 2012. Foreign exchange gain (loss) reflects the impact of changes in foreign currency exchange rates on cash that we hold in U.S. dollars, Great British Pounds and Euros. In the 2013 fiscal year, 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 2012 fiscal year, 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 2012 fiscal year, the Australian dollar depreciated against the Great British Pounds and Euros, which had a favorable impact on the Australian dollar value of our cash held in Great British Pounds and Euros. In the 2013 fiscal year, we incurred a foreign exchange gain of A\$102,280 attributable to the cash balances that we held in U.S. dollars, a foreign exchange gain of A\$102,280 attributable to cash balances that were held in Euros and a foreign exchange gain of A\$33,097 attributable to foreign currency transactions. In the 2012 fiscal year, we incurred a foreign exchange gain of A\$27,059 attributable to the cash balances that were held in U.S. dollars, a foreign exchange gain of A\$207 attributable to the cash balances that were held in U.S. dollars, a foreign exchange gain of A\$207 attributable to foreign currency transactions. In the 2012 fiscal year, we incurred a foreign exchange loss of A\$23,396 attributable to cash balances that were held in Euros and a foreign exchange gain of A\$2,911 attributable to foreign currency transactions.

# Gain (loss) on fair value of financial liabilities

We recorded a loss on fair value of financial liabilities of A\$126,059 for the year ended June 30, 2013 compared to a gain on fair value of financial liabilities of A\$33,139 for the year ended June 30, 2012. The loss in 2013 and gain in 2012 are attributable to the change in value of warrants that were issued in connection with an agreement signed with the ADDF. We issued warrants to purchase 612,397 of our ordinary shares to the ADDF, representing 30% of the value of the first tranche of a grant of US\$350,000 received from the ADDF during the fiscal year ended June 30, 2011. The warrants have an exercise price of A\$0.17 and expire on February 25, 2016. The gain and loss on fair value of financial liabilities is also attributable to the changes in the market price of our ADRs and the volatility of the ADR market price.

#### 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, 2014 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, 2014 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

Pronouncement	Title (Issue date)	Effective date			
Annual Improvements to IFRSs 2012-2014 Cycle	International Financial Reporting Standards (September 2014)	Annual periods beginning on or after January 1, 2016 Earlier application is permitted.			
Annual Improvements to IFRSs 2012-2014 Cycle	International Financial Reporting Standards (September 2014)	Annual periods beginning on or after January 1, 2016 Earlier application is permitted.			
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (September 2014)(2)	Annual periods beginning on or after January 1, 2016. Earlier application is permitted.			
Amendments to IAS 27	Equity Method in Separate Financial Statements (August 2014) (2)	Annual periods beginning on or after January 1, 2016. Earlier application is permitted.			
IFRS 9	Financial Instruments (July 2014)	Annual periods beginning on or after January 1, 2018. Earlier application is permitted.			
Amendments to IAS 16 and IAS 41	Agriculture: Bearer Plants (June 2014) (2)	Annual periods beginning on or after January 1, 2016. Earlier application is permitted			
IFRS 15	Revenue from Contracts with Customers (May 2014)	Annual periods beginning on or after January 1, 2017. Earlier application is permitted.			
Amendments to IAS 16 and IAS 38	Clarification of Acceptable Methods of Depreciation and Amortisation (May 2014)	Annual periods beginning on or after January 1, 2016. Earlier application is permitted.			

Pronouncement	Title (Issue date)	Effective date
Amendments to IFRS 11	Accounting for Acquisitions of Interests in Joint Operations (May 2014)	Annual periods beginning on or after January 1, 2016. Earlier application is permitted.
IFRS 14	Regulatory Deferral Accounts (January 2014)	Annual periods beginning on or after January 1, 2016. Earlier application is permitted.
Annual Improvements to IFRSs 2011–2013 Cycle	International Financial Reporting Standards (December 2013) (2)	Annual periods beginning on or after July 1, 2014. Earlier application is permitted.
Annual Improvements to IFRSs 2010–2012 Cycle	International Financial Reporting Standards (December 2013)	Annual periods beginning on or after July 1, 2014. Earlier application is permitted.
Amendments to IAS 19	Defined Benefit Plans: Employee Contributions (November 2013) (2)	Annual periods beginning on or after July 1, 2014. Earlier application is permitted.
Amendments to IFRS 9, IFRS 7, and IAS 39	IFRS 9 Financial Instruments – Hedge Accounting and amendments to IFRS 9, IFRS 7, and IAS 39 (November 2013)	The amendments to IFRS 9 have removed the previous mandatory effective date of January 1, 2015, but the standard is available for immediate application. The standard provides an accounting policy choice for an entity to continue to apply hedge accounting (and hedge accounting only) under IAS 39 instead of IFRS 9 until the IASB completes its separate macro hedging project. The European Union has not yet endorsed any aspects of IFRS 9, and therefore the new guidance may not be adopted by entities subject to regulation by the European Union.
Amendments to IAS 39	Novation of Derivatives and Continuation of Hedge Accounting (June 2013)	Annual periods beginning on or after January 1, 2014. Earlier application is permitted.
Amendments to IAS 36	Recoverable Amount Disclosures for Non-Financial Assets (May 2013)	Annual periods beginning on or after January 1, 2014. Earlier application is permitted.
Amendments to IFRS 10, IFRS 12 and IAS 27	Investment Entities (October 2012)	Annual periods beginning on or after January 1, 2014. Earlier application is permitted.
Amendments to IAS 32 Amendments to IFRS 9 and 7	Offsetting Financial Assets and Financial Liabilities (December 2011) Mandatory Effective Date and Transition Disclosures (December 2011)	Annual periods beginning on or after January 1, 2014. January 1, 2013 to January 1, 2015 (TBD).
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# B. LIQUIDITY AND CAPITAL RESOURCES

We are a development stage company and have had no sales income to date, and as of June 30, 2014 our accumulated deficit totaled A\$111,260,562. 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 (approximately A\$5.7 million net of costs) in a private placement to one of our institutional shareholders in the United States of 30 million ordinary shares (equivalent to three million ADRs) at a price of A\$0.20 per share (A\$2.0 per ADR). We also agreed to grant the investor, subject to shareholder approval, options to purchase 10 million ordinary shares (equivalent to one million ADRs) at an exercise price of A\$0.30 per share (A\$3.0 per ADR) that will 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 0.7 million ADRs) to Quintiles, at a price of A\$0.1624 per ordinary share (US\$1.624 per ADR). 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 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 have also agreed to issue an additional five-year warrant to purchase US\$105,000 of ordinary shares of our company at a price per share equal to the closing price of our ordinary shares on the ASX on the date on or dinary shares on the ASX on the date on the second instalment of US\$350,000. The note was due and payable on February 25, 2014. As at June 30, 2014 both instalments totalling US\$700,000 received in prior reporting periods were repaid in full. We may, under certain conditions, elect to issue our ordinary shares to satisfy our repayment obligation at a price per shares equal to 80% of the then prevailing volume weighted average price of our ordinary shares of our company following the consumation by us of a debt or equity financing to third party investors resulting in gross proceeds to our company of at least US\$1.0 million, or upon a sale of our company. Following the completion of the private placement described in the following paragraph, the ADDF is now entitled to convert the note under the same terms as such private placement, or under the same terms as any subsequent financing that we may complete prior to the conversion or repayment of the note. The purpose of the grants is 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.

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 2,720,000 ADRs) at a price of A\$0.225 per share (A\$2.25 per ADR). We also granted to the investors options to purchase up to an aggregate of approximately 6.8 million ordinary shares (equivalent to 680,000 ADRs) at an exercise price of A\$0.225 per share (A\$2.25 per ADR). 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 process 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 will expire 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 ten ordinary shares, from time to time through MLV, as our agent for the offer and sale of the ADSs. During such time as we do not qualify as an accelerated filer, as defined by the SEC, the aggregate ordinary shares represented by ADSs which we may sell in any one year period may not exceed one-third of our public float. The ADSs are evidenced by ADRs. We 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. The actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. As of June 30, 2014, we issued a total amount of 3.7 million ADSs under this At-The-Market Issuance Sales Agreement for gross proceeds of A\$7.0 million (US\$7.25 million). For additional information regarding the agreement, see Item 10.C. "Additional Information - Material Contracts."

Commencing October 2011, we entered into research and development agreements that support and service the Phase II clinical trials in Huntington's disease and Alzheimer's disease that are currently enrolling patients. We have budgeted expenditures of approximately AS8.7 million for the Huntington's disease trial and A\$0.9 million for the Alzheimer's disease trial, which is otherwise supported by a grant from the ADDF. Of these amounts, approximately A\$973,513 has been incurred in the period ended June 30, 2014. The agreements can be terminated at any time with 30 days' notice and without penalty. The successful completion of these trials is dependent on raising the necessary additional funding. See Item 5.F. "Tabular Disclosure of Contractual Obligations" for additional information on our R&D contractual commitments.

In October 2012, we raised approximately A\$6.0 million through a private placement of 32.5 million ordinary fully paid shares (equivalent to 3.25 million ADRs) at a price of A\$0.185 per 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 of our 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 any 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.

In August 2013, we issued a prospectus providing for the sale of up to US\$47,184,000 of our ordinary shares under an amended At-The-Market Issuance Sales Agreement with MLV dated August 30, 2013.

From inception to June 30, 2014, our capital expenditures have totaled A\$598,742 (including A\$200,000 of non-cash expenditures), 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, 2014 of A\$47,557. 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\$34,167,018 of cash and cash equivalents at June 30, 2014, compared to A\$13,346,760 at June 30, 2013. For the years ended June 30, 2014 and 2013, we incurred an operating loss of A\$13.3 million and A\$7.8 million, respectively, and an operating cash outflow of A\$13.8 million and A\$8.0 million, respectively.

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 offset. In the year ended June 30, 2014, we recorded A\$7.2 million in other income with respect to funds we will receive in relation to the 2014 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, 2014. 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:

	Yea	Year ended June 30,			
	2014	2013	2012		
		(A\$)			
Net cash used in operating activities	(13,536,223)	(7,951,254)	(6,845,906)		
Net cash used in investing activities	(23,048)	(28,151)	(26,763)		
Net cash provided by financing activities	34,960,792	15,582,031	3,622,023		
Net increase (decrease) in cash and cash equivalents	21,401,521	7,602,626	(3,250,646)		
Cash and cash equivalents at beginning of period	13,346,760	5,636,469	8,838,245		
Exchange rate adjustments on cash held in foreign currencies	(581,263)	107,665	48,870		
Cash and cash equivalents at end of period	34,167,018	13,346,760	5,636,469		

Net cash used in operating activities was A\$13,536,223, A\$7,951,254 and A\$6,845,906 during the years ended June 30, 2014, 2013 and 2012, respectively. Our payments to suppliers and employees during the years ended June 30, 2014, 2013 and 2012 were A\$18,011,310, A\$10,650,823 and A\$7,874,010, respectively. Our operating activity receipts for the years ended June 30, 2014, 2013 and 2012 of A\$4,475,087, A\$2,699,569 and A\$1,028,104 consisted of R&D tax refunds, interest and grants. The A\$7,360,487 increase in payments to suppliers and employees for the year ended June 30, 2014 when compared to the year ended June 30, 2013 reflects expenditure to complete the 'Reach2HD' Huntington's 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. The A\$1,105,348 increase in payments to suppliers and employees for the year ended June 30, 2013 when compared the year ended June 30, 2012 reflects our continued maintenance of our research and development programs. During the years ended June 30, 2014, 2013 and 2012, our payments to suppliers and employees was offset by interest income of A\$377,587, A\$93,789 and A\$186,794, respectively.

Net cash used in investing activities was A\$23,048, A\$28,151 and A\$26,763 during the years ended June 30, 2014, 2013 and 2012, respectively. Cash flows used for investing activities was primarily attributable to payments for the purchase of property and equipment for the years ended June 30, 2014, 2013 and 2012.

Net cash provided by financing activities was A\$34,960,792, A\$15,582,031 and A\$3,622,023 for the years ended June 30, 2014, 2013 and 2012. Cash flows provided by financing activities during the year ended June 30, 2014 is primarily attributable to funds raised under our At-The-Market facility of A\$32,37 million (US\$29.74 million). Cash flows provided by financing activities during the year ended June 30, 2013 are attributable to funds raised under our At-The-Market facility of A\$3.21 million (US\$2.97 million) and A\$6.01 and A\$5.00 million private placements of our securities to high net worth and institutional investors in September 2012 and March 2013. We also raised A\$2.02 million in April 2013 through a share purchase plan of our securities and grants awarded to us by the ADDF. Cash flows provided by financing activities during the year ended June 30, 2012 is primarily attributable to funds raised under our At-The-Market facility of A\$4.57 million (US\$4.74 million).

We realized a foreign exchange loss of A\$581,263 for the year ended June 30, 2014 compared to a foreign exchange gain of A\$107,665 for the year ended June 30, 2013 and a foreign exchange loss of A\$48,870 for the year ended June 30, 2012. In 2014, the Australian dollar appreciated against the U.S. dollar by 3%. In 2013, the Australian dollar depreciated against the U.S. dollar by 10%, while in 2012, the Australian dollar depreciated against the U.S. dollar by 4%.

# C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES

Early in our company's history, our activities were primarily focused on the acquisition and development of patents to enable the research and development of our core technology. In January 2001, we entered into an exclusive license agreement with the General Hospital Corporation to access patented technologies that could be of assistance in the discovery and characterization of lead compounds (see Item 4.B. "Information on the Company - Business Overview - Patents and License Agreements"). To build a cost effective research and development company, in December 2000 we entered into an agreement with the University of Melbourne to conduct on our behalf certain research programs in Alzheimer's disease and other neurological disorders, to undertake basic mechanistic research on our compounds and conduct screens to assess therapeutic utility of our compounds (see Item 10.C. "Additional Information - Material Contracts"). In recent years, we increased 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's disease, Parkinson's disease and 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 indications, 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 pre-clinical and clinical development and manufacturing activities. Typically, we engage a clinical research organization to manage patient recruitment, data management, clinical site coordination and statistical analysis, as was the case with the development of our lead compound PBT2 through Phase I and currently the case with Phase II development. All clinical, pre-clinical development and manufacturing of our compounds is performed in compliance with the appropriate governing authorities and standards (for example, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use).

Research and development expenses, net amounted to A\$14,908,098, A\$8,203,822 and A\$4,252,002 during the years ended June 30, 2014, 2013 and 2012, respectively. Costs associated with patent applications and defense of patent applications are classified as intellectual property expenses and amounted to A\$477,079, A\$294,894 and A\$261,706 during the years ended June 30, 2014, 2013 and 2012, 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. We do not maintain accounting systems to accurately track research and development costs on an individual project basis because a significant portion of our historic research and development expenses benefited our two major research and development projects, and therefore were not tracked individually by project; rather, we tracked these costs by the type of costs incurred. Such costs are charged to operations as incurred. 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 complete our activities 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 candidate, PBT2.

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 recent financial crisis and the increased burden of healthcare costs 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. Furthermore, while falling drug prices in the mature drug markets such as the U.S. and the EU are having a negative impact on general sales growth levels for the biopharmaceutical industry as a whole in those markets, we expect such sales growth to continue at higher levels in emerging markets. 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.

## 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, 2014. The majority of our contracts for research and development programs have a termination notice period of 30 days. As at June 30, 2014, we had research and development termination commitments approximating A\$2.35 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		Pay	ments due by period	y period				
	Total	less than 1 year	1-3 years	3-5 Years	more than 5 years			
Operating lease obligations	63,189	60,021	3,168	-	-			
Total	63,189	60,021	3,168	-	-			

# 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	59	Chairman of the Board of Directors and Chief Executive Officer
Richard Revelins	52	Chief Financial Officer and Secretary
Phillip A. Hains	55	Acting Chief Financial Officer
Dianne M. Angus	54	Chief Operating Officer
Peter A. Marks(1)	58	Director
Brian D. Meltzer(1)(2)(3)	61	Director
George W. Mihaly(1)(2)(3)	61	Director
Lawrence B. Gozlan(3)	35	Director
Ira Shoulson	68	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. Richard Revelins has served as our Company Secretary since February 2000 and was appointed Chief Financial Officer of our company in June 2004. Mr. Revelins is an executive director and principal of Peregrine Corporate Limited, an Australian-based investment bank, and Managing Director at Cappello Group Inc., a Santa Monica, Los Angeles based investment bank. Mr. Revelins has held senior positions in international merchant banks and is currently a director of Mining Project Group Limited, which is listed on the ASX as well as of a number of private companies. Mr. Revelins holds a Bachelor of Economics degree from Monash University, Melbourne. Mr. Revelins serves as our Chief Financial Officer on a part-time basis and devotes approximately one to two work days a week to such position.

Mr. Phillip Hains was appointed as Acting Chief Financial Officer of our company on May 1, 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 from Monash University, a Graduate Diploma in Intellectual Property Law from Monash University, a Diploma in Intellectual Property Law from Monash University, a Diploma in Intellectual Property Law from Monash University, a 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.

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 Halcyon Corporate Pty Ltd, a corporate and capital markets advisory firm specializing in advising small to mid-cap companies. 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, 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 Eised and unlisted companies on issues ranging from corporate and company structure, to valuation, business strategies, acquisitions and international opportunities. Mr. Marks has also certed as an Associate Director of Edinomics degree, a Bachelor of Law degree and Graduate Diploma in Commercial Law from

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 Deloite. Mr. Gozlan is also a Director of ASX-listed companies Oncosil Medical (ASX:OSL) and Phosphagenics (ASX:POH). 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 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's 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 Food and Drug Administration (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, 2014 with respect to each of our executive officers and directors during the 2014 fiscal year.

	com bon	ries, fees, missions, uses and other	Pension, retirement and other similar benefits
Geoffrey P. Kempler (1)	A\$	477,990	
Richard Revelins	A\$	80,013	
Phillip A. Hains (3)	A\$	50,000	
Dianne M. Angus (2)	A\$	385,447	
Peter A. Marks	A\$	60,000	
Brian D. Meltzer	A\$	85,000	
George W. Mihaly	A\$	75,000	
Lawrence B. Gozlan	A\$	50,000	
Ira Shoulson (4) (5)	A\$	28,625	

(1) Mr. Kempler has elected not to accept an A\$100,000 incentive bonus to which he is entitled until further notice.

(2) During the 2014 fiscal year, Ms. Angus received options to purchase 160,000 ordinary shares, which are exercisable for a price of at least 60% greater than the closing market price on the day before the date of issue, exercisable on or before 3 November 2018, as remuneration for her services.

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

(4) Prof. Ira Shoulson was appointed as a director of our company on May 13, 2014.

(5) Prof. Ira Shoulson provides consulting services to the company 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 \$23,000 was paid to Prof. Ira Shoulson for the period May 13, 2014 to June 30, 2014 in his capacity as a consultant to the 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 nonexecutive directors for their services (payable in cash, ordinary shares or options) is A\$1,250,000.

As of June 30, 2014, our directors and executive officers as a group, then consisting of nine persons, held options to purchase an aggregate 8,817,819 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 8,500,000 ordinary shares are exercisable for A\$0.33 consideration on or before December 13, 2017; and (iii) options to purchase 160,000 ordinary shares are exercisable for A\$0.73 consideration on or before November 3, 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.

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.

# The agreement contains customary confidentiality provisions.

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%. 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 (as defined below). 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. Under Australian law, directors who have reached the age of 72 must stand for re-election annually. Our Board of Directors has the power to appoint any person to be a director, either to fill a vacancy or as an additional director (provided that the total number of directors does not exceed the maximum allowed by law), and any director so appointed may hold office only until the next annual general meeting when he or she shall be eligible for election. Mr. Kempler is our Managing Director. Mr. Brian Meltzer must retire and may stand for re-election at our 2014 annual general meeting of shareholders. Dr. Mihaly must retire and may stand for re-election at our 2015 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 Best Practice Guide, 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 five directors, of which four are non-executive directors within the meaning of the ASX Best Practice Guide, and our audit committee consists of such three non-executive directors. Accordingly, we currently comply with the foregoing recommendations of the ASX Best Practice Guidance.

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. 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 ADR option and employee benefit plans. Additionally, the Remuneration Committee administers our share and ADR 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 ADR 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. Dr. Mihaly and Mr. Meltzer 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 Scientific Advisory Board are as follows:

Dr. Jeffrey Cummings is the Chairman of our Research and Development Advisory Board. Dr. Cummings is the Camille and Larry Ruvo chair for Brain Health of the Neurological Institute of Cleveland Clinic. The Lou Ruvo Center for Brain Health provides clinical care to patients, promotes innovative programs for caregivers, and advances translational research and clinical trials for patients with neurocognitive deficits. Dr. Cummings was formerly the director of the UCLA Alzheimer's Disease Center; the Augustus S. Rose Professor of Neurology at UCLA and the Director of the Deane F. Johnson Center for Neurotherapeutics. Dr. Cummings' interests embrace clinical trials and the development of new treatments for neurodegenerative disorders and other neurological diseases. Dr. Cummings has broad interests in dementing disorders, neuropsychiatry, neurotherapeutics and the interface of neuroscience and society.

Professor Jean-Marc Orgogozo, MD, is the Chair of the Department of Clinical Neurosciences and Professor of Neurology at the University of Bordeaux, France. Professor Orgogozo has extensive experience in neuroepidemiology and clinical trials, particularly in stroke and dementia. Professor Orgogozo's early publications on the amyloid vaccines have helped to shape the field of anti-amyloid therapeutics. Professor Orgogozo's main therapeutic research now is on the prodromal phase of Alzheimer's disease.

Dr. Craig Ritchie is the Clinical Research Fellow (Senior), Old Age Psychiatry at Imperial College, London. In 2011 Dr. Ritchie was appointed Co-Director of the London (Northwest) Comprehensive Local Research Network. Dr. Ritchie is heavily involved, both clinically and academically, in psychiatric disorders of late life, in particular Alzheimer's disease, delirium and schizophrenia. Dr. 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.

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 tortuous 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 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, 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.

At June 30, 2013, we had nine employees. Of such employees, six persons were employed in research and development, two persons in management and administration and one person in operations. All such employees were located in Australia.

At June 30, 2012, we had eight employees. Of such employees, five persons were employed in research and development, two 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.

# E. SHARE OWNERSHIP

# **Beneficial Ownership of Executive Officers and Directors**

The following table sets forth certain information as of October 31, 2014 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:

Norma	Number of Ordinary Shares Beneficially Owned (1)	Percentage of Ownership <sup>(2)</sup>
Name Geoffrey P. Kempler (3)	21,811,000	4.29%
Richard Revelins <sup>(4)</sup> 437437	520,308	4.2970
Phillip A. Hains (5) 437437	211.800	*
Dianne M. Angus <sup>(6)</sup>	1,463,947	*
Peter A. Marks <sup>(7)</sup>	1,043,111	*
Brian D. Meltzer (8)	1,326,666	*
George W. Mihaly <sup>(9)</sup>	1,226,666	*
Lawrence B. Gozlan (10)	1,000,000	*
Ira Shoulson	-	*
All directors and executive officers as a group (9 persons)	28,603,498	5.62%

# 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 508,711,934 ordinary shares issued and outstanding as of October 31, 2014.
- 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 17,811,000 outstanding ordinary shares, 30,000 ordinary shares are held of record by Mr. Kempler, 13,965,000 ordinary shares are held by Baywick Pty Ltd., an Australian corporation owned by Mr. Kempler, 756,000 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, 90,000 ordinary shares are held of record by Mr. Kempler and 2,970,000 ordinary shares are held of record by NRB Developments Pty Ltd., an Australian corporation in which Mr. Kempler holds a 50% interest. Mr. Kempler may be deemed to be the beneficial owner of the ordinary shares held of record by Baywick Pty Ltd., Crystal Triangle Pty Ltd. and NRB Developments Pty Ltd.
- 4. Includes options to purchase 500,000 ordinary shares that are exercisable for A\$0.33 consideration on or before December 13, 2017. The 20,308 outstanding ordinary shares are held of record by Darontack Pty Ltd., an Australian corporation owned by Mr. Revelins.
- 5. The 211,800 outstanding ordinary shares are held of record by Shared Office Services Pty. Ltd., an Australian corporation owned by Mr. Hains.
- 6. 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.
- 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.
- 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 RBC Dexia Pty Ltd., a superannuation fund of Mr. Meltzer.
- 9. 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.

### 10. 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 and la 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 be interctor); 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 500,000 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 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, 2014, 2013 and 2012, and changes during the years ended on those dates, is presented below:

				As of J	une 3	0,		
	20	14		2013			2012	
	Amount		Weighted average exercise price	Amount		Weighted average exercise price	Amount	Weighted average exercise price
Options outstanding at the beginning of the year	17,031,476	\$	0.23	10,147,683	\$	0.27	7,831,311	\$ 0.26
Granted	3,926,490	\$	0.69	10,683,793	\$	0.34	4,158,674	\$ 0.25
Exercised	(4,582,384)	\$	0.11				(341,865)	
Expired				(3,800,000)	\$	0.55		
Forfeited							(1,500,437)	\$ 0.25
Options outstanding at the end of the year	16,375,582	\$	0.41	17,031,476	\$	0.23	10,147,683	\$ 0.27
Options exercisable at the end of the year	16,175,582	\$	0.40	16,010,786	\$	0.28	9,126,993	\$ 0.27
Options that may be granted as of the end of the year	19,629,202			21,135,692			31,819,485	

# ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

# A. MAJOR SHAREHOLDERS

There are no major shareholders as of October 31, 2014, known to us who own beneficially more than 5% of our ordinary shares.

# Significant Changes in the Ownership of Major Shareholders

Mr. Geoffrey Kempler. On April 11, 2013, Mr. Kempler, who previously reported to hold a substantial amount of our ordinary shares, filed with the ASX a Notice of Ceasing to be a Substantial Holder.

Jagen Nominees Pty Ltd. On October 9, 2012, Jagen Nominees Pty Ltd, who previously reported to hold a substantial amount of our ordinary shares, filed with the ASX a Notice of Ceasing to be a Substantial Holder.

BAM Capital. On January 6, 2011, BAM Capital and the other reporting persons filed Amendment No. 7 to their Schedule 13G with the Securities and Exchange Commission indicating that they have ceased to beneficially own 5% or more of our outstanding shares.

Bank of America Corporation. On August 19, 2011, Bank of America Corporation, who previously reported to hold a substantial amount of our ordinary shares, filed with the ASX a Notice of Ceasing to be a Substantial Holder.

Morgan Stanley Australia Securities Limited. On February 14, 2011, Morgan Stanley Australia Securities Limited, who previously reported to hold a substantial amount of our ordinary shares, filed Amendment No. 2 to Schedule 13G with the Securities and Exchange Commission indicating that it has ceased to beneficially own 5% or more of our outstanding shares.

### Major Shareholders Voting Rights

Our major shareholders do not have different voting rights.

# **Record Holders**

As of October 31, 2014, there were 3,667 holders of record of our ordinary shares, of which 20 record holders, holding approximately 1.76% 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 ADRs that are held of record by National Nominees Ltd., which held 68.23% of our ordinary shares as of such date.

# B. RELATED PARTY TRANSACTIONS

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

# C. 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, 2014.

# 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 Ordinar	y Share (A\$)
	High	Low
Fiscal Year Ended June 30,		
2010	0.25	0.12
2011	0.38	0.11
2012	0.22	0.14
2013	0.31	0.14
2014	1.37	0.16
Fiscal Year Ended June 30, 2013:		
First Quarter	0.29	0.14
Second Quarter	0.31	0.20
Third Quarter	0.26	0.19
Fourth Quarter	0.25	0.20
Fiscal Year Ended June 30, 2014:		
First Quarter	0.74	0.24
Second Quarter	0.85	0.38
Third Quarter	1.37	0.62
Fourth Quarter	0.29	0.16
Fiscal Year Ended June 30, 2015:		
First Quarter	0.35	0.22
Second Quarter (through October 30)	0.25	0.20
Month Ended:		
April 2014	0.29	0.18
May 2014	0.23	0.16
June 2014	0.23	0.17
July 2014	0.29	0.23
August 2014	0.25	0.22
September 2014	0.35	0.23
October 2014 (through October 30)	0.25	0.20



# 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:

	Per ADI	R (US\$)
	High	Low
Fiscal Year Ended June 30,		
2010	3.35	1.02
2011	4.50	1.09
2012	2.31	1.40
2013	3.06	1.50
2014	13.29	1.47
Fiscal Year Ended June 30, 2013:		
First Quarter	2.74	1.50
Second Quarter	3.06	1.81
Third Quarter	2.94	2.06
Fourth Quarter	2.45	2.12
Fiscal Year Ended June 30, 2014:		
First Quarter	6.50	2.31
Second Quarter	7.87	3.62
Third Quarter	13.29	2.78
Fourth Quarter	2.71	1.47
Fiscal Year Ended June 30, 2015:	2.04	1.02
First Quarter	2.94	1.93
First Quarter (through October 30)	2.29	1.75
Month Ended:		
April 2014	2.71	1.67
May 2014	2.71	1.67
May 2014 June 2014	2.24	1.66
July 2014	2.38	2.12
August 2014	2.85	2.00
September 2014	2.28	1.93
October 2014 (through October 30)	2.94	1.95
	2.29	1.75

# **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 represents ten of our ordinary shares.

# D. SELLING SHAREHOLDERS

Not applicable.

# E. DILUTION

Not applicable.

# F. EXPENSES OF THE ISSUE

Not applicable.

# ITEM 10. ADDITIONAL INFORMATION

# A. SHARE CAPITAL

Not applicable.

# B. MEMORANDUM AND ARTICLES OF ASSOCIATION

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 Ltd. 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. No dividend may be paid except out of our profits.

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.

#### **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 15% 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 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 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, 2009 and expired on December 1, 2012. The parties entered into a new research funding and intellectual property assignment agreement is deemed to have commenced as of the expiration date of the previous agreement on December 31, 2013. The University of Melbourne subcontracted substantial parts of the research to The Florey Institute of Neuroscience and Mental Health. From Ist January 2014 the parties have agreed to neuro dental the agreement is to be novated to The Florey Institute of Neuroscience and Mental Health.

On January 8, 2004, we entered into a ten year consultancy services agreement with Professor Ashley Bush, effective as of February 1, 2003. This agreement was terminated by Professor Bush effective January 18, 2012. The services are provided for a maximum of 40 days per year of service under the agreement. Under the agreement, we agreed to pay Professor Bush a consulting fee of US\$100,000 per year, which were then reduced to A\$60,000 per year effective June 1, 2009, increasing on the anniversary of the agreement by the Australian consumer price index. We also agreed, as a bonus package, to issue to Professor Bush 1,650,000 ordinary shares and to grant to him options to purchase 825,000 ordinary shares at an exercise price of A\$0.50 per share, all of which has been vested. The ordinary shares issued and options granted to Professor Bush under the agreement are subject to certain resale restrictions. In addition, subject to the achievement of certain milestones, Professor Bush is entitled to purchase up to 5,000,000 additional ordinary shares at a price per share that is 10% below the mean market price of our ordinary shares. During the 30-day period prior to their purchase. In 2007, the first milestone has been achieved (the publication of results of a Phase II trial) and Professor Bush acquired 250,000 ordinary shares. During the period of 20 years after the effective date of the agreement, Professor Bush is also entitled to receive royalties equal to 5% of the income that we derive from the exploitation of new intellectual property developed by him or contributed to our company though his services pursuant to the agreement.

On July 28, 2004, we and The General Hospital Corporation of Massachusetts settled all outstanding litigation with P.N. Gerolymatos S.A., or P.N.G., regarding the exploitation rights to certain patents relating to pharmaceutical compositions and uses of cliquinol, or PBT1. As a result of the settlement agreement, we now hold the rights to selected uses of cliquinol and pharmaceutical compositions in the United States and in Japan, and P.N.G. holds certain patent rights on the uses of cliquinol for Europe and other territories for eight years after the date of this agreement. Under the settlement agreement we also agreed to pay a sales royalty to P.N.G. on sales of PBT1 in the United States and Japan and we are entitled to receive a percentage of P.N.G.'s income on sales of PBT1 in the other territories. In April 2005, we announced our decision not to proceed with the PBT1 study and the royalty obligations in respect of PBT1 expired in 2012. P.N.G. is also entitled to receive 2% of our worldwide income from PBT2 and any other future cliquinol derivative.

On May 22, 2007, we entered into an agreement with Patheon to undertake the capsule formulation development and prospective clinical trial manufacturing of PBT2 into capsules to support prospective further development of PBT2 into a Phase IIb study and/or other secondary clinical applications of PBT2. During the 2008 fiscal year, Patheon undertook the development of a capsule formulation suitable for large scale manufacture, as well as the development and validation of analytical methods to release the capsules. During the 2009 fiscal year, Patheon undertook the development anaufactured a feasibility batch of capsules using the newly developed process. During the 2010 and 2011 fiscal years, Patheon undertook the capsules which are currently being used in the Alzheimer's Phase II trial, "IMAGINE," and the Huntington's Phase IIa trial, "Reach2HD." In fiscal year 2013, Patheon undertook the manufacture of additional capsules which have subsequently been used in the IMAGINE extension trial. In addition, we have engaged Patheon to undertake formulation optimization in preparation for prospective Phase III clinical development. In fiscal year 2014, Patheon has supplied capsules for additional Phase 1 trials on PBT2 and we extended the scope of works with Patheon to include encapsulation of PBT2 for the prospective Phase III. We paid Patheon US\$249,517, US\$220,935, US\$97,629, US\$196,654 and US\$296,551 for the fiscal years 2014, 2013, 2012, 2011 and 2010, respectively, for services provided under the 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. At this time, most of the work is completed, including the large scale manufacture of approximately 50kg of PBT2 API. Ongoing work includes stabilization 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 underway. We paid Dr. Reddy's US\$473,500, US\$14,100, US\$190,500 and US\$685,000 for the fiscal years 2014, 2013, 2012 and 2011, respectively, for services provided under the agreement.

On June 21, 2013, we entered into an Agreement with Bioreliance Corporation based in Rockville, Maryland to commence an initial toxicity study to support the prospective carcinogenicity study in transgenic mice. We paid Bioreliance Corporation US\$220,192 for the fiscal year 2014.

On December 19, 2013, we entered into an Agreement with WIL Research Laboratories LLC based in Ashland, Ohio, to commence a two year carcinogenicity study in the rat. We paid WIL Research Laboratories LLC US\$561,296 for the fiscal year 2014.

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. 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 August 30, 2013, which amount is US\$47,184,000. The ADSs are evidenced by ADRs. We will 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 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, may make it impracticable or inadvisable to market or sell our ADSs or a suspension or gross proceeds of AS39.37 million (US\$36.99 million).

On October 7, 2011, we entered into a Clinical Trial Agreement with the University of Rochester to perform the Phase IIa "Reach2HD" study in patients with Huntington's disease. The scope of works under the agreement includes study preparation, clinical site selection, study establishment, clinical site monitoring, preparation of operations manuals, database design to capture patient data, administer site payments and conduct investigator meetings, safety reporting and day to day study management. Our budget to perform these activities is approximately US\$5,000,000 and is paid in milestones on achievement of their execution, such as opening an IND, receipt of Institutional Review Board approval, initial enrollment, database lock, provisions of results and the clinical study report. In addition, quarterly payments are paid during the enrollment and implementation phases of the trial. Either party may terminate the Agreement on 30 days' notice. We paid the University of Rochester US\$1,340,914 and US\$2,834,289 for the fiscal year ended June 30, 2014 and 2013.

On June 14, 2012 we entered into a Clinical Research Support Agreement with GHC to undertake analysis of biomarkers from biological samples taken from patients and perform neuroimaging on a subset of patients from the "Reach2HD" clinical trial. The budget to perform these activities is \$US303,125. Either party may terminate the Agreement on 30 days' notice for breach of the Agreement. We may terminate the Agreement on 30 days' notice for any reason.

On August 6, 2012 Prana entered into an agreement with INC Research to provide study monitoring and safety management activities for Australian sites participating in the Reach2HD Phase II study for \$280,921 AUD. A change order was agreed to on April 16, 2013 to address the requirement for additional monitoring activities for \$48,505 AUD. During the study, the decision was made to assign the statistical analysis and auditing services to INC which resulted in a separate work order being agreed to and entered into on March 27, 2013 for \$176,064 AUD. A further work order was agreed to on December 10, 2013 following the decision to recollect study data from all sites which resulted in the assignment of further Australia and US monitoring activities, data management services and additional statistical analysis and medical writing services. This resulted in an agreement for \$1,671,890.56 to be paid to INC during the 2014 financial year. Two change orders were respectively agreed to on March 11, 2014 to address a correction in the activities covered in the work order.

Prana entered into an agreement dated April 2, 2012, with INC Research to provide study monitoring, safety management, data management, statistical analysis, and medical writing services for the IMAGINE Phase II study for \$363,588 AUD. A series of change orders have been required, with the first change order being agreed to on June 27, 2012 for additional monitoring services for \$33,388 AUD. The second change order was agreed to on July 29, 2013 and was required following the decision to provide study conduct services for an extension study for eligible patients for \$330,780 AUD. The third change order was for additional data management and statistical analysis activities and was for \$193,291 AUD. The fourth change order was for additional data management and statistical analysis activities and was for \$193,291 AUD. The fourth change order was agreed to on September 8, 2014 and was for \$36,014 AUD.

# 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\$248 million or more. In addition, a foreign person may not acquire shares in a company having total assets of A\$248 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," a threshold of A\$1,078 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 ADRs. At present, we do not have total assets of A\$248 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\$244 million; or (ii) any direct or indirect ownership interest in Australian residential real estate.

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

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

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

# E. TAXATION

The following is a discussion of Australian and United States 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 US 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. From July 1, 2015, the marginal tax rate for non-Australian residents will start at 33%. 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 tax and does not require a shareholder to register for Australian goods and services tax purposes.



### **Research and Development Tax Incentives**

The Australian Government tax incentive scheme, introduced on July 1, 2011, replaces the former R&D Tax Concession scheme for research and development activities in income years commencing on or after July 1, 2011. Subject to certain exclusions, the scheme provides benefits for eligible research and development activities (R&D activities). 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 (a) and (b).

Under the R&D Tax incentive scheme, entities will be entitled to either

- (i) a 45% refundable tax offset for eligible companies with an aggregated turnover of less than \$20 million per annum; or
- (ii) a non-refundable 40% tax offset for all other eligible companies.

Our aggregated turnover is less than \$20 million, and therefore we will be entitled to claim a 45% refundable tax offset for costs relating to eligible R&D activities during the year. We have also been authorized under the Advance Finding provisions to qualify for the R&D Tax incentive for certain R&D activities conducted overseas.

The Australian Government as part of the 2014 Budget announced proposed changes to the R&D tax offset rates from 1 July 2014. Subject to the required legislative changes being passed by Parliament, the rates will be as follows in order to account for the proposed change in the corporate tax rate from 30% to 28.5%:

- (i) Refundable R&D tax offset rate from 45% to 43.5%
- (ii) Non-refundable R&D tax offset rate from 40% to 38.5%

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

This summary does not address the effect of any U.S. federal taxation other than U.S. federal income taxation. In addition, this summary does not include any discussion of state, local or foreign taxation. You are urged to consult your tax advisors regarding the foreign and U.S. federal, state and local tax considerations of an investment in ADRs.

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

### **Taxation of Dividends**

For U.S. federal income tax purposes, U.S. Holders of ADRs will be treated as owning the underlying ordinary shares, or ADSs, represented by the ADRs held by them. Subject to the passive foreign investment company rules discussed below, the gross amount of any distributions received with respect to the underlying ordinary shares represented by the ADRs, including the amount of any Australian taxes withheld 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 ADRs, and any amount in excess of your tax basis will be treated as gain from the sale of ADRs. See "Disposition of ADRs" below for the discussion on the taxation of capital gains. Dividends will not qualify for the dividends-received deduction generally available to corporations under Section 243 of the Code.

Dividends that we pay 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 credits.

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 out in the Code include computational rules under which foreign tax credits allowable with respect to specific classes of income cannot exceed the U.S. federal income taxes otherwise payable with respect to each such class of income. 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 ADRs to the extent such U.S. Holder has not held the ADRs 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 ADRs are not counted toward meeting the 16-day holding period required by the statute. The rules relating to the determination of the foreign tax credit are complex. You should consult with your personal 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 shares 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 ADRs currently are readily tradable on an established securities market in the United States. However, no assurance can be given that the ADRs will remain readily tradable. Furthermore, the reduction 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 ADRs should consult their own tax advisors regarding the effect of these rules in their particular circumstances.

### **Disposition of ADRs**

If you sell or otherwise dispose of ADRs, you will recognize gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amount realized on the sale or other disposition and your adjusted tax basis in the ADRs. Subject to the passive foreign investment company 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 ADRs for more than one year at the time of the sale or other disposition. In general, any gain that you recognize on the sale or other disposition of ADRs will be U.S.-source for purposes of the foreign tax credit limitation; losses will generally be allocated against U.S.-source income. Deduction of capital losses is subject to certain limitations under the Code.

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

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

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

There is a substantial risk that we are a passive foreign investment company, or 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 ADRs 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 each of the subsequent fiscal years and that we will once again qualify as a PFIC for the taxable year ended June 30, 2014.

If we are 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 ADRs, 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 ADRs. An "excess distribution" is the amount by which distributions during a taxable year in respect of an ADR exceed 125% of the average annual distributions during the three preceding taxable years (or, if shorter, your holding period for the ADRs).
- 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 Internal Revenue Service 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

- 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 ADRs 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 not recognized. A U.S. Holder's basis in its ADRs 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 ADRs as beginning on the day following the last taxable year in which we were a PFIC.

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

is:

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 ADRs, subject to certain limitations and exceptions.



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

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

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be credited against a U.S. Holder's U.S. tax liability. 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 Internal Revenue Service, 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 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 ADRs.

#### 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 20-F on our website (<u>www.pranabio.com</u>) 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 <u>www.sec.gov</u> 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 2, 1233 High Street, Armadale, Victoria, Australia, 3143.

### SUBSIDIARY INFORMATION

Not applicable.

I.

### 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\$26,398,943, A\$2,035,769 and A\$4,166,664 in cash held in U.S. dollars GBP and Euro as of June 30, 2014, 2013 and 2012, respectively. A hypothetical 4%, 5% and 6% adverse movement in end-of-period exchange rates for U.S. dollars, GBP and Euro, respectively, would reduce or increase the cash balance by approximately A\$164,633, 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, 2014, the Australian dollar appreciated against the U.S. dollar by 3%. In the financial years 2013 and 2012, the Australian dollar depreciated by 10% and appreciated by 4% against the U.S. dollar, respectively. As of June 30, 2014, payables in U.S. dollars and other currencies were immaterial. A hypothetical 4% adverse movement in the U.S. dollar, 6% adverse movement in the Euro and 5% adverse movement in the Great British Pound exchange rates would increase the cost of these payables by approximately A\$14,720.

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 depositary, 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:

• US\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

For:

- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
- Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
- Any cash distribution to you

• US\$0.005 (or less) per ADS

- shares and the shares had been deposited for issuance of ADSs
- US\$1.50 (or less) per ADR
- Expenses of the depositary
- A fee equivalent to the fee that would be payable if securities distributed to you had been Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to ADS holders
  - Transfers, combination and split-up of ADRs
  - Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)
  - Converting foreign currency to U.S. dollars •
    - As necessary
- Taxes and other governmental charges the depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes
- Any charges incurred by the depositary or its agents for servicing the deposited securities As necessary

The depositary 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 depositary 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 depositary may collect its annual fee for depositary 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 depositary may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary 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 depositary may use brokers, dealers or other service providers that are affiliates of the depositary 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, 2014, we paid BoNY a total of US\$15,898 (comprised of payments for the distribution and printing of meeting material and proxy vote tabulation). We also paid BoNY US\$107,916 in connection with the conversion of ordinary shares into ADSs for issuance under our "At-The-Market" facility. The conversion charge ranged from US\$0.01 to US\$0.02 per ADR plus international wire charges.

### PART II

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

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 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 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 acting chief financial officer concluded that, as of June 30, 2014, 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 of 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, 2014. 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, 2014, our internal control over financial reporting is effective.

The effectiveness of our internal control over financial reporting as of June 30, 2014 has been audited by PricewaterhouseCoopers, an independent registered public accounting firm, as stated in their report which is included on page [F-\_\_] of this Annual Report on Form 20-F.

### **Changes in Internal Control over Financial Reporting**

During the year ended June 30, 2014, 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 <u>www.pranabio.com</u>. 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.

	Year Ended June 30,			e 30,
Services Rendered	_	2014		2013
Audit (1)	A\$	145,187	A\$	164,060
Audit-Related (2)	A\$	187,422		-
Other (3)	A\$	65,000		-
Total	A\$	397,609	A\$	164,060

(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. Preapproval 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, 2014.

# 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.

			Incorporated by Reference	
Exhibit Number	Exhibit Description	Form	Exhibit	Filing Date/ Period End Date
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 Depositary, 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.	20-F	4.21	6/30/04
4.6	Prana Biotechnology Limited, 2004 American Depository Share (ADS) Option Plan.	6-K	Annexure A	11/3/04
4.7	Prana Biotechnology Limited, 2004 Employees', Directors' and Consultants' Share and Option Plan.	6-K	to Item 1 Annexure B	11/3/04
4.8	Fourth Research Funding and Intellectual Property Assignment Agreement dated December 1, 2009.	20-F	to Item 1 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	GMP 30kg Manufacture Agreement dated June 6, 2007, between the Registrant and Institute of Drug Technology Australia Limited.	20-F	4.9	6/30/07
4.11	GMP 4kg Manufacture Agreement dated June 6, 2007, between the Registrant and Institute of Drug Technology Australia Limited.	20-F	4.10	6/30/07
4.12	Employment Agreement dated September 21, 2007, among the Registrant and Mr. Kempler.	20-F	4.19	6/30/07

4.13	Letter Agreements effective as of June 12, 2007 between the Registrant and Ms. Dianne Angus.		4.21	6/30/07
4.14	Agreement dated May 22, 2007, between the Registrant and Patheon Inc. regarding the formulation, development and manufacture of capsules of PBT2.	20-F	4.22	6/30/07
4.15	PBT2 Capsules Phase III Manufacturing Proposal for Prana Biotechnology Limited dated April 16, 2013 between the Registrant and Patheon Inc.	20-F	4.15	6/30/13
4.16*	Change of Scope amendments to the PBT2 Capsules Phase III Manufacturing Proposal for Prana Biotechnology Limited dated April 16, 2013 between the Registrant and Patheon Inc., issued as of July 10, 2013, August 13, 2013, February 11, 2014, March 3, 2014, April 11, 2014 and August 22, 2014.			
4.17	Placement Confirmation Letter dated September 8, 2009, between the Registrant and BAM Capital LLC.	20-F	4.25	6/30/07
4.18	Consultancy Services Agreement dated January 8, 2004, between the Registrant and Professor Ashley Bush.	6-K	Item 1	6/18/09
4.19	Letter agreement dated November 14, 2007, between the Registrant and Professor Ashley Bush.	6-K	Item 2	6/18/09
4.20	Letter agreement dated May 22, 2009, between the Registrant and Professor Ashley Bush.	20-F	4.20	6/30/09
4.21	Process Development and Manufacturing Agreement dated December 26, 2008, between the Registrant and Dr. Reddy's Laboratories Limited, as amended by Amendment No. 1 effective February 3, 2009 and Amendment No. 2 effective March 13, 2009.	20-F	4.21	6/30/09
4.22	Amendments to Process Development and Manufacturing Agreement dated December 26, 2008 between the Registrant and Dr. Reddy's Laboratories Limited, as amended: Amendment No 3 effective July 6, 2009; Amendment No. 4 effective September 15, 2009; Amendment No. 5 effective November 13, 2009; Amendment No. 6 effective December 22, 2009; Amendment No. 7 effective December 22, 2009; Amendment No. 8 effective May 7, 2010; and Amendment No. 9 effective May 20, 2010.	20-F	4.21	6/30/10
4.23	Amendments to Process Development and Manufacturing Agreement dated December 26, 2008 between the Registrant and Dr. Reddy's Laboratories Limited, as amended: Amendment No. 10 effective October 21, 2010; Amendment No. 11 effective March 21, 2011 and Amendment No. 12 effective May 18, 2011.	20-F	4.22	6/30/11
4.24	Amendments to Process Development and Manufacturing Agreement dated December 26, 2008 between the Registrant and Dr. Reddy's Laboratories Limited, as amended: Amendment No. 13 effective February 14, 2012.	20-F	4.23	6/30/12
4.25	Amendments to Process Development and Manufacturing Agreement dated December 26, 2008 between the Registrant and Dr. Reddy's Laboratories Limited, as amended: Amendment No. 14 effective September 18, 2012; and Amendment No. 15 effective May 1, 2013.	20-F	4.24	6/30/13

4.26	Master Services Agreement for Provision of Clinical Research Services between the Registrant and INCResearch Australia Pty Limited dated September 22, 2011, or the INCResearch Master Agreement.	20-F	4.25	6/30/13
4.27	Work Order under the INCResearch Master Agreement for Research Project #1000504, Protocol PBT2-203 dated August 14, 2012 and Change Order No. 1 to Work Order #1000504 dated April 16, 2013.	20-F	4.26	6/30/13
4.28*	Work Order under the INCResearch Master Agreement for Research Project #1000504, Protocol PBT2-203 dated August 3, 2012 and Change Order No. 1 to Work Order #1000504 dated April 10, 2013.			
4.29	Work Order under the INCResearch Master Agreement for Research Project #1002213, Protocol PBT2-203 dated March 27, 2013.	20-F	4.27	6/30/13
4.30*	Change Order No. 1 to Work Order #1002213 dated March 4, 2014.			
4.31	Work Order under the INCResearch Master Agreement for Research Project #800089, Protocol PBT2-204 dated April 2, 2012, First Amendment to Work Order for Research Project #800089 dated July 17, 2013 and Change Order No. 2 to Work Order #1000504 dated July 17, 2013.	20-F	4.28	6/30/13
4.32*	Change Order No. 3 to Work Order #800089 (PBT2-204) dated March 14, 2014 and Change Order No. 4 to Work Order #800089 (PBT2-204) dated July 18, 2014.			
4.33	Letter Agreement between the Registrant and INCResearch Australia Pty Limited dated October 2, 2013 re Clinical Trial Services for Study Entitled: "A randomized, double-blind, placebo controlled study to assess the safety and tolerability and efficacy of PBT2 in patients with early to mid-stage Huntington's disease," Protocol PBT2-203.	20-F	4.29	6/30/13
4.334	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
4.35*	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.			
4.36*	Manufacturing Services Agreement for PBT2 434 Supply dated March 28, 2014 between the Registrant and Dr. Reddy's Laboratories Limited.			
4.37	28-day Oral Toxicity Study in CbyB6F1 mice dated June 21, 2013 between the Registrant and Bioreliance Corporation.	20-F	4.31	6/30/13
4.38	Clinical Trial Agreement between the Registrant and the University of Rochester dated October 7, 2011.	20-F	4.27	6/30/12
4.39*	Amendment No. 1, dated February 17, 2012, and Amendment No. 2, dated September 28, 2012, to the Clinical Trial Agreement between the Registrant and the University of Rochester dated October 7, 2011.			
4.40	Clinical Research Support Agreement between the Registrant and the General Hospital Corporation dated June 14, 2012.	20-F	4.28	6/30/12
4.41*	Master Laboratory Services Agreement between the Registrant and WIL Research Laboratories, LLC dated August 26, 2013, Amendment 1 to Master Laboratory Services Agreement dated November 19, 2013, and Work Order dated December 19, 2013.			
4.42*	Master Services Agreement between the Registrant and Quotient Clinical Limited, or Quotient Clinical, dated December 10, 2013, or the Quotient Clinical Master Agreement, Work Order No. 1 to the Quotient Clinical Master Agreement dated December 12, 2013 and Change Order Form dated March 20, 2014.			
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 Sarbar	nes-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 Sarban	es-Oxley Act of	2002.	
15.1*	Consent of PricewaterhouseCoopers, Registered Public Accounting Firm.			
* Filed be				

\* Filed herewith.

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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, of changes in shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Prana Biotechnology Limited and its subsidiaries at June 30, 2014 and June 30, 2013, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2014 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2013, suade on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Freadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 15. Our responsibility is to express opinions on these financial statements and one the Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurace about whether the financial statements included 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. Our audits of internal control over financial reporting included obtaining an understanding oi internal control over financial statements, assessing the accounting principles used on the assessed risk. Our audits dinternal control over financial repor

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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. Also, 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.

/s/ PricewaterhouseCoopers Melbourne, Australia October 31, 2014

### PricewaterhouseCoopers, ABN 52 780 433 757

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# CONSOLIDATED STATEMENTS OF FINANCIAL POSITION (in Australian dollars, except number of shares)

		June 30,		
	Notes	2014	2013	
Assets				
Current Assets				
Cash and cash equivalents		34,167,018	13,346,760	
Trade and other receivables	5	7,285,409	3,523,938	
Other current assets	6	96,883	112,242	
Total Current Assets		41,549,310	16,982,940	
Non-Current Assets				
Property and equipment, net of accumulated depreciation of A\$367,347 and A\$397,774, respectively	7	47,557	46,893	
Other non-current assets	6	43,988	43,988	
Total Non-Current Assets		91,545	90,881	
Total Assets		41,640,855	17,073,821	
Liabilities				
Current Liabilities				
Trade and other payables	8	3,358,358	1,775,666	
Other financial liabilities	9	98,398	870,801	
Provisions	10	494,784	419,176	
Unearned income	12		33,332	
Total Current Liabilities		3,951,540	3,098,975	
Non-Current Liabilities				
Provisions	10	3,028	133	
Total Non-Current Liabilities		3,028	133	
Total Liabilities		3,954,568	3,099,108	
Net Assets		37,686,287	13,974,713	
Equity				
Issued capital 2014: 488,646,960 fully paid ordinary shares Nil options over fully paid ordinary shares				
2013: 381,610,426 fully paid ordinary shares	12	140,009,415	101 270 111	
Nil options over fully paid ordinary shares	13	140,009,415 8,937,434	101,379,111 10,526,925	
Reserves Accumulated deficit during the development stage	14	(111,260,562)	(97,931,323)	
Total Equity		37,686,287	13,974,713	

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

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

		Years ended June 30,			
	Notes	2014	2013	2012	
Revenues from ordinary activities	2	363,775	150,867	186,664	
Other income	2	7,845,396	4,488,526	2,340,851	
Research and development expenses	3	(14,908,098)	(8,203,822)	(4,252,002)	
Corporate personnel expenses	3	(2,059,642)	(2,298,426)	(1,835,279)	
Intellectual property expenses	3	(477,079)	(294,894)	(261,706)	
Auditor and accounting expenses	3	(342,609)	(166,086)	(153,597)	
Travel expenses	3	(421,013)	(131,710)	(91,624)	
Public relations and marketing expenses	3	(358,597)	(136,186)	(124,970)	
Depreciation expenses	3	(22,384)	(23,130)	(19,621)	
Other expenses	3	(2,142,179)	(1,169,407)	(1,095,739)	
Interest expense - ADDF		(29,978)	(17,676)	(11,544)	
Foreign exchange gain (loss)	3	(746,593)	140,761	45,959	
Gain (loss) on fair valuation of financial liabilities	3	(30,238)	(126,059)	33,139	
Loss before income tax expense		(13,329,239)	(7,787,242)	(5,239,469)	
Income tax expense	4	-	-		
Loss for the year		(13,329,239)	(7,787,242)	(5,239,469)	
Other comprehensive loss		-	-	-	
Total comprehensive loss for the year	16a	(13,329,239)	(7,787,242)	(5,239,469)	
Loss per share (basic and diluted - cents per share)	20	(3.11)	(2.30)	(1.82)	
Weighted average number of ordinary shares used in computing basic and diluted net loss per share		428,047,123	338,700,006	287,765,812	

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

# CONSOLIDATED CASH FLOW STATEMENTS (in Australian dollars)

		Years Ended June 30,			
	Notes	2014	2013	2012	
Cash Flows from Operating Activities					
Payments to suppliers and employees		(18,011,310)	(10,650,823)	(7,874,010)	
Interest received		377,587	93,789	186,794	
Grants received		-	107,097	144,345	
R&D tax refund		4,095,000	2,492,683	691,301	
Other		2,500	6,000	5,664	
Net cash flows used in operating activities	16(a)	(13,536,223)	(7,951,254)	(6,845,906)	
Cash Flows from Investing Activities					
Payment for rental security deposits		-	(6,151)	-	
Payments for purchase of plant and equipment		(23,048)	(22,000)	(26,763)	
Net cash flows used in investing activities		(23,048)	(28,151)	(26,763)	
Cash Flows from Financing Activities					
Proceeds from exercise of options and issue of securities		37,110,325	16,260,806	3,843,495	
Payment of share issue costs		(1,339,369)	(1,015,775)	(221,472)	
Proceeds from borrowings		-	337,000	-	
Repayment of borrowings		(810,164)			
Net cash flows provided by financing activities		34,960,792	15,582,031	3,622,023	
Net increase (decrease) in cash and cash equivalents		21,401,521	7,602,626	(3,250,646)	
Opening cash and cash equivalents brought forward		13,346,760	5,636,469	8,838,245	
Exchange rate adjustments on cash and cash equivalents held in foreign currencies		(581,263)	107,665	48,870	
Closing cash and cash equivalents carried forward	16(b)	34,167,018	13,346,760	5,636,469	

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

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

				_	Accumulated Deficit During	
	Notes	Number of Shares	Issued Capital	Reserves	Development Stage	Total Equity
Balance, June 30, 2011		275,286,783	82,340,819	9,494,995	(84,904,612)	6,931,202
Transactions with owners in their capacity as owners:						
Issuance of shares in connection with At-The-Market						
facility, net of costs	13(b)	22,042,170	3,622,022	-	-	3,622,022
Non-cash issuance of shares to consultants	13(b)	310,000	50,700	-	-	50,700
Non-cash issuance of options to employees	14(b)	-	-	140,926	-	140,926
Non-cash issuance of options to consultants	14(b)	-	-	145,940	-	145,940
Options lapsed	14(b)	-	-	(75,022)	-	(75,022)
Issuance of shares in connection with exercise of options,						
net of costs	13(b) & 14(b)	341,865	120,536	(120,536)	-	-
Share options - value of employee services	14(b)	-	-	47,148	-	47,148
		22,694,035	3,793,258	138,456	-	3.931.714
Net loss	15		-		(5,239,469)	(5,239,469)
Total comprehensive loss for the year	10		······································		(5,239,469)	(5,239,469)
1 0		297,980,818	86,134,077	9.633.451	(90,144,081)	
Balance, June 30, 2012		297,980,818	86,134,077	9,633,451	(90,144,081)	5,623,447
Transactions with owners in their capacity as owners:						
Issuance of shares in connection with private placement,						
net of costs	13(b)	58,141,030	10,629,011	-	-	10,629,011
Issuance of shares in connection with share purchase plan,						
net of costs	13(b)	10,370,488	1,570,863	-	-	1,570,863
Issuance of shares in connection with At-The-Market						
facility, net of costs	13(b)	15,008,090	3,023,160	-	-	3,023,160
Non-cash issuance of shares to consultants	13(b)	110,000	22,000	-	-	22,000
Non-cash issuance of options to employees	14(b)	-	-	86,969	-	86,969
Non-cash issuance of options to consultants	14(b)	-	-	215,083	-	215,083
Non-cash issuance of options to directors	14(b)	-	-	591,422	-	591,422
		83,629,608	15,245,034	893,474	-	16,138,508
Net loss	15	-	-	-	(7,787,242)	(7,787,242)
Total comprehensive loss for the year					(7,787,242)	(7,787,242)
		381,610,426	101,379,111	10.526.925	(97,931,323)	
Balance, June 30, 2013		381,010,420	101,579,111	10,526,925	(97,931,323)	13,974,713
Transactions with owners in their capacity as owners:						
Issuance of shares in connection with At-The-Market						
facility, net of costs	13(b)	85,108,500	30,818,030	-	-	30,818,030
Issuance of shares in connection with share purchase plan,						
net of costs	13(c)	1,000,000	276,950	-	-	276,950
Non-cash issuance of options to employees	14(b)	-	-	33,824	-	33,824
Non-cash issuance of options to consultants	14(b)	-	-	959,084	-	959,084
Issuance of shares in connection with exercise of options,						
net of costs	13(b) & 14(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)
Total comprehensive loss for the year		-		-	(13,329,239)	(13,329,239)
Balance, June 30, 2014		488,646,960	140.009.415	8.937.434	(111,260,562)	37,686,287
Datance, June 30, 2014		400,040,200	140,009,415	0,757,454	(111,200,302)	57,000,207

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

# 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 and the eye as the aging process progresses. 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, 2014 was authorized for issue in accordance with a resolution of the Board of Directors on September 30, 2014.

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, 2013 and the comparative information presented in these financial statements for the years ended June 30, 2012 and 2011. Where necessary, comparatives have been reclassified and repositioned for consistency with current year disclosure.

#### 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 Depository 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 are exercisable at A\$0.17 consideration and expire on February 25, 2016. Options for ADRs remain outstanding.

#### 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 nonrefundable 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.



### 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 July1,2011. 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, 2014 the Company has recorded an item in other income of A\$7.22 million (2013: A\$3.47 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, 2014, the Company incurred an operating loss of A\$13.3 million (2013: Loss: A\$7.8 million) and an operating cash outflow of A\$13.5 million (2013: A\$8.0 million). As at year end the net assets of the Group stood at A\$37.7 million (2013: A\$14.0 million) and the cash position has increased to A\$34.2 million from A\$13.3 million at 30 June 2013.

Cash on hand at June 30, 2014 plus subsequent capital inflows 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 an inherent uncertainty in the Group'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 Group 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 Group had an "at the market" (ATM) facility through which it could raise additional funds of up to US\$48.73 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 May, 2011, and amended in August 2013, expired at the end of May 2014. The Company sold 12.2 million of its ADRs for aggregate gross proceeds of approximately A\$39.37 million (US\$37 million) pursuant to the facility.
- The Company has on issue a total of 18.77 million unlisted, unexercised options. The options have exercise prices ranging from nil to A\$1.12. If all unlisted options were exercised, the Group would receive consideration of A\$6.9 million in total.
- 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 Group has recorded a Trade Receivable at June 30, 2014 in the amount of A\$7.18 million from the Australian Tax Office in respect of its 2014 R&D claim. The Group expects to receive this amount during the 12 months ended 30 June 2015.

On this basis, the Directors are satisfied that the Group 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, 2014.

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 Group 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, 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.



# 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 Group operated in one segment, being research into Alzheimer's Disease and other major age-related degenerative 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 Group 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 Group expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities.

### 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 Group 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 which the unused losses and unused tax credits can be utilized, given the nature of the Group's business (research and development) and its history of losses.

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:

Depreciation Rate
5-33%
33%
10-33%
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.



# 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 (p) 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.

The convertible note liability is accounted for on an amortized cost basis.

#### (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, 2013.

#### (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, 2014, 2013 and 2012, 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).



# 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.

#### Group companies

- 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.



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.

# 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 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 services 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 necorded 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 antidilutive.

### (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

When required by IFRS, comparative figures have been adjusted to conform to changes in presentation for the current financial year.

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

During the year, corporate personnel costs have been identified as being directly attributable to research and development and have been reclassified into the appropriate classification for our consolidated Statement of Profit or Loss for the year ending June 30, 2014. The change in presentation is considered to provide more relevant information and has been adopted in the current and prior years.

For the years ended June 30, 2013 and June 30, 2012 find presented below adjusted comparatives for research and development and corporate personnel expenses.

Financial Year		20	13			20	12	
	Pre	eviously			Pi	reviously		
	re	eported	A	djusted	I	reported	A	djusted
Research and development expenses	\$A	7,946,005	\$A	8,203,822	\$A	4,228,719	\$A	4,252,002
Corporate personnel expenses	\$A	2,556,243	\$A	2,298,426	\$A	1,858,562	\$A	1,835,279

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - in Australian dollars (unless otherwise noted)

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

#### **Parent Information** (w)

The financial information for the parent entity, Prana Biotechnology Limited, disclosed in note 2 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.

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

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, 2014 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, 2014 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

Pronouncement	Title (Issue date)	Effective date
Annual Improvements to IFRSs	International Financial Reporting	Annual periods beginning on or after January 1, 2016
2012-2014 Cycle	Standards (September 2014)	Earlier application is permitted.
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	Annual periods beginning on or after January 1, 2016.
	(September 2014)(2)	Earlier application is permitted.
Amendments to IAS 27	Equity Method in Separate Financial Statements (August 2014) (2)	Annual periods beginning on or after January 1, 2016.
	Statements (August 2014) (2)	Earlier application is permitted.
WDG 0		Annual periods beginning on or after January 1, 2018.
IFRS 9	Financial Instruments (July 2014)	Earlier application is permitted.
		Annual periods beginning on or after January 1, 2016.
Amendments to IAS 16 and IAS 41	Agriculture: Bearer Plants (June 2014) (2)	Earlier application is permitted
IFRS 15	Revenue from Contracts with Customers	Annual periods beginning on or after January 1, 2017.
IFKS 15	(May 2014)	Earlier application is permitted.
Amendments to IAS 16 and IAS	Clarification of Acceptable Methods of	Annual periods beginning on or after January 1, 2016.
38	Depreciation and Amortisation (May 2014)	Earlier application is permitted.
	Accounting for Acquisitions of Interests in	Annual periods beginning on or after January 1, 2016.
Amendments to IFRS 11	Joint Operations (May 2014)	Earlier application is permitted.
IED 0.14	Regulatory Deferral Accounts (January	Annual periods beginning on or after January 1, 2016.
IFRS 14	2014)	Earlier application is permitted.
Annual Improvements to IFRSs	International Financial Reporting Standards	Annual periods beginning on or after July 1, 2014.
2011–2013 Cycle	(December 2013) (2)	Earlier application is permitted.
Annual Improvements to IFRSs	International Financial Reporting Standards	Annual periods beginning on or after July 1, 2014.
2010–2012 Cycle	(December 2013)	Earlier application is permitted.

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

Pronouncement	Title (Issue date)	Effective date
Amendments to IAS 19	Defined Benefit Plans: Employee Contributions (November 2013) (2)	Annual periods beginning on or after July 1, 2014. Earlier application is permitted.
Amendments to IFRS 9, IFRS 7, and IAS 39	IFRS 9 Financial Instruments – Hedge Accounting and amendments to IFRS 9, IFRS 7, and IAS 39 (November 2013)	The amendments to IFRS 9 have removed the previous mandatory effective date of January 1, 2015, but the standard is available for immediate application. The standard provides an accounting policy choice for an entity to continue to apply hedge accounting (and hedge accounting only) under IAS 39 instead of IFRS 9 until the IASB completes its separate macro hedging project. The European Union has not yet endorsed any aspects of IFRS 9, and therefore the new guidance may not be adopted by entities subject to regulation by the European Union.
Amendments to IAS 39	Novation of Derivatives and Continuation of Hedge Accounting (June 2013)	Annual periods beginning on or after January 1, 2014. Earlier application is permitted.
Amendments to IAS 36	Recoverable Amount Disclosures for Non- Financial Assets (May 2013)	Annual periods beginning on or after January 1, 2014. Earlier application is permitted.
Amendments to IFRS 10, IFRS 12 and IAS 27	Investment Entities (October 2012)	Annual periods beginning on or after January 1, 2014. Earlier application is permitted.
Amendments to IAS 32	Offsetting Financial Assets and Financial Liabilities (December 2011)	Annual periods beginning on or after January 1, 2014.
Amendments to IFRS 9 and 7	Mandatory Effective Date and Transition Disclosures (December 2011)	January 1, 2013 to January 1, 2015 (TBD).

	Y	Years Ended June 30,		
	2014	2013	2012	
2. REVENUE AND OTHER INCOME FROM CONTINUING OPERATIONS				
Other revenue				
Interest	363,775	150,867	186,664	
Total other revenue	363,775	150,867	186,664	
Other income				
Other Grants	2,500	6,000	5,664	
R&D Tax Concession	7,802,947	4,408,761	2,241,673	
Michael J Fox Foundation Grant	39,949	73,765	93,514	
Total other income	7,845,396	4,488,526	2,340,851	
Total revenue	8,209,171	4,639,393	2,527,515	

		Ye	ears Ended June 30,	
	Notes	2014	2013	2012
3. EXPENSES FROM ORDINARY ACTIVITIES				
Research and development expenses	3(a) and 3(b)	14,908,098	8,203,822	4,252,002
Corporate personnel expenses				
Employee expenses	3(b)	751,004	649,430	867,999
Equity based payments to employees	3(b)	33,824	18,252	88,191
Consultant and director expenses	5(6)	773,601	761,584	745,167
Equity-based payments to consultants and directors		438,639	800,833	32,000
Defined contribution superannuation expenses	3(b)	62,574	68,327	101,922
Defined contribution superannuation expenses	5(0)	02,574	00,527	101,722
Total corporate personnel expense*		2,059,642	2,298,426	1,835,279
Intellectual property expenses				
Overseas		195,092	145,233	77,902
Local		281,987	149,661	183,804
Total intellectual property expense		477,079	294,894	261,706
Depreciation of non-current assets				
Laboratory equipment		44	2,831	5,159
Computer equipment		19.605	17,569	11,751
Furniture and fittings		2,735	2,730	2,711
Leasehold improvements		2,755	2,750	2,711
Write-off non-current assets				
Total depreciation expense		22,384	23,130	19,621
Other expenses				
Corporate compliance		487,632	251,552	403,981
Office expenses		1,365,151	634,552	437,427
Computer expenses		22,316	21,609	28,994
Insurance		103,497	84,679	64,046
Office rental under operating lease		163,583	177,015	161,291
Interest Expense - ADDF		29,978	17,676	11,544
Total other expenses		2,172,157	1,187,083	1,107,283
Auditor and accounting expenses		342,609	166,086	153,597
Travel expenses		421,013	131,710	91,624
Public relations and marketing expenses		358,597	136,186	124,970
Foreign exchange gain (loss)		746,593	(140,761)	(45,959
Gain (loss) on fair valuation of financial liabilities		30,238	126,059	(33,139
Total expenses		21,538,410	12,426,635	7,766,984

\*Corporate personnel expenses excludes salaries and fees paid to employees and consultants involved in research and development activities.

	Y	ears Ended June 30,	
(a) Research and development expenses (1) and (2)	2014	2013	2012
Personnel expenses related to research and development	1,827,934	777,272	735,628
Research and development expenses	13,080,164	7,426,550	3,516,374
Total research and development expenses	14,908,098	8,203,822	4,252,002

Research and development expenses consist of expenses paid for contracted research and development activities conducted by third parties on behalf of the Company. Prior year corporate personnel costs of \$257,817 have been changed to R&D personnel costs for comparative purposes. (1) (2)

	Ye	ars Ended June 30,	
(b) Employee benefits expenses	2014	2013	2012
Employee expenses	1,948,607	1,413,368	1,406,828
Equity payments to employees	33,824	382,678	130,453
Defined contribution superannuation expenses	121,165	90,217	107,948
Total employee benefits expenses	2,103,596	1,886,263	1,645,229
	Ye	ars Ended June 30,	
	2014	2013	2012
4. INCOME TAX			
(a) The prima facie tax on net (loss) before tax is reconciled to the income tax is as follows:			
Prima facie tax on net (loss) before income tax at 30% (2014, 2013 & 2012: 30%)	(3,998,772)	(2,336,173)	(1,571,841)
Effect of lower tax rates of tax on overseas income	(43)	(499)	(286)
Add tax effect of:			
(Over)/Under provision of income tax in previous year relating to a correction of estimates (1)	2,214,342	1,408,791	336,146
Equity issued for nil consideration	1,269,857	274,642	92,908
Research and development tax concession	(7,180,486)	(1,039,919)	(465,112)
Gain on fair value of financial liabilities	(30,238)	(9,381)	9,942
Other	5,761	1,766	2,508
Deferred tax asset not recognized	7,719,579	1,700,772	1,595,736
Income tax expense attributable to loss before income tax	<u> </u>		
(b) Potential deferred tax asset at June 30, 2014, 2013 and 2012 in respect of: tax losses not brought to account is:	39,143,186	35,566,969	33,969,324
Temporary differences	(37,806)	(338,714)	433,178
remporary anterences	(37,000)	(550,714)	+55,170

(1) This is the result of the difference between the accounting estimate included in the prior year's tax note, as disclosed in the annual report on Form 20-F for the year ended June 30 and the tax return lodged with the Australian Tax Office after the filing of the Form 20-F for such period.

	Years Ended	June 30,
	2014	2013
5. TRADE AND OTHER RECEIVABLES		
Accrued income, primarily relates to R&D tax receivable from the Australian Taxation Office	7,224,216	3,523,938
Goods and services tax receivable	61,193	-
	7,285,409	3,523,938

	Years Ende	ed June 30,
	2014	2013
6. OTHER ASSETS		
Current		
Prepayments	62,771	110,373
Other receivables	34,112	1,869
Total	96,883	112,242
Non-current		
Term deposit	43,988	43,988
Total	43,988	43,988
F	- 18	

		Years Ended	June 30,
	Notes	2014	2013
7. PROPERTY AND EQUIPMENT			
Gross carrying amount			
Balance at beginning of year		445,432	423,460
Additions		23,048	21,972
Disposals		-	-
Balance at end of year		468,480	445,432
Accumulated depreciation			
Balance at beginning of year		(398,539)	(375,409)
Disposals		-	-
Depreciation expense	3	(22,384)	(23,130)
Balance at end of year		(420,923)	(398,539)
· · · ·		<u> </u>	
Net book value at end of year		47,557	46,893
		11,001	10,075

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

	Years Ended J	une 30,
	2014	2013
Laboratory equipment, at cost	116,007	166,264
Less accumulated depreciation	(113,486)	(166,253)
Total laboratory equipment	2,521	11
Computer equipment, at cost	185,641	165,146
Less accumulated depreciation	(149,190)	(129,585)
Total computer equipment	36,451	35,561
Furniture and fittings, at cost	37,598	37,598
Less accumulated depreciation	(29,012)	(26,277)
Total furniture and fittings	8,586	11,321
Leasehold improvements, at cost	75,659	75,659
Less accumulated depreciation	(75,659)	(75,659)
Total leasehold improvements		-
Total	47,557	46,893

	Years Ended	June 30,
	2014	2013
8. TRADE AND OTHER PAYABLES		
Trade creditors	651,152	278,641
Accrued research and development expenses	2,222,881	1,195,370
Accrued intellectual property expenses	60,380	24,464
Accrued corporate personnel expenses	361	441
Accrued audit and accounting fees	336,866	237,042
Accrued travel expenses	10,609	-
Accrued marketing expenses	22,645	-
Other accrued expenses	53,464	39,708
•		
Total	3,358,358	1,775,666

	Years Ended June 30,			
	2014	2013	2014	2013
9. FINANCIAL LIABILITIES	No.	No.	A\$	A\$
Current				
Convertible Promissory Note (a)	-	-	-	802,641
Warrants over ordinary shares (b)	612,397	612,397	98,398	68,160
Total			98,398	870,801

(a) Convertible Promissory Note.

In the year ended 30 June 2011 the Company entered into an agreement with the Alzheimer's Drug Discovery Foundation ("ADDF") to receive a grant of up to US\$700,000, receivable in two instalments of US\$350,000. As a condition to receiving the grant and on execution of the agreement, the Company executed a Convertible Promissory Note, which was equal to the amount of the first instalment. As at June 30, 2014 the Convertible Promissory Note was repaid in full. As a condition to receiving the grant, the Company issued a Warrant to ADDF to purchase ordinary shares of the Company.

The convertible promissory note was classified as a financial liability in accordance with IAS 32 and IAS 39 for recognition and measurement.

The terms of the convertible promissory note were as follows:

Interest Payable -	Per annum rate equal to the United States "prime" rate as published by the Wall Street Journal, compounds annually and payable at maturity.
Maturity –	All unpaid principal, together with any unpaid and accrued interest, will be due and payable on the 3rd anniversary of the date of the agreement.
Note holder conversion -	Upon the Company closing an equity financing of at least US\$1M, excluding the principle amount of the convertible promissory note, the outstanding principal,
	together with unpaid and accrued interest, the convertible promissory note holder may elect to convert the total outstanding amounts into units of securities
	issued in the equity financing at a conversion price equal to the lowest per unit price paid by investors in that financing.
Company conversion -	If, at any time, any unpaid principal, together with any unpaid and accrued interest, would be due and payable and the Company does not have the capacity to
	repay the total outstanding amounts in cash, the Company may elect to substitute an issue of ordinary shares equal to the total outstanding amount at a 20%
	discount to a 5 day VWAP.

#### (b) 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 are convertible to ordinary shares on or before February 25, 2016 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.



		Years Ended .	June 30,
	Notes	2014	2013
10. PROVISIONS			
Current			
Annual leave (1)	21	217,646	179,609
Long service leave (1)(2)		277,138	239,567
Total		494,784	419,176
Non-Current			
Long service leave (2)	21	3,028	133

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 J	lune 30,
	2014	2013
Annual leave		
Carrying amount at start of year	179,609	159,557
Charged/(credited) to profit or loss		
-additional provisions recognized	152,041	126,926
-unused amounts reversed		-
Amounts used during the year	(114,004)	(106,874)
Carrying amount at end of year	217,646	179,609
Long service leave		
Carrying amount at start of year	239,700	210,176
Charged/(credited) to profit or loss		
-additional provisions recognized	40,466	29,524
-unused amounts reversed	-	-
Amounts used during the year	<u>-</u>	-
Carrying amount at end of year	280,166	239,700
TOTAL	497,812	419,309

#### (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 Ende	ed June 30,
	2014	2013
Long service leave obligation expected to be settled after 12 months	277,138	239,567

#### 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 17.



			Years Ended June 30,	
		-	2014	2013
12. UNEARNED INCOME				
Unearned income: Michael J Fox Foundation Grant			-	33,332
				33,332
			ears Ended June 30,	
	Notes	2014	2013	2012
13. ISSUED CAPITAL				
(a) Issued Capital				
488,646,960 (2013: 381,610,426) fully paid ordinary shares	13(b)	137,307,771	98,677,467	83,432,433
Nil (2013: Nil) options for fully paid ordinary shares	13(c)	2,701,644	2,701,644	2,701,644
		140,009,415	101,379,111	86,134,077

#### (b) Movements in Issued Shares

			June	30,		
	2014		201	2013		12
	No.	A\$	No.	A\$	No.	A\$
Beginning of the year	381,610,426	98,677,467	297,980,818	83,432,433	275,286,783	79,639,175
Movement during the year	107,036,534	38,630,304	83,629,608	15,245,034	22,694,035	3,793,258
End of the year	488,646,960	137,307,771	381,610,426	98,677,467	297,980,818	83,432,433

Details of share issuances are as follows:

Date	Details	Notes	Number	Issue Price	A\$
Year ended					
June 30, 2011			41,240,912		7,220,655
September 15, 2011	Shares to investors as part of at-the-market facility		196,000	0.19	36,827
September 19, 2011	Shares to investors as part of at-the-market facility		4,913,630	0.21	1,031,094
September 20, 2011	Shares to investors as part of at-the-market facility		1,211,970	0.18	223,976
November 17, 2011	Shares to investors as part of at-the-market facility		1,052,000	0.16	169,980
November 23, 2011	Shares to investors as part of at-the-market facility		2,736,530	0.17	461,556
December 22, 2011	Exercise of options – employees		91,865	-	36,746
December 22, 2011	Exercise of options – consultants		250,000	-	83,790
January 9, 2012	Shares to investors as part of at-the-market facility		3,396,190	0.16	536,228
January 10, 2012	Shares to investors as part of at-the-market facility		712,350	0.15	103,893
January 11, 2012	Shares to investors as part of at-the-market facility		703,140	0.15	102,263
January 17, 2012	Shares to investors as part of at-the-market facility		312,070	0.15	45,687
January 30, 2012	Shares to investors as part of at-the-market facility		145,000	0.16	22,570
February 1, 2012	Non cash share issue in consideration for services provided by				
	consultants	(i)	405,150	0.16	65,549
February 1, 2012	Shares to investors as part of at-the-market facility		110,000	0.17	18,700
February 7, 2012	Shares to investors as part of at-the-market facility		745,000	0.16	119,271

#### 13. ISSUED CAPITAL (continued)

February 8, 2012	Shares to investors as part of at-the-market facility		1,250,030	0.17	207,627
February 9, 2012	Shares to investors as part of at-the-market facility		1,228,820	0.18	217,609
February 10, 2012	Shares to investors as part of at-the-market facility		460,110	0.18	83,430
February 16, 2012	Shares to investors as part of at-the-market facility		311,380	0.16	50,168
March 1, 2012	Shares to investors as part of at-the-market facility		183,000	0.16	29,042
March 21, 2012	Shares to investors as part of at-the-market facility		1,000,000	0.16	159,647
March 21, 2012	Non cash share issue in consideration for services provided by				
	consultants	(i)	200,000	0.16	32,000
March 29, 2012	Shares to investors as part of at-the-market facility		265,500	0.17	44,333
May 21, 2012	Shares to investors as part of at-the-market facility		366,020	0.16	59,799
May 25, 2012	Shares to investors as part of at-the-market facility		448,280	0.16	72,945
	Security issuance costs				(221,472)
Year ended June 30, 2012			22,694,035		3,793,258
August 24, 2012	Shares to investors as part of at-the-market facility		1,364,190	0.18	239,238
August 27, 2012	Shares to investors as part of at-the-market facility		1,656,440	0.17	288,162
August 28, 2012	Shares to investors as part of at-the-market facility		52,000	0.17	8,970
August 29, 2012	Shares to investors as part of at-the-market facility		164,770	0.17	28,252
August 31, 2012	Shares to investors as part of at-the-market facility		347,000	0.17	58,771
September 3, 2012	Shares to investors as part of at-the-market facility		816,330	0.17	138,954
September 4, 2012	Shares to investors as part of at-the-market facility		169,060	0.17	27,909
September 14, 2012	Shares to investors as part of at-the-market facility		1,249,450	0.19	242,432
September 17, 2012	Shares to investors as part of at-the-market facility		2,507,610	0.20	507,067
September 18, 2012	Shares to investors as part of at-the-market facility		354,500	0.20	70,973
September 25, 2012	Shares to investors as part of at-the-market facility		1,196,500	0.25	296,530
September 26, 2012	Shares to investors as part of at-the-market facility		189,210	0.24	46,289
September 27, 2012	Shares to investors as part of at-the-market facility		121,350	0.22	27,055
September 28, 2012	Shares to investors as part of at-the-market facility		20,700	0.23	4,665
October 8, 2012	Shares to investors as part of private placement		32,500,000	0.18	6,012,500
March 1, 2013	Non cash share issue in consideration for services provided by				
	consultants	(i)	110,000	0.20	22,000
March 7, 2013	Shares to investors as part of at-the-market facility		1,843,240	0.27	502,879
March 7, 2013	Shares to investors as part of at-the-market facility		1,499,870	0.27	407,541
April 8, 2013	Shares to investors as part of private placement		25,641,030	0.20	5,000,000
April 8, 2013	Shares to investors as part of at-the-market facility		1,045,150	0.21	218,981
April 8, 2013	Shares to investors as part of at-the-market facility		244,740	0.22	53,110
April 8, 2013	Shares to investors as part of at-the-market facility		165,980	0.22	36,284

#### 13. ISSUED CAPITAL (continued)

May 3, 2013	Share Purchase Plan	10,370,488	0.19	2,022,245
	Security issuance costs			(1,015,775
Year ended June 30, 2013		83,629,608		15,245,034
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
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

#### 13. ISSUED CAPITAL (continued)

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
	Non cash share issue in consideration for services provided by			
April 7, 2014	consultants	1,000,000	0.25	252,750
June 30, 2014	Non cash share issue in consideration for services provided by			
	consultants	-	-	24,200
August 2, 2013	Security issuance costs	-	-	(1,339,369)
Year ended June 30, 2014		107.036.534		38,630,304

(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:

#### April 7, 2014 and March 1, 2013.

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,			
	2014	2014		2013		2012	
	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, 2014, 2013 and 2012.

#### (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.



#### 13. ISSUED CAPITAL (continued)

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

After reporting date the following equity issues occurred:

Details	Notes	Number	Issue Price A\$	A\$
Non cash share issue in consideration for services provided by consultants		110,000	0.23	25,300
Exercise of options – employees		180,000	0.14	25,488
		290,000		50,788
	Non cash share issue in consideration for services provided by consultants	Non cash share issue in consideration for services provided by consultants	Non cash share issue in consideration for services provided by consultants       110,000         Exercise of options – employees       180,000	Non cash share issue in consideration for services provided by consultants       110,000       0.23         Exercise of options – employees       180,000       0.14

#### 14. RESERVES

		Years Ended June 30,		
	Notes	2014	2013	2012
(a) Share Based Payments				
18,542,577 (2013: 35,544,121) options for fully paid ordinary shares	14(b)	6,968,437	8,557,928	7,664,454
Nil (2013: Nil) options for ADRs	14(c)	1,515,434	1,515,434	1,515,434
612,397 (2013: 612,397) warrants for ADRs	14(d)	453,563	453,563	453,563
		8,937,434	10,526,925	9,633,451

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.

#### 14. RESERVES (continued)

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

			Years Ende	d June 30,		
	201	4	201	2013		2
	Number of Options	Comp. Expense (A\$)	Number of Options	Comp. Expense (A\$)	Number of Options	Comp. Expense (A\$)
Beginning of the year	35,544,121	8,557,928	28,360,328	7,664,454	26,043,956	7,525,998
Issued during the year	3,926,490	992,908	10,683,793	893,474	4,158,674	286,866
Expired during the year	-	-	(3,500,000)	-	-	-
Forfeited during the year	-	-	-	-	(1,500,437)	(75,022)
Amortization of option expenses	-	-	-	-	-	47,148
Exercised during the year (Note 14(b))	(20,928,034)	(2,582,399)		<u> </u>	(341,865)	(120,536)
End of the year	18,542,577	6,968,437	35,544,121	8,557,928	28,360,328	7,664,454

Details of option grants are summarized as follows.

#### Year ended June 30, 2012:

• On December 19, 2011, the Company granted options to purchase 1,650,000 ordinary shares to consultants under the 2004 ASX Plan (see Note 18) in recognition of services rendered to the Company. The options are exercisable at A\$0.25 consideration and expire on December 19, 2014. The fair value of the options is A\$0.05.

• On December 19, 2011, the Company granted options to purchase 850,437 ordinary shares to employees under the 2004 ASX Plan (see Note 18) in recognition of future contributions to the growth and success of the Company. The options are exercisable at A\$0.25 consideration and expire on December 19, 2014. The fair value of the options is A\$0.05.

• On March 21, 2012, the Company granted options to purchase 650,000 ordinary shares to consultants under the 2004 ASX Plan (see Note 18) in recognition of services rendered to the Company. The options are exercisable at A\$0.25 consideration and expire on March 20, 2017. The fair value of the options is A\$0.10.

• On March 21, 2012, the Company granted options to purchase 1,008,237 ordinary shares to employees under the 2004 ASX Plan (see Note 18) in recognition of future contributions to the growth and success of the Company. The options are exercisable at A\$0.25 consideration and expire on March 20, 2017. The fair value of the options is A\$0.10.

#### Year ended June 30, 2013:

• On December 12, 2012, the Company granted options to purchase 8,000,000 ordinary shares to directors under the 2004 ASX Plan (see Note 18) in recognition of services rendered to the Company. The options are exercisable at A\$0.33 consideration and expire on December 13, 2017. The fair value of the options is A\$0.07.

• On December 12, 2012, the Company granted options to purchase 1,000,000 ordinary shares to key management personnel under the 2004 ASX Plan (see Note 18) in recognition of services rendered to the Company. The options are exercisable at A\$0.33 consideration and expire on December 13, 2017. The fair value of the options is A\$0.07.

• On June 26, 2013, the Company granted options to purchase 641,923 ordinary shares to employees under the 2004 ASX Plan (see Note 18) in recognition of future contributions to the growth and success of the Company. The options are exercisable at A\$0.37 consideration and expire on June 25, 2018. The fair value of the options is A\$0.14.

• On June 26, 2013, the Company granted options to purchase 1,041,870 ordinary shares to consultants under the 2004 ASX Plan (see Note 18) in recognition of future contributions to the growth and success of the Company. The options are exercisable at A\$0.37 consideration and expire on June 25, 2018. The fair value of the options is A\$0.14.

#### 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 18) 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 18) 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 18) 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 18) 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.

#### 14. RESERVES (continued)

• On February 7, 2014, the Company granted options to purchase 300,000 ordinary shares to consultants under the 2004 Plan (see Note 18) 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 18) 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 18) 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 18) 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.

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

			Years Ende	d June 30,				
	201	2014		2013		2012		
		Comp. Comp.			Comp.			
	Number of Options	Expense (A\$)	Number of Options	Expense (A\$)	Number of Options	Expense (A\$)		
Beginning of the year	-	1,515,434	380,000	1,515,434	380,000	1,515,434		
Expiration of options (1)	-	-	(380,000)	-	-	-		
End of the year	-	1,515,434	-	1,515,434	380,000	1,515,434		

(1) Options exercisable at US5.00 on or before December 17, 2012. These options are convertible to ADRs, 1 ADR = 10 ordinary shares. These options expired without being exercised on December 17, 2012.

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

			Years Ende	d June 30,		
	2014		2013		2012	
Number of WarrantsComp.Expense (A\$)		1	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	-
End of the year	612,397	453,563	612,397	453,563	612,397	453,563

(1) Warrants exercisable at US8.00 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.

#### (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	
	_	2014	2013
15. ACCUMULATED DEFICIT DURING DEVELOPMENT STAGE			
Balance at beginning of year		(97,931,323)	(90,144,081)
Net loss for the year		(13,329,239)	(7,787,242)
Balance at end of year	_	(111,260,562)	(97,931,323)
	Ye	ars Ended June 30,	
	2014	2013	2012
16. CASH FLOW INFORMATION			
(a) Reconciliation of Net Loss to Net Cash Flows From Operations			
Net loss	(13,329,239)	(7,787,242)	(5,239,469)
Non-cash items			
Depreciation of property and equipment	22,384	23,130	19,621
Non-cash issue of equity in consideration of operating expenses	1,269,857	893,477	310,835
Loss on disposal of plant and equipment	-	(150)	762
Foreign exchange (gain) loss	581,263	(110,816)	(48,870)
(Gain) loss on fair value of financial liabilities	37,473	197,898	(23,669)
Changes in assets and liabilities			
Decrease (increase) in trade and other receivables	(3,761,471)	(1,973,102)	(1,547,463)
Decrease (increase) in other current assets	15,359	(43,567)	21,913
(Decrease) increase in trade and other payables	1,582,980	817,041	(435,779)
(Decrease) increase in other current liabilities	(33,332)	(17,499)	50,831
(Decrease) increase in provision for employee entitlements	78,503	49,576	45,382
Net cash flows used in operating activities	(13,536,223)	(7,951,254)	(6,845,906)
(b) Reconciliation of Cash and Cash Equivalents			
Cash and cash equivalents balance comprises:			
- cash and cash equivalents on hand	34,167,018	13,346,760	5,636,469
Closing cash and cash equivalents balance	34,167,018	13,346,760	5,636,469

#### (c) Non-Cash Financing and Investing Activities

During the years ended June 30 2014, 2013 and 2012, the Company issued shares and granted options in connection with non-cash transactions. See Notes 13(b) and 14(b).

#### 17. 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\$60,021 and greater than one year but less than three years of A\$3,168. The property lease is a non-cancellable lease with a 24 month term, with rent payable monthly in advance. The property lease commenced November 1, 2012 and expires on October 31, 2014. The Company has the option to renew the lease for a further 5 years. The photocopier lease is a non-cancellable lease with a 48 month term, with rent payable monthly in advance. The photocopier lease commenced April 1, 2012 and expires on March 31, 2016.

Details in relation to commitments under employee service agreements with Directors and Key Management Personnel are outlined in Note 21.

#### 18. 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 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 ADS Plan. At June 30, 2013, equity had been issued to one former Director under the 2004 ADS Plan and six Directors, three key management personnel, 16 employees and 18 consultants under the 2004 ASX Plan. At June 30, 2012, equity had been issued to one former Director under the 2004 ADS Plan and five Directors, three key management personnel, 16 employees and 18 consultants under the 2004 ASX Plan. At June 30, 2012, equity had been issued to one former Director under the 2004 ADS Plan and five Directors, three key management personnel, 16 employees and 17 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, 45 million ordinary shares at the 2008 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.



#### 18. SHARE BASED PAYMENTS (continued)

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

	Years Ended June 30,						
	201	14	20	13	2012		
	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	17,031,476	0.23	6,347,683	0.14	4,031,311	0.05	
Issued during the year	3,926,490	0.69	10,683,793	0.34	4,158,674	0.25	
Exercised during the year	(4,582,384)	0.11	-	-	(341,865)	Nil	
Expired during the year	-	-	-	-	-	-	
Lapsed during the year	-	-	-	-	(1,500,437)	0.25	
Forfeited during the year		-		-			
Outstanding at year end	16,375,582	0.41	17,031,476	0.23	6,347,683	0.14	
Exercisable at year end	16,175,582	0.40	16,010,786	0.28	5,326,993	0.16	

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

Series	Grant Date	Expiry Date	Exercise Price \$A	Share options 2014	Share options 2013
PBTAA	October 25, 2013	October 24, 2018	0.61	200,000	-
PBTAB	June 8, 2010	August 7, 2014	0.00	180,000	2,270,690
PBTAC	June 26, 2013	June 25, 2018	0.37	1,649,573	1,683,793
PBTAD	November 4, 2013	November 3, 2018	0.73	360,000	-
PBTAE	December 13, 2013	December 11, 2018	1.04	1,200,000	-
PBTAF	February 1, 2014	February 5, 2019	1.12	300,000	-
PBTAG	April 7, 2014	April 6, 2018	0.25	1,200,000	-
PBTAQ	December 12, 2012	December 13, 2017	0.33	8,500,000	9,000,000
PBTAS	June 8, 2010	March 31, 2014	0.15	-	1,418,756
PBTAU	December 19, 2011	December 19, 2014	0.25	1,000,000	1,000,000
PBTAW	March 21, 2012	March 20, 2017	0.25	1,119,519	1,658,237
PBTAY	August 5, 2013	August 4, 2018	0.66	306,490	-
PBTAZ	October 2, 2013	October 1, 2018	0.66	360,000	-
			Total	16,375,582	17,031,476

Weighted average remaining contractual life of options outstanding at end of period

The weighted average fair value of options granted during the period was determined in accordance with Note 1(q) as A\$0.29, A\$0.08 and A\$0.07 for the years ended [June 30,] 2014, 2013 and 2012, respectively. The weighted average assumptions in calculating fair value were as follows: • risk-free interest rate of 3.26% for 2014, 2.83% for 2013 and 3.35% for 2012;

3.42 years

3.51 years

• no dividends:

- expected volatility of 134.50% for 2014, 57.15% for 2013 and 72% for 2012;
- expected life of 4.69 years for 2014, 5.00 years for 2013 and 3.80 years for 2012;

underlying share price of \$0.50 for 2014, \$0.21 for 2013 and \$0.15 for 2012; and

exercise price of \$0.69 for 2014, \$0.34 for 2013 and \$0.25 for 2012.

*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.

#### PRANA BIOTECHNOLOGY LIMITED

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - in Australian dollars (unless otherwise noted)

#### 18. SHARE BASED PAYMENTS (continued)

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.

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
	Grant Date		Orant Date Ap		Tears to Expiry	Dividenta Tieta	Kate
PBTAQ	December 12, 2012	0.33	0.21	52.30%	5.00	0%	2.73%
PBTAC	June 26, 2013	0.37	0.23	83.10%	5.00	0%	3.23%
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%

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

	Ye	Years Ended June 30,		
	2014	2013	2012	
	Number of Shares	Number of Shares	Number of Shares	
Beginning of the year	7,405,331	7,295,331	6,643,466	
Issued during the year (1)	5,582,384	110,000	651,865	
End of the financial year	12,987,715	7,405,331	7,295,331	

(1) In the years ended June 30, 2014 and 2012 this includes options to purchase 4,582,384 and 341,865 ordinary shares, respectively granted under the 2004 ASX Plan that were exercised. In the year ended June 30, 2013 no options to purchase ordinary shares, respectively granted under the 2004 ASX Plan were exercised.

The weighted average fair value of the shares granted during the year ended June 30, 2014, 2013 and 2012 was \$0.25. \$0.20 and \$0.16.

#### 18. SHARE BASED PAYMENTS (continued)

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

			Years En	ded June	30,				
	2	014	20	)13		20	2012		
	Number of Options	Weighted Average Exercise Price	Number of Options		ed Average cise Price	Number of Options		ted Average cise Price	
					US\$5.00		-	US\$5.00	
Beginning of the year	-	-	380,000	A\$	(5.48)	380,000	A\$	(4.92)	
					US\$5.00				
Expired during the year 1	-	-	(380,000)	A\$	(5.48)	-		-	
								US\$5.00	
Outstanding at year end	-	-	-		-	380,000	A\$	(4.92)	
								US\$5.00	
Exercisable at year end 1	-	-			-	380,000	A\$	(4.92)	

<sup>1</sup> These options are exercisable into ADRs (one option granted under the 2004 ADS Plan is exercisable for one ADR which represents ten ASX shares)

The benefit to executives, employees, director and consultants is recognized in the financial statements over the period in which the services are provided. Refer to Notes 13, 14 and 21 for further information.

Options granted that have not been exercised carry no dividend rights or right to vote.

#### 19. SUBSEQUENT EVENTS

On September 5, 2014, the Company announced the US Food and Drug Administration (FDA) granted Orphan Drug designation to PBT2 for the treatment of Huntington Disease.

Orphan drug designation is granted by the FDA to promote the development of drugs for diseases affecting less than 200,000 people in the United States. Orphan drug designation entitles the Company to seven years of market exclusivity for the use of PBT2 in the treatment of Huntington disease; protocol assistance by the FDA to optimize drug development in the preparation of a dossier that will meet regulatory requirements; and reduced fees associated with applying for market approval.

No other 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.

	Years Ended June 30,		
	2014	2013	2012
20. LOSS PER SHARE			
Basic and diluted loss per share (cents per share)	(3.11)	(2.30)	(1.82)
Weighted average number of ordinary shares on issue used in the calculation of basic and diluted loss per share	428,047,123	338,700,006	287,765,812

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

#### 21. KEY MANAGEMENT PERSONNEL COMPENSATION

	-	2014	2013
Short-term employee benefits		1,139,860	1,061,873
Post-employment benefits		77,775	76,039
Long-term benefits		17,615	18,283
Termination benefits		-	
Share-based payments		33,824	665,351
		1,269,074	1,821,546
	Ye	ears Ended June 30,	
	2014	2013	2012
22. AUDITORS' REMUNERATION			
- audit and review fees: current year	145,187	164,060	145,000
and it is a dimensioner for an intermediate start in for the second start of the second start in the second start is the secon			
- audit and review fees: internal controls for Sarbanes Oxley requirement	187,422	-	-
- audit and review rees: internal controls for Sarbanes Oxfey requirement	187,422 65,000	-	-

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 2014, 2013 and 2012 fiscal years.

#### 23. 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 Independent Director (appointed May 13, 2014)

The Key Management Personnel of the Company during the year:

Dianne Angus	Chief Operating Officer
Richard Revelins	Company Secretary and Chief Financial Officer
Phillip Hains	Acting Chief Financial Officer (appointed May 1, 2014)

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.



#### 23. RELATED PARTY TRANSACTIONS (continued)

	Short Term Bene	fits	Post-Employment	Long Term Benefits	Equity	
2014			Superannuation	Long-service	<u> </u>	
	Base Fee	Bonus	Contribution	Leave	Options	Total
Directors' remuneration	A\$	A\$	A\$	A\$	A\$	A\$
Geoffrey Kempler (1) (2)	444,389	-	25,000	8,601	-	477,990
Brian Meltzer (2)	50,000	-	35,000	-	-	85,000
George Mihaly (2)	75,000	-	-	-	-	75,000
Peter Marks (2)	60,000	-	-	-	-	60,000
Lawrence Gozlan (2)	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;

				Long Term		
	Short Term Bene	efits	Post-Employment	Benefits	Equity	
2013			Superannuation	Long-service		
	Base Fee	Bonus	Contribution	Leave	Options	Total
Directors' remuneration	A\$	A\$	A\$	A\$	A\$	A\$
Geoffrey Kempler (1) (2)	428,278	-	25,000	11,980	295,711	760,969
Brian Meltzer (2)	62,500	-	25,000	-	73,928	161,428
George Mihaly (2)	75,000	-	-	-	73,928	148,928
Peter Marks (2)	57,500	-	-	-	73,928	131,428
Lawrence Gozlan (2)	45,000	-	-	-	73,928	118,928
	668,278	-	50,000	11,980	591,423	1,321,681

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

(2) The Directors received unlisted options during the year ended June 30, 2013. The option prices were calculated using the Black-Scholes Model applying the following inputs:

Grant Date: December 12, 2012	Volatility: 52.30%
Exercise Price: A\$0.33	Risk-free Interest Rate: 2.73%
Stock Price: A\$0.21	Dividend Yield: 0%
Years to Expiry: 5.00	Option Price: A\$0.0739

				Long Term		
	Short Term Bene	fits	Post-Employment	Benefits	Equity	
2012			Superannuation	Long-service		
	Base Fee	Bonus	Contribution	Leave	Options	Total
Directors' remuneration	A\$	A\$	A\$	A\$	A\$	A\$
Geoffrey Kempler (1)	409,362	-	28,415	6,325	-	444,102
Brian Meltzer	82,569	-	7,431	-	-	90,000
George Mihaly	75,000	-	-	-	-	75,000
Peter Marks	55,000	-	-	-	-	55,000
Lawrence Gozlan (2)	36,667	-	-	-	-	36,667
	658,598	-	35,846	6,325	-	700,769

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

(2) Mr. Lawrence Gozlan was appointed to the Board of Directors on August 8, 2011.

#### 23. RELATED PARTY TRANSACTIONS (continued)

				Long Term		
	Short Term Bene	fits	Post-Employment	Benefits	Equity	
2014			Superannuation	Long-service		
	Base Fee	Other	Contribution	Leave	Options	Total
Executives' Remuneration	A\$	A\$	A\$	A\$	A\$	A\$
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.

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.

	Short Term Bene	fits	Post-Employment	Long Term Benefits	Equity	
2013			Superannuation	Long-service		
	Base Fee	Other	Contribution	Leave	Options	Total
Executives' Remuneration	A\$	A\$	A\$	A\$	A\$	A\$
Richard Revelins (2)	77,343	-	-	-	73,928	151,270
Dianne Angus (1)	316,251	-	26,040	6,303	-	348,595
	393,594	-	26,040	6,303	73,928	499,865

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

(2) Mr. Revelins received unlisted options during the year ended June 30, 2013. The option prices were calculated using the Black-Scholes Model applying the following inputs:

Grant Date: December 12, 2012	Volatility: 52.30%
Exercise Price: A\$0.33	Risk-free Interest Rate: 2.73%
Stock Price: A\$0.21	Dividend Yield: 0%
Years to Expiry: 5.00	Option Price: A\$0.0739

	Short Term Bene	fits	Post-Employment	Long Term Benefits	Equity	
2012		01	Superannuation	Long-service		TT ( 1
	Base Fee	Other	Contribution	Leave	Options	Total
Executives' Remuneration	A\$	A\$	A\$	A\$	A\$	A\$
Richard Revelins	81,681	-	-	-	-	81,681
Dianne Angus (1) (2)	317,180	-	28,407	17,980	30,806	394,373
	398,861	-	28,407	17,980	30,806	476,054

(1) Base Fee includes movements in annual leave provision for Ms<sub>2</sub> Dianne Angus accrued in accordance with his employment contract.

(2) Ms. Angus received unlisted options during the year ended June 30, 2012. The option prices were calculated using the Black-Scholes Model applying the following inputs:

Volatility: 84.90%
Risk-free Interest Rate: 3.87%
Dividend Yield: 0%
Option Price: A\$0.0976

#### 23. RELATED PARTY TRANSACTIONS (continued)

The following Director was under contract during the year ended June 30, 2014:

<u>Directors</u> Mr. Geoffrey Kempler	Duration Until termination by either party Signed September 21, 2007	<u>Notice Requirements</u> 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> <li>Termination</li> <li>Pay Mr. Kempler within ninety (90) days of the termination date A1,000,000 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 Key Management Personnel	contract during the year ended June 30, 2014: Duration	Notice Requirements	Termination
<u>Key Management Personnel</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	<ul> <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> </ul>
		Without Good Reason Ms. Angus may terminate with 120 days' notice Or With Cause the Company may terminate without notice	<ul> <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>
		F - 38	

#### 23. RELATED PARTY TRANSACTIONS (continued)

#### c. Key Management Personnel Equity Holdings

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
Funy Faid Ordinary Shares of the Company		No.	No.	No.	No.
Geoffrey Kempler	17,811,000	110.	110.	-	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 (4)		-			-
Richard Revelins	20,308	-	500.000	(500,000)	20,308
Dianne Angus		-	868,547	(722,419)	146,128
Phillip Hains (5)	211,800	-	-	-	211,800
	211,000			· · · · · · · · ·	211,000
	18,639,551	-	1,368,547	(1,222,419)	18,785,679
	Balance July 1,	Received as	Received on	Net Change Other	Balance
Fully Paid Ordinary Shares of the Company	2012	Remuneration	Exercise of Options	(1)	June 30, 2013
	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 (2)	-	-	-	-	-
Richard Revelins	20,308	-	-	-	20,308
Dianne Angus	<u> </u>	-		<u> </u>	-
	18,427,751	-		<u> </u>	18,427,751
	Balance July 1,	Received as	Received on	Net Change Other	Balance
Fully Paid Ordinary Shares of the Company	2011	Remuneration	Exercise of Options	(1)	June 30, 2012
runy rule ordinally bhares of the company		No.	No.	No.	No.
Geoffrey Kempler	17,055,000	INO.	10.	756,000	17,811,000
Brian Meltzer	326,666	-	-		326,666
George Mihaly	226,666	-	-	-	226,666
Peter Marks	43,111	-			43,111
Paul Marks (3)	45,111	-	-	-	43,111
Richard Revelins	20,308			-	20,308
Dianne Angus	100,000	-	-	(100,000)	20,308
Diame Angus	100,000			(100,000)	
	17,771,751	-		656,000	18,427,751

Net change other refers to shares purchased or sold during the financial year.
 Balance at date of appointment, August 8, 2011.
 Balance at date of retirement, January 4, 2011.
 Balance at date of appointment, May 13, 2014.
 Balance at date of appointment, May 1, 2014.

#### 23. RELATED PARTY TRANSACTIONS (continued)

								Total Vested	
	Balance	Granted as	Options	Options		Options Vested	Balance	and Exercisable	Total Unvested
Share Options of	July 1, 2013	Remuneration	Exercised	Forfeited	Net Change	During 2014	June 30, 2014	June 30, 2014	June 30, 2014
the Company	No.	No.	No.	No.	Other (1)	fiscal year	No.	No.	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 (4)	-	-	-	-	-	-	-	-	-
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 (5)	-	-	-	-	-	-	-	-	-
	11,052,730	160,000	(1,368,547)	-	(1,026,364)	-	8,817,819	8,817,819	-

Share Options of the Company	Balance July 1, 2012 No.	Granted as Remuneration No.	Options Exercised No.	Options Forfeited No.	Net Change Other (1)	Options Vested During 2013 fiscal year	Balance June 30, 2013 No.	Total Vested and Exercisable June 30, 2013 No.	Total Unvested June 30, 2013 <u>No.</u>
Geoffrey		1 000 000					4 000 000	4 000 000	
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									
(2)	-	1,000,000		-	-	-	1,000,000	1,000,000	
Richard Revelins	-	1,000,000	-	-	-	-	1,000,000	1,000,000	-
Dianne Angus	2,052,730	-	-	-	-	-	2,052,730	1,857,893	194,837
	2,052,730	9,000,000	-	-	-	-	11,052,730	10,857,893	194,837

Share Options of the Company	Balance July 1, 2011 No.	Granted as Remuneration No.	Options Exercised No.	Options Forfeited No.	Net Change Other (1)	Options Vested During 2012 fiscal year	Balance June 30, 2012 No.	Total Vested and Exercisable June 30, 2012 No.	Total Unvested June 30, 2012 No.
Geoffrey									
Kempler	-	-	-	-	-	-	-	-	-
Brian Meltzer	-	-	-	-	-	-	-	-	-
George Mihaly	-	-	-	-	-	-	-	-	-
Peter Marks	-	-	-	-	-	-	-	-	-
Paul Marks (3)	-	-	-	-	-	-	-	-	-
Richard Revelins	-	-	-	-	-	-	-	-	-
Dianne Angus	1,737,093	315,637	-	-	-	-	2,052,730	1,857,893	194,837
	1,737,093	315,637	-	-	-	-	2,052,730	1,857,893	194,837

Net change other refers to shares purchased or sold during the financial year.
 Balance at date of appointment, August 8, 2011.
 Balance at date of retirement, January 4, 2011.
 Balance at date of appointment, May 13, 2014.
 Balance at date of appointment, May 1, 2014.

#### 24. 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's disease, Parkinson's disease and other major age-related degenerative disorders. Accordingly, the Company has identified one reportable segment.

#### 25. 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:

	Consolidate	d Entity
	2014	2013
	A\$	A\$
Cash and cash equivalents (USD)	26,398,943	2,035,812
Cash and cash equivalents ( <sup>^</sup> EUR)	-	(43)
Cash and cash equivalents (£GBP)	-	-
Trade and other payables (USD)	(37,934)	(108,654)
Trade and other payables ( <sup>^</sup> EUR)	(36,168)	-
Trade and other payables (£GBP)	(205,649)	-
Total exposure	26,119,192	1,927,115

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 Great 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 4%, 5% and 6% respectively. All the amounts in the table below are displayed in A.

Based on the financial instruments held at June 30, 2014, had the Australian dollar weakened/strengthened by 4% against the US dollar, 5% against the GBP and 6% against the EURO with all other variables held constant, the Company's post-tax profit for the year would have been A\$1,002,039 lower/A\$1,085,236 higher (2013: A\$74,110 lower/A\$80,286 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.



#### 26. 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, 2014, the Company had the following cash accounts:

- A\$154,747 in an Australian dollar transaction account at an interest rate of 0.05% as of June 2014;
- A\$2,612,870 in an Australian Business Cash High Interest account at an interest rate of 2.35% as of June 2014;
- A\$258 in an Australian Trust account at an interest rate of 0% as of June 2014;
- US\$24,881,751 (A\$26,397,678) in U.S. checking accounts at an interest rate of 0.03% as of June 30, 2014;
- A\$5,000,000 in a three month term deposit at a fixed interest rate of 3.76% which matures on July 6, 2014;
- A\$43,988 in a twelve month term deposit at a fixed interest rate of 3.35% which matures on March 7, 2015;
- A\$200 in petty cash which does not earn any interest; and
- US\$1,192 (A\$1,265) in petty cash which does not earn any interest.

The weighted average interest rate is 0.75% for cash and cash equivalents and 1.05% 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, 2013, the Company had the following cash accounts:

- A\$34,949 in an Australian dollar transaction account at an interest rate of 0.05% as of June 2013;
- A\$4,775,852 in an Australian Business Cash High Interest account at an interest rate of 2.60% as of June 2013;
- US\$1,859,015 (A\$2,035,621) in U.S. checking accounts at an interest rate of 0% as of June 30, 2013;
- A\$5,000,000 in a three month term deposit at a fixed interest rate of 4.45% which matures on 11 July 2013;
- A\$1,500,000 in a three month term deposit at a fixed interest rate of 4.20% which matures on 08 August 2013;
- A\$43,988 in a twelve month term deposit at a fixed interest rate of 4.20% which matures on 07 March 2014;
- A\$200 in petty cash which does not earn any interest; and
- US\$174 (A\$191) in petty cash which does not earn any interest.

The weighted average interest rate is 3.07% for cash and cash equivalents and 1.18% 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.

#### 26. 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, 2014	Floating Interest Rate (A\$)	Fixed Int Maturin (A\$)	ng in	Non-Interest bearing (A\$)	Total (A\$)	Average Interest Rate
		1 year or less	1-5 years			
Financial Assets						
Cash and cash equivalents	34,165,553	-	-	1,465	34,167,018	0.75%
Trade and other receivables	-	-	-	7,285,409	7,285,409	
Other current assets	-	43,988	-	96,883	140,871	1.05%
Total Financial Assets	34,165,553	43,988	-	7,383,757	41,593,298	
Financial Liabilities						
Payables	-	-	-	3,358,358	3,358,358	
Other financial liabilities	-	-	-	98,398	98,398	
Total Financial Liabilities	-	-	-	3,456,756	3,456,756	
				- / /		

#### 26. FINANCIAL INSTRUMENTS (continued)

June 30, 2013	Floating Interest Rate (A\$)	Fixed In Maturi (A\$	ng in	Non-Interest bearing (A\$)	Total (A\$)	Average Interest Rate
		1 year or less	1-5 years			
Financial Assets						
Cash and cash equivalents	13,346,369	-	-	391	13,346,760	3.07%
Trade and other receivables	-	-	-	3,523,938	3,523,938	
Other current assets		43,988		112,242	156,230	1.18%
Total Financial Assets	13,346,369	43,988		3,636,571	17,026,928	
Financial Liabilities						
Payables	-	-	-	1,775,666	1,775,666	
Other financial liabilities	<u> </u>		802,641	68,160	870,801	1.05%
Total Financial Liabilities			802,641	1,843,826	2,646,467	

#### (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.

#### 26. FINANCIAL INSTRUMENTS (continued)

		Matu	rities of Financial Liabi	lities	
2014	Less than 6 months	6-12 months	Greater than 12 months and less than 5 years	Total contracted cash flows	Carrying amounts
		Consolidated Entity			
Trade and other payables	3,358,358	-	-	3,358,358	3,358,358
Total	3,358,358	-	-	3,358,358	3,358,358
2013	-	Consolidated			
		Entity			
Trade and other payables	1,775,666	-	-	1,775,666	1,775,666
ADDF Convertible Promissory Note	-	819,479	-	819,479	819,479
Total	1,775,666	819,479	-	2,595,145	2,595,145

#### (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 13, 14 and 15. 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.

#### 26. ADDITIONAL COMPANY INFORMATION

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

Registered Office	Principal Place of Business
Suite 2	Level 2
1233 High Street	369 Royal Parade
Armadale Vic 3143	Parkville Vic 3052
Australia	Australia
Tel: +61 (03) 9824 8166	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 31, 2014

Exhibit 4.16
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	tch Manufacturing e of Scope
Prana Biotecl	nnology Limited
COS REFERENCE #: P-	TRP-54564-R1-COS-01-R0
	La La persona 1
Patheon Inc. ("Patheon")	Prana Biotechnology Limited ("Client")
2100 Syntex Court Mississauga, Ontario L5N 7K9 Canada	Level 2, 269 Royal Parade Parkville, VIC3052 Australia
hard 1 311	
By: Mary La Ellis	Name: Dipune moul
Title: SR. Pryect Manage	Title: Chief Openity Office.
	Date: 18 The 2013.
Date: 11 JUL 2013	
Date: 11 JUL 2013	Finance Contact:



#### Part A: Overview

This change of scope describes development activities to be performed for Prana Biotechnology Limited ("Client") by Patheon Inc. ("Patheon") under the terms and conditions of a Development Manufacturing Agreement P-TRP-54564-R1 by and between Patheon and the Client, dated April 16, 2013, which is hereby revised to include this change of scope in its entirety.

This change of scope reflects the costs associated to manufacture, package, and release two active lots of PBT2 Capsules for a Phase I bioequivalency clinical trial. Also included are the costs for the stability studies on these same batches.

COS Reference #: P-TRP-54564-R1-COS-01-R0 Issue Date: July 10, 2013 Confidential Prana Biotechnology Limited PBT2 Capsules - Phase I BE Batch Manufacturing Page 2 of 5



Part B: Pricing

## BUDGET SUMMARY

	FOLLOWING COSTS AR			<u>USD</u>						
CTM	BATCHES (ED)								USI	
		ACTIVITY				1	MILESTONE PRICI	ŝ	PRIC	ĽE
		tch Manufacturing Packaging Analytical Support		Total Per Batch 1 Batch TOTAL			\$ 37,632 \$ 9,403 \$ 19,142 \$ 66,177 \$ 33,638		\$ 66,	5,177
		Packaging Analytical Support		Total Per Batch 1 Back to Back Batch TOTAL			\$ 8,328 <u>\$ 10,400</u> <u>\$ 52,366</u>		<u>\$ 52,</u>	2,366
		Total					Material and Supply	y Fee:	\$ 118,5 \$ 5,927	7
4.0 STAB	ILITY - CTM	ACTIVITY							USI PRIC	
		Number of Lots Total Samples	2 24						Three	
		Protocol Generation							\$	791
ullpoint Months	40°C/75% RH	25°C/60% RH			Microbiology	AET	Samples per pullpoint		Cost per pull <sub>]</sub> Milestone Pi	
T=1	40 C / / 5 /0 KH X	25 C / 00 /0 KH X			Microbiology	ALI	<b>punpoint</b> 4	\$	9,505	
T=3	X	X					4	\$	9,505	
T=6	Х	Х					4	\$	9,505	
T=9		Х					2	\$	6,380	
T=12		Х			Х		2	\$	7,593	
T=18		Х					2	\$	6,380	
T=24		Х			Х		2	\$	7,593	
T=36		X			X		2	\$	7,593	
T=48		X Summary Report Generation			Х		2	\$\$	7,593	
		Summary Report Generation						\$	1,150	
		Total		Ma	aterial and Supply Fee:	:		\$ \$	73,568 3,678	
BI	UDGET TOTAL						USD	\$	192,111	
							USD	\$	9,605	
M	aterial and Supply Fee RAND TOTAL						USD	φ	9,005	

COS Reference #: P-TRP-54564-R1-COS-01-R0 Issue Date: July 10, 2013 Confidential Prana Biotechnology Limited PBT2 Capsules - Phase I BE Batch Manufacturing Page 3 of 5

#### Part C: Descriptions of work to be added to the Project Scope

#### 1. Clinical Trial Material (CTM) Active Manufacturing

Process train: high shear granulation (PMA-25), fluid bed drying (S2), encapsulation (Romaco)

Patheon will manufacture:

- 2 CTM Active batches (one 100 mg, one 250 mg strength), back-to-back manufacturing and testing
- Approximately 5 kilograms per batch
- Excipients released as per USP/NF/EP
- Batch record, cGMP conditions & QA review
- Packaged into HDPE bottles (i.e. 35's)
- In-Process Testing: Blend Homogeneity (one blend, 10 samples); Bulk & Tap Densities (including one sieve analysis), Flow Properties, Moisture (LOD or KF) and Physical Parameters (i.e. appearance, weight, weight variation) for beginning, middle and end of run
- Finished Product Testing: Potency & Related Substances; Content Uniformity (n=10); Dissolution (profile, n=6); Moisture (LOD or KF); Microbial Limit Testing (MLT)

#### 2. Stability - CTM Active

Patheon shall design a stability program to monitor 1 batch of PBT2 Capsules under ICH conditions. Additional samples will be stored as contingency samples if required to generate data for long-term stability of the product.

The following storage conditions and test-points are suggested for testing:

- 1, 3 and 6 months for  $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$  RH
- 1, 3, 6, 9, and 12 months for  $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$  RH\*
- 1, 3, 6, 9, 12, 18, 24, 36, and 48 months for 25°C ± 2°C / 60% ± 5% RH

(\* Tested only if required due to significant changes in the next level condition)

The analytical data used for the release of each lot manufactured at Patheon will be considered as initial (T=0) data provided that stability initiation occurs within 30 days of release testing. Should this not be the case the cost for the additional T=0 testing will be the subject of a future change of scope.

Cost efficiencies for analytical testing have been built into the stability program based upon the number of samples pulled in a given month.

Pullpoint Month	1	2	6	0	12	10	24	26	10
Pumpoint Month	1	3	0	9	12	10	24	30	40
Number of Samples Pulled	4	4	4	2	2	2	2	2	2

COS Reference #: P-TRP-54564-R1-COS-01-R0 Issue Date: July 10, 2013 Confidential

Prana Biotechnology Limited PBT2 Capsules - Phase I BE Batch Manufacturing Page 4 of 5

Therefore, the stability sample breakdown is:

0 single sample pullpoints (0 samples) 6 double sample pullpoints (12 samples)

3 three to four sample pullpoints (12 samples) 0 more than five sample pullpoints (0 samples)

The following standard tests will be performed as part of the stability program:

- Potency & related substances .
- Physical appearance
- ٠ Moisture
- Dissolution (profile by HPLC) MLT (annually) ٠
- •

## Appendix 1 – COS Revision History

COS Revision Number	Description of Activities	Overall Cost (USD)
R0	Phase I BE batch manufacturing	\$201,716

COS Reference #: P-TRP-54564-R1-COS-01-R0 Issue Date: July 10, 2013 Confidential

Prana Biotechnology Limited PBT2 Capsules - Phase I BE Batch Manufacturing Page 5 of 5

# **PBT2 Capsules**

# Stability Change of Scope

# Prana Biotechnology Limited

COS REFERENCE #: P-TRP-54564-R1-COS-02-R0

Patheon Inc. ("Patheon") 2100 Syntex Court Mississauga, Ontario L5N 7K9 Canada	Prana Biotechnology Limited ("Client") Level 2, 269 Royal Parade Parkville, VIC3052 Australia
By: <u>ARMO</u> Name: <u>BISELLE PINTO</u> Title: <u>PROJECT MANAGER</u> Date: <u>20/AUG/2013</u>	Name: Ortune Anous. Title: <u>C.O.O.</u> Date: <u>30 Carrol 2013</u> .
Effective Date:	Finance Contact:
Patheon.	



#### Part A: Overview

This change of scope describes development activities to be performed for Prana Biotechnology Limited ("Client") by Patheon Inc. ("Patheon") under the terms and conditions of a Development Manufacturing Agreement P-TRP-54564-R1 by and between Patheon and the Client, dated April 16, 2013, which is hereby revised to include this change of scope in its entirety.

This change of scope adjusts the costs of the T=1m and T=2m stability time-points on the formulation development batches to include dissolution testing on all 4 batches, as opposed to the originally planned 2 batches. The original cost of the deliverables quoted in P-TRP-54564-R1 is cancelled within.

The grand total cost for all added activities is \$18,604 USD.

The total value for all cancelled tasks is (\$15,214) USD.

The net project budget impact is \$3,390 USD.

#### Part B: Pricing

BUDGET SUMMARY THE FOLLOWING COSTS ARE ALL QUOTED IN: <u>USD</u> STABILITY - PROTOTYPE BATCH USD ACTIVITY PRICE 2 Number of Lots 6 Total Samples Samples Cost per pullpoint Pullpoint (Milestone Price) per Months 40°C/75% RH 25°C/60% RH Microbiology AET pullpoint 11,060 T = 1Х Х 4 \$ T = 2 Х \$ 6,658 2 17,718 Total \$ \$ Material and Supply Fee: 886 BUDGET TOTAL USD 17,718 \$ Material and Supply Fee USD \$ 886 GRAND TOTAL USD \$ 18,604 COS Reference #: P-TRP-54564-R1-COS-02-R0 Prana Biotechnology Limited Issue Date: August 13, 2013 PBT2 Capsules - Stability Confidential Page 2 of 3

#### Part C: Descriptions of work to be added to the Project Scope

#### 1. Stability

Patheon shall design a stability program (single orientation, single container type) to monitor:

• 2 batches\* under ICH conditions \*: 4 batches to be tested in dissolution only

The following storage conditions and test-points are suggested for testing:

• Testing per sample: potency & related substances; dissolution (profile, n=6)\*; physical (appearance, moisture)

#### Part D: Descriptions of work to be Cancelled from the Project Scope

Project Name: 11311 - Prana Biotechnology Ltd, - PBT2 Immediate Release Capsules	
Client Name: Prana Biotechnology Ltd.	
Product Name: PBT2 Immediate Release Capsules	
Currency: USD	
Task Name	Fee
P-TRP-54564-R1	
STABILITY - T = 1 (Includes 5% Material and Supply Fee)	\$9,169
STABILITY - T = 2 (Includes 5% Material and Supply Fee)	\$6,045
Fee Summary:	-\$15.214

#### Appendix 1 – COS Revision History

COS Revision Number	Description of Activities	Overall Cost (USD)
R0	Stability	\$3,390

COS Reference #: P-TRP-54564-R1 -COS-02-R0 Issue Date: August 13, 2013 Confidential Prana Biotechnology Limited PBT2 Capsules - Stability Page 3 of 3

Change of Scope M to Proposal No. P- For Prana Biotech	TRP-54564-R1
Patheon Inc. ("Patheon") 2100 Syntex Court Mississauga, Ontario L5N 7K9 Canada	Prana Biotechnology Ltd. ("Client") Level 2, 269 Royal Parade Parkville, VIC3052 Australia
By:	By: <u>Anne</u> <u>Anne</u> <u>Anne</u> Name: <u>Altone</u> <u>Anne</u> Title: <u>C-O-D</u> Date: <u>2.G./S./.4</u> Finance Contact:
	Performance the World Over



#### Part A: Overview

This change of scope describes development activities to be performed for Prana Biotechnology Ltd. ("Client") by Patheon Inc. ("Patheon") under the terms and conditions of a Development Manufacturing Agreement P-TRP-54564-R1 by and between Patheon and the Client, dated April 16, 2013, which is hereby revised to include this change of scope in its entirety.

This change of scope reflects the costs associated with the manufacture of two active CTM batches plus stability. The Phase I stability study quoted for two batches in P-TRP-54564-R1-COS-01-R0 is revised to cover one batch.

The grand total cost for all added activities is \$291,269 USD.

The total value for all cancelled tasks is (\$130,209) USD.

The net project budget impact is \$161,060 USD.

#### Part B: Descriptions of Work to be Added to the Project Scope

#### 1. Clinical Trial Material (CTM) Active Manufacturing

Process train: high shear granulation (PMA-65), fluid bed drying (S2), encapsulation (Romaco)

Patheon will manufacture:

- 2 CTM Active batches (one 100 mg, one 250 mg strength), back-to-back manufacturing and testing
- Approximately 12 kilograms per batch
- Excipients released as per USP/NF/EP
- Batch record, cGMP conditions & QA review .
- Packaged into HDPE bottles (i.e. 35's)
- In-Process Testing: Blend Homogeneity (one blend, 10 samples); Bulk & Tap Densities (including one sieve analysis), Flow Properties, Moisture (LOD or KF) and Physical Parameters (i.e. . appearance, weight weight variation) for beginning, middle and end of run Finished Product Testing: Potency & Related Substances; Content Uniformity (n=10); Dissolution (profile, n=6); Moisture (LOD or KF); Microbial Limit Testing (MLT)

#### 2. Stability – Phase III CTM Active

Patheon shall design a stability program to monitor 2 batches of PBT2 Capsules under ICH conditions. Additional samples will be stored as contingency samples if required to generate data for long-term stability of the product.

The following storage conditions and test-points are suggested for testing:

Change of Scope COS-03-R0 to Proposal No. P-TRP-54564-R1 Issue Date: February 11, 2014 Confidential

Prana Biotechnology Ltd. Page 2 of 6



- 1, 3 and 6 months for  $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$  RH
- 1, 3, 6, 9, and 12 months for  $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$  RH\*
- 1, 3, 6, 9, 12, 18, 24, 36, and 48 months for  $25^\circ C \pm 2^\circ C \,/\,60\% \pm 5\%$  RH

(\* Tested only if required due to significant changes in the next level condition)

The analytical data used for the release of each lot manufactured at Patheon will be considered as initial (T=0) data provided that stability initiation occurs within 30 days of release testing. Should this not be the case the cost for the additional T=0 testing will be the subject of a future change of scope.

Cost efficiencies for analytical testing have been built into the stability program based upon the number of samples pulled in a given month.

Pullpoint Month Number of Samples Pulled	1 4	3 4		12 2	18 2	24 2	36 2	48 2

Therefore, the stability sample breakdown is:

0 single sample pullpoints (0 samples)

6 double sample pullpoints (12 samples)3 three to four sample pullpoints (12 samples)

0 more than five sample pullpoints (12 samples)

The following standard tests will be performed as part of the stability program:

- Potency & related substances
- Physical appearance
- Moisture
- Dissolution (profile by HPLC)
- MLT (annually)

#### 3. Stability – Phase I CTM Active

Patheon shall design a stability program to monitor 1 batch of PBT2 Capsules under ICH conditions. Additional samples will be stored as contingency samples if required to generate data for long-term stability of the product.

The following storage conditions and test-points are suggested for testing:

- 1, 3 and 6 months for  $40^{\circ}C \pm 2^{\circ}C / 75\% \pm 5\%$  RH
- 1, 3, 6, 9, and 12 months for  $30^{\circ}C \pm 2^{\circ}C / 65\% \pm 5\%$  RH\*
- 1, 3, 6, 9, 12, 18, 24, 36, and 48 months for  $25^\circ C \pm 2^\circ C \,/\,60\% \pm 5\%$  RH

(\* Tested only if required due to significant changes in the next level condition)

Change of Scope COS-03-R0 to Proposal No. P-TRP-54564-R1 Issue Date: February 11, 2014 Confidential Prana Biotechnology Ltd. Page 3 of 6



Cost efficiencies for analytical testing have been built into the stability program based upon the number of samples pulled in a given month.

cost efficiencies for analytical testing have been built into t	ine studinty p	iogram ouse	r	unoer or sum	P	8			
Pullpoint Month	1	3	6	9	12	18	24	36	48
Number of Samples Pulled	2	2	2	1	1	1	1	1	1
1									
Therefore, the stability sample breakdown is:									
6 single sample pullpoints (6 samples)									
3 double sample pullpoints (6 samples)									
0 three to four sample pullpoints (0 samples)									
0 more than five sample pullpoints (0 samples)									
The following standard tests will be performed as part of the	e stability pro	gram:							
• Potency & related substances									
Physical appearance									
Moisture									
<ul> <li>Dissolution (profile by HPLC)</li> </ul>									
MLT (annually)									
Part C: Description of work to be removed from	n the Projec	ct Scope							
Desite of Niccours 11211 Descue Distanticular (14.) DDTA (									
Project Name: 11311 - Prana Biotechnology Ltd PBT2 In Client Name: Prana Biotechnology Ltd.	mmediate Ke	lease Capsu	les						
Product Name: PBT2 Immediate Release Capsules									
Currency: USD									
Currency. 03D									
Task Name									Fee
P-TRP-54564-R1 -COS-01-R0									
CTM BATCHES (ED) - Back to Back Batch MZYM Manufa									\$35,319
CTM BATCHES (ED) - Back to Back Batch MZYS Packagin									\$8,744
CTM BATCHES (ED) - Back to Back Batch MZYM/MZYS									\$10,920
STABILITY - CTM lots MZYS, MZYN - T= 1 Months (40°C									\$9,980
STABILITY - CTM lots MZYS, MZYN - T= 3 Months (40°C									\$9,980
STABILITY - CTM lots MZYS, MZYN - $T = 6$ Months (40°C					and Supply Fe	e)			\$9,980
STABILITY - CTM lots MZYS, MZYN - T= 9 Months (25°C									\$6,699
STABILITY - CTM lots MZYS, MZYN - $T = 12$ Months (25°									\$7,972
STABILITY - CTM lots MZYS, MZYN - T = 18 Months (25°									\$6,699
STABILITY - CTM lots MZYS, MZYN - $T = 24$ Months (25°									\$7,972
STABILITY - CTM lots MZYS, MZYN - T= 36 Months $(25^{\circ})$									\$7,972
STABILITY - CTM lots MZYS, MZYN - T = 48 Months (25°	~(`/60% RH)	(Included 5)							
Fee Summary:	C/ 00/0 Iui)	(includes 5	% Material an	a Supply Fee	)				\$7,972 - <b>\$130,209</b>

Change of Scope COS-03-R0 to Proposal No. P-TRP-54564-R1 Issue Date: February 11, 2014 Confidential

Prana Biotechnology Ltd. Page 4 of 6

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Part D: Pricing

THE FOLLOWING COSTS A	RE ALL QUOTED IN:		<u>USD</u>					
							_	*10 <b>*</b>
CTM BATCHES (LD)	ACTIVITY				MILES	STONE PRICE		USD PRICE
						JOINE I MCL		THICL
First Batch	Manufacturing				\$	51,954		
	Packaging				\$	17,377		
	Analytical Support		Total Per Ba	atch	<u>\$</u> \$	10,124 79,455		
			1 Batch TOT		, p	19,455	\$	79,455
Back to Back Batch	Manufacturing		I Dutth 101		\$	47,697	,	19,400
	Packaging				\$	15,780		
	Analytical Support				\$	10,124		
			Total Per Ba		\$	73,601	th.	72 (01
			1 васк то ва	ck Batch TOTAL			<u>)</u>	73,601
						5	5	153,056
	Total				Mate	rial and Supply Fee: \$	\$	7,653
STABILITY - Phase III CTM								USD
STADILITT - Fliase III CTM	ACTIVITY							PRICE
	Number of Lots	2						
	Total Samples	2 24						
	- • • • • • • • • • • • • • • • • • • •							
	Protocol Generation					5	\$	994
						Samples		
point						per		st per pullp
onths 40C/75% RH	25C/ 60% RH			Microbiology	AET	pullpoint		ilestone Pr
= 1 X	X					4 5		8,185
=3 X = 6 X	X X					4 5		8,185
= 6 X = 9	X					4 5		8,185 6,380
= 12	X			Х		2 3		7,593
= 18	X					2 5		6,380
= 24	Х			Х		2 5	\$	7,593
= 36	Х			Х		2 5	5	7,593
= 48	Х			Х		2 5		7,593
	Summary Report Generation					5	\$	1,420
	Total					5		70,101
			Material	and Supply Fee:		5	\$	3,505
STABILITY - Phase I CTM								USD
	ACTIVITY						<i>P</i> .	RICE
	Number of Lots	1						
	Total Samples	12						
						Samples	Car	st per pullp
point	250/ (00/ DW			M:		per	(Mi	ilestone Pr
anths         40C / 75% RH           = 1         X	25C/ 60% RH X			Microbiology	AET	pullpoint 2 5	\$	6,380
= 1 X $= 3$ X	X						\$ \$	6,380
= 6 X	X			-			\$	6,380
= 9	X					1 5		5,421
= 12	Х			Х			\$	6,065
= 18	Х					1 5		5,421
= 24	Х			Х			\$	6,065
= 36	X			X		1 5		6,065
	Х			Х		1	\$	6,065
= 48	Total					5		54,242
= 48	1 oral		Material	and Supply Fee:		5		2,712
= 48								
BUDGET TOTAL						USD		277,399
						USD S USD S USD S	5	277,399 13,870 291,269



#### Appendix 1 - COS Revision History

COS Revision Number	Description of Activities	Overall Cost
R0	CTM manufacturing	\$161,060 USD

Change of Scope COS-03-R0 to Proposal No. P-TRP-54564-R1 Issue Date: February 11, 2014 Confidential

Prana Biotechnology Ltd. Page 6 of 6

Change of Scope No. COS-03-R0 to Proposal No. P-TRP-54564-R1 For Prana Biotechnology Ltd.	



#### Part A: Overview

This change of scope describes development activities to be performed for Prana Biotechnology Ltd. ("Client") by Patheon Inc. ("Patheon") under the terms and conditions of a Development Manufacturing Agreement P-TRP-54564-R1 by and between Patheon and the Client, dated April 16, 2013, which is hereby revised to include this change of scope in its entirety.

This change of scope reflects the costs associated with addendum Phase III method validation for the potency & related substances and dissolution methods.

#### Part B: Descriptions of Work to be Added to the Project Scope

#### 1. Analytical Services

Patheon will prepare a protocol and generate a report for each method validation activity for Client review.

#### Method Validation

- Product potency and related substances assay (phase III addendum method validation)
- Product dissolution assay profile by HPLC (phase III addendum method validation)

Patheon will validate the test methods required to support the Project. The validation will challenge the following parameters:

- Accuracy (related substances only)
- Robustness

Change of Scope COS-04-R0 to Proposal No. P-TRP-54564-R1 Issue Date: March 3, 2014 Confidential Prana Biotechnology Ltd. Page 2 of 3



Part C: Pricing

#### BUDGET SUMMARY

#### THE FOLLOWING COSTS ARE ALL QUOTED IN: USD

1.0 ANALYTICAL DEVELOPMENT		USD
ACTIVITY		PRICE
Product Potency and Related Substances Assay (Method Validation Phase III)	\$	13,686
IR - Product Dissolution Assay by HPLC (Method Validation Phase III)	\$	13,686
Total	\$ Material and Supply Fee: \$	27,372 1,369
BUDGET TOTAL	USD \$	27,372
Material and Supply Fee	USD \$	1,369
GRAND TOTAL	USD \$	28,741

#### Appendix 1 - COS Revision History

COS Revision Number	Description of Activities	Overall Cost
R0	Analytical services	\$28,741 USD

Change of Scope COS-04-R0 to Proposal No. P-TRP-54564-R1 Issue Date: March 3, 2014 Confidential Prana Biotechnology Ltd. Page 3 of 3

	Change of Scope to Proposal No. F Fo	P-TRP-54564-R1
Pra	ana Biotec	hnology Ltd.
Patheor	n Inc. ("Patheon")	Prana Biotechnology Ltd.
	ntex Court	("Client") Level 2, 269 Royal Parade
Mississa	auga, Ontario L5N 7K9	Parkville, VIC3052
Canada		Australia
By:	Ulised fl	By:
Name:	Melissa Dange	Name: DIANE tosteto
	eject manuger	Title: Maint Operite Office
	3-Mar-2014	Date: 11. 17al 2013.
Effective	Data	Einance Contact:
		Patheon. Performance the World Over



#### Part A: Overview

This change of scope describes development activities to be performed for Prana Biotechnology Ltd. ("Client") by Patheon Inc. ("Patheon") under the terms and conditions of a Development Manufacturing Agreement P-TRP-54564-R1 by and between Patheon and the Client, dated April 16, 2013, which is hereby revised to include this change of scope in its entirety.

This change of scope covers the cost to perform an Environmental Health and Safety toxicity categorization of PET434 API. Also included are the costs for the preparation of a CTM manufacturing report.

#### Part B: Descriptions of Work to be Added to the Project Scope

#### 1. Environmental, Health and Safety Assessment

Goal:

• To ensure the correct handling, storage and safety instructions are generated for the PBT434 API.

#### Deliverables:

• EH&S safety categorisation letter for the API.

#### 2. CTM Manufaturing Report

At the Client's request, Patheon will provide a CTM manufacturing report to the Client upon completion of CTM manufacturing of lot NWCK.

Change of Scope COS-06-R0 to Proposal No. P-TRP-54564-R1 Issue Date: April 11, 2014 Confidential

Prana Biotechnology Ltd. Page 2 of 3



Part D: Pricing

BUDGET SUMMARY

THE FOLLOWING COSTS ARE ALL QUOTED IN:	USD	
ENVIRONMENTAL HEALTH AND SAFETY		USD
ACTIVITY		PRICE
EH&S Assessment		\$ 2,000
CTM BATCHES (LD)		USD
ACTIVITY	MILESTONE PRICE	PRICE
Manufacturing Report		\$ 8,600
Total		\$ 8,600
BUDGET TOTAL	USD	\$ 10,600

#### Appendix 1 - COS Revision History

COS Revision Number	Description of Activities	Overall Cost
R0	EH&S and manufacturing	\$10,600 USD

Change of Scope COS-06-R0 to Proposal No. P-TRP-54564-R1 Issue Date: April 11, 2014 Confidential Prana Biotechnology Ltd. Page 3 of 3

Change of Scope P to Proposal No. P- For	TRP-54564-R1
Prana Biotech	nology Ltd.
Patheon Inc. ("Patheon")	Prana Biotechnology Ltd. ("Client")
2100 Syntex Court Mississauga, Ontario L5N 7K9 Canada By: formality Name:	Level 2, 269 Royal Parade Parkville, VIC3052 Australia By:
Name:	Title:
	Performance the World Over

and the second second



#### Part A: Overview

This change of scope describes development activities to be performed for Prana Biotechnology Ltd. ("Client") by Patheon Inc. ("Patheon") under the terms and conditions of a Development Manufacturing Agreement P-TRP-54564-R1 by and between Patheon and the Client, dated April 16, 2013, which is hereby revised to include this change of scope in its entirety.

This change of scope covers the cost of additional dissolution method development that was not included as part of the original Proposal.

#### Part B: Descriptions of Work to be Added to the Project Scope

#### 1. Analytical Development

At the Client's request, Patheon shall perform additional dissolution method development to challenge the operating ranges for the medium buffer concentration, apparatus (i.e. baskets vs. paddles), and stirring rate.

Upon completion of the development work a peer-reviewed data summary shall be presented to the Client.

#### Part D: Pricing

	BUDGET SUMMARY			
THE FOLLOWING COSTS ARE ALL QUOTED IN:	USD			
ANALYTICAL DEVELOPMENT				USD
ACTIVITY				PRICE
IR - Product Dissolution Assay by HPLC (	Method Development)		\$	9,652
Total			\$	9,652
		Material and Supply Fee:	\$	483
BUDGET TOTAL		USD	\$	9,652
MATERIAL AND SUPPLY FEE		USD	Ŧ	483
GRAND TOTAL		USD	\$	10,13



#### Appendix 1 – COS Revision History

COS Revision Number	Description of Activities	Overall Cost
R0	Analytical development	\$10,135 USD

Change of Scope COS-08-R0 to Proposal No. P-TRP-54564-R1 Issue Date: August 22, 2014 Confidential

Prana Biotechnology Ltd. Page 3 of 3



#### WORK ORDER INC Research Project # 1000504 Protocol # PBT2-203

This Work Order (hereinafter "Work Order") is between **Prana Biotechnology Limited** (hereinafter "Sponsor") with principal offices located at Level 2, 369 Royal Parade, Parkville VIC 3052 Australia and **INCResearch Australia Pty Limited**, together with its parent company, subsidiaries and legal affiliates (hereinafter "INC Research") with offices located at 124 Lipson Street, Port Adelaide SA 5015 Australia and relates to the Master Services Agreement effectively dated 22<sup>nd</sup> September 2011 which expressly incorporates this Work Order hereto by reference into the Master Services Agreement. Pursuant to the Master Services Agreement, INC Research has agreed to perform certain services in accordance with written work orders, such as this one, entered into from time to time describing such services.

This document constitutes a Work Order under the Master Services Agreement and this Work Order and the Services contemplated herein are subject to the terms and provisions of the Master Services Agreement.

1. SERVICES: INC Research will render such services (hereinafter "Services") as may be necessary to complete in a professional manner the project described below:

### A Randomized, Double-blind, Placebo-controlled Study to Assess the Safety and Tolerability, and Efficacy of PBT2 in Patients with Early to Mid-stage Huntington Disease (#PBT2-203)

INC Research will perform the Services as specified in Attachment A to this Work Order.

- 2. **PROJECT SCHEDULE:** The major project milestones and target dates are described in Attachment B to this Work Order. Both parties agree that the Project Schedule is a reasonable schedule for the Services to be performed and will put forth all reasonable efforts to comply with these dates.
- 3. COMPENSATION AND EXPENSES: Sponsor shall pay the fees for INC Research's Services in accordance with the Project Budget and Payment Schedule provided in Attachment C of this Work Order. INC Research shall invoice Sponsor for taxes or duties actually incurred by INC Research which are imposed upon INC Research by any governmental agency, including, but not limited to Value Added Tax, Stamp Tax, and/or General Sales Tax, as a result of this Agreement with the exception of taxes based on INC Research's income.

INCResearch Australia Pty Limited

Prana Work Order 1000504 v4 3rd August 2012

# Research

4. NOTICES AND PAYMENTS: All communications, notices and payments required under this Work Order shall be mailed by first class mail, postage prepaid, or by overnight carriers, to the respective parties at the addresses set forth below, or to such other addresses as the parties may from time to time specify in writing.

If to INC Research:

If to Sponsor:

For Communications:	Contracts Management INCResearch Australia Pty Limited 124 Lipson Street Port Adelaide SA 5015 Australia Phone: +61 (0) 8 8447 3500
	Facsimile: +61 (0) 8 8447 3510 Facsimile: +61 (0) 8 8447 3511
For Payments (Via Wire):	
Beneficiary Bank:	Bank of South Australia (A Division of

 Account Name:
 INCResearch Australia (YD/HMM

 BSB (Routing Number):
 105-018

 Account Number:
 082 159 540

 Swift:
 SGBLAU2S

5. TRANSFER OF OBLIGATIONS: Sponsor assigns the responsibilities pertaining to the Study to INC Research as indicated in Attachment A, Services.

• Research

IN WITNESS WHEREOF, the undersigned have caused this Work Order to be executed by a duly authorized individual on behalf of each requisite party effective as of the day and year last written below. In the event that the parties execute this Work Order by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Work Order shall become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence of the existence of this Work Order with the expectation that original documents may later be exchanged in good faith. Thereafter, the parties agree that in connection with request for information that either party may need from the other related to the Services provided hereunder, both parties expressly permit communication via facsimile to the extent allowed by applicable laws and regulations to be disseminated in that manner.

Prana Biotechnology Limited

By: DIANNE ANGUS Name: Title: Chief Operating Officer 6th August 2012 Date: **INCResearch Australia Pty Limited** U By: Name: Garth Tierney Title: Regional General Manager, Australia and South East Asia Date: 14th August 2012 INCResearch Australia Pty Limited Prana Work Order 1000504 v4 3rd August 2012

ATTACHMENT A Services

DETAILED AS	SUMPTIONS
GENERAL	
DRUG NAME	PBT2
INDICATION	Huntington Disease
PHASE	2a
SITES	
NUMBER OF COUNTRIES	1 - Australia
NUMBER OF SITES	5
NUMBER OF APPLICABLE LANGUAGES	1 - English
CASE REPORT FORM (CRF)	
PAPER OR ELECTRONIC CRF	eCRF
NUMBER OF PAGES PER ENROLLED PATIENT	70
TOTAL PAGES	2,100
INVESTIGATOR MEETING	
NUMBER OF MEETING(S)	1 - Melbourne
DURATION OF MEETING(S)	1.5 days
NUMBER OF SITE ATTENDEES	3 attendees per site (15 total site attendees)
NUMBER OF CUSTOMER ATTENDEES	5
NUMBER OF INC RESEARCH ATTENDEES	2  CRAs + 1  PM
SITE MONITORING	
NUMBER OF CRAs	3 - based in Sydney, Melbourne and Perth
NUMBER OF INITIATION VISITS	5
NUMBER OF MONITORING VISITS	25 one-day visits - 5 visits/site
NUMBER OF CLOSEOUT VISITS	5
PHARMACOVIGILANCE (SAFETY)	
NUMBER OF SERIOUS ADVERSE EVENTS (SAEs)	Assume 1
NUMBER OF REPORTABLE SAEs	Assume 1
NUMBER OF SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTIONS	1
NUMBER OF SAEs REPORTING TO LOCAL REGULATORY AUTHORITY	1
PROJECT MANAGEMENT	
NUMBER OF CUSTOMER TELECONFERENCES	21
FREQUENCY OF TELECONFERENCES	Monthly
INCResearch Australia Pty Limited	

Prana Work Order 1000504 v4 3rd August 2012

# **ENC** Research

DETAILED ASSUMPTIONS				
DURATION OF TELECONFERENCES	1 hour			
TELECONFERENCE ATTENDEES	Project Manager			

ACTIVITY	Prana	INCResearch
Study Start-up Activities		
Study Sponsorship - Australia	✓	
Protocol Development	✓	
Approval and Authorisation of Final Protocol	✓	
Patient Information Sheet & Consent Template Development	✓	
Creation of Study Manual/Monitoring Guidelines	✓	
List Trial on Public Register e.g. ANZCTR, Clinicaltrials.gov	✓	
Conduct Internal Team Kick-Off Meeting		✓
Investigator/Site Identification	✓	
Approval of Final Investigator's/Sites	✓	
Finalise Clinical Trial Agreements	✓	
Creation and Collection of Essential Documents		✓
Conduct Pre-study/Site Qualification Visits	✓	
Complete Ethics Submissions and Follow-up	✓	
Respond to Issues Raised by the Ethics Committee	✓	
Regulatory Submissions	✓	
Import/Export Permit Handling	✓	
Customer Project Team Meetings		
Attend Project Team Meeting	✓	✓
Organise Project Team Meeting	✓	
Investigator's Meeting		
Attend Investigator's Meeting	✓ ✓	v
Present at Investigator's Meeting	×	
Organise Investigator's Meeting	✓	
Investigational Product (IP)	<b>√</b>	
IP Packaging and Labelling	· · · · · · · · · · · · · · · · · · ·	
IP Storage IP Distribution	· · · · · · · · · · · · · · · · · · ·	

## **ENC** Research

ACTIVITY	Prana	INCResearch
IP Accountability		✓
IP Destruction	√	
Site Visits		
Site Initiation Visits		×
Monitoring Visits		✓
Close-out Visits		×
Completion of Visit Reports		$\checkmark$
Site Management		
Site Management		✓
Project Management		✓
Project Management (Local)		· · · · · · · · · · · · · · · · · · ·
Project Tool Development		Ý
Create Master Study Files		
Maintenance of Master Study Files During Study	· · ·	
Create Investigator In-house and Site Study Files		×
Maintain In-house Investigator Study Files During Study		×
Manage and Make Payments to Investigators/Sites	✓	
Archiving of Study Files Post-study	✓	
Safety Reporting & Medical Monitoring Handling of SAEs (notification)		✓
Medical Review of SAEs & Narrative Creation		V
Reporting to Local Regulatory Authority		✓
Follow-up of SAEs	✓	1
Creation and Distribution of Investigator Notification Letters	✓	
Medical Monitoring	√	
Safety Management Plan (review)		✓

Prana Work Order 1000504 v4 3rd August 2012

## ATTACHMENT B Project Schedule

Project Timeline/Activities							
Project Milestones	Duration	Start Date	End Date				
Pre-Study Period	3 Months	1-Mar-12	31-May-12				
Enrolment Period	8 Months	1-Jun-12	31-Dec-12				
Treatment Period	8 Months	1-Jan-13	30-Sep-13				
Close-out Period	2 Months	1-Oct-13	30-Nov-13				
Total Study Duration		21 Months	-				

#### ATTACHMENT C Project Budget and Payment Schedule

#### Goods and Services Tax (GST)

In Australia all goods and services are subject to GST of 10%. Unless otherwise specified, fees are expressed as exclusive of Goods and Services Tax (GST). Where fees are GST exclusive and INC Research is liable to pay GST in respect of any Services provided pursuant to this Agreement, INC Research may add the GST amount to invoices provide to Sponsor for the Services. Provided that the relevant invoice complies with the requirements of a tax invoice to enable Sponsor to claim a credit or refund of GST, Sponsor shall pay the GST amount at the same time and in the same manner as other amounts invoiced under this Agreement.

Where the services are directly contracted by an overseas Sponsor GST will not be applicable.

#### **Project Costs and Payment Schedule**

The project budget has been provided in AUD. This will also be the prime currency for invoicing and payment on this project.

All clinical services will be invoiced on a unit basis as per the proposed direct cost estimate budget.

Upon execution of this Work Order, Sponsor shall make a payment of \$58,338.40 (20% of the total direct costs). Thereafter, INC Research will invoice Sponsor on a monthly basis for actual units completed and reconciled at the end of the study.

If services requirement exceeding those specified in the cost estimate are required then written approval will be obtained from the Sponsor before conducting the additional services.

All professional services have been adjusted to take into account standard fee reviews that would occur over the period of the trial. If the timelines extend beyond the period estimated then INC Research may increase fees beyond the period stated.

#### Indirect costs will be invoiced separately on a monthly basis.

INC Research shall provide Sponsor with itemized invoicing of all expenses and fees. Undisputed invoices are payable within 30 days of date of Sponsor's receipt of invoice as per MSA clause 12.

INCResearch Australia Pty Limited

Prana Work Order 1000504 v4 3rd August 2012

### ind Research

#### DIRECT COSTS

Service/Item	Comments	Responsibility	Unit	Unit Cost (AUD)	Number of Units	Item Cost	AUD\$
Study Start Up Activities							
Study Training/Internal Kick Off Meeting	Familiarisation, Protocol, IB	CRA	per CRA	1123	3.00	3,370	ļ
Study Training/Internal Kick Off Meeting	Familiarisation, Protocol, IB	PM	per PM	1290	1.00	1,290	
Essential Document Collection	Creation, Collection and Tracking	CRA	per site	1123	5.00	5,616	
Study Files	Set-up of Study Master Files and Investigator Site Files	РА	per study	749	1.00	749	
	Communications - Customer, Site,						
CRA Administration (March 2012 - May 2012)	Project Manager	CRA	per month	3019	3.00	9,056	
						Subtotal	\$20,080
Customer Project Team Meetings	<b>T</b> 1 6	D) (	DM	222	1.00	222	
Customer Kick-off Meeting	Teleconference	PM	per PM	322	1.00	322	
Sponsor Teleconference Participation	21 x 1 hour Telecon	PM	per telecon	165	21.00	3,456	¢2.770
Investigator's/Monitor's meeting						Subtotal	\$3,778
Travel Time	4 hours Return	PM	per PM	645	1.00	645	
Travel Time	8 hours Return	CRA	per CRA	1123	1.00	1,123	
Attendance	Assume 1.5 day Meeting, 1 PM	PM	per PM	1934	1.00	1,934	
Attendance	Assume 1.5 day Meeting, 2 CRAs	CRA	per CRA	1685	2.00	3,370	
Attonduned	rissume i.e day meeting, 2 citris	Citit	per ciur	1005	2.00	Subtotal	\$7,072
Site Visits						Bubtotai	<i>\$1,012</i>
Study Initiation	Includes Preparation, Travel, Time On- site, Reporting and Follow-up	CRA	per visit	1404	5.00	7,020	
	Including Preparation, Travel, 1 day On- site, Reporting and Follow-up 5		-				
Monitoring Visits (1 Day Visits)	Visits/Site	CRA	per visit	1579	25.00	39,478	
Closeout Visits	Includes Preparation, Travel, Time On- site, Reporting and Follow-up	CRA	per visit	1752	5.00	8,761	
						Subtotal	\$55,258
Site Management							
Site Management (June 2012 - September 2013)	per Month	CRA	per month	3086	16.00	49,383	
Site Management (October 2013 - November 2013)	per Month	CRA	per month	1460	2.00	2,920	
						Subtotal	\$52,303
Project Management Local Coordination/Supervision (March 2012 - May							
2012)	per Month	PM	per month	5158	3.00	15,475	
Local Coordination/Supervision (June 2012 - September 2013)	per Month	PM	per month	3296	16.00	52,743	
Local Coordination/Supervision (October 2013 -	per wonth	1 101	per monui	3290	10.00	52,745	
November 2013)	per Month	PM	per month	3353	2.00	6,706	
Project Assistance (March 2012 - November 2013)	per Month	PA	per month	2054	21.00	43,144	
			1			Subtotal	\$118,068
Safety Monitoring							
	Includes Set-up, Maintenance and						
Safety Administration	Completion Activities	Safety Officer	per study	4597	1.00	4,597	
Handling of SAEs (Notifications)	All Events - Assume 1 SAE	Safety Officer	per SAE	330	1.00	330	
Medical Review of SAEs and Narrative Creation	All Events - Assume 1 SAE	Medical Monitor	per SAE	851	1.00	851	
Reporting to Local Authorities	Assume 1 Reportable Event	Safety Officer	per SAE	659	1.00	659	
Safety Management Plan (review)		Safety Officer	per study	659	1.00	659	
Teleconference	Assume 1 hour teleconference	Safety Officer	per telecon	165	1.00	165	<u> </u>
	ļ					Subtotal	\$7,261
	1	í				TOTAL	\$263,821



#### INDIRECT COSTS

Expense/Item	Comments	Unit Cost	Number of Units	Item Cost AUD\$	AUD\$
Investigator's/Monitor's Meeting Attendance					
	Airfares, accommodation & meals				
	provided by Client, \$500 - taxis, currency				
Travel/Attendance Costs	exchange, meals in transit, phone	\$500/person	2	1,000	
				Subtotal	\$1,000
Site Visits					
	Parking/tolls/meals and incidentals for				
Other Site visit Costs	site visits	\$50/day	35	1,750	
				Subtotal	\$1,750
General Expenses					
Couriers, Express Post, Teleconferences		\$7,000	1	7,000	
Copying (Excluding ethics submissions), postage, telecommunications (excluding teleconferences), stationery					
(files)	\$70/site/month, 5 sites for 21 months	\$350/month	21	7,350	
				Subtotal	\$14,350
				TOTAL	\$17,100

#### Change Orders/Changes in Scope

INC Research's participation in this study is based upon the parameters outlined in Attachment A – Services and Attachment B – Project Schedule. Unless otherwise specified in this Work Order, all study Services will be performed under the INC Research Standard Operating Procedures (SOPs). If the scope of the study varies from these study parameters, a Contract Modification (CM) may be necessary. A CM may be due to, but is not limited to, the following project specific situations that change the study parameters (i.e., timeline<sup>1</sup>, number of subjects or sites) or the scope of work (i.e., additional services; tasks for current services; or costs for current services are modified). These changes in scope may modify the time or costs (direct or indirect) required to complete the study. Requests to engage additional contractors or to incur additional costs with existing contractors engaged by INC Research are considered changes in scope. Accordingly, negotiating efforts to secure confidentiality agreements and service agreements with newly engaged contractors are also considered changes in scope.

Once a CM is identified, INC Research will log the out-of-scope activities in a Change Order Log and obtain written acknowledgement from the Sponsor confirming the scope of the possible CM. Once the out-of-scope services reach an estimated 3% of direct project costs (or \$10,000, whichever is reached first), a Change Notification Form (CNF) will be submitted to the Sponsor for verification of the project change and to determine if INC Research should wait to begin out-of-scope trial activities or continue while good faith negotiations move towards an executed Change Order (CO).

A CO shall be completed once the following threshold amount is reached (which is based on the original contract value of the study).

- \$100,000 threshold if contract value is less than \$3,000,000; or
- \$300,000 threshold if contract value is over \$3,000,000.

If out of scope activities do not reach the threshold amount for longer than 180 days since the first CNF or particular CO was initiated, then a CO shall be issued once the time threshold is reached.

If out of scope activities do not reach the value or time thresholds prior to end of study, then a CO shall be issued and signed by Sponsor prior to release of the final project deliverable.

<sup>1</sup> An increase in the study timeline may increase the inflation calculation. Change orders will only address an increase in costs due to inflation for uncompleted activities if the study timeline is pushed into a <u>new calendar year</u>

#### CHANGE ORDER N°1 to Work Order #1000504

This Change Order number 1 to Work Order #1000504 (hereinafter "Change Order") is made and entered into as of the date of last signature (hereinafter "Effective Date") by and between **Prana Biotechnology Limited** (hereinafter "Sponsor") with an office located at Level 2, 369 Royal Parade, Parkville VIC 3052, Australia and **INCResearch Australia Pty** Limited, together with its parent company, subsidiaries and legal affiliates (hereinafter "INC Research") with principal offices located at 124 Lipson Street, Port Adelaide SA 5015, Australia.

#### RECITALS

WHEREAS, Sponsor and INC Research have entered into Work Order #1000504 (hereinafter "Agreement") to perform Services for Protocol # PBT2-203 for study entitled: A Randomized, Double-blind, Placebo-controlled Study to Assess the Safety and Tolerability, and Efficacy of PBT2 in Patients with Early to Mid-stage Huntington Disease (hereinafter "Study"), which was signed by Sponsor and INC Research on 14th August 2012, and

WHEREAS, during the course of the performance of the Study, Sponsor and INC Research have identified changes in assumptions; and

WHEREAS, Sponsor desires to retain additional services from INC Research and INC Research desires to supply such services to Sponsor under the terms and conditions set forth herein; and

WHEREAS, Sponsor and INC Research agree that all other terms and conditions of the Agreement shall remain in full force and effect, unless specifically agreed otherwise in this Change Order; and

WHEREAS, Sponsor and INC Research agree that the services and costs covered by this Change Order are additional to the services and costs covered by the Agreement;

NOW THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, INC Research and Sponsor agree as follows:

#### SECTION I: CHANGES IN SCOPE

This section contains an overview of the changes in assumptions, timelines, and revision in Scope of services. In summary, this Change Order mainly reflects the following changes:

#### Direct Costs

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- Addition of seven (7) x One Day Monitoring Visits, to be invoiced only if required.
- Addition of eight (8) x Two Day Monitoring Visits, to be invoiced only if required.
- Addition of one (1) x Four Day Monitoring Visit.
- Addition of nine (9) x Serious Adverse Events (SAE) Notifications, to be invoiced only if required.
- Addition of four (4) x Reporting to Local Authorities of SAEs, to be invoiced only if required.
  - Addition of 6 Monthly Suspected Unexpected Serious Adverse Reaction (SUSAR) Line Listings time for Safety Officer, to be invoiced only if required.

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INCResearch Australia Pty Limited - 1000504

Prana Change Order #1, v2, 10th April 2013

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#### INC Research, LLC Change Order Form

Indirect Costs

• Addition of twenty-seven (27) x Other Site Visit Costs.

The parties hereby agree the total cost associated with this Change Order is AUD \$48,505.00.

#### SECTION II: COSTS OVERVIEW

The additional deliverables and tasks performed by INC Research are specified in Attachment A. This Attachment includes an overview of the total prices of deliverables in the original agreement and previous change orders, and an overview of the additional total prices of the new deliverables and services. The total amount of all contracted deliverables (original agreement including all change orders) is shown in Attachment A.

A summary of both direct and indirect costs related to the original agreement and all changes in scope as occurred is provided in the table below:

	Effective Date	Direct Costs AUD\$	Indirect Costs AUD\$	Grand Total AUD\$
Original Contract	14th August 2012	\$263,821.00	\$17,100.00	\$280,921.00
Change Order # 1	Upon Execution	\$47,155.00	\$1,350.00	\$48,505.00
Total Contract Value		\$310,976.00	\$18,450.00	\$329,426.00

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INCResearch Australia Pty Limited - 1000504

Prana Change Order #1, v2, 10th April 2013

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## ir Research

#### **Revised Direct Costs**

Service/Item	Comments	Responsibility	Unit	Unit Cost (AUD)	Original Number of Units	CO#1 Number of Units	Original Item Cost (AUD\$)	CO#1 Item Cost (AUD\$)	TOTAL COST AUD\$
Study Start Up Activities									
Study Training/Internal Kick Off Meeting	Familiarisation, Protocol, IB	CRA	per CRA	1123	3	0	3,370	0	
Study Training/Internal Kick Off Meeting	Familiarisation, Protocol, IB	РМ	per PM	1290	1	0	1,290	0	
Essential Document Collection	Creation, Collection and Tracking	CRA	per site	1123	5	0	5,616	0	
Study Files	Set-up of Study Master Files and Investigator Site Files	РА	per study	749	1	0	749	0	
CRA Administration (March 2012 - May 2012)	Communications - Customer, Site, Project Manager	CRA	per month	3019	3	0	9,056	0	
•						Subtotal	20,080	0	\$20,080
Customer Project Team Meetings									
Customer Kick-off Meeting	Teleconference	PM	per PM	322	1	0	322	0	
Sponsor Teleconference Participation	21 x 1 hour Telecon	РМ	per telecon	165	21	0	3,456	0	
						Subtotal	3,778	0	\$3778
Investigator's/Monitor's meeting									
Travel Time	4 hours Return	PM	per PM	645	1	0	645	0	
Travel Time	8 hours Return	CRA	per CRA	1123	1	0	1,123	0	

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INCResearch Australia Pty Limited - 1000504 Prana Change Order #1, v2, 10th April 2013

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INC Research, LLC Change Order Form

Service/Item	Comments	Responsibility	Unit	Unit Cost (AUD)	Original Number of Units	CO#1 Number of Units	Original Item Cost (AUD\$)	CO#1 Item Cost (AUD\$)	TOTAL COST AUD\$
A	Assume 1.5 day	РМ	DM	1934	1	0	1.934	0	T
Attendance	Meeting, 1 PM	PM	per PM	1934	1	0	1,934	0	
Attendance	Assume 1.5 day Meeting, 2 CRAs	CRA	per CRA	1685	2	0	3,370	0	
Attendance	Meeting, 2 Citris	CIUT	per eter	1005	2	Subtotal	7,072	0	\$7,072
Site Visits						Subtotal	1,012	0	\$7,072
Study Initiation	Includes Preparation, Travel, Time On-site, Reporting and Follow- up	CRA	per visit	1404	5	0	7,020	0	
Monitoring Visits (1 Day Visits)	Including Preparation, Travel, 1 day On-site, Reporting and Follow- up - only if required	CRA	per visit	1579	25	7	39,478	11,054	
Monitoring Visits (2 Day Visits)	Including Preparation, Travel, 2 days On-site, Reporting and Follow- up - only if required	CRA	per visit	3015	0	8	0	24,117	
Monitoring Visits (4 Day Visits)	Including Preparation, Travel, 4 days On-site, Reporting and Follow- up	CRA	per visit	5886	0	1	0	5,886	
Closeout Visits	Includes Preparation, Travel, Time On-site, Reporting and Follow- up	CRA	per visit	1752	5	0	8,761	0	
						Subtotal	55,258	41,057	\$96,315
Site Management									
Site Management (June 2012 - September 2013)	per Month	CRA	per month	3086	16	0	49,383	0	
Site Management (October 2013 -November 2013)	per Month	CRA	per month	1460	2	0	2,920	0	
						Subtotal	52,303	0	\$52,30

INC Research Australia Pty Limited - 1000504 Prana Change Order #1, v2, 10th April 2013

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INC Research, LLC Change Order Form

Service/Item	Comments	Responsibility	Unit	Unit Cost (AUD)	Original Number of Units	CO#1 Number of Units	Original Item Cost (AUD\$)	CO#1 Item Cost (AUD\$)	TOTAL COST AUDS
Project Management									
Local Coordination/Supervision (March 2012 -May 2012)	per Month	РМ	per month	5158	3	0	15,475	0	
Local Coordination/Supervision (June 2012 - September 2013)	per Month	PM	per month	3296	16	0	52,743	0	
Local Coordination/Supervision (October 2013 - November 2013)	per Month	PM	per month	3353	2	0	6,706	0	
Project Assistance (March 2012 -November 2013)	per Month	PA	per month	2054	21	0	43,144	0	
C-C-t- Manitania						Subtotal	118,068	0	\$118,068
Safety Monitoring Safety Administration	Includes Set-up, Maintenance and Completion Activities	Safety Officer	per study	4597	1	0	4,597	0	
Handling of SAEs (Notifications)	All Events - Assume 10	Safety Officer	per SAE	330	1	9	330	2,967	
Medical Review of SAEs and Narrative Creation	All Events - Assume 1 SAE	Medical Monitor	per SAE	851	1	0	851	0	
Reporting to Local Authorities	All Events - Assume 5	Safety Officer	per SAE	659	1	4	659	2,637	
6-Monthly SUSAR Line Listing	Preparation, distribute and tracking	Safety Officer	per study	494	0	1	0	494	
Safety Management Plan (review)		Safety Officer	per study	659	1	0	659	0	

INCResearch Australia Pty Limited - 1000504 Prana Change Order #1, v2, 10th April 2013

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#### INC Research, LLC Change Order Form Original Item Cost (AUD\$) CO#1 TOTAL COST AUD\$ Unit Original CO#1 Number of Units Item Cost (AUD\$) Cost (AUD) Service/Item Responsibility Comments Unit Number of Units per telecon Teleconference Assume 1 hour teleconference Safety Officer 165 0 165 0 1 Subtotal 7,261 6,098 \$13,360 TOTAL 263,821 47,155 \$310,976

#### **Revised Indirect Costs**

Expense/Item	Comments	Unit Cost	Original Number of Units	CO#1 Number of Units	Original Item Cost AUD\$	CO#1 Item Cost AUD\$	TOTAL COST AUD\$
Investigator's/Monitor's Meeting Attendance							
Travel/Attendance Costs	Airfares, accommodation & meals provided by Client, \$500 - taxis, currency exchange, meals in transit, phone	\$500/person	2	0	1,000	0	
				Subtotal	1,000	0	\$1,000
Site Visits							
Other Site visit Costs	Parking/tolls/meals and incidentals for site visits	\$50/day	35	27	1,750	1,350	
				Subtotal	1,750	1,350	\$3,100
General Expenses							
Couriers, Express Post, Teleconferences		\$7,000	1	0	7,000	0	

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INCResearch Australia Pty Limited - 1000504 Prana Change Order #1, v2, 10th April 2013

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INC Research, LLC Change Order Form										
Copying (Excluding ethics submissions), postage, telecommunications (excluding teleconferences), stationery (files)	\$70/site/month, 5 sites for 21 months	\$350/month	21	0	7,350	0				
				Subtotal	14,350	0	\$14,350			
				TOTAL	17,100	1,350	\$18,450			

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INCResearch Australia Pty Limited - 1000504 Prana Change Order #1, v2, 10th April 2013

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#### SIGNATURE

**COUNTERPARTS.** This Change Order may be signed in counterparts and said counterparts shall be treated as though signed as one document. The parties acknowledge legal validity of facsimile, portable document format or other commercially acceptable electronic exchange of copies of the documents, which are essential for Change Order execution. A party which uses a facsimile, portable document format or other commercially acceptable electronic exchange copy of an authorized person's signature in the documents guaranties its authenticity.

IN WITNESS WHEREOF, the undersigned have caused this Change Order to be executed by a duly authorized individual on behalf of each requisite party effective as of the day and year last written below.

#### Prana Biotechnology Limited

**INCResearch Australia Pty Limited** 

u

Executive Vice President, Asia/Pacific

Signature By: DIANNE ANGUS Name (print) C.O.O Title 16/April/2013

Date

INC Research, LLC - CONFIDENTIAL

Title 24/04/2013 Date

Signature By: Garth Tierney

Name (print)

INCResearch Australia Pty Limited - 1000504 Prana Change Order #1, v2, 10th April 2013

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#### CHANGE ORDER N°1 to Work Order #1002213

This Change Order number 1 to Work Order #1002213 (hereinafter "Change Order") is made and entered into as of the date of last signature (hereinafter "Effective Date") by and between **Prana Biotechnology Limited** (hereinafter "Sponsor") with an office located at Level 2, 369 Royal Parade, Parkville VIC 3052 Australia and **INCResearch Australia Pty Limited**, together with its parent company, subsidiaries and legal affiliates (hereinafter "INC Research") with offices located at 124 Lipson Street, Port Adelaide SA 5015, Australia.

#### RECITALS

WHEREAS, Sponsor and INC Research have entered into Work Order #102213 (hereinafter "Agreement") to perform Services for Protocol # PBT2-203, for study entitled: A randomized, doubleblind, placebo controlled study to assess the safety and tolerability and efficacy of PBT2 in patients with early to mid-stage Huntington disease (hereinafter "Study"), which was signed by Sponsor and INC Research on 28th March 2013 and

WHEREAS, during the course of the performance of the Study, Sponsor and INC Research have identified changes in assumptions; and

WHEREAS, Sponsor desires to retain additional services from INC Research and INC Research desires to supply such services to Sponsor under the terms and conditions set forth herein; and

WHEREAS, Sponsor and INC Research agree that all other terms and conditions of the Agreement shall remain in full force and effect, unless specifically agreed otherwise in this Change Order; and

WHEREAS, Sponsor and INC Research agree that the services and costs covered by this Change Order are additional to the services and costs covered by the Agreement;

NOW THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, INC Research and Sponsor agree as follows:

#### SECTION I: CHANGES IN SCOPE

This section contains an overview of the changes in assumptions, timelines, and revision in Scope of services. In summary, this Change Order mainly reflects the following changes:

- Addition of Project Meetings, Teleconferences and Face to Face meetings with Sponsor.
- Addition of Client Database Review.
- Additional Statistical Analysis Plan (SAP) includes Text and Table and Listing Shells.
- Removal of Identifying Protocol Deviations and Analysis populations.
- Additional Analysis Datasets, Specification, Programming and Quality Control.
- Reduction in Production of Tables & Listings (Lost or redundant programming due to closure of HSG involvement).
- Removal of Statistical Analysis
- Removal of Input to Final report
- Removal of Unit based Data Management Costs for Program consistency checks and raising manual data queries.
- Removal of Clinical Study Report (CSR).
  Removal of Quality Assurance (QA) Site Audits.

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INCResearch Australia Pty Limited - 1002213

Prana (PBT2-203) Change Order #1, v4, 4th March 2014

#### INC Research, LLC Change Order Form

The parties hereby agree the total cost associated with this Change Order is **AUD \$53,809.00** 

#### SECTION II: COSTS OVERVIEW

The additional deliverables and tasks performed by INC Research are specified in Attachment A. This Attachment includes an overview of the total prices of deliverables in the original agreement and previous change orders, and an overview of the additional total prices of the new deliverables and services. The total amount of all contracted deliverables (original agreement including all change orders) is shown in Attachment A.

A summary of both direct and indirect costs related to the original agreement and all changes in scope as occurred is provided in the table below:

	Effective Date	Direct Costs AUD\$	Indirect Costs AUD\$	Grand Total AUD\$
Original Contract	28th March 2013	\$173,754.00	\$2,310.00	\$176,064.00
Change Order # 1	Upon Execution	\$53,809.00	\$0.00	\$53,809.00
Total Contract Value		\$227,563.00	2,310.00	\$229,873.00

#### SIGNATURE

IN WITNESS WHEREOF, the undersigned have caused this Change Order to be executed by a duly authorized individual on behalf of each requisite party effective as of the day and year last written below. In the event that the parties execute this Change Order by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Change Order shall become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence of the existence of this Change Order with the expectation that original documents may later be exchanged in good faith.

Prana Biotechnology Limited	INCResearch Australia Pty Limited
Mag	
Signature By:	Signature By:
DIANNE ANGUS	
Name (print)	Name (print)
Chief Operating Officer	
Title	Title
11 March 2014	
Date	Date
INC Research, LLC	2 – CONFIDENTIAL
INCResearch Australia Pty Limited - 1002213	
Prana (PBT2-203) Change Order #1, v4, 4th March 2014	2



#### **Revised Direct Costs**

Service/Item	Comments	Responsibility	Unit	Unit Cost (AUD)	Original Number of Units	CO#1 Number of Units	Original Item Cost	CO#1 Item Cost	AUD\$
Data Management & Statistics									
Project familiarization	Arrange test data extract from database, assess data structure and data quality. Receive final transfer from HSC.	Clinical Programmer	1hr	108	16.00	0.00	1,728	0	
Project Meetings	Teleconference and face to face meetings with Prana, CTCC and key opinion leaders	Statistician	10hr/week	2120	0.00	26.00	0	55,120	
HSG Meeting (USA)	Three days of meetings plus travel time. (Jan Steyn or Melanie Bailey Tippetts and Peter Fursdon). Travel & accommodation arranged by Prana		40hrs per person	8000	2.00	0.00	16,000	0	
Database design	Review annotated CRF and database specification documentations	Clinical Programmer	0.5hr/dat aset	30	25.00	0.00	750	0	
Data Validation Manual	Review DVM text/data management plan specifying edit checks	CDA	40hrs	104	16.00	0.00	1,664	0	
Import BM, PK, ECG and immunology data	Electronic transfer of Biomarker, PK, ECG and MRI data (Data transfer plans, test transfers & final transfer)	DBA	1 study	1122	4.00	0.00	4,488	0	

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INCResearch Australia Pty Limited - 1002213 Prana (PBT2-203) Change Order #1, v4, 4th March 2014

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# INC Research, LLC Change Order Form

Service/Item	Comments	Responsibility	Unit	Unit Cost (AUD)	Original Number of Units	CO#1 Number of Units	Original Item Cost	CO#1 Item Cost	AUD\$
Client Database Review	Database Report prepared by Karen Reynolds	DM Systems	40hrs	7400	0.00	1.00	0	7,400	
Statistical Analysis Plan (SAP)	Includes text and table and listing shells	Statistician	1 SAP	9426	1.00	0.00	9,426	0	
Statistical Analysis Plan (SAP)	Additional text and table and listing shells	Statistician	1 SAP	13936	0.00	1.00	0	13,936	
Statistical Analysis Plan (SAP)	SAP Amendment 1 (24 hours)	Statistician	1 SAP	5088	0.00	1.00	0	5,088	
Identify Protocol Deviations and define Analysis populations	Unblinding, Protocol deviations and Definition of populations	Statistician	1 study	1600	1.00	-1.00	1,600	-1,600	
Analysis Datasets	Specification, Programming & QC	SAS Programmer	1 study	21294	1.00	0.00	21,294	0	
Data Cleaning Issues	Resolving data issues in CTCC data sets	SAS Programmer	per hour	169	0.00	400.00	0	67,600	
Production of Tables & Listings	14 Unique tables. Cost per extra \$1014 20 Repeat tables. Cost per extra \$338 36 Figures. Cost per extra \$592 38 Listings. Cost per extra \$422	SAS Programmer	1 study	52221	1.00	0.00	52,221	0	
Production of Tables & Listings (Lost or redundant programming due to closure of HSG involvement)	Primary programming lost: 20 analyses programs lost @ \$212, 19 unique tables lost @\$507, 68 tables requiring modification @ \$126.75, 51 Listings requring minor modification @ \$84.50.	SAS Programmer	1 study	29152	0.00	-1.00	0	-29,152	

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INCResearch Australia Pty Limited - 1002213 Prana (PBT2-203) Change Order #1, v4, 4th March 2014

TW3.05C Version 04

	Ι	NC Research, LLC Cha	nge Order Fo	orm					
Service/Item	Comments	Responsibility	Unit	Unit Cost (AUD)	Original Number of Units	CO#1 Number of Units	Original Item Cost	CO#1 Item Cost	AUD\$
Statistical Analysis	Analysis endpoints. Cost per extra \$424	Statistician	1 analysis endpoint	424	19.00	-19.00	8,056	-8,056	
Input to Final report	Text for inclusion in study report	Statistician	1 Study	5088	1.00	-1.00	5,088	-5,088	
Unit based Data Management Costs	Program consistency check	Clinical Programmer	1 check	60	1.00	-1.00	60	-60	
Unit based Data Management Costs	Raise manual data query	CDA	1 query	52	1.00	-1.00	52	-52	
						Subtotal	122,427	105,136	\$227,56
Medical Writing									
Clinical Study Report (CSR)		Medical Writer	per CSR	25418	1.00	-1.00	25,418	-25,418	
						Subtotal	25,418	-25,418	\$
Quality Assurance - Site Audits									
Quality Assurance Site Audits	GCP Audits preparation time	QAA	Site Audit	1314	2.00	-2.00	2,628	-2,628	
	GCP Audits on-site	QAA	Site Audit	2628	2.00	-2.00	5,255	-5,255	
	GCP Audits report preparation	QAA	Site Audit	1971	2.00	-2.00	3,941	-3,941	
	GCP Audits travel time	QAA	Site Audit	1570	2.00	-2.00	3,140	-3,140	
	Review of Audit reports	QAA	Site Audit	443	2.00	-2.00	886	-886	
QA Audit of Vendor(s)		QAA	Audit	10059	1.00	-1.00	10,059	-10,059	
						Subtotal	25,909	-25,909	\$
						TOTAL	173,754	53,809	\$227,50

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INCResearch Australia Pty Limited - 1002213 Prana (PBT2-203) Change Order #1, v4, 4th March 2014

TW3.05C Version 04

# INC Research, LLC Change Order Form

# Pass-Through Costs – NIL changes

Expense/Item	Comments	Unit Cost (AUD)	Original Number of Units	CO#1 Number of Units	Original Item Cost AUD\$	CO#1 Item Cost AUD\$	AUD\$
Site Visits							
Travel Costs (flights/accommodation/taxis)		\$1,155/visit	2	0	2,310	0	
				Subtotal	2,310	0	\$2,310
				TOTAL	2,310	0	\$2,310

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INCResearch Australia Pty Limited - 1002213 Prana (PBT2-203) Change Order #1, v4, 4th March 2014

**ENC** Research

### CHANGE ORDER N°3 to Work Order # 800089 (PBT2-204)

This Change Order number 3 to Work Order # 800089 (PBT2-204) (hereinafter "Change Order") is made and entered into as of the date of last signature (hereinafter "Effective Date") by and between **Prana Biotechnology Limited** (hereinafter "Sponsor") with an office located at Level 2,369 Royal Parade, Parkville, VIC 3052, Australia and **INC Research Australia Pty Limited**, together with its parent company, subsidiaries and legal affiliates (hereinafter "INC Research") with offices located at 124 Lipson Street, Port Adelaide SA 5015, Australia.

#### RECITALS

WHEREAS, Sponsor and INC Research have entered into Work Order # 800089 hereinafter "Agreement") to perform Services for Protocol PBT2-204 for study entitled: Randomised, Doubleblind, Placebo-controlled, Parallel-group, Phase 2 Study to Evaluate the Effect of One Dose of PBT2 (250mg daily) for 52 Weeks on Aß Deposition in the Brains of Patients with Mild Alzheimer's Disease Compared to Placebo and to Evaluate the Safety and Tolerability of PBT2 (250mg daily) for 52 Weeks in Patients with Mild Alzheimer's Disease (hereinafter "Study"), which was signed by Sponsor and INC Research on 18th April 2012 and

WHEREAS, during the course of the performance of the Study, Sponsor and INC Research have identified changes in assumptions; and

WHEREAS, Sponsor desires to retain additional services from INC Research and INC Research desires to supply such services to Sponsor under the terms and conditions set forth herein; and

WHEREAS, Sponsor and INC Research agree that all other terms and conditions of the Agreement shall remain in full force and effect, unless specifically agreed otherwise in this Change Order; and

WHEREAS, Sponsor and INC Research agree that the services and costs covered by this Change Order are additional to the services and costs covered by the Agreement and previous Change Orders;

NOW THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, INC Research and Sponsor agree as follows:

### SECTION I: CHANGES IN SCOPE

This section contains an overview of the changes in assumptions, timelines, and revision in Scope of services. In summary, this Change Order mainly reflects the following changes:

Services

- Additional Cost for work related to Case Report Form (CRF) design guidelines
- Edits and revisions for CRF version 2
- Database and edit check programming in support of CRF version 2
- Data Entry for 3,640 questionnaires
- Additional queries and pages cleaned/monitored
- Quality Check (QC) of additional Safety Lab programming
- Programming of two biomarker labs.

INC Research Australia Pty Limited - 800089

Prana PBT2-204, Change Order #3 version 1

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- Statistical Analysis Plan updates to include expansion of analysis, editing, additional text, additional tables and listing shells.
- Additional analysis datasets to support increased analysis.
- Addition of 22 Unique tables
- Addition of 70 Repeat tables
- Addition of 40 Listings
- Addition of 190 analysis endpoints

The parties hereby agree the total cost associated with this Change Order is AUD \$193,000.00

### SECTION II: COSTS OVERVIEW

The additional deliverables and tasks performed by INC Research are specified in Attachment A. This Attachment includes an overview of the total prices of deliverables in the original agreement and previous change orders, and an overview of the additional total prices of the new deliverables and services. The total amount of all contracted deliverables (original agreement including all change orders) is shown in Attachment A.

A summary of both direct and indirect costs related to the original agreement and all changes in scope as occurred is provided in the table below:

	Effective Date	Direct Costs AUD\$	Indirect Costs AUD\$	Grand Total AUD\$
Original Contract	18th April 2012	\$353,588.00	\$10,000.00	\$363,588.00
Change Order # 1	19th July 2012	\$30,398.00	\$2,990.00	\$33,388.00
Change Order # 2	29th July 2013	\$322,360.00	\$8,420.00	\$330,780.00
Change Order #3	Upon Execution	\$193,291.00	\$0.00	\$193,291.00
Total Contract Value		\$899,637.00	\$21,410.00	\$921,047.00

### SECTION III: REVISED PAYMENT TERMS

INC will invoice the Sponsor for Data Management, Statistics and Medical Writing Direct costs according to the following schedule:

•	Execution of Agreement
•	Database Complete

Invoiced AUD \$36,827.00 from original WO Invoiced AUD \$36,827.00 from original WO

New contract total for Data Management, Statistics and Medical Writing Direct costs = AUD \$530,246.00, less total already invoiced = AUD \$73,654.00. New total to be invoiced = AUD \$456,592.00

<ul> <li>50% Data Entered</li> </ul>	-	25% of new total = AUD \$114,148.00
<ul> <li>100% Data Entered</li> </ul>	-	25% of new total = AUD \$114,148.00
<ul> <li>Database Lock</li> </ul>	-	25% of new total = AUD \$114,148.00
<ul> <li>1st Draft 1st Study Report</li> </ul>	-	15% of new total = AUD \$68,488.80
<ul> <li>1st Draft 2nd Study Report</li> </ul>	-	5% of new total = AUD \$22,829.60
Final Study Report	-	5% of new total = AUD \$22,829.60
INC Research Australia Pty Limited – 800089		INC Research, LLC – CONFIDENTIAL

Prana PBT2-204, Change Order #3 version 1

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# SIGNATURE

COUNTERPARTS. This Change Order may be signed in counterparts and said counterparts shall be treated as though signed as one document. The parties acknowledge legal validity of facsimile, portable document format or other commercially acceptable electronic exchange of copies of the documents, which are essential for Change Order execution. A party which uses a facsimile, portable document format or other commercially acceptable electronic exchange copy of an authorized person's signature in the documents guaranties its authenticity.

IN WITNESS WHEREOF, the undersigned have caused this Change Order to be executed by a duly authorized individual on behalf of each requisite party effective as of the day and year last written below.

### Prana Biotechnology Limited

### INC Research Australia Pty Limited

ple of	
Signature By:	Signature By:
DIANNE ANGUS	
Name (print)	Name (print)
Chief Operating Officer	
Title	Title
14 March 2014	
Date	Date
INC Research Australia Pty Limited - 800089	INC Research, LLC – CONFIDENTIAL

Prana PBT2-204, Change Order #3 version 1

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			_ Revised Total Bu	ldget		_			
Service/Item	Comments	Unit Cost	WO & CO#1 Number of Units	CO#2 Number of Units	CO#3 Number of Units	WO & CO#1 Item Cost	CO#2 Item Cost	CO#3 Item Cost	AUD\$
Study Start Up Activities									
Study Training/ Internal Kick Off	Familiarization, Protocol, IB, CRF,								
Meeting	procedures etc.	1080	1.00	0.00	0.00	1,080	0	0	
Study Training/ Internal Kick Off	Familiarization, Protocol, IB, CRF,	620	0.00		0.00	0	0	0	
Meeting	procedures etc. Contract/insurance review,	620	0.00		0.00	0	0	0	
Study Sponsorship	Indemnification	5000	0.00		0.00	0	0	0	
Study Manual/Monitoring Manual	To be confirmed by client if			1					-
Development	required	3100	0.00		0.00	0	0	0	
List Trial on Public Register	e.g., ACTR, Clintrials.gov	310	0.00		0.00	0	0	0	1
Investigator/Site Identification	Identify up to sites to select final 5	540	0.00		0.00	0	0	0	
	Negotiation / coordination with								
Clinical Trial Agreements	site	930	0.00		0.00	0	0	0	_
Study Training	Familiarization etc	540	1.00	0.00	0.00	540	0	0	<u> </u>
Study Training on Protocol		270	0.00	2.00	0.00	0	540		
Amendment	Familiarization etc	270	0.00	2.00	0.00	0	540	0	+
Study Training on Protocol Amendment	Familiarization etc	310	0.00	1.00	0.00	0	310	0	
Essential document collection	Creation, Collection and tracking	1350	5.00	4.00	0.00	6,750	5,400	0	+
2.55 cartai document concetion	Per site includes application,	1350	5.00	4.00	0.00	0,750	5,400		+
	customize IC/PI document,							1	
	copying/collation, follow up with							1	
Ethics submissions - Australia	ethics questions	1890	0.00		0.00	0	0	0	
	Per site includes application,								
	customize IC/PI document,								
Ethics submissions - New Zealand	copying/collation, follow up with ethics questions	2160	0.00		0.00	0	0	0	
Ethics submissions - New Zealand	Creation of CTN form and TGA	2100	0.00		0.00	0	0	0	+
Regulatory Submissions - Australia	liaison	270	0.00		0.00	0	0	0	
Toguntory Submissions Trustiana	Creation of SCOTT form and	270	0.00	1 1	0.00	, , , , , , , , , , , , , , , , , , ,			+
Regulatory Submissions - New Zealand	MedSafe liaison	810	0.00		0.00	0	0	0	
Regulatory Submissions Follow-up -	6-monthly status reports and close								1
New Zealand	out final report	851	0.00		0.00	0	0	0	
Study Manual/Monitoring Manual									
Development		3100	1.00	0.00	0.00	3,100	0	0	
0( 1 F1)	Set up of study master files and	720	1.00	1.00	0.00	720	720	0	
Study Files File Management	Investigator site files per month	720 283	1.00 24.00	1.00 0.00	0.00	720 6,787	720	0	
The Management	Communications - Customer, site,	283	24.00	0.00	0.00	0,787	0	0	+
CRA Administration	project Manager	2903	0.00		0.00	0	0	0	
Citi i i idaministration	TGA/AQIS liaison, application,	2705	0.00		0.00	Ŭ		0	
Import/Export Permit Handling	distribution	620	0.00		0.00	0	0	0	
	Study status, issue resolution, client								
Senior Management overview	liaison	0	0.00		0.00	0	0	0	
File Management - 2 new sites	per month from August 2012	283	14.00	0.00	0.00	3,959	0	0	
File Management - 4 Sites	per month from October 2013	377	0.00	14.00	0.00	0	5,279	0	
					Subtotal	22,937	12,249	0	\$35,18
Customer Project Team Meetings	01	^	0.00	4 4	_				
Travel time	0 hours return	0	0.00			0		<u> </u>	+
Travel time	0 hours return	0	1.00			0			+
Attendance Attendance	Location Location	0	0.00			0		<u> </u>	+
	Teleconference	0	0.00	┥───┤		0		+	+
Customer Kick-off Meeting Customer Kick-off Meeting	Teleconference	0	0.00			0		+	+
Coordination of meeting	releconterence	90	0.00	1 1		0		+	+
Teleconference participation	25 x 1 hour Telecon, 1 CRAs	138	25.00	0.00	0.00	3,450	0	0	+
recessiverence participation	16 x monthly hour Telecon, 1	150	25.00	0.00	0.00	5,450			+
Teleconference participation	CRA	138	16.00	0.00	0.00	2,208	0	0	
r	24 x fortnightly 1 hour Telecon, 2					,	i		1
Teleconference participation	CRAs	276	0.00	24.00	0.00	0	6,624	0	
	24 x fortnightly 1 hour Telecon, 1								T
Teleconference participation	PM	155	0.00	24.00	0.00	0	3,720	0	
	ļ [				Subtotal	5,658	10,344	0	\$16,002
Investigator's/Monitor's Meeting									4
	Trident & Customer shared	1.000		0.00	0.00	1.000	c.		
Preparation of presentations	responsibility	1620	1.00	0.00	0.00	1,620	0	0	

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_		Revise	d Total Budget						
Travel time	0 hours return	0	0.00		0.00	0	0	0	
Travel time	0 hours return	0	1.00		0.00	0	0	0	
Attendance	assume 1 day meeting, 0 PM	1240	0.00		0.00	0	0	0	
Attendance	assume 1 day meeting, 1 CRA	1080	1.00	0.00	0.00	1,080	0	0	
Coordination of meeting	Mlg coordination, travel, dinner, binders, etc	155	0.00			0			
Coordination of meeting	Mlg coordination, travel, dinner, binders, etc	90	0.00			0			
					Subtotal	2,700	0	0	\$2,700
Site Visits									
Additional Travel time for each round of site									
visits	0 hours return	0	0.00		ļ				
Pre-Study Visits	Incl. prep, travel, on-site, reporting & follow-up	1215	0.00			0			
Study Initiation	Incl. prep, travel, on-site, reporting & follow-up	1620	5.00	0.00	0.00	8,100	0	0	
Study Initiation	Incl. prep, travel, on-site, reporting & follow-up	1080	0.00	2.00	0.00	0	2,160	0	
Monitoring Visits (1 Day visits)	Incl. prep, travel, 1 day on-site, reporting & follow-up 4 visits/site	1932	20.00	24.00	0.00	38,640	46,368	0	
Monitoring Visits (2 Day visits)	Incl. prep, travel, 2 days on-site, reporting & follow-up 3 visits/site	3174	15.00	10.00	0.00	47,610	31,740	0	
Monitoring Visits (3 Day visits)	Incl. prep, travel, 3 days on-site, reporting & follow-up 0 visits/site	4666	0.00		0.00	0	0	0	
Follow-up Monitoring Visits	Incl. prep, travel, on-site, reporting & follow-up 0 visits/site	146	0.00		0.00	0	0	0	
Unblinded Monitoring Visits	Incl. prep, travel, on-site, reporting & follow-up 0 visits/site	848	0.00		0.00	0	0	0	
Closeout visits	Incl. prep, travel, on-site, reporting & follow-up	2070	5.00	0.00	0.00	10,350	0	0	
Closeout visits	Incl. prep, travel, on-site, reporting & follow-up	1656	0.00	4.00	0.00	0	6,624	0	
Site Audit attendance	Incl. prep, travel, 1 day on-site, reporting & follow-up 0 visits	1845	0.00			0			
					Subtotal	104,700	86,392	0	\$191,592
Site Management:									
Site Management (October 2011 - Nov 2011)	1 site	593	2.00	0.00	0.00	1,187	0	0	
Site Management (Dec 2011 - May 2012)	2 sites	1187	6.00	0.00	0.00	7,121	0	0	
Site Management (June 2012 - July 2013)	3 sites	1780	14.00	0.00	0.00	24,923	0	0	
Site Management (August 2012 - July 2013)	per month - 2 new sites	1187	12.00	0.00	0.00	14,242	0	0	
Site Management (August 2013 - September 2013)	3 sites	828	2.00	0.00	0.00	1,656	0	0	
Site Management (August 2013 - September 2013)	per month - 2 new sites	552	2.00	0.00	0.00	1,104	0	0	
Site Management (October 2013 - November 2014)	per month - 4 Sites	2208	0.00	14.00	0.00	0	30,912	0	
Management/Supervision	per month	340	24.00	14.00	0.00	8,160	4,760	0	
-	1		1		Subtotal	58,392	35,672	0	\$94,064
Project Management			Î	ſ					1
Local coordination/supervision (June 2011 -	1		1						1
August 2011) Local coordination/supervision (August 2011	per month	3100	0.00	 		0			┠────
- May ***) Biotechnology Limited	per month	1580 471	0.00			0			<b> </b>
File Management	per month	4/1	0.00			0			

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	Revised Tot	al Budget							
Administer Site Payments	per site	3448	0.00			0			
	0 x 1 hour Sponsor Telecon, and 0 x 1 hour					[			
Teleconference participation with client/PM	Team Tetecon	158	0.00			0			
Project Status Reporting	per month	163	0.00			0			
Project Assistance (June 2011 - July 2013)	per month	378	0.00			0			
						Subtotal			\$0
Safety Monitoring			1			[			
Familiarization and Set up		1280	1.00			1,280			
Study Completion	Archiving, collation and client correspondence	501	1.00			501			
Study administration (first 6 months)	Correspondence, tracking, client liaison, filing	160	6.00			960			
Study administration (XXXX - XXXX)	Correspondence, tracking, client liaison, filing	83	15.00			1,238			
Safety Administration	Incl. set up, maintenance and completion activities	3979	1.00	0.00	0.00	3,979	0	0	
Safety Administration	Study Extension	83	0.00	14.00	0.00	0	1,155	0	
Initial Receipt and handling SAEs	All events- assume 1 SAE	330	1.00	10.00	0.00	330	3,300	0	ļ
Medical Review of SAEs and Narrative creation	Optional - as required	838	0.00	10.00	0.00	0	8,380	0	
Reporting to local Authorities	Assume 1 Reportable events	860	1.00	10.00	0.00	660	6,600	0	
Follow up of SAEs	Assume 2 hours/Follow-up/SAE. 1 Follow-ups	330	1.00	10.00	0.00	330	3,300	0	
Investigator Notification Letters	preparation and oversight	165	1.00	10.00	0.00	165	1,650	0	
Medical Monitor	only if required	419	0.00			0			
Set Up DSMB Charter		1257	0.00			0			
Attend DSMB meetings (via teleconference)	assume 1 hr meetings x 2 meetings	168	0.00			0			
Prepare Minutes/Reports from DSMB meetings		670	0.00			0			
					Subtotal	5,464	24,385	0	\$29,848
Data Management & Statistics									
	25 unique pages. 80 pages of CRF and 11 pages of questionnaire 91 Total pages. One								
CRF Design	print run.	14520	1.00	0.00	0.00	14,520	0	0	
CRF Design	CRF design guidelines	85	0.00	0.00	16.00	0	0	1,360	
CRF Design	Edits and revisions for version 2	120	000	0.00	16.00	0	0	1,920	
CRF Design (extension)	80 pages of CRF (70 on average entered ) One print run.	2834	0.00	1.00	0.00	0	2,834	0	
Database design and build		463	25.00	0.00	0.00	11.563	0	0	
Database design and build (extension)		57	0.00	25.00	0.00	0	1.429	0	
Database design and build (extension) Database / Consistency Check programming		53	208.25	0.00	0.00	11.114	0	0	
Database / Consistency Check programming	Database and edit check programming in		208.23	0.00	0.00	11,114	0	0	
Database / Consistency Check programming	support of version 2	120	0.00	0.00	24.00	0	0	2,880	
Database / Consistency Check programming extension)		33	0.00	202.00	0.00	0	6,676	0	
Data Validation Manual / Data Management Plan		3400	1.00	0.00	0.00	3,400	0	0	
Data Validation Manual / Data Management Plan (extension)		1664	0.00	1.00	0.00	0	1,664	0	
Data entry	Double Data Entry 40 patients x 80 CRF pages plus 40 x 11 questionnaires=3640 tolal pages. Cost per extra page=5.87	6	3640.00	0.00	294.00	21,385	0	1.727	
	COST PET CALLA PARC-J.0/	. 0	1 0040.00	0.00	224.00	21,303		1,141	

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	Re	vised Total I	Budget						
	Double Data Entry 33 patients x 70		Ŭ						
	entered CRF pages 2310 total pages. Cost								
Data entry (extension)	per extra page=36.26	6	0.00	2310.00	0.00	0	14,453	0	
Medical Coding	MedDRA-AE, WHO - Drug	6	800.00	0.00	0.00	5,036	0	0	
Medical Coding (extension)	MedDRA-AE, WHO - Drug	7	0.00	660.00	0.00	0	4,600	0	
	3200 CRF pages. Cost per extra								
	page=\$5.10 224 Queries. Cost per extra								
Data Cleaning / Monitoring	query=\$42.50	29617	1.00	0.00	0.00	29,617	0	0	
Data Cleaning / Monitoring	Additional pages cleaned/monitored	5.10	0.00	0.00	734.00	0	0	3,743	
Data Cleaning / Monitoring	Additional queries raised	42.50	0.00	0.00	646.00	0	0	27,455	
	2310 CRF pages. Cost per extra								
	page=\$7.00 162 Queries. Cost per extra								
Data Cleaning / Monitoring (Extension)	query=\$52.00	26270	0.00	1.00	0.00	0	26,270	0	
	10% of all patients, 100% of all critical								
Quality Control	data (15% critical /85% non critical)	2.95	811.40	0.00	0.00	2,391	0	0	
Quality Control	Additional Safety Lab QC programming	120	0.00	0.00	4.00	0	0	480	
Quality Control	Additional Safety Lab QC (pages)	2.81	0.00	0.00	91.00	0	0	256	
	10% of all patients, 100% of all critical								
Quality Control (extension)	data (15% critical / 85% non critical)	3.34	0.00	543.00	0.00	0	1,813	0	
Import laboratory data	1 central lab	3680	1.00	0.00	0.00	3,680	0	0	
Import laboratory data	2 biomarker labs -programming	120	0.00	0.00	6.00	0	0	720	
Import laboratory data	2 biomarker labs -data review	85	0.00	0.00	6.00	0	0	510	
Import laboratory data (extension)	1 central lab. Import and review	3182	0.00	1.00	0.00	0	3,182	0	
Data exports	Assume 2 exports	360	200	0.00	0.00	720	0	0	
Data exports (extension)	Assume 2 exports	327	0.00	2.00	0.00	0	054	0	
Database maintenance	Study Duration = 18 months	240	18.00	0.00	0.00	4,320	0	0	
Database maintenance (extension)	Study Duration = 18 months	218	0.00	18.00	0.00	0	3,924	0	
()	Client meetings & corresp, DM metrics				0100		-,/-:	-	
DM & Statisties - Project Management	1hrs/month x 18 months	120	16.00	0.00	0.00	1,530	0	0	
DM & Statisties - Project Management	Client meetings & corresp, DM metrics					,			
(extension)	1hrs/month x 18 months	104	0.00	18.00	0.00	0	1,872	0	
Input to protocol	Text and sample size calculation / power	200	4.00	0.00	0.00	800	0	0	
Generation of Randomisation schedule	envelope \$12.50	1175	1.00	0.00	0.00	1.175	0	0	
Statistical Analysis Plan	Includes text and table and listing shells.	5840	1.00	0.00	0.00	5,840	0	0	
Statistical Final Join Final	includes text and taste and listing siterio.	2010	1.00	0.00	0100	2,010	0	Ŭ	
	Additional hours to cover expansion of								
	analysis. Includes discussion, editing,								
	additional text additional tables and listing								
Statistical Analysis Plan	shells.	200	0.00	0.00	116.00	0	0	23,200	
·									
	Adaption of SAP for extension and								
	combined analysis. Includes text plus								
Statistical Analysis Plan	table & listing shells	6072	0.00	1.00	0.00	0	6,072	0	
populations	populations	1600	1.00	0.00	0.00	1,600	0	0	
(extension)Analysis populations	populations	1600	0.00	1.00	0.00	0	1,600	0	
Analysis Datasets	Specification, Programming & QC	4800	1.00	0.00	0.00	4,800	0	0	
	Additional analysis datasets to support								
Analysis Datasets	increased analysis	600	0.00	0.00	14.00	0	0	8,400	
Analysis Datasets (extension)	Specification, Programming & QC	3936	0.00	1.00	0.00	0	3,936	0	
	15 Unique tables. Cost per extra \$720 20						- ,		i i
	Repeat tables. Cost per extra \$240								
	0 Figures. Cost per extra \$420								
Production of Tables & Listings	35 Listings. Cost per extra \$300	26100	1.00	0.00	0.00	26,100	0	0	

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	Revi	sed Total B	udget						
Production of Tables & Listings	22 Unique tables. Cost per extra \$720 70 Repeat tables. Cost per extra \$240 0 Figures. Cost per extra \$420 40 Listings. Cost per extra \$300	44640	0.00	0.00	1.00	0	0	44,640	
Production of Tables & Listings (extension)	2 Unique tables. Cost per extra \$720 68 Repeat tables. Cost per extra \$240 0 Figures. Cost per extra \$420 35 Listings. Cost per extra \$300	38622	0.00	1.00	0.00	0	38,622	0	
Statistical Analysis	10 analysis endpoints. Cost per extra \$400	400	10.00	0.00	190.00	4,000	0	76,000	
Statistical Analysis (extension)	10 analysis endpoints. Cost per extra \$424	424	0.00	10.00	0.00	0	4,240	0	
Provision of data to DSMB	Assumes Interim running and QC of 6 TFLs in now Programming Tables and listings.	960	3.00	0.00	0.00	2,880	0	0	
Provision of data to DSMB (extension)	Assumes provision of excel spreadsheets and graphed laboratory values	1312	0.00	3.00	0.00	0	3,936	0	
Input to Final report	Text for Inclusion in study report.	2400	1.00	0.00	0.00	2,400	0	0	
Input to Final report (extension)	Text for Inclusion in study report.	2544	0.00	1.00	0.00	0	2,544	0	
					Subtotal	158,869	130,321	193,291	\$482,482
Medical Writing (Optional)									
Clinical study report (CSR)		22497	1.00	1.00	0.00	22,497	22,497	0	
QA review of CSR	Optional for Client	2769	1.00	0.00	0.00	2,769	0	0	
					Subtotal	25,266	22,497	0	\$47,763
					TOTAL	383,986	322,360	193,291	\$899,637

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Expense/Item	Comments	Unit Cost	WO & CO#1 Number of Units	CO#2 Number of Units	WO & CO#1 Item Cost AUD\$	CO#2 Item Cost AUD\$	CO#3 Item Cost AUD\$	AUD\$
Site Visits								
Other Site visit Costs	Parking/tolls/meals and incidentals for site visits	\$50/day	60.00	50.00	3,000	2,500	0	
				Subtotal	3,000	2,500	0	\$5,500
General Expenses								
General Expenses - Couriers, Postage, Telecommunications, Copying, stationery (files)	\$70/site/month, 3 sites for 25 months	S210/month	25	0.00	5,250	0	0	
General Expenses - Couriers, Postage, Telecommunications, Copying, stationery (files)	\$70/site/month, 2 new sites for 16 months	\$140/month	16	0.00	2,240	0	0	
General Expenses - Couriers, Postage, Telecommunications, Copying, stationery (files)	\$70/site/month, 4 sites for 14 months	\$280/month	0	14.00	0	3,920	0	
CRF Printing		\$2,500	1	1.00	2,500	2,000	0	
				Subtotal	9,990	5,920	0	\$15,910
				TOTAL	12,990	8,420	0	\$21,410

Prana Biotechnology Limited Protocol #: PBT2-204 INCR Project Code: 800089

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### CHANGE ORDER N°4 to Work Order # 800089 (PBT2-204)

This Change Order number 4 to Work Order # 800089 (PBT2-204) (hereinafter "Change Order") is made and entered into as of the date of last signature (hereinafter "Effective Date") by and between **Prana Biotechnology Limited** (hereinafter "Sponsor") with an office located at Level 2, 369 Royal Parade, Parkville, VIC 3052, Australia and **INC Research Australia Pty Limited**, together with its parent company, subsidiaries and legal affiliates (hereinafter "INC Research") with offices located at 159 Port Road Hindmarsh, SA 5007, Australia.

### RECITALS

WHEREAS, Sponsor and INC Research have entered into Work Order # 800089 hereinafter "Agreement") to perform Services for Protocol PBT2-204 for study entitled: Randomised, Doubleblind, Placebo-controlled, Parallel-group, Phase 2 Study to Evaluate the Effect of One Dose of PBT2 (250mg daily) for 52 Weeks on Aβ Deposition in the Brains of Patients with Mild Alzheimer's Disease Compared to Placebo and to Evaluate the Safety and Tolerability of PBT2 (250mg dally) for 52 Weeks in Patients with Mild Alzheimer's Disease (hereinafter "Study"), which was signed by Sponsor and INC Research on 18th April 2012 and

WHEREAS, during the course of the performance of the Study, Sponsor and INC Research have identified changes In assumptions; and

WHEREAS, Sponsor desires to retain additional services from INC Research and INC Research desires to supply such services to Sponsor under the terms and conditions set forth herein; and

WHEREAS, Sponsor and INC Research agree that all other terms and conditions of the Agreement shall remain in full force and effect, unless specifically agreed otherwise in this Change Order; and

WHEREAS, Sponsor and INC Research agree that the services and costs covered by this Change Order are additional to the services and costs covered by the Agreement and previous Change Orders;

NOW THEREFORE, subject to the terms, conditions and covenants hereinafter set forth, INC Research and Sponsor agree as follows:

### SECTION I: CHANGES IN SCOPE

This section contains an overview of the changes in assumptions, timelines, and revision in Scope of services. In summary, this Change Order mainly reflects the following changes:

Services

- Case Report Form (CRF) version#2 update
- Database update and testing due to CRF version# 2 update
- Edit Checks update and testing due to CRF version#2 update

The parties hereby agree the total cost associated with this Change Order is AUD \$1,440

INC Research Australia Pty Limited – 800089 Prana PBT2-204, Change Order #4 version 1 INC Research, LLC - CONFIDENTIAL

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### SECTION II: COSTS OVERVIEW

The additional deliverables and tasks performed by INC Research are specified in Attachment A. This Attachment includes an overview of the total prices of deliverables in the original agreement and previous change orders, and an overview of the additional total prices of the new deliverables and services. The total amount of all contracted deliverables (original agreement including all change orders) is shown in Attachment A.

A summary of both direct and indirect costs related to the original agreement and all changes In scope as occurred is provided in the table below:

	***	***	***	***
Original Contract	18th April 2012	\$353,588.00	\$10,000.00	\$363,588.00
Change Order #1	19th July 2012	\$30,398.00	\$2,990.00	\$33,388.00
Change Order # 2	29th July 2013	\$322,360.00	\$8,420.00	\$330,780.00
Change Order #3	18 March 2014	\$193,291.00	\$0.00	\$193,291.00
Change Order #4	Upon Execution	\$1,440.00	\$0,00	\$1,440.00
Total Contract Value		\$901,077.00	\$21,410.00	\$922,487.00

### SECTION III: REVISED PAYMENT TERMS

INC will Invoice the Sponsor for Data Management, Statistics and Medical Writing Direct costs according to the following schedule:

- Invoiced AUD \$36,827.00 from original WO Execution of Agreement . -
- Invoiced AUD \$36,827.00 from original WO • Database Complete -

New contract total for Data Management, Statistics and Medical Writing Direct costs = AUD \$531,686.00, less total already invoiced = AUD \$73,654.00. New total to be invoiced = AUD \$458,032.00

INC R	esearch Australia Pty Limited – 800089		INC Research, LLC – CONFIDENTIAL
•	Final Study Report	-	5% of new total = AUD \$22,901.60
٠	1st Draft 2nd Study Report	-	5% of new total = AUD \$22,901.60
٠	1st Draft 1st Study Report	-	15% of new total = AUD \$68,704.80
•	Database lock	-	25% of new total = AUD \$114,508.00
٠	100% Data Entered	-	25% of new total = AUD \$114,508.00
٠	50% Data Entered	-	25% of new total = AUD \$114,508.00

INC Research Australia Pty Limited - 800089

Prana PBT2-204, Change Order #4 version 1

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# SIGNATURE

**COUNTERPARTS**. This Change Order may be signed in counterparts and said counterparts shall be treated as though signed as one document. The parties acknowledge legal validity of facsimile, portable document format or other commercially acceptable electronic exchange of copies of the documents, which are essential for Change Order execution. A party which uses a facsimile, portable document format or other commercially acceptable electronic exchange copy of an authorized person's signature in the documents guaranties its authenticity.

IN WITNESS WHEREOF, the undersigned have caused this Change Order to be executed by a duly authorized individual on behalf of each requisite party effective as of the day and year last written below.

Prana Biotechnology Limited	INC Research Australia Pty Limited
B-p-	A FL
Signature By:	Signature By:
GEOFFREY KEMPLER	David Fuller
Name (print)	Name (print) Senior Vice President
	Clinical Development
Title	Title
CEO	11th July 2014
Date	Date
1st July 2014	Duc
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Prana PBT2-204, Change Order #4 version 1

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***	***	***	* * *	***	***	***	***	***	非非非	***	非非非
Study Start Up/***			1		1	1			1		
Study Training/ Internal Kick Off Meeting	***Protocol, IB, CRF, procedures etc.	1080	1.00	0.00	0.00		1,080	0	0		
Study Training	*** etc	840	1.00	0.00	0.00		540	0	0		
Study Training on Protocol Amendment	*** etc	270	0.00	2.00	0.00		0	540	0		
Study Trainig on Protocol Amendment	*** etc	310	0.00	1.00	0.00		0	310	0		
Essential document collection	Creuton, Collection and tracloting	1350	6.00	400	0.00		6,750	5,400	0		
Study Manual/Monitoring Manual Development		3100	1:00	0.00	0.00		3,100	0	0		
	Set up of study master files and Investigator *he							1			
Study Files	files	720	1.00	1.00	0.00		720	720	0		
File Management	per month	283	24.00	0.00	0.00		6,787	0	0		
File Management - 2 new sites	per month from August 2012	283	14.00	0.00	0.00		3,959	0	0		
File Management - 4 sites	per month from October 2013	377	0.00	14.00	0.00		0	6,279	0		
					Subtotal		22,837	12,249	0		***
***											
Teleconference participation	25 x 1 hour Telecon, 1 CRAs	138	26.00	0.00	0.00		3,450	0	0		
Teleconference participation	16 x monthly hour Telecon, 1 CRA	138	16.00	0.00	0.00		2,208	0	0		
Teleconference participation	24 x *** 1 hour Telecon, 2 CRAs.	276	0.00	24.00	0.00		0	6,624	0		
Teleconference participation	24 x *** 1 hour Telecon, 1 PM	155	0.00	24.00	0.00		0	3,720	0		
			ļ		Subtotal		5,654	10,344			\$16,002
***											
Preparation of Presentations	Trident & Customer shared responsibility	1620	1.00	0.00	0.00		1,820	0	0		
Attendance	*** 1 day meeting, 1. CRA	1080	1.00	0,00	0.00		1,080	0	0		
							2,760	0	0		\$2,700
Site Visits											
Sutdy Initiation	Incl. prop, travel, on-site, reporting & follow-up	1620	5.00	0.00	0.00		8,100	0	0		
Study Initiation	Incl. prop, travel, on-site, reporting & follow-up	1080	0.00	2.00	0.00		0	2,160	0		
	Incl. prop, travel, 1 day on-site, reporting &										
Monitoring Visits (1 Day visits)	follow-up 4 visits/site	1932	20.00	24.00	0.00		38,640	46,366	0		
Monitoring visits (2 Day visits)	Incl. prop, travel, 2 day's on-site, reporting & follow-up 3 visits/site	3174	15.00	10.00	0.00		47.610	31.740	0		
Monitoring visits (2 Day visits) Closeout visits	Incl. prop. travel, on-site, reporting & follow-up	2070	5.00	0.00	0.00		47,610	0	0		
Closeout visits	Incl. prop, travel, on-site, reporting & follow-up Incl. prep, travel, on-site, reporting & follow-up	1656	0.00	4.00	0.00		0	6,824	0		
Closeout visits	inci, prep, traver, on-site, reporting & tonow-up	1030	0.00	4.00	Subtotal		164,700	0,824	0		\$101,502
Site Management					Subtotal	-	104,700				\$101,302
Site Management											
Site Management (October 2011 -Nov 2011)	1 site	593	2.00	0.00	0.00		1,187	0	0		
Site Management (Dec 2011 - May 2012)	2 sites	1187	6.00	0.00	0.00		7.121	0	0		
Site Management (June 2012- July 2013)	3 sites	1780	14.00	0.00	0.00		24,923	0	0		
Site Management August 2012 - July 2013)	per month - 2 new sites	1187	12.00	0.00	0.00		14.242	0	0		
Site Management (August 2013 - September 2013)	3 sites	828	2.00	0.00	0.00		1,858	0	0		
Site Management (August 2013 - September 2013)	per month - 2 now sites	552	2.00	0.00	0.00		1.104	0	0		
Site Management (October 2013 - November 2014)	per month - 4sites	2208	0.00	14.00	0.00		0	30,912	0		
Management/Supervision	per month	340	24.00	14.00	0.00		8.160	4.760	0		
			1		Subtotal		***	35.672	0		***
***			İ	1				1			1
*** and Set up		1280	1.00		1		1,280	1			
· ·	www.llt.	501	1.00	i	1		501	1			
Study Completion	*** and client correspondance										
Study Completion Study administration (first 8 months)	*** and client correspondance Correspondence, tracking, client, vision, filing	160	6.00		-		960				

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***	***	***	***	***	***	***	***	***	非非非	***	***
	Incl. set up, maintenance and completion	1									
Safety Administration	activities	3979	1.00	0.00	0.00		3,979	0	0		
Safaty Administration	Study Extension	83	0.00	14.00	0.00		0	1,155	0		
Initial Receipt and handing SAEs	All events - assume 1 SAE	330	1.00	10.00	0.00		330	3,300	0		
Medical Review of SAEs and Narrative creation	Optional as required	838	0.00	10.00	0.00		0	8,380	0		
Reporting to local Authorities	Assume 1 Reportable events	680	1.00	10.00	0.00		560	6,600	0		
Follow up of SAEs	Assume 2 hours/Follow-up/SAE, 1 Follow ups.	330	1.00	10.00	0.00		330	3,300	0		
Investigator Notification Latters	properstion and oversight	185	1.00	10.00	0.00		165	1,650	0		
	1	1		1	Subtotal		5,464	24,385	0		非非非
***		1	1	1	1			1		1	
	25 unique pages. 60 pages of CRF and 11 pages										
CRF Design	of questionsite 91 Total pages One print run.	14,520	1.00	0.00	0.00		14,520	0	0		
CRF Design	CRF design guidelines	85	0.00	0.00	18.00		0	0	1,360		
CRF Design	Edits and revisions for version 2	120	0.00	0.00	18.00		0	0	1,820		
CRF design update to version 2.0	Update to version 2	120				4.00				480	
	80 pages of CRF (70 on average entered ). One										
CRF Design (extension)	print run.	2834	0.00	1.00	0.00		0	2,834	0		
Datebase design and build		463	25.00	0.00	0.00		11,563	0	0		
Database design and build (extension)		57	0.00	25.00	0.00		0	1,428	0		
Database update and testing per V2 of the CRFs	Update to version 2	120				4.00				480	
Edit Checks updete. end testing per V2 of the CRFS	Update to version 3	120		[		4.00				480	
Database/ Consistance Check programning		53	208.25	0.00	0.00		11,114	0	0		
	Datebase and edit check programaning in										
Database /Consistancy Check programming	support of version 2	120	0.00	0.00	24.00		0	0	2,880		
Database / Consistancy Check programming (extension)		33	0.00	202.00	0.00		0	6,676	0		
Data Validation Manual / Date Management Plan		3400	1.00	0.00	0.00		3,400	0	0		
Date Validation Manual/ Date Management		1664	0.00	1.00	0.00		0	1,664	0		
	Double Data Entry 40 patterns x 80 CRF pages										
	plus 40 x 11 questionaires 3640 total pages.										
Data entry	Cost per extra pages=5.87	6	3640.00	0.00	294.00		21,385	0	1,727		
	Double Data Entry 33 patients X TO entered										
	CRF pages 231D total pages. Coat oar extra				0.00						
Data entry (extension)	pages=\$6.28	6	0.00	2310.00	0.00		0	14,453	0		
Medical Coding	MedDRA - AE. WHO - Drug	6	800.00	0.00	0.00		5,036	0	0		
Medical Coding (extension)	MedDRA - AE. WHO - Drug	7	0.00	680.00	0.00		0	4,600	0		l
	3200. CRF pages. Cost per. extra										
Data Clearing /Monitoring	pages=\$5.10 224 Queries. Cost per extra quaery=\$42.50	29617	1.00	0.00	0.00		29.617	0	0		
Data Cleaning / Monitoring	Additional pages cleaned/montored	5.10	0.00	0.00	734.00		0	0	3.743		
Data Clearing / Monitoring	Additional gueries raised	42.50	0.00	0.00	846.00		0	0	27.455		
Data Clearing / Mointoring	2310 CRF pages. Cost per em	42.50	0.00	0.00	840.00	-	0	0	27,435		
	page=\$7.00 182 Queries. Cost per										
Data Clearing Monitoring (Externsion)	extra query=\$52.00	28270	0.00	1.00	0.00		0	26,270	0		
	10% of all patients 100% of all critical data		0100								
Quality Control	(15% critical / 85% non critical)	2.95	811,40	0.00	0.00		***	0	0		
Quality Control	Additional Safety Lab QC Programming	120	0.00	0.00	4.00		0	0	480	1	
Quality Control	Additional Safety Lab QC(pages)	2.81	0.00	0.00	91.00		0	0	256		
	10% of all patients, 100% of all critical data	1	1	1	1		i —				
Quality Control (extension)	(15% critical / 85% non critical)	3.34	0.00	543,00	0.00		0	1,313	0	1	
Import laboratory data	1 central lab.	3680	1.00	0.00	0.00		3,680	0	0	1	
***	2 biomarker labs - programming	120	0.00	0.00	***		0	0	720	1	
****	2 biomarker labs - data review	85	0.00	0.00	***		0	0	910		
	2 biomarker labs - data review	6.5	0.00	0.00	4.4.4		0	U	910		J

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***	***	***	***	***	***	***	***	***	***	***	***
Import laboratory data (extension)	1 central lab. Import and review.	3182	0.00	1.00	0.00		0	3,182	0		
Data exports	Assume 2 exports	360	2.00	0.00	0.00		720	0	0		
Data exports (extension)	Assume 2 exports	327	0.00	2.00	0.00		0	854	0		
Database maintenance	Study Duration = 18 months	240	18.00	0.00	0.00		4,320	0	0		
Database maintenance (extension)	Study Duration = 18 months	218	0.00	18.00	0.00		0	3,934	0		
DM & Statistics - Project Management	Client meetings & corresp. DM metrics, 1hrs/month x 18 months	120	18.00	0.00	0.00		1,530	0	0		
,	Client meetings & corresp. DM metrics,				1						
DM & Statistics - Project Management	1hrs/month x 18 months           Text and sample size calcualtion /	104	0.00	18.00	0.00		0	1,872	0		
Input to protocol	power	200	4.00	0.00	0.00		800	0	0		
Generation of Randomisation schedule	extra envelope \$12.50	1175	1.00	0.00	0.00		1,175	0	0		
Statistical Analysis Plan	Includes text and tables and listing shells	5840	1.00	0.00	0.00		5,840	0	0	· · · · ·	
Statistical Analysis Plan	Additional hours to cover expansion of analysis. Includes discussion, editing, additional text additional tables and listing shells.	200	0.00	0.00	116.00		0	0	23,200		
	Adaption of SAP for entension and comoined analysis. Includes text plus										
Statistical Analysis Plan	table & listing shells	6072	0.00	1.00	0.00		0	6,072	0		
Analysis populations	Definition of populations	1600	1.00	0.00	0.00		1,600	0	0		
(extension) Analysis populations	Populations	1600	0.00	1.00	0.00		0	1,600	0		
Analysis ***	Specification, Programming & QC	4800	1.00	0.00	0.00		4,800	0	0		
Analysis ***	Additional analysis *** to support increased analysis	600	0.00	0.00	14.00		0	0	8,400		
Analysis *** (extension)	Specification, Programming & QC	3936	0.00	1.00	0.00		0	3,936	0		1
Production of Tables & Listings	15 Unique tables, Cost per extra \$720 20 Repeat tables. Cost per extra \$240 0 Figures. Cost per extra \$420 35 Listings. Cost per extra \$300 22 Unique tables. Cost per extra \$720	26100	1.00	0.00	0.00		26,100	0	0		
Production of Tables & Listings	70 Report tables. Cost per extra \$240 0Figures. Cost per extra \$42040 Listings. Cost per extra \$300	44640	0.00	0.00	1.00		0	0	44,640		
Production of Tables & Listings (extension)	2 Uniques tables. Cost per extra \$720 68 Repeat tables. Cost per extra \$240 0 Figures. Cost per extra \$420 35 Listings. Cost per extra \$300	38622	0.00	1.00	0.00		0	38,622	0		
Statistical Analysis	10 analysis endpoints. Cost per extra \$400	400	10.00	0.00	190.00		4,000	0	76,000		
Statistical Analysis (extension)	10 analysis endpoints. Cost per extra \$424	424	0.00	10.00	0.00		0	4,240	0		
Provision of *** to DSMB	Assumes interim running and QC of 6 TFLs In row Programming Tables and ***.	960	3.00	0.00	0.00		2,880	0	0		
Provision of *** to DSMB (extension)	Assumes provisional excel spredsheets and graphed laboratory values	1312	0.00	3.00	0.00		0	3,936	0		
Input to Final report	Text for inclusion in study report	2400	1.00	0.00	0.00		2,400	0	0		
Input to Final report (extension)	Text for inclusion in study report	2544	0.00	1.00	0.00	ļ	0	2,544	0	***	¢462.02
					Subtotal		158,369	130,321	193,291	***	\$483,822
Medical/Writing/(Optional)			1.00								
Clinical study report (CSR)		22497	1.00	1.00	0.00		22,497	22,497	0	<u> </u>	L
QA review of CSR	Optional for Client	2769	1.00	0.00	0.00		2,769	0	0	───	───
					Subtotal		25,288	22,497	0	L	\$47,76
					TOTAL		***	***	183,231	***	**:

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***	***	***	***	***	***	***	***	***	***	***
Site Visits										
Other Site visit Costs	Pariding/tolls/meals and incidentals for site visits	\$50/day	60.00	50.00	3,000	2,500	0	0		
				Subtotal	3,000	***	0	0	\$5,500	\$5,610
General Expenses										
General Expenses - Couriers, Postage, Telecommunications, Copying; stationary (files)	\$70/site/month, 3 sites for 25 months	\$210/month	25	0.00	5,250	0	0	0		
General Expenses - Couriers, Postage, Telecommunications, Copying, stationery (files)	\$70/site/month, 2 new sites for 16 months	\$140/month	16	0.00	2,240	0	0	0		
General Expenses - Couriers, Postage, Telecommunications, Copying, stationery (files) CRF Printing	\$70/site/month, 4 sites for 14 months	\$280/month \$2,500	0	14.00	0 2,500	3,920	0	0		
				Subtotal	***	***	0	0	\$15,919	\$16,228
		-								
		İ		TOTAL	12,990	5,420	0	0	\$21,410	\$21,833

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Amendment 1 to Agreement dated 19th Aug'13 signed by and between Dr. Reddy's Laboratories Limited Bollaram Road, Miyapur, Hyderabad 500 049 India (Hereinafter referred to as "Dr. Reddy's") and Prana Biotechnology Ltd Level 2,369 Royal Parade, Parkville Victoria, 3052 Australia (Hereinafter referred to as "Prana") Dr. Reddy's and Prana are collectively referred to as the "PARTIES"

This amendment will include the following amended clauses in the above mentioned agreement and will be in effect from 26th September 2013.

# 1. Terms to varied.

The following project item (Sub-Project 1) in Appendix A (Project works and time table section) is set for amendment.

# i. Bifurcation of Sub project 1 in Appendix A(project works and time table section)

Project item	Responsible	Milestone	Timeline
(Sub-Project)	Party	Payment	
1-Completion of Process Development work (towards filtration)	Dr.Reddy's	USD 45,000	Commence April lst 2013, "start date". Milestone payment on completion.

# Is amended as follows

Project item (Sub-Project)	Responsible Party	Milestone Payment	Timeline
l(a)- Completion of Process Development work (towards filtration) till stage 4 (CDDQ-4)	Dr.Reddy's	USD 36,000	Commence April lst 2013, "start date". Milestone payment on completion.
1(b)- Completion of Process Development work (towards filtration) from stage 4 (CDDQ-4) to stage 5 (CDDQ-5)	Dr.Reddy's	USD 9,000	Commence April lst 2013, "start date".Milestone payment on completion.

Page 1 of 2

The deliverables of sub project 1 (a) and 1(b) will be in line with the deliverables of Sub project 1, mentioned in the master service agreement dated 19th Aug 13.

All other terms and conditions of the original Agreement dated 19th Aug'13 remain unchanged.

In witness whereof, the parties hereto have signed this Agreement

Signed for and on behalf of Dr. Reddy's Laboratories Limited

M. M

Signature Name: Manoj Mehrotra

Witness Signature Witness Name: Animesh Kondiparthy

Signed for and on behalf of Prana Biotechnology Ltd.

eles

Signature Name: Dianne Angus

oun

Witness Signature Witness Name: Elisabeth Gautier

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Amendment 2 to Agreement Commencement Date 5th April'13 signed by and between Dr. Reddy's Laboratories Limited Bollaram Road, Miyapur, Hyderabad 500 049 India (Hereinafter referred to as "Dr. Reddy's") and Prana Biotechnology Ltd Level 2, 369 Royal Parade, Parkville Victoria, 3052 Australia (Hereinafter referred to as "Prana") Dr. Reddy's and Prana are collectively referred to as the "PARTIES"

 $This amendment will include the following amended clauses in the above mentioned agreement and will be in effect from 31 {\rm st} August 2013.$ 

# 1. Terms to the amendment would remain as same as that of MSA Commencement Date 5th April'13

The following project item (Sub-Project) in Appendix A (Project works and time table section) is added with the following activities as additional section -8

Sub project-section -8 in Appendix A (project works and time table section) is added with the additional line items as described below

Page 1 of 2

Sr. No.	Project item (Sub-Project) Appendix A	Responsible Party	Milestone Payment in USD on completion of line item	Expected / Estimated Timeline and invoicing
<u>8. EOP2,</u>	analytical & crystallization work package			
	<ul> <li>Analysis of IDT batches &amp; sharing required set of data as per the revised Assay &amp; RS methods</li> </ul>	Dr. Reddy's & Prana (sample to be provided by Prana	2,000	
a.	<ul> <li>Comparing physical properties for all key API batches Batch Number 1457(2011 campaign), 1433(current campaign) are plant scale batches and DA1020702.1 is IDT batch. These batches will be analyzed &amp; compared for physical properties e.g. PSD, DSC, XRPD and bulk density (if sufficient quantity is available)</li> </ul>	Dr. Reddy's & Prana (sample to be provided by Prana)	6,000	Sep'14
	• Expanding specifications of CDDQ-3 as a regulatory starting material & related analytical work.			
	Specification development as per requirement of Regulatory starting material	Dr. Reddy's & Prana	10,000	
	<ul> <li>Part Compilation of data as part of CMC package for EOP2 meeting Creating batch history for CDDQ-3,4,5i-impurity profiling, showing equivalency to the earlier material, method. Old batches may not be available, however impurity profile would be created for all the batches manufactured now onwards – Compiled data would be presented</li> </ul>	Dr. Reddy's & Prana	5,000	
	CMC summary for EOP2:			
b.	• Expanding specifications of CDDQ-3 as a regulatory starting material & related analytical work- Method development and validation for related substances by HPLC and assay by HPLC – Compiled data would be presented	Dr. Reddy's & Prana	13,000	Sept' 14
	• Analytical support for crystallization development work including PSD analysis- Compiled data would be presented	Dr. Reddy's & Prana	14,000	
	Material Generation for Crystallization work	Dr. Reddy's	5,500	
с.	Analysis for the support on Crystallization studies for the lab samples	Dr. Reddy's	13,500	Oct'14
d.	Analysis of Optimized Samples and Report Finalization for Crystallization work	Dr. Reddy's	8000	Nov'14

EOP2 means- End of phase 2 meeting, all other terms and conditions of the original Agreement commencement date 5th April'13 remain unchanged.

In witness whereof, the parties hereto have signed this Agreement

Signed for and on behalf of Dr. Reddy's Laboratories Limited

25th Sept 2014

Signature Name: Anurag Roy

25th Sept 2014

Witness Signature Witness Name: Suresh Kumar Ramachandran

Signed for and on behalf of Prana Biotechnology Ltd.

Helg. - 2/9/14.

Signature Name: Dianne Angus

Witness Signature Witness Name: Elisabeth Gautier

2 Sept 2014

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### Exhibit 4.36

### MANUFACTURING SERVICES AGREEMENT FOR PBT 434 SUPPLY

This MANUFACTURING SERVICES AGREEMENT (hereinafter called "Agreement") is made on 28th day of March, 2014 by and between Prana Biotechnology Ltd ACN 080 699 065 ("Prana"), a company incorporated in Australia whose registered office and principal place of business is at Level 2, 369 Royal Parade, Parkville Victoria 3052 and Dr. Reddy's Laboratories Limited ("Dr. Reddy's"), a company incorporated and existing under the laws of India, having its principal place of business at # 8-2-337, Road No.3, Banjara Hills, Hyderabad 500 034, Andhra Pradesh, India.

Dr. Reddy's and Prana are individually referred to as a "Party" and jointly as the "Parties".

### WHEREAS:

- A. The parties executed a Confidentiality Agreement dated 19th August 2013 and Letter of Intent dated 24th January, 2014 in relation to Prana's requirement for Dr. Reddy's to undertake process development, analytical method validations, cGMP manufacture and stability studies of Prana's compound known as PBT 434.
- B. The parties now enter this manufacturing services agreement to definitively record all the terms and conditions upon which Dr. Reddy's will perform the Project.

# NOW THEREFORE, IN CONSIDERATION TO THE MUTUAL COVENANTS AGREED HEREIN THE PARTIES HERETO HAVE AGREED TO BE LEGALLY BOUND BY THE FOLLOWING TERMS, WHICH SHALL HEREAFTER GOVERN THE TERMS OF THIS AGREEMENT

1. Definitions

For the purposes of this Agreement, capitalized terms, whether used in the singular or plural, shall have the following meanings, unless the context clearly requires otherwise:

- (a) "Affiliate" shall mean, with respect to a Party, any entity controlling, controlled by, or under common control with such Party. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise; or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an entity.
- (b) "Agreement" means this agreement and includes any schedule or annexure to it.

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- (c) "API" means an active pharmaceutical ingredient of the Compound.
- (d) "Approved Purposes" for a given Party means the performance of the Project and its obligations under this Agreement, and for Prana also means the use of the Compound and Results for its business purposes which will necessarily include the satisfaction of any regulatory requirements in relation to the Compound.
- (e) "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.
- (f) "Commencement Date" means 25th October, 2013.
- (g) "Compound" or "PBT434" means 5,7-dichloro-2-((ethylamino)methyl)-8-hydroxy-3- methylquinazolin-4(3H)-one hydrobromide.
- (h) "Confidential Information" means Dr. Reddy's Confidential Information or Prana Confidential Information as the context allows.
- (i) "Deliverables" means the quantities of Compound, reports, materials, licences or other deliverables specified in the Scope of Project Works for each Sub-Project.
- (j) "Dr. Reddy's Background IP" means all Intellectual Property owned or controlled by or licensed to Dr. Reddy's or any Affiliate of it as at the Commencement Date.
- (k) "Dr. Reddy's Confidential Information" means:
  - (i) the Proposal (excluding any Prana Confidential Information contained in it);
  - (ii) Dr. Reddy's Background IP;
  - (iii) all information concerning Dr. Reddy's comprising its research projects, plans and strategies, trade secrets, know-how, technology, business operations and financial dealings which is or has been disclosed to or obtained by Prana prior to or after the date of this Agreement (whether orally, electronically or in writing) other than Prana Confidential information and information that Prana can establish:
    - (A) was already in the public domain at the time of its provision to Prana; or
    - (B) became part of the public domain after its provision to Prana, otherwise than though a disclosure by Prana or any person to whom Prana has disclosed Dr. Reddy's Confidential Information;

- (C) is or came lawfully into the possession of Prana otherwise than as a result of disclosure in breach of an obligation of confidence; or
- (D) was independently discovered by Prana without the aid, application or use of the Dr. Reddy's Confidential Information.
- (1) "Force Majeure Event" has the meaning given to it in clause 13.
- (m) "GMP" or "cGMP" means the current good manufacturing practices, standards and requirements specified in US 21 CFR parts 210 and 211 and ICH Q7.
- (n) "Intellectual Property" ("IP") means any and all Technology and all intellectual, industrial and commercial property rights throughout the world subsisting in or in relation thereto including rights and interests in respect of or in connection with Patents, trade secrets, rights in confidential information, copyright (including future copyright and rights in the nature of or analogous to copyright), trade marks, service marks, database rights, designs, whether or not registered or registrable and includes applications for any of the foregoing and the right to apply for any of the foregoing in any part of the world.
- (o) "Letter of Intent" or "LOI" means the Letter of Intent between the parties in relation to the Project dated 24th January, 2014.
- (p) "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 Materials, means the materials themselves.
- (q) "Patents" mean all patent applications, patents, or letters patents, and any claims in any such patent applications or patents, in any part of the world, including, without limitation, all continuations, continuation-in-parts, reissues, extensions, substitutions, confirmations, registrations, re-validations, and additions, and any supplementary protection certificates in respect thereof.
- (r) "Prana Arising IP" means all Intellectual Property generated, developed, conceived, created, invented, discovered, derived, modified, improved or adapted by Dr. Reddy's, Prana or their respective Affiliates and Representatives in the course of performing the Project.
- (s) "Prana Background IP" means all Intellectual Property owned or controlled by or licensed to Prana or any Affiliate of it as at the Commencement Date.

(t) "Prana Confidential Information" means:

(i) the Prana Materials;

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- (ii) the Results and Deliverables;
- (iii) the RFP;
- (iv) Prana Background IP and Prana Arising IP;
- (v) all information concerning Prana, the Compound and Prana's research projects, plans and strategies, products, materials and compounds, trade secrets, know how, technology, business operations and financial dealings which is or has been disclosed to or obtained by Dr. Reddy's prior to or after the date of this Agreement (whether orally, electronically or in writing) other than information that Dr. Reddy's can establish:
  - (A) was already in the public domain at the time of its provision to Dr. Reddy's; or
  - (B) became part of the public domain after its provision to Dr Reddy's, otherwise than though a disclosure by Dr. Reddy's or any person to whom Dr. Reddy's has disclosed Prana Confidential Information;
  - (C) is or came lawfully into the possession of Dr. Reddy's otherwise than as a result of disclosure in breach of an obligation of confidence; or
  - (D) was independently discovered by Dr. Reddy's outside the Project without the aid, application or use of the Prana Confidential Information.
- (u) "Prana Materials" means:
  - (i) samples of the Compound in the possession of Dr. Reddy's as at the Commencement Date and any other materials including reference standards provided by Prana to Dr. Reddy's for the purpose of the Project; and
  - (ii) any APIs of the Compound or other materials manufactured by Dr. Reddy's in the course of the Project.
- (v) "Project" means a process development and manufacturing project to carry out (by way of Sub-Projects) process development, analytical method validations, cGMP manufacture and Stability Studies of the Compound.
- (w) "Project Price" means US\$300,000 (subject to an increase of \$20,000 if the bonus payment for Project item 6 specified in Appendix A becomes payable).

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- (x) "Project Works" means the works (comprising the Sub-Projects) described in Appendix A and specified in detail in Appendix B.
- (y) "Proposal" means Dr. Reddy's proposal for PBT434 manufacture provided in response to the RFP. The proposal is set out in Dr. Reddy's letter dated 3rd October, 2013.
- (z) "Quality Agreement" means the quality agreement put in place pursuant to the Manufacturing Service Agreement of PBT 2 HCI Supply dated 19th August, 2013 that will be modified and updated to support this Agreement (attached as Appendix C to this Agreement).
- (aa) "Representatives" in relation to a Party means a director, officer, employee, contractor, consultant, agent or adviser of that Party.
- (bb) "Results" means:
  - all results, data, information, processes, procedures, methodologies, techniques, concepts, ideas, compounds, materials, items or things conceived, created, developed, discovered, derived, modified, improved or adapted by Dr. Reddy's or Prana or their respective Affiliates and Representatives during, or as a consequence of, the Project; and
  - (ii) all papers, materials, records, laboratory notebooks and documents (in written or electronic form) which have been produced by Dr. Reddy's or Prana or their respective Affiliates and Representatives in relation to the Project and the Results.
- (cc) "RFP" means Prana's Request for Proposal: Process Development and cGMP API Manufacture of PBT434 dated 19th August 2013.
- (dd) "Scope of Project Works" means the specifications, requirements and Deliverables for the Project Works as set out in Appendix B.
- (ee) "Sub-Projects" means the sub-projects described in Appendix A and specified in detail in Appendix B for performance by Dr Reddy's, subject in each case to Dr Reddy's receiving prior written approval from Prana.
- (ff) "Technology" means trade secrets, ideas, knowledge, information, discoveries, inventions, technology, data, results, reports, formulae, techniques, strategies, concepts, methodologies, processes, procedures for experiments and tests and manufacturing scale ups, compounds, materials, methods or schemes for synthesising compounds, uses of/or indications for chemical compounds, technical data, information or specifications, testing methods, assays, isolation and purification methods, designs, sketches, records, biological materials and analyses.

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(gg) "Timetable" means the timetable contained in Appendix A for the commencement and completion of each Sub-Project.

### 2. Engagement and Obligations of Dr. Reddy's

- (a) Prana engages Dr. Reddy's to perform the Project (to the extent of those Sub-Projects authorised by Prana in accordance with clause 2 (b)), and Dr. Reddy's agrees to accept the engagement on the terms and conditions contained in this Agreement,
- (b) Dr. Reddy's must receive written authority from Prana's Head of Discovery and Non-Clinical Development Manager (E. Gautier) or its Principal Scientist (J. Parsons) or its Head of Toxicology (S. Foran) or its Chief Operating Officer (D. Angus) before commencing any Sub-Project. Without such authority for a given Sub-Project, Dr. Reddy's must not undertake and may not charge Prana its fee for the Sub-Project or any other amount. The work undertaken and the costs of a Sub-Project cannot be altered without the express written permission of Prana. 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 Timetable, then Dr. Reddy's 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.
- (c) The parties acknowledge the grant of approval by Prana in the LOI for Dr. Reddy's to commence Sub-Projects 1, 2 and 3 in Appendix A. The parties also acknowledge and agree to the milestone payments totalling US\$76,000 in relation to Sub-Project 3.
- (d) Dr. Reddy's will perform and carry out the Project Works with all due care and skill in accordance with this Agreement, and in particular the Scope of Project Works and the Timetable
- (e) Dr. Reddy's must provide the following updates and reports to Prana:
  - (i) weekly written updates (in a format acceptable to Prana, which will be communicated to Dr. Reddy's in a separate email) of the work undertaken and the Results obtained for the week, problems encountered by Dr. Reddy's, the stage of the Timetable that Dr. Reddy's is up to and any other information that would be relevant to Prana in relation to the Project; and

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- (ii) a written report (in a format acceptable to Prana) detailing all of the work carried out and all the Results obtained for each Sub-Project undertaken, including all practices, procedures, processes and data (including spectra) and information developed or generated in the conduct of the Sub-Project along with any future recommendations on completion of the work specified in the Scope of Project Works for that Sub-Project.
- (f) Dr. Reddy's will participate in weekly teleconferences with Prana to present its updates and reports and allow Prana to ask any questions that it may have concerning the Project and set the work priorities for the following week. A Representative of Dr. Reddy's must take the minutes of each telephone conference and prepare these for the consideration and approval of the Parties at the next telephone conference.
- (g) All Results arising out of the Project must be recorded in a written format. These results captured in a written format must:
  - (i) be maintained and signed in accordance with best industry practice; and (ii) be made available for inspection by Prana upon request by Prana in writing.
- (h) Dr. Reddy's must comply with cGMP (in relation to the manufacturing work to be undertaken by it) and all applicable laws in the performance of its obligations under this Agreement.
- (i) Prana and Dr. Reddy's have executed the Quality Agreement to the extent required for the purpose of the Project. The Quality Agreement shall be co terminus to this Agreement.
- (j) On 15 days prior written notice and not more than twice in each twelve (12) month period, Dr. Reddy's must allow Prana or any Representative of it to attend any premises at which Project Works are being conducted for the purpose of auditing all Project Works, materials and information to ensure the compliance by Dr. Reddy's with its obligations under this Agreement. Prana's Representative shall only have the right to access works, materials and information that relate exclusively to the Project, and only if such access would not compromise Dr. Reddy's confidentiality obligations to another party and/or its internal QA programs. Notwithstanding the foregoing, if Prana's Representative is not an employee of Prana, (i) he/she must not be a competitor of Dr. Reddy's or any of its Affiliates, and (ii) will not be permitted to access or to examine any Project Works, materials and information, until he/she has entered into a non-disclosure agreement with Dr. Reddy's.
- (k) At any time during the conduct of the Project Works with prior notice by Prana, Dr. Reddy's must allow Prana or any Representative of it to attend any premises at which Project Works are being conducted for the purpose of assessing the progress of the Project Works. Notwithstanding the foregoing, if Prana's Representative is not an employee of Prana, or Neil Mhaskar or John Devlin (in their capacity as contractors of Prana) (i) he/she must not be a competitor of Dr. Reddy's or any of its Affiliates, and (ii) will not be permitted to access or to examine any Project works, materials and information, until he/she has entered into a non-disclosure agreement with Dr. Reddy's.

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- (1) If at any time during or after the termination of this Agreement, Prana requires a third party to perform any work relating to PBT434 including its manufacture, then Dr. Reddy's 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 Dr Reddy's, provided that any anticipated expenses in excess of USD\$1,000 are approved by Prana in writing before they are incurred.
- (m) It is agreed in relation to the Deliverables for each Sub-Project that Prana shall have fifteen (15) days ("Testing Period") from the date they are received to perform acceptance testing on the Deliverables in order to confirm that they comply with the specifications set out in this Agreement ("Acceptance Testing"). If Prana is satisfied that the Deliverables meet specification, then it will confirm this in writing to Dr. Reddy's and pay the applicable milestone payment. If Prana finds that any Deliverables supplied by Dr. Reddy's do not meet specification, then Prana will immediately notify Dr. Reddy's in writing of any non-compliance. If the non-compliance for a Sub-Project relates to:
  - (i) Compound supplied to Prana, then Prana may by written notice:
    - (A) require that Dr. Reddy's manufacture and supply the applicable quantity of Compound based on a manufacture start within 28 days of Prana's notice or 7 days of initiating plant modification required for the manufacturing, whichever is the earlier and a manufacturing period less than or equal to the period of time originally allocated for the activity in the corresponding Sub-Project in Appendix A; or
    - (B) terminate the Sub-Project in whole or in part, in which case Prana will not be liable to pay for, and Dr. Reddy's must immediately refund any moneys paid by Prana (if any) on account of, the Sub-Project or the terminated part of it;
  - (ii) services or documents or Results supplied, then:
    - (A) Prana may require that Dr. Reddy's immediately repeat the services or re-write the documents to rectify the non-compliance within the period specified by Prana; or
    - (b) terminate the Sub-Project in whole or in part, in which case Prana will not be liable to pay for, and Dr. Reddy's must immediately refund any moneys paid by Prana (if any) on account of, the Sub-Project or the terminated part of it.

### 3. Payment

- (a) The total cost of the Project (including all milestone payments) is three hundred and twenty thousand United States Dollars (USD 300,000/-) for Sub-Projects 1 to 6 inclusive, payable to Dr. Reddy's. A further bonus payment of US\$20,000 may be payable in respect of Sub-Project 6, subject to Dr. Reddy's complying with the conditions specified in Appendix A for the payment of that sum.
- (b) The amount payable by Prana to Dr. Reddy's for each Sub-Project and the timelines and conditions attaching to each such payment are specified in Appendix A.
- (c) All payments are to be made within 30 days of invoicing. Each of the Sub-Projects that attract and satisfy a milestone payment, other than Sub-Project 6(a) Stability Studies, shall be invoiced on completion of the Sub-Project. Each Sub-Project will be invoiced independent of the completion of other Sub-Projects. If any Sub-Project is not authorised by Prana (for whatever reason), then Prana will have no liability to pay Dr. Reddy's for the Sub-Project fees or any other amount. Sub-Project 6(a) will be invoiced within 30 days of completing the time points mentioned in Appendix A.
- (d) All payments are subject to:-
  - (i) Prana having received the requisite Deliverables; and
  - (ii) Completion of the Sub-Project. Completion of a Sub-Project will be determined by the provision of all Deliverables for that Sub-Project that will include the required written documentation, records and Results and relevant materials in the quantities, form and purity as per the Scope of Project Works and satisfactory Acceptance Testing of the Deliverables.
- (e) Property in the physical quantity of Compound or any API of it (or any other materials or samples) produced by Dr. Reddy's under any Sub-Project (Goods) will pass to Prana on delivery of the Compound to Prana's carrier or payment for the Sub-Project in full, whichever is earlier. At Prana's request (in case of delay in acceptance of Goods from freight forwarder), Dr. Reddy's will store the Goods at its cost and at the risk of Prana for up to 90 days at appropriate conditions. In the interim, Dr. Reddy's will liaise with Prana or its nominee in relation to the transport of the Goods to Prana and will obtain at its own risk and expense any export licence or other official authorisation and carry out where applicable all customs formalities necessary for the export of the Goods. On the agreed date, Dr. Reddy's will deliver the Goods to Prana's carrier at Dr. Reddy's premises at which time risk in the Goods will pass to Prana. The payment amounts mentioned herein do not include freight, insurance and other shipping expenses for transportation of Goods from Dr. Reddy's is called upon to incur any such expenses. If requested by Prana, Dr. Reddy's will help Prana to identify an appropriate freight forwarder.

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(f) All payments by Prana to Dr. Reddy's pursuant to this Agreement shall be made without any withholding or deduction of any withholding tax or other tax or mandatory payment to governmental agencies. If Prana is legally required to make any such withholding or deduction from any payment to Dr. Reddy's under this Agreement, the sum payable by Prana upon which such withholding or deduction is based shall be increased to the extent necessary to ensure that, after such withholding or deduction, Dr. Reddy's receives and retains, free from liability for such withholding or deduction, a net amount equal to the amount Dr. Reddy's would have received and retained in the absence of such required withholding or deduction.

### 4. Intellectual Property

- (a) Dr. Reddy's acknowledges and agrees that the Prana Background IP will at all times remain the exclusive property of Prana or its relevant Affiliate. Similarly, Prana acknowledges and agrees that the Dr. Reddy's Background IP will at all times remain the exclusive property of Dr. Reddy's or its relevant Affiliate.
- (b) The Parties acknowledge and agree that all Prana Arising IP is hereby assigned to and will vest in and be solely owned by Prana as and from the time of its creation.
- (c) During the term of this Agreement Prana hereby grants Dr. Reddy's a royalty free, non exclusive, non-transferable, revocable licence for the term of this Agreement to use Prana Background IP and Prana Arising IP solely for the Approved Purposes. Similarly, during the term of this Agreement Dr. Reddy's hereby grants Prana a royalty free, non-exclusive, non-transferable licence to use Dr. Reddy's Background IP solely for the Approved Purposes.
- (d) Dr. Reddy's will provide all assistance and advice and execute all necessary documents as may be required by Prana from time to time, in relation to:
  - (i) any assignment that may be required to transfer Prana Arising IP to Prana;
  - (ii) any applications by Prana for Patents or other registrable intellectual property rights in respect of the Prana Arising IP; and
  - (iii) 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 the testing, manufacture or sale of the Compound or an API of it,

and Prana shall pay all reasonable costs and expenses incurred by Dr. Reddy's in providing such assistance.

### 5. Term and Termination

(a) This Agreement shall commence on the Commencement Date and shall, subject always to earlier termination under this Clause 5, continue until ninety (90) days after delivery by Dr. Reddy's to Prana of the final written report for the last Sub-Project approved by Prana.

- (b) Notwithstanding any other provision of this Agreement, either Party shall have the right at any time by giving notice to the other to terminate this Agreement (or a Sub-Project in the case of the events described in paragraphs (i), (ii) or (iv)) forthwith in any of the following events:
  - (i) if the other Party commits a material breach of this Agreement and the breach is not capable of remedy;
  - (ii) if the other, Party commits a material breach of this Agreement and, where such breach is capable of remedy, that Party does not remedy such breach within 30 days from service of notice upon it that it is in breach and requiring it to remedy such breach; or
  - (iii) if the other Party enters into liquidation, whether compulsory or voluntary (other than for the purposes of solvent reconstruction or amalgamation where the resulting Party assumes all such Party's obligations under this Agreement), or has a receiver, controller or administrator or similar official appointed over some or all it assets or compounds with its creditors or suffers any similar action in consequence of its indebtedness to creditors; or
  - (iv) if either Party is delayed or incapable of performing its obligations under this Agreement as a result of a matter described in Clause 13 (Force Majeure) for continuous period of 90 days or more.
- (c) Notwithstanding any other provision of this Agreement, Prana may terminate this Agreement (in whole or in part) at any time by giving the Dr. Reddy's 30 days written notice.
- (d) The obligations of the Parties under clauses 1, 2 (g) and (l) and (m), 3, 4, 5, 7, 8, 9 (b), 11, 15, 16 and 17 will survive the expiry or termination of this Agreement. The obligations of the Parties under clause 6 will survive the expiry or termination of this Agreement for seven (7) years.
- (e) On the expiry or termination of this Agreement or on the termination of a Sub-Project and subject to payment of consideration due under this Agreement:
  - (i) Dr. Reddy's must provide Prana with all outstanding updates and reports as existing at the date of such expiry/termination under clause 2 (e) for any completed or partly completed Sub-Project;
  - (ii) Dr. Reddy's must deliver to Prana all materials produced by it as part of any completed or partly completed Sub-Project in the quantities, form and purity that complies with Prana's requirements as set forth in the Scope of Project Works (Appendix B);
  - (iii) Prana must pay all sums which have accrued or been invoiced by Dr. Reddy's up to the expiry or termination date and are payable in accordance with the terms of this Agreement. If a Sub-Project is only partly completed on the expiry or termination date, then provided this Agreement or the Sub-Project has not been terminated by Prana pursuant to clauses 2 (m) (i) or (ii) or 5 (b)), Dr. Reddy's will be entitled to a proportion of its fee for that Sub-Project and non-cancellable pass-through expenses necessary to wind down such Sub-Project. Proportion of the fee shall be calculated on the basis of the percentage of the Sub-Project completed by Dr. Reddy's. If this amount is less than the total of the advance and other progress payments already paid by Prana for the Sub-Project, then Dr. Reddy's must refund the difference within 30 days of its fee being agreed with Prana.

- (iv) Dr. Reddy's must return the Prana Materials and all Material Forms of the Prana Confidential Information to Prana. In the case of Prana Materials, the Parties acknowledge and agree that Dr. Reddy's may retain samples of the Prana Materials manufactured by it so that it may comply with its cGMP obligations;
- (v) Prana must return all Material Forms of the Dr. Reddy's Confidential Information to Dr. Reddy's.
- (f) No expiry or termination of this Agreement shall affect any of the rights and obligations of the Parties accrued up to the date of expiry or termination.

# 6. Confidentiality

- (a) Each Party acknowledges and agrees that the Confidential Information of the other Party will at all times remain the exclusive property of that other Party. Each Party also undertakes to keep the Confidential Information of the other secret and to protect and preserve the confidential nature and secrecy of that Confidential Information.
- (b) Prana agrees and acknowledges in relation to Dr. Reddy's Confidential Information, and Dr. Reddy's agrees and acknowledges in relation to Prana Confidential Information, that it:
  - (i) may only use or reproduce the other Party's Confidential Information for the Approved Purposes;
  - (ii) must not disclose the other Party's Confidential Information to any person except as permitted by this Agreement;
  - (iii) must not permit unauthorised persons to have access to the other Party's Confidential Information;
  - (iv) 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;



- (v) 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;
- (vi) 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
- (vii) 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.
- (c) 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.
- (d) Each Party must procure that its Representatives (whether or not still employed or engaged in that capacity) do not do or omit to do anything which, if done or omitted to be done by that Party, would breach its obligations under this Agreement.
- (e) The obligations of confidentiality and non-disclosure contained in this clause 6 do not apply if and to the extent that the Confidential Information is required to be supplied by virtue of any statute, law or regulation. Each Party must notify the other immediately if it becomes aware of any legal requirement to disclose part or all of the other Party's Confidential Information.
- (f) Each Party must:
  - (i) establish and maintain effective security measures to safeguard the other Party's Confidential Information from access or use not authorised under this Agreement;
  - (ii) keep the other Party's Confidential Information under its own control;
  - (iii) maintain complete, accurate and up-to-date records of use, copying and disclosure of the other Party's Confidential Information and immediately produce these records to the other Party, on request; and

- (iv) immediately notify the other Party of any suspected or actual unauthorised use, copying or disclosure of the other Party's Confidential Information.
- (g) Either Party may at any time by notice in writing to the other Party request the return 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 Materials to be returned by Dr. Reddy's, the parties acknowledge and agree that Dr. Reddy's may retain samples of the Prana Materials manufactured by it so that it may comply with its GMP obligations.
- (h) Return of the Material Forms of Confidential Information under clause 6(g) does not release a Party from its obligations under this clause 6.

#### 7. Liability

- (a) Prana will defend, indemnify and hold harmless Dr. Reddy's and its Representatives and Affiliates from and against any and all liability losses, costs, damages or expenses (including court costs and reasonable attorneys fees) incurred from or arising in connection with any claim (including claims for infringing third party intellectual property rights) arising out of or are in any way relating to:
  - (i) Prana's use of the Prana Arising IP, the Results, Compound, APIs or any materials produced during a Sub-Project and supplied to Prana, provided Dr. Reddy's has complied with this Agreement in relation to its performance of the Sub-Project and the Sub-Project Deliverables have been accepted by Prana in writing;
  - (ii) personal injuries or death to persons or property loss or damage which occur on Dr. Reddy's premises or the premises of Dr. Reddy's Affiliates as a result of the conduct of the Project to the extent that they are directly attributable to circumstances that could have been avoided by Dr. Reddy's if it had been aware of relevant information about the Compound that was knowingly or negligently withheld from Dr. Reddy's by Prana; or
  - (iii) the breach of clauses 4 or 6 by Prana or its Affiliates or Representatives.
- (b) Prana will defend, indemnify and hold harmless Dr. Reddy's and its Representatives and Affiliates from and against any and all liability losses, costs, damages or expenses (including court costs and reasonable attorneys fees) incurred from or arising in connection with any claim for infringing third party intellectual property rights arising out of or are in any way relating to Dr. Reddy's use, for Approved Purposes, of the Prana Materials, Compound APIs, Prana Background IP or Prana Arising IP.

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- (c) Dr. Reddy's will indemnify and hold harmless Prana, its Representatives and Affiliates from and against all costs, expenses, liabilities, losses, damages, claims and proceedings suffered or incurred by them (including proceedings for infringing third party intellectual property rights) which have arisen out of or are in any way relating to:
  - (i) personal injuries or death to persons or property loss or damage which occur on Dr. Reddy's' premises or the premises of Dr. Reddy's' Affiliates as a result of or in connection with any act or omission, negligence or breach of this Agreement by Dr. Reddy's or its Affiliates or any of their respective Representatives;
  - (ii) any use (other than for the Approved Purposes) by Dr. Reddy's or its Affiliates (or by third parties under licence from or other arrangement with Dr. Reddy's or its Affiliates) of the Prana Materials, Prana Background IP, the Prana Arising IP, the Results or Compound APIs;
  - (iii) the use of Dr. Reddy's Background IP by Prana, its Representatives and Affiliates for the Approved Purposes; or
  - (iv) the breach of clauses 4 or 6 by Dr. Reddy's or its Affiliates or Representatives.
- (d) Notwithstanding any other provision of this Agreement, neither Party will have any liability to the other Party (or any Affiliate of it) for any consequential or indirect loss or damage (including loss of profits) ("Consequential Loss") suffered or incurred by the other Party (or any Affiliate of it), howsoever arising This paragraph (e) will not prevent a Party recovering from the other, Consequential Loss suffered or incurred by it (or an Affiliate of it) under paragraphs(a) and (b) and(c) above.
- (e) In no event will the aggregate liability of either Party for any claims made by the other Party under or in connection with this Agreement exceed the Project Price (except in relation to their respective liabilities for any claims made under clauses 7 (a), (b) and (c) which will not be subject to this limitation).

#### 8. Warranties

- (a) Each Party warrants to the other that it is duly organised, validly existing and in good standing in accordance with the applicable laws and has all necessary power and authority to enter into this Agreement and to carry out its obligations under this Agreement and to consummate the transactions contemplated hereby and that it is duly licensed or qualified to do business in its principle place of business.
- (b) Each Party warrants to the other that the execution and delivery by it of this Agreement, the performance by it of its obligations hereunder and the consummation of the transactions contemplated by this Agreement have been duly authorised by all requisite action on the part of the Party, and no other corporate proceedings by it or any of its Affiliates are required in connection therewith.
- (c) Each Party represents that there is no litigation pending or threatened (judicial, regulatory or otherwise) or other operational issues within its business that would or might prevent or adversely interfere with the performance of its obligations under this Agreement.

- (d) During the term of this Agreement and before commencing the development and manufacture of the Compound, each Party warrants that it will (at its own cost) obtain, maintain and secure all permits, registrations and licences (including but not limited to those in respect of manufacturing and regulatory) required under applicable laws to allow it to perform its obligations under this Agreement. If requested by a Party, the other Party shall submit copies of any such documents for its inspection and records. Further, the Parties hereby agree that they will promptly notify the other of any notices and non- compliances issues that have been noticed, issued or reported by any regulatory or statutory authorities and ensure that they are complied with immediately without any delay or continuing default.
- (e) Each Party warrants that it has the requisite skills, resources, technology and all the rights and licences necessary for rendering services and fulfilling its contractual obligations under this Agreement.
- (f) Prana warrants that the Prana Background IP and other information provided by it for use by Dr. Reddy's in the manufacture and development of the Compound pursuant to this Agreement will not violate or infringe upon the intellectual property rights of any third person. Dr. Reddy's warrants that the use of Dr. Reddy's Background IP or other Dr. Reddy's Confidential Information by either Party for the Approved Purposes will not violate or infringe upon the intellectual property rights of any third person.
- (g) EXCEPT AS AGREED UNDER THIS AGREEMENT DR. REDDY'S MAKES NO WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY REGARDING OR RELATING TO THE PERFORMANCE OF THE OBLIGATIONS UNDER THIS AGREEMENT. TO THE EXTENT PERMITTED BY LAW, DR. REDDY'S SPECIFICALLY DISCLAIMS ALL IMPLIED WARRANTIES OR MERCHANTABILITY FOR A PARTICULAR PURPOSE OF RENDERING SERVICES FOR THE PROJECT UNDER THIS AGREEMENT.

# 9. Hazardous Information

Prana will make all information (if any) which it has available to it concerning the health and other hazards of the Compound and its synthesisand any other materials including reference standards provided by Prana to Dr. Reddy's for the purpose of the Project. Dr. Reddy's must assess these hazards and take the necessary measures in relation to the Project to:

- (a) ensure the safety of its Representatives; and
- (b) avoid any loss or damage to its premises or property.

### 10. Assignment and Subcontracting

(a) Neither Party shall assign this Agreement or any of its rights and obligations under it to any third party without first obtaining the prior written consent from the other.(b) Dr. Reddy's must not subcontract any of its obligations under this Agreement without the prior written consent of Prana.

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Plot No. 338, S.V.Co-operative Industrial Estate, Jeedimetla, Hyderabad, Andhra Pradesh, India-500 055)

- (c) If Prana, in its absolute discretion, consents to the subcontracting of the performance of any of the Project Works, then:
  - (i) Dr. Reddy's shall remain fully responsible for the performance of the Project Works and must continue to comply with each and every one of its obligations under this Agreement;
  - (ii) without limitation, all acts or omissions of the subcontractor shall be deemed acts or omissions of Dr. Reddy's; and
  - (iii) Dr. Reddy's must ensure that any subcontractor so engaged complies with, and enters into a written agreement with Dr. Reddy's under the terms of which:
    - a. the subcontractor agrees to comply with all relevant provisions of this Agreement (including in respect of performance of the relevant subcontracted Project Works, compliance with cGMP and all applicable laws, record keeping, confidentiality and Intellectual Property) as if it were a party to this Agreement;
    - b. the subcontractor is prohibited itself from subcontracting any part of the performance of the subcontract.

# 11. Notices

- (a) A notice, consent, approval or other communication (each a **Notice**) under this agreement must be signed by or on behalf of the Party giving it, addressed to the Party to whom it is to be given and:
  - (i) delivered to that Party's address;
  - (ii) sent by pre-paid mail to that Party's address; or
  - (iii) transmitted by facsimile to that Party's address.

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- (b) A Notice given to a Party in accordance with this clause 10 is treated as having been given and received:
  - (i) if delivered to a Party's address, on the day of delivery if a Business Day, otherwise on the next Business Day;
  - (ii) if sent by pre-paid mail, on the tenth Business Day after posting; or
  - (iii) if transmitted by facsimile to a Party's address and a correct and complete transmission report is received, on the day of transmission if a Business Day, otherwise on the next Business Day.
- (c) For the purpose of this clause the address of a Party is the address set out below or another address of which that Party may from time to time give notice to the other Party:

# If to Prana:

Dianne Angus Chief Operating Officer Prana Biotechnology Ltd Level 2, 369 Royal Parade, Parkville Victoria 3052

Facsimile: +61 3 9348 0377

If to Dr. Reddy's: Mr. Anurag Roy Vice President – Global CPS head Custom Pharmaceutical Services, Dr. Reddy's Laboratories Limited Bollarum Road, Miyapur, Hyderabad, Andhra Pradesh, India- 500049

Facsimile: +91 40 4465 8654

# 12. Entire Agreement

The Confidentiality Agreement between the Parties dated 19<sup>th</sup> August 2013, the LOI, the Quality Agreement (as amended pursuant to clause 2 (i)) and this Agreement set forth the entire agreement between the Parties as to its subject matter. In the event of any incompatibility between the terms of this Agreement and the said Confidentiality Agreement LOI and Quality Agreement, the terms of this Agreement shall prevail and take priority. None of the terms of this Agreement shall be amended except in writing signed by both Parties.



# 13. Force Majeure

A Party shall not be liable for a failure to perform any of its obligations under this Agreement (other than a payment obligation) due to any cause or circumstance which is beyond its reasonable control, including without limitation, acts of God, wars, riots, interference by military or para-military, strikes, lock-outs or other labour unrest, fires, explosions, shipwrecks, shortage in material if the supplier(s) of such material is unable to supply due to causes and circumstances beyond their control as exemplified above ("Force Majeure Event") provided always that such failure or delay could not have been prevented by reasonable precautions. In the case of Force Majeure, the obligations of the Party affected shall be suspended and it shall not be liable for damages or for penalties for non-performance to the extent that such non-performance is caused by the Force Majeure event with the proviso that if the Force Majeure period should extend more than three (3) months then the other Party shall have the right to terminate this Agreement forthwith upon written notice at any time after expiration of said three (3) months period. In addition, non-performance shall only be excused during the continuation of the Force Majeure event.

# 14. Independent Contractors

The parties are independent contractors and this Agreement shall not be construed as creating or evidencing a partnership, agency, employment or joint venture relationship between them.

#### 15. Dispute Resolution

- (a) If a dispute arises in connection with this Agreement or relating to this Agreement including its interpretation and any question regarding its existence, validity or termination, then a Party wishing to have the dispute resolved must give the other Party a notice specifying the dispute and requiring its resolution under this clause 15 ("**Dispute Notice**").
- (b) Within 14 days of the date of service of the Dispute Notice, each Party must:
  - (i) appoint a Representative with authority to negotiate and settle the dispute; and
  - (ii) notify the other Party in writing of the appointed Representative's name and contact details.
- (c) The authorised Representatives and the Parties that they represent must then use their reasonable endeavours to resolve the dispute within 42 days of the date of service of the Dispute Notice. If they fail to resolve the dispute within this period, then either Party may institute court proceedings.
- (d) A Party may not commence court or any other proceedings in relation to a dispute arising in connection with this Agreement until it has exhausted the procedures in this clause, unless the Party seeks injunctive or other interlocutory relief to preserve property or rights or to avoid losses that are not compensable in damages.

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# 16. Governing Law and Jurisdiction

- (a) This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of England and the courts located at London shall have the exclusive jurisdiction to entertain and resolve all the disputes between the Parties.
- (b) Each Party irrevocably and unconditionally:
  - (i) submits to the jurisdiction of the courts of England; and
  - (ii) waives any claim or objection based on absence of jurisdiction or inconvenient forum.
- (c) The rights and obligations of the parties under this Agreement shall not be governed by the United Nations Convention on Contracts for the International Sale of Goods (1980).

# 17. Miscellaneous

- (a) No forbearance or tolerance on the part of the either Party of any breach of this Agreement by the other shall constitute waiver of the requirements of this Agreement. A right may only be waived in writing, signed by the Party giving the waiver.
- (b) The parties hereby agree that any provision/s of this agreement which are held to be invalid and unenforceable in law shall not by itself make this Agreement invalid nor effect the other provisions of this agreement and the other terms shall remain fully enforceable and valid in law.
- (c) Each Party agrees to do all things and execute all agreements, instruments, transfers or other documents as may be necessary or desirable to give effect to the provisions of this Agreement and the transactions contemplated by it.
- (d) This Agreement may be executed in any number of counterparts. All counterparts together will be taken to constitute one instrument.

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Executed by the Parties by their duly authorised representatives

# Prana Biotechnology Ltd

Ву

(Name): Dianne Angus

(Title): Chief Operating Officer

(Date):

By

Dr. Reddy's Laboratories Limited

Kon

(Name): Anurag Roy

(Title): Vice President - Head of Global CPS business

(Date): <u>28th March 2014</u>

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# Appendix A

PROJECT WORKS AND TIMETABLE

Project item	Responsible Party	Milestone Payment USD	Timeline
1- Sourcing of Raw material (for process development of PBT 434).	Dr. Reddy's		Completion date 15 <sup>th</sup> November 2013
2- Submission of Manufacturing License	Dr. Reddy's**		
3- Process development of current and proposed route will take place in parallel.	Dr. Reddy's		Commencement date - November 18th 2013 "four weeks after start date of procurement of raw materials".
(a) Process development work of current route.		USD 40,000*	Completion date December 13th 2013.
(b) Process development work of proposed route		USD 36,000*	Completion date December 13th 2013.

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4- Completion of both Process optimization of selected route and analytical method validation (selected route).	Dr. Reddy's	USD 24,000*	Commencement date - 16th December 2013. Completion date - 19th January 2013
5- Receipt of Manufacturing License	Dr. Reddy's		Within 4 weeks of commencing 4kg manufacturing campaign being no later than the 3 <sup>rd</sup> February 2014.
<ul> <li>6- <u>4 Kg Campaign</u> <ul> <li>a) Commencement of Manufacturing Campaign Commence 4kg PBT434 HBr Manufacture in plant under cGMP (as per agreed specifications)</li> <li>b) Includes the contracting by Dr Reddy's of AR Life Sciences to perform Step 4 (only) of a 7 step synthesis under cGMP conditions. Step 4 is a Raney Nickel hydrogenation.</li> <li>The optimised process for Step 4 has been developed by Dr. Reddy's. AR Life Sciences will prepare Master Batch records for approval by Dr. Reddy's will oversee the batch execution at AR Life Sciences. The intermediate, CDCH4, will get tested and by AR Life Sciences in accordance with Dr. Reddy's method of analysis</li> </ul> </li> </ul>	Dr. Reddy's	USD 160,000* Completion of 4 kg manufacturing of PBT 434 under agreed specifications and acceptance of COA. Bonus payment of USD 20,000 if manufacturing of 4 kg PBT 434 is completed on or before the completion date.	Commencement date – 20th Jan 2014 Completion date – 31th March 2014 Timeline – Within 10 weeks from commence date. Analysis and Dispatch – in the week of 1st April 2014

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<ul> <li>c) Completion of 4 kg Manufacturing Campaign of PBT 434 under cGMP (as per agreed specifications), acceptance of Certificate of Analysis and executed batch records by Prana. Analysis and Dispatch completed.</li> <li>d) Manufacturing Report of PBT 434</li> </ul>	USD 20,000 Submission of manufacturing report and executed batch records.	Milestone payment upon completion
e) Stability Study (36 months as per ICH guidelines		Payment of USD \$9000 towards initial pull point of 1 <sup>st</sup> month. Remaining payments as incremental payments (USD 1000) per timepoint over 36 months

\*Milestone payment on completion.

\*Completion means completion of the laboratory work and finalization of the relevant Project Item in Development Report.





# Sub Project 1: Sourcing of Raw Material (for process development of PBT434)

Raw materials for the project will be sourced and procured by Dr. Reddy's

# Deliverables:.

3-Chloro-2-nitrobenzoic acid with Dr. Reddy's to begin process development work.

# Sub Project 2: Submission of Manufacturing License

Prana to send Purchase Orders to Dr. Reddy's for Manufacturing Licence for PBT434. Dr. Reddy's to apply for Manufacturing License

#### **Deliverables:**

Manufacturing Licence for PBT434

# Sub Project 3: Process Development of current and proposed route

# a) Process Development of current route

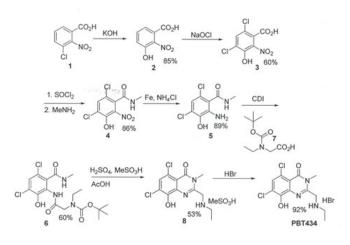
#### **Deliverables**

To repeat the synthesis of the current synthetic route from AMRI global as outlined in Scheme 1. Reaction of 3-chloro-2-nitrobenzoic acid with KOH to generate phenol 2 followed by reaction with sodium hypochlorite to provide 4,6-Dichloro-2-hydroxy-3-nitrobenzoic acid 3. Acid 3 is converted to the acid chloride followed by reaction with methylamine to generate amide 4. Reduction of amide 4 with Fe and ammonium chloride to afford Anthranilic acid derivative 5.

The coupling of intermediate S to N-Boc-N-Ethyl glycine 7 to provide the bis-amide 6. Cyclisation of bis-amide 6 to quinazolinone derivative 8 using methanesulfonic acid in acetic acid, in the presence of catalytic conc. H<sub>2</sub>SO<sub>4</sub>. Finally, conversion of quinazolinone derivative 8 to **PBT434** with HBr. Yields will be comparable to those outlined in Scheme 1.

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Synthesis of Compound 7

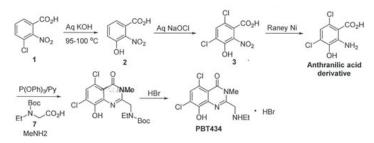
Scheme 1: Current Synthetic Route to PBT434

# b) Process Development of Alternate Route

# Alternate route to PBT434:

Alternatively, PBT434 synthesis can be evaluated based on a five step process, as enclosed below. This approach is based on known methods using a three component and one-pot reaction starting from anthranilic acid, aniline and

N-Boc glycine in the presence of coupling reagent, triphenyl phosphite. (see examples in Bioorg. Med. Chem. 2008, 16, 2570-2578 & Bioorg. Med. Chem. Lett. 2007, 17, 3339-3343).

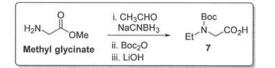


# Scheme 2: Alternative Route to PBT434

Based on this, to adopt this approach for PBT434 synthesis, anthranilic acid derivative could be synthesized starting from 3-chloro-2-nitrobenzoic acid 1 in a three step process. Further, anthranilic acid derivative on one-pot reaction with side chain 7 in the presence of triphenyl phosphite in pyridine can generate the intermediate benzoxazinone derivative, which on reaction with methyl amine (reaction requires anhydrous conditions, methyl amine in toluene may require for the synthesis and in-house preparation would need to be considered) can generate the required quinazolinone derivative. Finally, reaction with HBr can undergo Boc deprotection and generate **PBT434** as a HBr salt. This approach would be the novel route for synthesis of quinazolinone derivatives and require additional efforts in establishing the proposed one-pot chemistry and to familiarize the process.

# Alternate route to N-Boc-N-ethylglycine (compound 7):

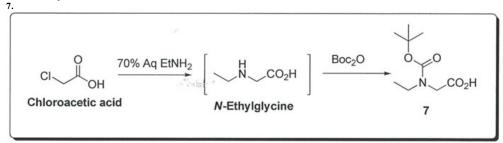
As per technical information, N-Boc-N-ethylglycine synthesis involved condensation of glyoxalic acid with ethyl amine and then reduction using Pd on carbon under hydrogenation conditions at 50 psi H2 pressure, and finally isolate product after Boc protection. Alternatively, compound **7** can also be synthesized from the methyl ester of glycine by reductive amination using acetaldehyde and sodium cyanoborohydride, followed by N-Boc protection and subsequent ester hydrolysis using LiOH (*Bioorg. Med. Chem. Lett.* **2009**, *19*, 2211-2214).



This approach is advantageous in avoiding the usage of palladium on carbon under hydrogenation conditions; however ester hydrolysis would be the additional stage in the process when compared with the current synthetic route



Another set of conditions to avoid hydrogenation is the use of chloroacetic acid and aqueous ethylamine solution to generate N-Ethylglycine in situ, followed by reaction with BOC anhydride to afford compound



# Deliverables for Sub-Project 3a) and 3b):

A comprehensive, detailed Familiarisation Report to be written up by Dr. Reddy's on the current and alternate routes to PBT434 and submitted to Prana for review and approval. Without limitation, the report will contain detailed synthetic methods and operations to manufacture PBT434 via the existing route. The report will contain reaction yields and HPLC purities for each step. The purity profiles will be tabulated with relative retention times and their percentages clearly shown. The report will also contain work to manufacture PBT434 via the alternative route detailed in Scheme 2, shown above.

# Sub-Project 4: Completion of both Process optimisation of selected route and analytical method validation (selected route)

#### a) Method development for specification tests:

- i) HPLC or GC method for starting material, intermediates and in-process controls will be in placed as per requirement. Retentions of reagents used; as well possible by-products will be recorded for the process development
- ii) HPLC method provided in the section 5.1 of document number HRC0000808 would be used to determine the purity in final compound. The method would be evaluated for the proposed scheme and would be modified/developed as per the requirements of process.
- iii) Method will be validated for parameters like LOD, LOQ, Linearity, repeatability, ruggedness, solution stability, mobile phase stability, accuracy and specificity with forced degradation (using LC-DAD) in compliance with current ICH guidelines and in compliance with EMA and FDA requirements for Phase I development.
- iv) Residual solvents in final compound will be monitored by GC and/or GCHS techniques. Method will be developed to analyse the samples for all process solvents in compliance with current ICH limits and in compliance with EMA and FDA requirements for Phase I development
- Nethod validation will be performed with minimum parameters like LOD, LOQ, Linearity, repeatability, ruggedness, recovery, solution stability, specificity of all solvents in intended methods (in compliance with current ICH limits and in compliance with EMA and FDA requirements for Phase I development)

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- vi) Suitable method will be developed for quantification of Anion and Cation used in the process. Method would be verified for minimum parameters e.g. LOD, LOQ, Linearity, repeatability, ruggedness, recovery, solution stability (as applicable to the process).
- vii) An assay method for API will be developed and validated with minimum parameters including linearity, precision, and accuracy (in compliance with ICH, EMA and FDA requirements for Phase I development.
- viii) Reference markers for intermediates will be qualified for appropriate tests.
- A reference standard of final API material will be qualified as per internal SOPs. ix)

Specification testing The limits/range can be mutually agreed between two parties based on process capabilities and phase requirements. The key raw material, isolated intermediates and API material will be analysed for several tests as below.

S. No.	Tests	Specification	MOA ref. No.
1.	Description	White to light brown color powder	AR&D-GTP-001
2.	Identification by		
	a) FT-IR	Shall matches to the standard	AR&D-GTP-003
	b) HPLC	The major peak in the sample chromatogram should match with that of standard in assay preparation	MF/CDCH7-002/00
3.	Water content by KF (%w/w)	Not more than 2.0	AR&D-GTP-005
4.	Residue on ignition (% w/w)	Not more than 0.30	AR&D-GTP-010
5.	Heavy metals (%)	Not more than 0.002	AR&D-GTP-011
6.	Assay by HPLC (on anhydrous and solvent free basis) (% w/w)	Between 97.0 and 103.0	MF/CDCH7-001/00
7.	<ul><li>Related substances by HPLC (% area)</li><li>a) Any maximum impurity</li><li>b) Total impurities</li></ul>	Not more than 0.25	MF/CDCH7-002/00
		Not more than 1.5	

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8.	Residual solvents by GC-HS (in ppm)		
	i) Ethyl acetate		
	ii) Toluene	Not more than 5000	
	iii) Methanol	Not more than 890	MF/CDCH7-003/00
	iv) Hexanes	Not more than 3000	
	v) Tetrahydrofuran	Not more than 290	
		Not more than 720	

\* Solvents are considered from stage 4 onwards

# Deliverables for Sub-project 4 (a)

- Develop and document analytical methods for key starting materials and intermediates for the manufacture of PBT434. Included are HPLC, Loss on Drying, GC and Infrared Spectroscopy.
- Set specifications and document for each intermediate according to the developed analytical methods that have to be agreed and approved by Prana.
- Dr. Reddy's to write a comprehensive validation report for the assay methods and submit to Prana for review and approval.
- Dr. Reddy's to develop and document a Related Substance Method for PBT434
- Dr. Reddy's to develop and document a GC Methods to determine solvent levels for stage 4 intermediates onwards.
- Dr. Reddy's to develop and document analytical methods to determine the final purity of PBT434
- Reference standard of PBT434 20 gm to be qualified according to Dr. Reddy's SOP's and the standard is to be reviewed and approved by Prana in writing. Reference standard of PBT 434 will be taken from Lab assurance batches.

# b) Completion of both Process optimisation of selected route

#### Stage-1:

As per the given process shown in Scheme 1, stage-1 involves 3-Chloro-2-nitrobenzoic acid 1 on treatment with aq KOH (14 eq) to generate the corresponding phenolic derivative 2 at reflux temperature. After completion of reaction, extract product at pH 2 with ethyl acetate and then product isolation by adding hexane.

#### Process optimization plan:

- The requirement of excess usage of KOH (14 eq) and lot wise addition will be evaluated.
- Product isolation at pH 2 directly from aqueous mixture will be studied, which can avoid ethyl acetate extraction and product isolation from ethyl acetate-hexane mixture.
- Exploring the possibility of direct subjection of stage-1 wet cake to chlorination with aq NaOCl (in-situ process).





# Stage-2:

Stage-2 involves aromatic chlorination using aqueous sodium hypochlorite solution at 80°C. After completion of reaction, extract product at pH 2 with ethyl acetate followed by concentration of organic layer and then finally product isolation by triturating with hexane.

# Process optimization plan:

- As per the technical information, stage-1 purity is more than 99%, which is the input for chlorination. After Chlorination, stage-2 product purity is ~90%.
- To improve the purity, purification of stage-2 will be explored.
  - Product isolation at pH 2 directly from aqueous mixture will be evaluated, which can avoid ethyl acetate extraction, concentration and product isolation by triturating with hexane.

# • Stage-3:

Stage-3 involves amide formation by converting acid to acid chloride using thionyl chloride followed by reaction with methyl amine. After completion of reaction, extract product at pH 2 with ethyl acetate followed by concentration of organic layer and then finally product isolation by triturating with hexane.

#### Process optimization plan:

- Studying acid chloride formation in the presence of a solvent, i.e. in toluene media
- Complete removal of thionyl chloride from the reaction mixture after acid chloride formation is necessary for amide formation.
- Acid chloride synthesis in toluene will be advantageous in complete removal of SOCI, from reaction mixture by co-distillation.
- As per scale up information from Prana, one of the batches is reported for low product purity (79% against the trend of ~94%) and yields varied from 86-99%.
- Since aq methyl amine is used in the process, re-generation of acid during the amide formation may be possible. Though, aromatic acid chlorides are stable to some extent, reaction conditions need to be established for robustness.

#### Stage-4:

Process involves synthesis of key intermediate 9 by reduction of nitro functionality using iron powder in the presence of ammonium chloride.

#### Process optimization plan:

- Based on our experience in reduction of aromatic nitro group, Raney Ni would be the preferred reagent.
- Alternate reaction conditions will be explored using Raney Ni under hydrogenation conditions and compare impurity profile and yield.

#### Stage-5:

Process involves compound 9 on reaction with side chain 7 (generated by condensing glyoxalic acid and ethyl amine followed by reduction under hydrogenation conditions using Pd/C and finally Boc protection) in the presence of CDI and triethyl amine at room temperature to generate compound 10. After completion of reaction, extract product with ethyl acetate and concentrate. Finally, isolate product from ethyl acetate.



# Process optimization plan:

• Establish reaction conditions and product isolation process for compound 10 as per the given process.

# Stage-6:

Stage-6 is the quinazolinone ring formation from compound 10 using acetic acid in the presence of H<sub>2</sub>SO<sub>2</sub> at 120°C and finally isolate compound 11 as methane sulfonic acid salt.

#### Process optimization plan:

- We will try to replace Ethanol with isopropanol in the process. •
- As per tech information, yields from the scale up batches varied from 36% to 52% with approximate product purity ~97%.
- Product purification trials will be explored to improve the purity.

# Stage-7:

PBT434 is synthesized by treating compound 11 with aq HBr at room temperature.

#### Process optimization plan:

- •
- We will try to replace Ethanol with isopropanol in the process. Specification for PBT434 is purity NLT 99% with single maximum impurity NMT 0.15%. One of batch from tech pack shows impurity at a level of 0.37% with product purity 99.49% .
- •
- Product purification trials will be explored to improve the purity. .

# Synthesis of N-Boc-N-ethylglycine (compound 7):

Process involves condensation of glyoxalic acid with ethyl amine at 40 °C followed by reduction under hydrogenation conditions using Pd/C at 50 psi hydrogen pressure. After completion of reaction, filter the catalyst and then finally subject for Boc protection. After completion of reaction wash reaction mixture with MTBE and adjust aqueous layer pH to 2-3 with citric acid. Extract aqueous layer using ethyl acetate and concentrate under reduced pressure to generate compound 7.

#### Process optimization plan:

Establish reaction conditions for compound 7 as per the given process.

# **Deliverables for Sub-Project 4b**

Dr. Reddys will write a comprehensive Process Development Report on the Selected Route. Without limitation, the report will contain reaction schemes to manufacture PBT434. There will be a detailed experimental write-up with HPLC, IR, proton and carbon NMR for each intermediate. Submit to Prana for review and written approval.



# **Deliverables for Sub-Project 5**

Dr. Reddy's to receive a manufacturing licence for PBT434 no later than February 3, 2014

# Sub-Project 6: GMP Manufacture of 4kg PBT434 HBr

# a) Commence 4kg PBT434 HBr Manufacture in plant under cGMP by the 20th of January, 2014

(i) Dr. Reddy's will manufacture 4kg of PBT434 drug substance according to the applicable regulatory and statutory requirements of current Good Manufacturing Practices (GMP) (US 21 CFR parts 210 and 211 and ICH Q7) in the following scenario:

(ii) Dr Reddy's will strictly adhere to all the decisions agreed and during Process Development (Sub-project 3) with regards to the type and material of construction of the equipment to be used in the manufacture, the quality and suppliers of reagents and solvents, the type of reactors to be used, the timing of use of the Cleanroom. Any changes in equipment, master batch records, specifications, methods or any other aspect of the manufacture from the previous 2010 manufacture that are not explicitly justified in the Familiarisation report (sub-project 3) will need written approval by Prana.

# **Deliverables for Sub-project 6a):**

- Technology transfer for Stage 1 to be completed by Dr. Reddy's by the 20th of January, 2014
- Master batch records for Stage 1 to be approved and signed off in writing by Prana
- Reactors assigned to Stage 1 to be washed and ready for use in PBT2 manufacture.
- All personnel assigned to PBT434 manufacture to be identified in writing and available.
- 3-Chloro-2-nitrobenzoic acid and all reagents and solvents to be used in Stage 1 to be received and released for use
- Stage 1 to be initiated in the plant by no later than January 20, 2014

# b) Completion of 4kg Manufacturing Campaign of PBT434 HBr under cGMP (as per agreed specifications), acceptance of Certificate of Analysis and executed batch records by Prana.

i) The manufacture will proceed as per the agreed master batch records. Prana will be informed of all deviations, however minor, and those will be dealt with as per the Quality Agreement

ii) All results will be communicated to Prana immediately. Any result that raises questions will be communicated to Prana ahead of any internal investigation so Prana can be take part in resolving issues.

iii) The existing analytical methods as well as the refined analytical methods as per Sub Project 3, will be used to release intermediates and final materials. All intermediates and final material will meet the specifications agreed in writing with Prana prior to manufacture

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# **Deliverables for Sub-project 6c):**

- Technology transfer for Stage 2 onwards to be completed by Dr. Reddy's
- Master batch records for Stage 2 onwards to be approved and signed off in writing by Prana
- Release data for all intermediates and final material to be received and approved in writing by Prana
- Certificate of Analysis, Certificate of GMP compliance and other release documents to be received by Prana and approved in writing.
- Master Batch records for all stages to be provided to Prana, reviewed and any amendments and comments promptly attended to by Dr Reddy's.
- All information relevant to the manufacture and required for regulatory purposes (including FDA IND) to be provided to Prana, including but not limited to, the description of the
  manufacturing process, batch traceability, Certificates of Analysis of all reagents and solvents. In addition, Dr Reddy's should record all suggestions for improvement in future
  campaigns or areas in need of further investigation. Such information should be provided in a Manufacturing Campaign Report.

#### c) Strategic Business Partner- Step 4 Raney Nickel Hydrogenation

Includes the use of AR Life Sciences to perform Stage 4 only of a 7 stage synthesis under cGMP conditions. Stage 4 is a Raney Nickel hydrogenation.

The optimised process for Stage 4 has been developed by Dr. Reddy's. AR Life Sciences will prepare Master Batch records for approval by Dr. Reddy's and Prana. Post mutual approval, Dr. Reddy's will oversee the batch execution at AR Life Sciences. Finally, the intermediate, **CDCH4**, will get tested and by AR Life Sciences in accordance with Dr. Reddy's method of analysis.

# Deliverables

- AR Life Sciences to write batch records for Stage 4 that require approval from both Dr. Reddy's and Prana.
- AR Life Sciences to write methods of analyses and in-process controls for Step 4 that require approval from both Dr. Reddy's and Prana.
- Stage 4 Intermediate released by Dr. Reddy's according to methods of analyses from AR Life Sciences.

# Stability Study (36 Months as per ICH guideline)

A stability study, conducted according to the according to the ICH guideline "Q1A(R2) Stability Testing of New Drug Substances and Products", will commence immediately after manufacture of 4 Kg GMP PBT434 API. The existing analytical methods as well as the refined analytical methods as per Sub Project 4a, will be used for the stability studies (6 month accelerated study and 36 months long term study). The accelerated study will have following data points - 0, 1, 2, 3, and 6 months. The long term study will have the following data points - 0, 1, 3, 6, 9, 12, 18, 24 and 36 months.

DRL IRN - 100004118

d)

# **Deliverables for each timepoint:**

• Dr. Reddy's to write a QA-checked stability report to be received by Prana within 2 weeks of pulling the samples. Raw data from each timepoint to be submitted to Prana.



# AMENDMENT

to the Clinical Trial Agreement between Prana Biotechnology Limited and The University of Rochester

WHEREAS, The University of Rochester ("Institution") and Prana Biotechnology Limited ("Sponsor") have entered into a Clinical Trial Agreement dated October 7, 2011 relating to clinical trial services with regard to the product PBT2 ("Agreement"), and

WHEREAS, the Protocol for the Study has been amended February 3, 2012 and thus changes are needed to the Budget, and the Institution and Sponsor have agreed upon a revised Budget,

NOW, THEREFORE, the parties hereby agree to amend the Agreement effective February 17, 2012, by replacing Attachment A to the Agreement with the amended Protocol attached hereto as Attachment Al, and also by replacing Attachment B to the Agreement with the revised Budget attached hereto as Attachment B1.

Except as provided herein, all terms and conditions of the Agreement remain unchanged and in full force.

PRANA BIOTECHNOLOGY LIMITED

BY: Contract Name: DIANNE ANGUS

Title: CHIEF OPERATING OFFICER

DATE: February 20, 2012

UNIVERSITY OF ROCHESTER

Cheryl K. Williams Assistant Director Office of Research & Project Administration

DATE:

BY:

ATTACHMENT A1

AMENDED PROTOCOL

ATTACHMENT B1

REVISED BUDGET

# **AMENDMENT 2**

# to the Clinical Trial Agreement between Prana Biotechnology Limited and The University of Rochester

WHEREAS, The University of Rochester ("Institution") and Prana Biotechnology Limited ("Sponsor") have entered into a Clinical Trial Agreement dated October 7, 2011, as amended February 17, 2012, relating to clinical trial services with regard to the product PBT2 ("Agreement"), and

WHEREAS, Institution and Sponsor have agreed upon a revised Budget,

NOW, THEREFORE, the parties hereby agree to amend the Agreement effective May, 2012, by replacing Attachment B1 to the Agreement with the revised Budget attached hereto as Attachment B2.

Except as provided herein, all terms and conditions of the Agreement remain unchanged and in full force.

PRANA BIOTECHNOLOGY LIMITED

Name: DIANNE ANGUS Title: CHIEF OPERATING OFFICER.

DATE: 28th September 2012.

BY:

UNIVERSITY OF ROCHESTER

BY:

Cheryl K. Williams Assistant Director Office of Research & Project Administration

DATE:10/3/2012

University of Rochester Encompassing the Huntington Study Group Clinical Trials Coordination Center (CTCC) Biostatistics Department 265 Crittenden Blvd. Rochester, NY 14642 585-275-7311

> Prana Project Name Reach2HD **Confidential**

Please note: This budget proposal is based on the Scope of Work and Protocol (version #2, February 3, 2012) agreed on February 3, 2012. Should the Protocol or SOW change, the HSG & CTCC will require a revised budget, adjusted SOW, protocol and Agreement with the potential for additional funding to complete the outlined tasks. This budget proposal is valid to June 30, 2012.

PROJECT TITLE:		Reach2HD										
Protocol Title:		PBT2-203 Randomized doses of PBT2.	PBT2-203 Randomized, Double Blind, Placebo Controlled, Parallel Group, Multi-Center, Phase lia Study of two doses of PBT2.									
Principal Investigator:												
Timeline:	Planning: Enrollment: Implementation: Close Out:		01 October 2011 to 31 M 31 March 2012 to 31 De 01 January 2013 to 30 J 01 July 2013 to 31 Octo	cember 2012 une 2013								
# of Sites		20	Approx 15 USA; Appro	ox 5 Aust								
# of Subjects		100 Randomized										
		Planning Phase										
		01 October 2011 to 31 March 2012										
			Enrollment Phase									
			31 March 2012 to 31 December 2012									
				LPI Phase								
				01 January 2013 to 30 June 2013								
					Close Out Phase							
					01 July 2013 to 31 October 2013							
op Level Summary		Planning	Enrollment	Implementation	Close Out Phase		Total					
							-					
CTCC Budget		221,587	580,374	347,240	219,478		1,368,679					
Other Budget		20,000	40,000	70,000	30,000		160,000					
Total UR Direct Costs		241,587	620,374	417,240	249,478		1,528,679					
Contract/Consortium (Sit	es, JHU)	89,637	1,222,081	971,351	283,646	#	2,566,715					
Total Direct Costs		331,224	1,842,456	1,383,590	533,123	#	4,095,393					
	tive Costs	93,305	392,131	146,034	87,317	#	718,787					
Facilities and Administra												

Pass Thru Costs Invoiced Directly to Sponsor outside of the payment schedule for Trial:

Source Document Worksheets printing and distribution -- to be a pass thru cost

Operations Manual Printing and Distribution -- to be a pass thru cost Drug Instruction Card printing and distribution -- to be a pass thru cost Travel and Conference costs -- to be a pass thru cost (include Orientation Meeting) IRB fees -- to be a pass thru cost Site Audit Fees (applicable for a 'not for cause' audit) -- to be a pass thru cost Site Pharmacy Start up fees as needed (\$1,000 to \$2,500 based upon actual needs at enrolling sites) -- to be a pass thru cost Screen Failures to be paid based upon assessments completed per subject, to be paid at the end of enrollment -- as a pass thru cost Subject Travel to attend study visits (above stipend for instances of hardship and pre-approved by sponsor) -- as a pass thru cost Unscheduled Visits for enrolled subjects to be invoiced to Sponsor as incurred Subcontracts to MGH (Hersch and Rosas) and Melborne, Australia (Stout) to be held by Sponsor Steering Committee and Safety Monitoring Committee Fees to be paid directly to committee members by Sponsor

Steering Committee and Safety Monitoring Committee Fees to be paid directly to committee members by Sponsor Monitoring visits to Australian sites to be the direct responsibility of Sponsor Central Laboratory analysis activities -- paid directly by Sponsor Central ECG analysis activities -- paid directly by Sponsor Copyright Fees -- paid directly by Sponsor

Any material changes to the SOW will necessitate a modification to the budget and a contract amendment. Example of SOW changes include, but not limited to: Protocol Amendments, Adding Sites, Interim Analyses, Ancillary Studies.

JHU Subcontact		Planning		Enrollment		LPI		Close Out	
Employement Costs Consultant POs		66,398		107,894		70,341		61,008	
Computing Costs Equipment Purchases		-		-		-		-	
Travel Costs Operating Costs (T, P/C, P Other Costs	, 0)	-		-		-		-	
Facilities and Administrati	ve Costs								
Total Direct Costs		66,398		107,894		70,341		61,008	
		Planning Phase 01 October 2011 to 31 M 6 months	larch 2012 31	Enrollment Phase 1 March 2012 to 31 D 9 months	December 2012	LPI Phase 2 01 January 2013 to 6 months	30 June 2013	Close Out Phase 01 July 2013 to 31 4 months	
<u>EMPLOYMENT COSTS</u> <u>% of Effort Data</u>		Planning		Enrollment		LPI		Close Out	
		% Effort	Person Months	% Effort	Person Months	% Effort	Person Months	% Effort	Person Months
Dorsey, Ray TBD TBD	Co Investigator Research Asst Asst Professor	30% 10% 15%	3.60 1.20 1.80	30% 10% 15%	3.60 1.20 1.80	30% 10% 15%	3.60 1.20 1.80	30% 30% 15%	3.60 3.60 1.80
Total Employment Costs		66,398		107,894		70,341		61,008	
Facilities and Administrativ	ve Costs to JHU	23,239		37,763		24,620		21,353	
JHU Total Cost		89,637		145,656		94,961		82,361	

Planning	Enrollment	LPI	Close Out
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
20,000	40,000	70,000	30,000
20,000	40,000	70,000	30,000
	20,000	20,000 40,000	20,000 40,000 70,000

One Time Start up Fee		\$	3,500				
Ophthalmologic Visit Costs:	Exam	\$	460		\$	180	\$ 180
	Color Vision	\$	186		\$	186	\$ 186
	OCT	\$	364		\$	364	\$ 354
	Confrontation VF	\$	140				\$ 140
	Ophthalmoscopy	\$	70		\$	70	\$ 70
	Fundus Photos	\$	165				\$ 165
		\$	1,385	\$	- \$	800	\$ 1,105
Visually Evoked Response****	The VER will occur for approxim includes the assessment and		jects enrolled; v	will be paid fo	or as occurring at \$425 per	VER	\$ 425
	Total Per Subject Fee for Subjec Fee composed of Screening				sessment Per Subject		\$ 20,129
	Total Per Subject Fee for Subjec	ts receiving the Visu	ual Evoked Res	ponse Assess	sment		\$ 21,404
SNAP Assessment	Cost to be d	etermined					

Budget Details: 100	Planning Phase 01 October 2011 to 31 March 2012		nrollment Phase March 2012 to 31	LPI Phase 01 January 2013 to 30 June 2013		
\$ 20,129 \$ 2,012,850	6 months	9 mon	ths	6 months		
0% 50% 40%		0 \$	1,006,425	\$	805,140	201205
10%						201285

PROJECT TITLE:		Reach2HD				
Protocol Title:			zed, Double Blind, Placebo Controlled udy of two doses of PBT2.	, Parallel Group, Multi-		
Principal Investigator:		Kayson, UR Prime Institution: U Subcontract to JHU Subcontracts to 20	l, Dorsey			
Timeline:	Planning: Enrollment: Implementations: Close Out:	6 Months 9 Months 6 Months 4 Months	01 October 2011 to 31 March 2012 31 March 2012 to 31 December 2012 01 January 2013 to 30 June 2013 01 July 2013 to 31 October 2013	:		
# of Sites		20	Approx 15 USA; Approx 5 Aust			
# of Subjects		100 Randomized				
	Total Budget				4,814,181	
		ciated with Site Subo d indirect costs	contract Payments		(2,154,100) (175,000)	
	Budget Subject to	Milestone Payment	Scheme		2,485,081	
	Payment Scheme:					
	The amount due to	the University of R	oachester will be invoiced according t	o the following		Billed and Rec'd
	Milestone driven s		U	U		
		Completion of Fully	/ Executed Contract	10%	248,508	390,445
		IND for Protocol op	bened	10%	248,508	390,445
		Receipt of initial IR	B approval of protocol	5%	124,254	-
		Initial Enrollment		10%	248,508	90,913
		Sub	total of cashflow through initial enroll	ment	869,778	871,803
		Quarterly Payment	During Enrollment and Implementatio	n Phases		
		Mor	nth 3 of Enrollment	9%	223,657	221,633
		Mor	nth 6 of Enrollment	9%	223,657	
		Mor	nth 9 of Enrollment	9%	223,657	
		Mor	nth 3 of Implementation	9%	223,657	
		Mor	nth 6 of Implementation	9%	223,657	
		Sub	total of cashflow thru Implementation		1,118,286	
		Payment upon comp	pletion of Subject Enrollment			
		Data	abase Lock	10%	248,508	
		Тор	Line Results	5%	124,254	
		CSF	1	5%	124,254	
		Sub	total of final payments		497,016	
		Total of all paymer	ats not subject to subcontract		2,485,081	
	) will be invoiced to s	sponsor, invoices wi	sis for costs incurred in paying sites j ll only include the costs of fully comp		ī.	
Quarter Ended Quarter Ended	September 30, 2012 December 31, 2012 January 31, 2013 March 31, 2013		\$ \$ \$ \$ \$	116,455 582,275 465,820 465,820 349,365 349,365		

Total

2,329,100

\$

NOTE: If the FDA delays the implementation of the study according to the agreed timeline, the parties have the right to re-negotiate the milestones according to a agreed, revised timeline.

(a) Should the above timeline for planning, Enrollment Implementation and/or Close out exceed the budgeted period for reasons outside the control of the Clinical Trials Coordination Center (CTCC), the CTCC will request that the Scope of Work be revisited and the budget be revised (if necessary) to allow for an expanded Planning, Enrollment, Implementation and/or Close out timeframe and associated additional costs. In good faith, Prana will decide if the proposed budget or timeframe changes can be accommodated by Prana. In any event, the CTCC will not be under an obligation to continue the study without the required additional funds to cover an extended budget period.

(b) If the above timeline for Planning, Enrolment, Implementation and Close out exceed the budgeted period for reasons within the control of the Clinical Trials Coordination Center (CTCC), Prana may withhold payments and/or require the CTCC to undertake activities to restore as far as possible the Study to the Initial Timeline at CTCC's cost. If a delay in recruitment timeline is for reason of particular obligations on patients as prescribed by the Protocol, and the impact of those Protocol obligations cannot otherwise be resolved by the parties Project Team, the delay will not be deemed an event within the control of the CTCC.

(c) If the above timeline for Planning, Enrollment, Implementation and Close Out is less than the budgeted period, the Scope of Work will be revisited by the parties and the budget be revised (if necessary) to adjust for the reduced timeframe and additional costs. For each month of reduced timeline of the Study, Prana will pay a pro-rata amount of the above Quarterly Payments to the CTCC as a bonus for earlier Study completion.

Analysis of mo	nitoring Activities					<b>.</b> .			
Budget Compo	nents	Planning		En	rollment	Impleme LP1 Du		Close	out Total
Effort Fees Travel TOTAL	Site Monitor Employee Independent Monitor/Contractor Fees Site Monitor Travel Costs		-	\$ \$ \$	80% 43,200 100,800 144,000	\$ 3	80% 1,600 6,000 7,600		0% \$ 64,800 7,200 \$ 144,000 7,200 \$ 208,800
	Based upon the budgeted effort, and the associated travel costs, a monitor visits are budgeted. The out below. Approximately 120 vi site over the enrollment and LPI	a total of 120 to 123 site e details of these visits is set sits will provide 8 visits per			, ,				· · · · · · ·
					Planning phase 6 months	Enrollment Phase 9 months		I Phase nonths	Close Out Phase 4 months
	Effort Analysis	Monitor Effort>			0%	80	1%	80%	0%
		Independent Contractor Hou	rly Fees>		\$-	\$ 43,200	\$	21,600	\$-
		Effort 80% of one FTE indicates 32 2080 total available hours div Therefore, in the 15 months t <u>Independent Contractor</u> A total of 9 visits to four site with each visit planned to be \$75 per hour. 36 visits x 24 hours per visit x In total approximately 123 si approximately 8 visits per sit more then once every two more	vided by 24 hours per here are enough hours are budgeted to be 24 hours at a rate of \$75 per hour results te monitor visits are e. 120 Visits divided	r monitor tri irs budgeted handled by \$75 per hou in \$64,800. budgeted ov	p yields 87 site visi I for approximately y up to three indepe r. The computatio yer the 15 month en	ts. 87 visits to sites. ndent contractors. I n is 36 visits multip rollment and LPI pl r site. Over the fiftee	in aggrega lied by 24 nase. This en month j	ate, 36 visit: hours per v represents l period, sites	isit multiplied by between will be visited
	<u>Travel Analysis</u>	Budgeted Dollars         For Travel         \$       100,800       paid durin         \$       36,000       paid durin         \$       7,200       paid durin         \$       144,000       Total Site	g LPI duration	lget		A total of \$144, monitoring visit A total of 8 visit budgeted = 120 A total of \$1,200 Trip Costs are cc \$300 for two nig \$150 for meals a costs. \$1,200 x 120 visi	s. total site ) is budge alculated a thts lodgir nd \$100 f	n of the 15 U visits. ted for each us follows: \$ ng, or all other o	S based sites is trip: 650 for airfare,



# Master Laboratory Services Agreement

This Master Laboratory Services Agreement (the "Agreement,") dated as of 26 August, 2013 is by and between **Prana Biotechnology Ltd** ACN 080 699 065, an Australian limited liability company whose address is Level 2, 369 Royal Parade, Parkville Victoria 3052 ("Sponsor") and **WIL Research Laboratories, LLC** (together with its subsidiaries), a Delaware limited liability company, whose address is 1407 George Road, Ashland, Ohio 44805 (hereinafter collectively referred to as "WIL").

#### WITNESSETH

WHEREAS, Sponsor has now, and from time to time in the future may have, the desire to engage WIL to perform research and/or laboratory services; and

WHEREAS, WIL desires to provide such services on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and of the mutual promises and covenants contained herein, the adequacy of which is hereby acknowledged by each of the parties, the parties hereto agree as follows:

#### 1. Services and Work Order

WIL shall use its commercially reasonable efforts to provide all services ("Services") for each study (each a "Study") as set forth in a Work Order (as defined below). Services provided by WIL shall be subject to the terms and conditions of this Agreement. All such Services shall be the subject of a Work Order substantially in the form of <u>Exhibit A</u> (each a "Work Order"). Each Work Order shall include, without limitation, the following with respect to the applicable Study: (i) the Study protocol ("Protocol") and deliverables; and (ii) a fee and payment schedule for the Services. After a Work Order is agreed upon and executed by the parties hereto, such Work Order shall then be a part of this Agreement. There will be no limit to the number of Work Orders that may be added to this Agreement. WIL shall have no obligation to reserve Study space at its facilities; to receive animal models; to purchase Study supplies; nor shall WIL have any obligation to commence Services with respect to a particular Study until the relevant Work Order is executed by both parties hereto; provided, that WIL may reserve Study space at its facilities and/or purchase non-anirnal Study supplies for a Study before a Work Order is executed upon the Sponsor executing a Study outline, which Study outline shall be substantially in the form attached hereto as <u>Exhibit B</u> (each a "Study Outline"). Notwithstanding the foregoing, in no event shall WIL be obliged to receive animal models until a Work Order is executed for the relevant Study.

P: 419-289-8700 Email: <u>info@wilresearch.com</u> 1407 George Road, Ashland, OH 44805

www.wilresearch.com

We have listening down to a science.

# 2. Change Orders

In the event that Sponsor would like WIL to alter the Services to be provided under a given Work Order, the parties hereto shall agree upon a written change order substantially in the form of Exhibit C (each a "Change Order") prior to the provision of said changed Services. The Change Order shall constitute an amendment to the applicable Work Order and shall be considered part of this Agreement.

# 3. Study Director

WIL shall appoint a study director to be responsible for each Study (the "Study Director"). The Study Director will coordinate performance of the Study with the Sponsor's designated representative, which representative shall have responsibility over all matters related to performance of the Study on behalf of Sponsor. WIL will not change the Study Director without the prior approval of Sponsor, which approval shall not be unreasonably delayed, conditioned, or withheld.

# 4. Payment for Services

Sponsor shall pay WIL for Services provided in connection with a Study in accordance with the terms of the applicable Work Order (subject to, where applicable, the delivery of the relevant deliverables referable to the payment). WIL shall electronically submit invoices to the Sponsor on each date a payment is due in accordance with the applicable Work Order. Invoices will be submitted to the following email address <u>sforan@pranabio.com</u> with a copy to krowe@pranabio.com. Sponsor shall remit payment through ACH or wire transfer to the bank account provided below and payment is due within 30 days of receipt of the electronically submitted invoice. In the event Sponsor fails to pay an invoice within 30 days of the due date, WIL, upon written notice to Sponsor, may in its sole discretion, charge the Sponsor a late fee equal to 1.5% per month on the unpaid balance of such invoice until such invoice is paid in full (including any assessed late fees).

The Sponsor shall remit all payments directly to WIL Research Laboratories, LLC at the following bank account:

For Direct Deposits/Wire Transfers:			
Bank Name:	Citibank N.A.		
Bank Address:	Totowa, NJ 07512		
Bank Routing #:	021272655		
Bank Account #:	759455772		
Swift Account #:	CITIUS33		
Account Name:	WIL Research Laboratories, LLC		

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# 5. Term and Termination

a) The term of this Agreement shall be five (5) years from the date hereof, unless earlier terminated as permitted herein. The term of this Agreement shall automatically extend for successive one year periods, unless either party gives the other party written notice that it will not extend this Agreement at least sixty (60) days prior to the end of the then current term.

b) Either party may terminate this Agreement upon ninety (90) days' prior written notice to the other party. In the event at the time of any such termination there are uncompleted Studies, then subject to paragraph (c) below, this Agreement shall remain in full force and effect with respect to and for the duration of such uncompleted Studies.

c) Sponsor may at any time terminate a Study upon written notice to WIL. Immediately upon receipt of such notice, WIL shall use its commercially reasonable efforts to minimize the cost to Sponsor resulting from such termination. In the event of such termination, Sponsor shall pay to WIL: (a) all amounts due and owing under the applicable Work Order through the date of termination, whether invoiced or not; (b) all charges for the work performed and expenses (including uncancellable or unreimbursed expenses) incurred by WIL prior to termination, and (c) any and all expenses which may reasonably be incurred, by WIL in connection with terminating the Study.

d) In circumstances where WIL is unable to mitigate all or part of the costs and expenses (collectively, "Costs") incurred by it as a result of a delay or termination (caused by Sponsor) prior to the commencement of a Study, then in full satisfaction of such Costs, Sponsor may be required to pay a fee (or an equitable proportion thereof having regard to amounts recovered through mitigation or otherwise from Sponsor under paragraph (c)). Any such fee due to WIL in respect of a delay to the agreed commencement date of the Study (caused by Sponsor) or termination for convenience by Sponsor, will be mutually agreed upon by both parties and set forth in the applicable Work Order.

e) In addition to any provisions which, by their nature, are intended to survive the termination or expiration of this Agreement, the following provisions shall survive the termination or expiration of this Agreement: 5(c) and (d), 6, 7, 8, 12 and 17.

# 6. Confidential Information

Each party hereto hereby agrees to continue to abide by the terms of the Confidentiality Agreement by and between Sponsor and WIL dated 17th July 2013 (the "Confidentiality Agreement"). For purposes of this Agreement, the term "Confidential Information" shall have the meaning ascribed in the Confidentiality Agreement. Any violation of the terms of the Confidentiality Agreement shall be deemed to be a violation of the terms of this Agreement. All Work Product (as defined below) and the compound(s) and information submitted by Sponsor for the purpose of a Study shall constitute Confidential Information of Sponsor.

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# 7. Work Product; Delivery and Archiving

a) Assuming the payment by Sponsor of all amounts invoiced hereunder, all tissues, tissue blocks, specimens, slides and data prepared or generated by WIL in the course of performing Services for Sponsor hereunder ("Work Product") shall be owned by Sponsor and shall be delivered to Sponsor upon its request. Any Work Product shipped by WIL to Sponsor or any third party will be appropriately packaged and labeled as defined by WIL's standard operating procedures and delivered to a common carrier for shipment. Sponsor shall hold WIL harmless from and against all loss or damage or claims of loss or damage to any Work Product during shipment by a common carrier. Sponsor shall be responsible for the insurance premium and for notifying WIL, in writing, of its desire to insure shipments at a rate that exceeds the common carrier's standard liability limit. In the event that a claim results, Sponsor shall be responsible for substantiating (if required by the insurer) the value of the Work Product and seeking reimbursement of any loss.

b) Subject to receipt of a delivery request from Sponsor in accordance with Section 7(a), WIL will archive the Work Product of each Study for a period of 1 year, or as otherwise set forth in the relevant Work Order or Protocol, from the date WIL issues the final report ("FR Date") under the Study. Upon expiration of such period, Sponsor shall provide written notification to WIL to either (i) request the transfer of such Study's Work Product to Sponsor or a third party (such transfer to be made in accordance with Section 7(a) above) or (ii) provide notification of its intention to continue to archive the Study's Work Product at WIL. If Sponsor fails to so notify WIL, subject to Section 7(c) below, WIL will archive such Work Product until Sponsor provides further written instructions. With respect to the archiving of such Work Product, unless otherwise set forth in the relevant Work Order, WIL may commence charging Sponsor at a mutually agreed rate not exceeding WIL's then standard current rates for the provision of such archiving services from and after the expiration of the period of year from the FR Date, WIL will invoice Sponsor on an annual basis for such archiving services and the payment provisions of Section 4 shall apply thereto.

c) Notwithstanding the foregoing, upon completion of a Study or at any time after the period of 3 years from the FR Date, WIL may make a written request to Sponsor for permission to dispose of the Work Product or any of Sponsor's other property. Failure by Sponsor to respond to such request within 120 days of receipt shall be considered as tacit approval by Sponsor for disposal of the Work Product or Sponsor's other property in the manner described in WIL's written request.

d) If Sponsor fails to pay any invoice for archiving services within 30 days of the due date, WIL may, in its sole discretion, upon 30 days written notice to Sponsor, destroy the archived Work Product.

e) Upon completion of a Study, all compounds and/or other substances that are furnished to WIL by Sponsor and which have not been consumed during the Study, or which are not required to be stored as samples for purposes of validating the Study, shall be returned to Sponsor or at Sponsor's direction, destroyed.

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# 8. Intellectual Property (IP) Ownership

a) WIL agrees that all (i) information, data and reports collected, generated or prepared during a Study; all discoveries, inventions or improvements, whether patentable or not, other than WIL IP (as defined below) arising out of a Study and relating to the articles or substances studied or the use thereof; and (iii) all intellectual and industrial property rights throughout the world subsisting in or relating to the foregoing shall be the property of the Sponsor ("Sponsor IP"). WIL hereby assigns any and all of WIL's right, title and interest in such Sponsor IP to Sponsor to confirm such assignment to Sponsor of any and all of WIL's right, title and interest in Sponsor IP.

b) Sponsor shall have no property rights in WIL's testing methods, practices, procedures, tests, test apparatus, equipment or information related to the conduct of WIL's business, or any inventions, improvements or developments related thereto ("WIL IP"). Such WIL IP shall be the sole and exclusive property of WIL and WIL warrants that its use of WIL IP will not infringe the intellectual property rights of any third party.

# 9. Independent Contractors

WIL and Sponsor agree that WIL is an independent contractor and that no provision in this Agreement shall be construed to make WIL an employee, agent or representative of Sponsor, or shall be deemed to create a partnership or joint venture between the parties. Neither party shall hold itself out to third persons as purporting to act on behalf of, or serving as the agent of, the other party.

#### 10. Subcontract

WIL shall not subcontract any Services to be provided hereunder, without obtaining Sponsor's prior consent, which shall not be unreasonably delayed, withheld or conditioned.

#### 11. Compliance with Law

In the performance of this Agreement, WIL shall comply fully with all applicable laws, rules, and regulations, including those of the United States Department of Agriculture, the Association for Assessment and Accreditation of Laboratory Animal Care International, Good Laboratory Practices as promulgated by the Food and Drug Administration, the Environmental Protection Agency and all other regulatory agencies having jurisdiction over a Study. In the event any such government regulatory requirements shall change during the course of a Study, and such new requirements necessitate a change in a Work Order (including a change to a Protocol), WIL will submit to Sponsor a revised technical and compensation proposal for Sponsor's review and acceptance prior to making any changes to such Study; provided, that WIL shall not under any circumstances be required to continue a Study if such continuance would be in violation of a law, rule or regulation. In the event of a conflict between government regulations, Sponsor ad WIL shall mutually agree in writing as to the applicable regulations to be followed by WIL in its performance of the Study. In fulfilling all its obligations hereunder, Sponsor agrees to comply fully with all applicable laws, rules and regulations.

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# 12. Indemnification and Limitations

a) WIL shall indemnify, defend and hold harmless Sponsor, its directors, officers, owners and employees from and against all third party loss or damage (including reasonable attorney fees and expenses) arising from (i) WIL's material breach of this Agreement or (ii) the gross negligence or willful misconduct of WIL, except to the extent such loss or damage relates to the gross negligence or willful misconduct of Sponsor or a Sponsor indemnitee or the material breach of this Agreement by Sponsor.

b) Sponsor shall indemnify, defend and hold harmless WIL, its directors, officers, owners and employees from and against all third party loss or damage (including reasonable attorney fees and expenses) arising from (i) Sponsor's material breach of this Agreement, (ii) the gross negligence or willful misconduct of Sponsor or (iii) Sponsor's use or exploitation of any Sponsor IP, Work Product or Sponsor Confidential Information, except to the extent such loss or damage relates to the gross negligence or willful misconduct of WIL or a WIL indemnitee or the material breach of this Agreement by WIL.

c) Other than as specifically set forth herein, WIL makes no representations or warranties concerning the services. Except in relation to claims arising out of a breach by either party of their obligations of confidentiality, under no circumstances shall either party be liable to the other for any indirect, consequential, punitive, exemplary or special damages, including lost profits or cost of replacement materials. Subject to any limitations on remedies set forth herein, in no event shall WIL be liable to Sponsor under a Work Order for any amounts in excess of the of the greater of (i) with respect to any claim arising under such Work Order, the value of insurance proceeds actually recovered by WIL on account of such claim for damages incurred by Sponsor; or (ii) the total contract price specified in the Work Order,. This limitation shall not apply in relation to any breach by WIL of its confidentiality obligations.

# 13. Material Errors

In the event WIL commits a material error in the performance of Services for a Study, which material error causes the results of such Study to be unusable for Sponsor's stated purposes set forth in the relevant Protocol, at Sponsor's election, WIL will at Sponsor's election either (i) rerun that part of the Study (or, if necessary, the whole Study) as soon as possible at WIL's cost or (ii) refund to Sponsor the sums paid to WIL as of that date on account of the Study. The foregoing shall be the Sponsor's sole remedy with respect to errors of WIL in the conduct of a Study.

#### 14. Force Majeure

Provided a party has, to the extent that it is reasonably capable of doing so, implemented reasonable precautions to avoid or minimize the impact of any of the following circumstances, a party shall not be liable in any delay in performing its obligations (other than payment obligations) under this Agreement if its performance is delayed or prevented by acts of God, fire, terrorist acts, explosion, war, riots, strikes, law or any other cause (except financial) beyond such party's control, but only to the extent of and during the reasonable continuance of such disability. A time for performance required by the Agreement which falls due during or subsequent to the occurrence of any of the causes referred to in this paragraph shall be deferred for a period of time equal to the period of disability resulting from such cause.



# 15. Insurance

WIL shall secure and maintain in full force and effect at all times during the term of this Agreement, a policy or policies of insurance which shall be commensurate with industry standards for services substantially similar to the Services.

# 16. Quality Assurance and Study Monitoring

Upon not less than five (5) days' prior written notice, Sponsor shall have the right to (i) inspect WIL's premises at reasonable times and with reasonable frequency, during the course of WIL's performance of Services hereunder and (ii) review procedures then being used by WIL in its performance of Services for Sponsor, as well as all experimental data generated from said Services, including, but not limited to all written reports, notes, schedules, or similar Work Product which may document work done and results achieved.

# 17. Miscellaneous

a) This Agreement shall be interpreted in accordance with the laws of the State of Ohio without regard for its conflicts of laws principles. Actions brought under this Agreement shall be brought in any court of competent jurisdiction in the State of Ohio. Should any Ohio court find any provision to be invalid or contrary to public policy, the provisions not so found shall remain in effect and binding upon the parties. Sponsor and WIL agree to attempt in good faith to replace any invalid or unenforceable provision of this Agreement with a provision which is valid and enforceable and which expresses as closely as possible the intention of the original provision.

b) This is a personal services contract and may not be assigned by either party without the express written consent of the other, which consent shall not be unreasonably withheld, provided, however, that either party is free to assign this Agreement without consent in connection with a transaction resulting in a change of control, merger, consolidation, acquisition of all or substantially all of its assets, or other similar transaction.

c) The word "Agreement" as used herein means and includes this instrument, all Work Orders, Protocols and Study Outlines and any amendments, supplements, additions, schedules, exhibits or appendices to any of the foregoing which are mutually executed by WIL and Sponsor.

d) This Agreement (including the Work Orders, Study Outlines and/or Protocols issued hereunder) and the Confidentiality Agreement represent the entire contract between Sponsor and WIL. There are no oral or written promises, terms, conditions, or obligations other than those contained in this Agreement (including the Work Orders, Study Outlines and/or Protocols issued hereunder) and the Confidentiality Agreement. This Agreement (including the Work Orders, Study Outlines and/or Protocols issued hereunder) and the Confidentiality Agreement supersede all prior negotiations, representations or agreements, either written or oral, between the parties on the subject. No waiver of any term, provision or condition of this Agreement (including the Work Orders, Study Outlines and/or Protocols issued hereunder) or the Confidentiality Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition of any other term, provision or condition of this Agreement (including the Work Orders, Study Outlines and/or Protocols issued hereunder) or the Confidentiality Agreement. In the event the terms of a Work Order, Study Outline, Protocol or any other agreement between the parties hereto contradict any provision of this Agreement, this Agreement shall control.



e) Each individual signing this Agreement certifies that he or she is authorized to sign this Agreement on behalf of the party which he or she represents, and to bind that party to the terms and conditions herein stated.

f) Any notices given hereunder shall be sent by fax or email, with a confirmation copy sent via overnight courier to the following addresses (or such other address as a party may designate as a notice address in a written notice to the other party) and shall be deemed delivered when received (or if received on a weekend or holiday, on the next business day thereafter) as follows:

If to Sponsor:

Dianne Angus Chief Operating Officer Prana Biotechnology Ltd Level 2, 369 Royal Parade, Parkville Victoria 3052 Australia Phone: +61 3 9349 4906 Fax: +61 3 9348 0377 Email: dangus@pranabio.com

If to WIL:

David R. Baumgartner, CPA Vice President WIL Research Laboratories, LLC 1407 George Road Ashland, OH 44805 Phone: (419) 289-8700 Email: dbaumgartner@wilresearch.com

g) Sponsor shall not use WIL's name or the names of WIL's employees in any advertising or sales promotional material or in any publication without prior written permission of WIL. WIL shall not use Sponsor's name or the names of Sponsor's employees in any advertising or sales promotional material or in any publication without prior written permission of Sponsor.

h) In the event of a dispute relating to this Agreement, the parties shall attempt to resolve the dispute prior to taking any action. Should the dispute not be resolved within thirty (30) days, each party shall be free to seek any remedy legally available to it in accordance with this Agreement before a court of competent jurisdiction in the State of Ohio. Notwithstanding the foregoing, either party shall be free to seek interim legal relief in a court of competent jurisdiction in the state of Ohio in the event that the other party's breach of this Agreement would reasonably be expected to cause such party irreparable harm.

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i) Unless otherwise agreed to in writing, neither party shall solicit for hire any employee of the other during the term of this Agreement and for twelve (12) months thereafter, provided, that this provision shall not prevent either party from utilizing general solicitations for hiring purposes, and hiring persons who respond to such general solicitations.

j) This Agreement, and any Work Order, Change Order, or Outline executed hereunder, may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Signatures to this Agreement and any Work Order, Change Order, or Outline transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the originals graphic and pictorial appearance of a document, will have the same effect as physical delivery of the paper document bearing the original signatures, and shall be deemed original signatures by both parties.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by the respective authorized representatives.

# PRANA BIOTECHNOLOGY LTD

By: Name: Dianne Angus

Title: Chief Operating Officer

Date: 29 August 2013

WIL RESEARCH LABORATORIES, LLC

Jaungarten 0

Date: 29 August 2013



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# EXHIBIT A

Date:

# SAMPLE WORK ORDER

#### WIL Project Number: WIL-\_\_\_\_

Pursuant to the Master Laboratory Services Agreement dated \_\_\_\_\_\_, 2013, by and between Sponsor and WIL Research Laboratories, LLC (the "Master Services Agreement") and in consideration of the mutual promises contained therein and for other good and valuable consideration the receipt and adequacy of which each of the parties does hereby acknowledge, the parties hereby agree to amend the Master Services Agreement by adding the attached Work Order entitled \_\_\_\_\_\_\_, which is designated Work Order WIL\_\_\_\_\_\_\_("Work Order")). This Work Order is effective as of \_\_\_\_\_\_, 200\_\_\_. Any capitalized terms used herein and not defined shall have the meanings ascribed to them in the Master Services Agreement.

# 1. PROTOCOL

WIL shall conduct the studies described in and required by the Protocol (as identified below). Except as otherwise provided by this Work Order or the Master Services Agreement, WIL shall follow the procedures and methodology, and shall observe and comply with the schedules, specified in the Protocol. Incorporated herein as a part of this Work Order is the study protocol (the "Protocol") identified as follows: "\_\_\_\_\_\_". Should the Protocol be amended, supplemented or revised in any fashion after the date hereof, WIL will have the right to adjust the Protocol (including fees and payment schedule) to reflect required changes. Any such amendment, supplement or revision shall only be effective if signed by both parties hereto.

#### 2. FEE AND PAYMENT SCHEDULE

Total contract price of \_\_\_\_\_\_ (\$\_\_\_\_\_) which the Sponsor shall pay upon receipt of proper invoices in the following installments:

- (a) <Insert>percent or \$\_\_\_\_\_upon authorization and/or execution of this Work Order;
- (b) <Insert>percent or \$\_\_\_\_\_ upon commencement of Study;
- (c) <Insert>percent or \$\_\_\_\_\_ upon completion of the in-life phase;
- (d) <Insert>percent or \$\_\_\_\_\_ upon issuance of audited draft report for Study; and
- (e) <Insert>percent or \$\_\_\_\_\_ upon issuance of final report or 45 days after the audited draft report has been issued.

#### P: 419-289-8700

Email: info@wilresearch.com 1407 George Road, Ashland, OH 44805

www.wilresearch.com

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The contract price set forth in this Section 2 does not include the archiving of Work Product beyond what is contemplated in the Master Services Agreement.

In the event that additional costs are incurred beyond the amount specified in this Work Order as a result of the need for additional Services or a change (having been agreed to by the Sponsor and WIL in writing) in the scope and/or schedule of the work to be performed, the Sponsor agrees to pay such reasonable additional costs upon receipt of a proper invoice.

IN WITNESS WHEREOF, the parties here have caused this Work Order to be executed by their respective authorized representatives.

# [NAME OF SPONSOR]

# By: SAMPLE – NOT FOR SIGNATURE

Name: Title:

Date:

# WIL RESEARCH LABORATORIES, LLC

By: SAMPLE – NOT FOR SIGNATURE

Name: Title:

Date:

# **Standard Payment Milestones**

Length of Study	Authorization	Commencement	Equal Quarterly Payments	End of In- Life (or Completion)	AD/UD Report	Final Report or 45 days after AD/UD
Studies < 1 mos.	50%			40%		10%
Studies < 6 mos.	20%	30%		40%	5%	5%
Studies $\geq 6$ mos.	20%	25%	45%		5%	5%
1 Yr. Studies	20%	20%	50%		5%	5%
2 Yr. Studies	15%	15%	60%		5%	5%
NOTE: Inhalation Studies, NHP St	udies may require higher au	thorization percentages				



«Date» Proposal: «Proposal\_Number»

Proposal for «Client»

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Proposal_Number»			Page: 15 of 16			
posal Summary						
Study	Base Study Fee		Optional		Total Study Fee	
						Authorized
					\$	
					\$	
					\$	

# Authorization Statement

«Client» ("Sponsor") hereby awards the above described proposal to WIL Research Laboratories, LLC ("WIL") and requests WIL to proceed with the necessary activities to initiate these studies, including but not limited to, protocol development, contract finalization, study room reservation and definitive scheduling of study-related activities.

Sponsor understands that by executing this document it acknowledges financial responsibility for all costs and expenses incurred by WIL in preparation of the Study, and if the Study is cancelled by Sponsor, Sponsor hereby agrees to reimburse WIL for all such costs and expenses.

Signature of Authorized Sponsor Representative	Date
Name:	_
Title:	_
Company:	_
CONFIDENTIAL	
	We have <b>listening</b> down to a science.

# WIL Research Laboratories, LLC Change Order

Spon Spon	sor Nar sor Stu	: WIL       Change Order #:         ne:       Date Issued:         dy #:
A.	The	ndicated Work Order is amended as follows:
	i.	Protocol
		The project description is identified as: [Enter study title as defined in original Work Order]
	ii.	Compensation
		An [increase] [or] [decrease] of US\$00 is agreed to by the Sponsor and WIL. The reason for this change is described in item B below.
		The total price is increased from (\$00) to(\$). The \$00 fee represents additional costs incurred for modifications to the project as requested by the Sponsor. One Hundred percent of the additional charge (\$) will be due upon execution of this Change Order.
B.	Reas	on for change:
	[	]
C.	Exce	pt as expressly amended hereby, the Work Order shall continue to be and remain in full force and effect in accordance with its terms.
AGR	EED T	O, ACKNOWLEDGED, AND ACCEPTED BY:
The p	oarties l	ave caused this Change Order to be executed by their duly authorized representatives, and entered into as of the date of the last party below to execute.
[Spor	isor Na	me] WIL Research Laboratories, LLC
By: S	AMPLI	E – NOT FOR SIGNATURE By: SAMPLE – NOT FOR SIGNATURE
Print	Name:	Print Name:
Title:		Tite:
Date:		Date:

#### AMENDMENT #1 TO MASTER LABORATORY SERVICES AGREEMENT

THIS AMENDMENT ("Amendment") is made as of 19th day of November, 2013 (the "Effective Date") by and between Prana Biotechnology, Ltd., ACN 080 699 065, an Australian limited liability company whose address is Level 2, 369 Royal Parade, Parkville Victoria 3052 ("Sponsor") and WIL Research Laboratories LLC (together with its subsidiaries), a Delaware limited liability company, with a principal place of business at 1407 George Road, Ashland, OH 44805 (hereinafter collectively referred to as "WIL").

Sponsor entered into a Master Laboratory Services Agreement with WIL, dated as of 26 August 2013 as amended (the "Agreement"). The parties hereby agree to amend the Agreement as follows:

1. Section 4. Payments for Services - In line 5, replace the text "following email address sforan@pranabio.com" with "email address of the Sponsor's designated representative".

2. Section 5. Term and Termination shall have section 5.c) and 5.d) replaced in its entirety and a new section 5.e) shall be added.

c) Sponsor may at any time terminate a Study upon written notice to WIL. Immediately upon receipt of such notice, WIL shall use its commercially reasonable efforts to minimize the cost to Sponsor resulting from such termination (Mitigation). In the event of such termination, where WIL is not in material breach of this Agreement or the applicable Work Order or Protocol, Sponsor shall pay to WIL (unless otherwise minimized or avoided through Mitigation): (a) all amounts due and owing under the applicable Work Order up to the date of termination, whether invoiced or not; (b) all charges for the work performed and expenses (including uncancellable or non-reimbursable expenses) reasonably incurred by WIL prior to or in connection with termination to the extent that they relate to then current and immediately following milestone payment of the Study (as described in the Fee and Payment Schedule in the Work Order) and have not otherwise been satisfied under sub-paragraph (a) herein.

d) If the commencement of a Study is delayed and this is solely caused by Sponsor, then provided WIL (i) is not in material breach of this Agreement or the applicable Work Order or Protocol and; (ii) has used its commercially reasonable efforts to minimize the costs resulting from the delay, Sponsor may be required to pay a weekly fee as mutually agreed between the parties and set the forth in the Work Order (or an equitable proportion thereof having regard to the results of WIL's mitigation efforts). If the Sponsor subsequently terminates the Work Order, then the weekly payments shall cease and the termination provisions of Section 5.c) shall apply.

e) For the purpose of paragraphs (c) and (d), WIL will provide Prana with all relevant documentation evidencing or supporting the amounts, charges and expenses which it seeks to recover from Sponsor on the termination or delay of a Study.

# 3. Section 12. Indemnification and Limitations section 12.c) shall be replaced in its entirety.

c) Other than as specifically set forth herein, WIL makes no representations or warranties concerning the services. Except in relation to claims arising out of a breach by either party of their obligations of confidentiality or claims made by Sponsor against WIL under Section 13 as a consequence of Major Errors made by WIL for Studies of duration greater than 12 months, under no circumstances shall either party be liable to the other for any indirect, consequential, punitive, exemplary or special damages, including lost profits or cost of replacement materials. Subject to any limitations on remedies set forth herein and with the exception of claims arising out of Major Errors which occur in Studies of duration greater than 12 months ("Major Event Claims") or claims in respect of any breach by WIL of its confidentiality obligations, in no event shall WIL be liable to Sponsor with respect to any claims arising under or in connection with a Work Order (whether for breach of the Work Order or otherwise) for any amounts in excess of the greater of (i), the value of insurance proceeds actually recovered by WIL on account of such claims for damages incurred by Sponsor; or (ii) the total contract price specified in the Work Order, For a Major Event Claim under a Work Order for a Study of duration greater than 12 months, WIL will not be liable to Sponsor for any amounts in excess of the greater of (i), one and one-half times the total contract price specified in the Work Order where the Major Event occurs within 9 – 18 months after the commencement of the Study; or (ii) two times the total contract price specified in the Work Order where the Major Event occurs later than 18 months after the commencement of the Study.

4. Section 13. <u>Material Errors</u> shall be replaced in its entirety.

If WIL commits a material error in the performance of Services as described in the relevant Protocol for a Study ("Error") then it must immediately notify Sponsor in writing and provide full details of the Error. Where the Error (whether notified by WIL or otherwise ascertained by Sponsor) has or will, as mutually agreed between Sponsor and WIL, caused the results of such Study (to be unusable for Sponsor's stated objectives set forth in the relevant Protocol ("Major Error"), WIL will at Sponsor's direction in writing either: (i) rerun that part of the Study (or, if necessary, the whole Study) as soon as possible at WIL's cost or (ii) refund to Sponsor the sums paid to WIL as of that date on account of the Study. Sponsor may also terminate the Work Order by written notice to Sponsor and/or claim from WIL in pursuance of its rights at law, whether in contract, tort (including negligence) or otherwise, any additional losses, costs, expenses, damages suffered or incurred by Sponsor as a result of the Major Error and the consequent delay in completion of the Study.

In all other respects, the terms of the Agreement shall remain unmodified and in full force and effect.

The parties have indicated their acceptance of the terms of this Amendment by the signatures set forth below. Each individual signing on behalf of a corporate entity hereby personally represents and warrants his or her legal authority to legally bind that entity.

PRANA BIOTECHNOLOGY LTD.

Bv

Print Name: GEOFFREY REMPLER

Title: CEO

Date: 18 December 2013

WIL RESEARCH LABORATORIES LLC

Print Name: John Maxwell

Title: Vice President

Date: 12-16-13





# WORK ORDER

# WIL Project Number: WIL-41505

PO Number:

Date: 19 December 2013

Pursuant to the Master Laboratory Services Agreement dated 26 August 2013, and as amended on 19 November 2013 by and between PRANA BIOTECHNOLOGY LIMITED (Sponsor) and WIL RESEARCH LABORATORIES, LLC (the "Master Services Agreement") and in consideration of the mutual promises contained therein and for other good and valuable consideration the receipt and adequacy of which each of the parties does hereby acknowledge, the parties hereby agree to amend the Master Services Agreement by adding the attached Work Order entitled "A 2year Oral Gavage Carcinogenicity Study in Sprague Dawley Rats," which is designated Work Order WIL-41505 ("Work Order"). This Work Order is effective as of 19 December 2013. Any capitalized terms used herein and not defined shall have the meanings ascribed to them in the Master Services Agreement.

#### PROTOCOL 1.

WIL shall conduct the studies described in and required by the Protocol (as identified below). Except as otherwise provided by this Work Order or the Master Services Agreement, WIL shall follow the procedures and methodology, and shall observe and comply with the schedules, specified in the Protocol. Incorporated herein as a part of this Work Order is the study protocol (the "Protocol") identified as follows: "A 2-year Oral Gavage Carcinogenicity Study in Sprague Dawley Rats." Should the Protocol be amended, supplemented or revised in any fashion after the date hereof, WIL will have the right to adjust the Protocol (including fees and payment schedule) to reflect required changes. Any such amendment, supplement or revision shall only be effective if signed by both parties hereto.

#### 2. FEE AND PAYMENT SCHEDULE

Total contract price of One Million Three Hundred Fifty One Thousand Six Hundred Dollars (\$1,351,600.00), which the Sponsor shall pay upon receipt of proper invoices in the following installments.

(a) Fifteen percent or \$202,740.00 upon authorization and/or execution of this Work Order;

- (b) Fifteen Five percent or \$202,740.00 upon commencement of Study;
- (c) Sixty percent or \$810,960.00 in 8 quarterly payments of \$101,370.00, to begin three months after commencement of study;
- (d) Five percent or \$67,580.00 upon issuance of audited draft report for Study; and
- (e) Five percent or \$67,580.00 upon issuance of final report or 45 days after the audited draft report has been issued.

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The contract price set forth in this Section 2 includes the archiving of Work Product for a period of five (5) years from the date WIL issues the final report ("FR. Date") under this Study.

In the event the study is delayed and such delay is caused solely by Sponsor. Sponsor will be required to pay W1L a weekly fee of \$8,000.00 throughout the period of the delay. If Sponsor subsequently terminates this Work Order, then the weekly payments will cease and the termination provisions of Section 5.c) of the Master Laboratory Service Agreement shall apply.

In the event that additional costs are incurred beyond the amount specified in this Work Order as a result of the need for additional Services or a change (having been agreed to by the Sponsor and WIL in writing) in the scope and/or schedule of the work to be performed, the Sponsor agrees to pay such reasonable additional costs upon receipt of a proper invoice.

IN WITNESS WHEREOF, the parties here have caused this Work Order to be executed by their respective authorized representatives.

Prana Biotechnology Limited

WIL Research Laboratories, LLC

By: Name: Geoffrey Kempler Title: Chief Executive Officer Date: 22 December 2013

In Mariny By:

Name: John Maxwell Title: Vice President Date: December 19,2013



# **Quotient Clinical Limited Master Services Agreement**

This Agreement is made on 10th December, 2013

#### Between

- (1) Quotient Clinical Limited a company registered in England and Wales under number 02393366 whose registered office is at Mere Way, Ruddington Business Park, Nottingham, NG11 6JS United Kingdom ("Quotient Clinical"); and
- (2) Prana Biotechnology Ltd a company registered in Australia under number ACN 080 699 065 whose registered office is at Level 2, 369 Royal Parade, Parkville 3052, Victoria, Australia ("Customer");

#### Recitals

(A) Quotient Clinical is engaged in the development of formulations and conduct of clinical research in relation to pharmaceutical products.

(B) Customer is engaged in the development of pharmaceutical products.

(C) Quotient Clinical and Customer wish to establish an ongoing relationship under which, from time to time, Customer may request that Quotient Clinical performs research and other services in relation to the Customer's pharmaceutical products. They have agreed to enter into this Agreement to set out the terms of such relationship.

#### It is agreed

# 1 Definitions

ABPI means the Association of British Pharmaceutical Industry in the United Kingdom.

Affiliates means any parent or subsidiary companies of a party

Agreement means this Master Services Agreement

Background Material means any and all data, materials, pharmaceutical products, formulation methods, software, know-how, inventions and/or discoveries of a party which is/are in existence at the date of this Agreement or which is/are developed or arise(s) independently of any Research

Background Intellectual Property means any Intellectual Property in and to any Background Material

Clinical Protocol means a protocol for the conduct of Research agreed in writing between the parties

Commencement Date means the date of this Agreement set out above

**Confidential Information** means all information disclosed by one party to the other whether in oral or written form in relation to Quotient Clinical performing the Research with Customer's Materials and includes without limitation in respect of Confidential Information of the Customer: Research Output, Customer's Materials, Customer Data, any information contained in Background Material provided by Customer, a Clinical Protocol (except to the extent that the same contains or constitutes any Background Material of Quotient Clinical) which shall all be deemed to be the Confidential Information of the Customer.

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Customer Data means documents, data and information relating to any Materials and/or Research

Force Majeure means any circumstance beyond the reasonable control of the party affected by it and includes for each party, acts of god, industrial disputes, telecommunications failure, power supply failure, computer breakdown, failure of suppliers to meet delivery requirements and absence of key personnel for an extended period due to illness or injury

Good Clinical Practice (GCP) means good clinical practice as set out in the ICH guidance on Good Clinical Practice as defined in ICH topic E6 and laid down in directive 2005/28/EC

Good Manufacturing Practice (GMP) means good manufacturing practice as laid down in directive 2003/94/EC and the requirements defined in: The Rules Governing Medicinal Products in the European Community Volume 4, including the Investigational Medicinal Products Annex 13, and as applied to APIs for Use in Clinical Trials, as covered within the EU Guidance to Good Manufacturing Practice Part II, Section 19 and ICH Q7 Section 19

Intellectual Property means all patents, trade marks or trading names (whether or not registered), rights in know-how, design rights (whether or not registered), copyright, database rights, rights in inventions and know-how, all applications for the same and all rights having equivalent or similar effect, in each case subsisting at any time, anywhere in the world

Materials means any materials and/or substances or pharmaceutical products which are the subject of Research

Payment Schedule means the document set out at appendix 2 of a Work Order

Proposal means the proposal and costing document set out at appendix 1 of a Work Order

QC Non-Cancellable Costs means such of the non-cancellable costs specified in the Work Order which Quotient Clinical has not been able to avoid or mitigate pursuant to clauses 7.2 or 8.8, as applicable.

Regulations means the Medicines for Human Use (Clinical Trials) Regulations 2004 and as amended in 2006 and any subsequent amendments made to those regulations

Research means any trial, study and/or services to be carried out by Quotient Clinical which are set out in the relevant Proposal

**Research Output** means any data, results and/or materials produced by Quotient Clinical, in the course of and relating to Research (whether individually, collectively or jointly with the Customer and on whatever media), which it is required to deliver to the Customer pursuant to the relevant Proposal, including, without limitation, any and all reports and case report forms, but excluding any Background Materials.

Service Providers means subcontractors (of whatever level) and agents of Quotient Clinical and their employees

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Sponsor has the meaning given to it in the Regulations

Term means the period of five (5) years from the Commencement Date

Trial Subject means a person who is administered and/or who consumes any Materials in connection with Research

Work Order means a document (in substantially the same form as that set out in schedule 1) which has been issued by Quotient Clinical and agreed by both parties as envisaged under clause 2.1.

# 2 The Research

- 2.1 In consideration of the first Work Order the parties agree that if, at any time during the Term, it is agreed that Quotient Clinical will perform any particular trial, study and/or services for the Customer, a document in substantially the form set out in schedule 1 will be completed and issued by Quotient Clinical in relation to such trial, study and/or services, and will be signed by both parties. Each such Work Order will constitute a separate contract between the parties for the performance by Quotient Clinical of the relevant Research, and the payment by the Customer of the amounts set out in the relevant Proposal (and the performance by the Customer of its other obligations), in accordance with the terms of this Agreement and the relevant Work Order (to the exclusion of any other terms and/or conditions which the Customer may attempt or purport to impose).
- 2.2 Quotient Clinical shall carry out all Research in accordance with the relevant Clinical Protocol and with due skill and care in accordance with industry best practice and strictly in accordance with the Proposal, the Regulations and all other applicable laws, Good Clinical Practice and Good Manufacturing Practice. Quotient Clinical must inform Customer within 24 hours of any serious adverse events and significant deviations from, or breaches of the standards applied to the Services, to enable Customer to meet its requirements for reporting such events to the applicable Regulatory Authority.
- 2.3 All services to be provided by Quotient Clinical under this Agreement and any Work Order will be deemed to be provided at the Customer's request and the Customer accepts that it is responsible for verifying that those services are suitable for its own needs.
- 2.4 The Customer may during this Agreement inspect and/or audit Quotient Clinical's performance of any Research on giving Quotient Clinical at least 48 hours written notice. The Customer shall use its reasonable endeavours not to cause any disruption to Quotient Clinical's business in carrying out such inspection or audit.
- 2.5 The Customer shall ensure that its employees co-operate fully with Quotient Clinical and any Service Providers in relation to the provision of any Research (including without limitation complying with Quotient Clinical's normal and reasonable codes of staff and security practice). The Customer shall comply with its obligations as set out in any Proposal in a timely manner.
- 2.6 The Customer shall provide to Quotient Clinical:
  - (a) all information and support necessary to enable Quotient Clinical to fulfil all of its obligations under the Regulations in relation to any Research including for the avoidance of doubt completing any necessary applications or notifications to the licensing authority under the Regulations, any ethics committee, any other investigator, any medical practitioner and/or any person subject to or connected with the relevant clinical trial; and

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(b) a copy of the Investigator's Brochure and where available, the Investigational Medicinal Product Dossier for the relevant pharmaceutical product and at all times during any Research and during the preparation of any report relating to the same, also promptly provide Quotient Clinical with written notifications containing details of any applicable and relevant new information and data (as it emerges) relating to the safety and safe usage of the relevant Materials including any new and relevant preclinical and clinical pharmacovigilence information and data.

The Customer warrants and undertakes to Quotient Clinical that all such information is and will at all times be to the best of its knowledge accurate, complete and not false or misleading.

- 2.7 Subject to this clause 2.7, where it states in a Work Order that Quotient Clinical will act as the Legal Representative of the Customer for the purposes of the relevant Research and to facilitate the parties' compliance with the Regulations, the provisions of schedule 2 shall apply to that Work Order. For the avoidance of doubt, Quotient Clinical shall be responsible for ensuring that Regulatory authorisations (clinical trial approval and ethics committee Approval) are in place on behalf of Customer. The Customer acknowledges and agrees that it shall be the Sponsor in relation to all Research and that Quotient Clinical is not taking on any Sponsor obligations pursuant to this Agreement or any Work Order. The Customer shall ensure that it complies with its obligations under the Regulations and with all other applicable laws and regulations. In particular, the Customer acknowledges that it shall be solely responsible for ensuring that it has all necessary intellectual property rights, licences and permissions in relation to its pharmaceutical products to allow Quotient Clinical's compliance with this clause 2.7, the Customer shall indemnify and keep indemnified Quotient Clinical against all losses, claims, costs, expenses, damages and liabilities arising out of a breach by the Customer of any laws or regulations in relation to any Research and/or the relevant Materials including its obligations as Sponsor of any Research pursuant to the Regulations.
- 2.8 Should Quotient Clinical become aware of any mistake or error or failure by it (or its Service Provider) to comply in any way with this Agreement (collectively called "Quality Breachs") Quotient Clinical must immediately notify Customer in writing. If in the reasonable opinion of Customer, a Quality Breach (whether notified by Quotient Clinical or otherwise ascertained by Customer) has or will render (on its own or together with any other Quality Breach) any Research Data or work performed by Quotient Clinical inaccurate, unusable or requiring repetition ("Major Quality Breach"), then Quotient Clinical will at the Customer's election either (i) repeat the relevant part or parts of a Work Order (or the whole Work Order, if the nature or scale of the Quality Breaches in the reasonable opinion of Customer necessitate this) as soon as possible at Quotient Clinical's cost in accordance with the agreed specification or Protocol (as applicable); or (ii) refund to Customer the sums paid to Quotient Clinical on account of the relevant part or parts of the Work Order or the whole Work Order, as applicable. The foregoing shall not be Customer's sole remedy in the event of such failure by Quotient and Customer shall retain its right to seek all other remedies available under law or equity.

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# 3 Payment

- 3.1 Unless otherwise stated in this Agreement, the Customer shall pay all Quotient Clinical's invoices within 30 days on presentation of such invoice.
- 3.2 Quotient Clinical shall present all invoices to the Customer for Research in accordance with the relevant Payment Schedule. All charges set out in this Agreement and/or any Work Order are exclusive of Value Added Tax or any similar taxes, levies or duties, for which the Customer will be additionally liable.
- 3.3 If any payment that is due to be made under this Agreement and/or a Work Order by the Customer to Quotient Clinical is not paid within the period of 30 days after presentation of the relevant invoice:
  - (a) Quotient Clinical reserves the right to charge interest thereon, on a day to day basis after the 30 day payment period has elapsed at an annual rate of 4% above the National Westminster Bank plc's base rate from time to time applicable until the sum is paid; and
  - (b) Quotient Clinical may suspend all work under this Agreement and any Work Order until payment has been made in accordance with clause 3.1 or arrangements as to payment or credit have been established which are satisfactory to Quotient Clinical.

## 4 Supply of Materials and Customer Data

- 4.1 The Customer shall promptly supply to Quotient Clinical, free of charge, the Customer Materials and Customer Data reasonably required by Quotient Clinical to enable it to perform any Research in accordance with a Proposal and hereby authorises Quotient Clinical and its Service Providers to use, modify and copy the same to the extent necessary to enable Quotient Clinical to carry out such Research. Any Customer Materials and Customer Data provided by the Customer shall remain the property of the Customer at all times and Quotient Clinical shall ensure that it uses such Materials and Customer Data solely for the purpose of carrying out the relevant Research and keeps them secure and in confidence.
- 4.2 Quotient Clinical shall maintain accurate records of its use, storage, handling and administration of Materials in accordance with best industry practice and in accordance with GCP and GMP requirements (as applicable) and otherwise in such format as the Customer shall require and shall supply the Customer with copies thereof upon the Customer's written request.
- 4.3 As soon as practicable following completion of Research or upon termination of a Work Order, Quotient Clinical shall, if so requested in writing by the Customer, return to the Customer any Materials which remain unused, any copies of Customer Data provided to it by the Customer pursuant to this Agreement, all Confidential information and Background Material of the Customer previously disclosed to Quotient Clinical, all Research Output and the Work Order which are in Quotient Clinicain's power, possession or control.
- 4.4 The Customer warrants and undertakes that it has the right to give to Quotient Clinical all Materials and Customer Data which it provides to Quotient Clinical and that the use by Quotient Clinical and its Service Providers of such Materials and/or Customer Data will not infringe the Intellectual Property or other rights of any person.

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4.5 The Customer shall indemnify and keep indemnified Quotient Clinical in respect of any losses, costs, damages, claims and/or expenses incurred by Quotient Clinical and/or any Service Provider due to any third party allegation or claim that any such use referred to at clause 4.4 infringes the Intellectual Property of any third party.

# 5 Confidentiality

- 5.1 Subject to clauses 5.2, 5.3, 6.5 and 6.6, each party agrees to keep confidential and not to disclose any and all Confidential Information of the other party, except to its Affiliates and to those of its employees (and in the case of Quotient Clinical any Service Providers) who are required to have access to such confidential information for the purpose of performing the obligations under this Agreement and/or any Work Order and who are legally obligated to maintain confidentiality on terms no less restrictive than provided for in this Agreement and have been informed of the confidential nature of such information.
- 5.2 The obligations set out in clause 5.1 shall not apply to any Confidential Information which:
  - (a) at the date of its disclosure is in the public domain or which subsequently enters the public domain through no act or omission on the part of the receiving party:
  - (b) at the date of its disclosure is already known to the receiving party as evidenced by written records:
  - (c) is independently developed by the receiving party or is lawfully disclosed to the receiving party by a third party as evidenced by written records; or
  - (d) is required to be disclosed by the receiving party in order to comply with a legal obligation.

In relation to any information which is created by (rather than disclosed to) one party but which is, pursuant to this Agreement and/or any Work Order, deemed to be the Confidential Information of the other party on creation, any reference in clauses 5.2 (a) to (b) above to "disclosure" shall mean "creation" and to "receiving party" shall mean "creating party".

- 5.3 All confidential information containing personal data shall be handled in accordance with applicable law, including but not limited to the UK Data Protection Act 1998
- 5.4 Subject to prior written approval of the Customer, Quotient Clinical may refer to the Customer as its client on its website and in marketing materials and proposals.

# 6 Intellectual Property

- 6.1 Subject to clauses 6.3 and 6.5, the Research Output and all Intellectual Property subsisting in it shall be solely owned by Customer and Quotient Clinical hereby assigns to the Customer all its right, title and interest in and to any Research Output and the Intellectual Property rights therein.
- 6.2 At the request and reasonable expense of the Customer, Quotient Clinical shall do all such things and sign all documents or instruments reasonably necessary to vest in the Customer the rights in Research Output and confirm the assignment pursuant to clause 6.1.

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- 6.3 Save as set out in clause 6.4, nothing in this Agreement and/or any Work Order shall transfer or grant any right, title or interest to any Background Material and/or Background Intellectual Property of either party to the other party.
- 6.4 The Customer hereby grants to Quotient Clinical a royalty-free, non-exclusive licence to use the Customer's Background Intellectual Property solely to the extent necessary for Quotient Clinical to perform its obligations set out in this Agreement and/or any Work Order.
- 6.5 Quotient Clinical shall own any improvements to its Background Intellectual Property arising and/or developed by it in the performance of this Agreement and/or any Work Order and shall be fully entitled to use and exploit in any way it deems fit any skills, techniques, concepts or know-how acquired, developed or used in the course of performing any Research.
- 6.6 Quotient Clinical may submit a copy of any proposed publication to the Customer who shall have 30 days in which to determine (a) if the timing is appropriate for any such publication, (b) amendments are required to enable Customer to approve the publication or (c) being mindful that the results are the Confidential Information of the Customer if the nature or content of the publication is appropriate for publication. Customer's determination on publication approval is final.
- 6.7 The Customer undertakes that, prior to publication of any information, article, paper, report or other material containing Research Results (other than company announcements and regulatory submissions), it will submit a copy of such publication to Quotient Clinical who shall have 30 days in which to request amendments thereto which, to the extent that such proposed amendment are reasonable and pertain to a correction of an error, the Customer shall be obliged to incorporate prior to such publication.

# 7 Delays

- 7.1 If any part of any Research is delayed soley due to a new request of the Customer not contemplated in the applicable Work Order or due to the wilful act or omission of the Customer and this occurs:
  - (a) greater than 90 days prior to dosing, then no part of the QC Non-Cancellable Costs will be payable by the Customer;
  - (b) between 90 and 61 days prior to dosing, then 50% of the QC Non-Cancellable Costs will be payable by the Customer:
  - (c) between 60 and 31 days prior to dosing, then 75% of the QC Non-Cancellable Costs will be payable by the Customer;
  - (d) 30 days or less prior to dosing, then all of the QC Non-Cancellable Costs will be payable by the Customer.

The Customer will also be liable to pay Quotient Clinical:

- (e) such tangible costs and expenses (excluding fixed operating costs) which:
  - (A) Quotient Clinical cannot avoid or mitigate pursuant to clause 7.2;
  - (B) do not constitute QC Non-Cancellable Costs; and

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- (C) have been directly incurred by Quotient Clinical in relation to the Work Order as a consequence of the delay and constitute non- cancellable sums which it is liable to pay third party subcontractors or service providers.
- 7.2 Quotient Clinical shall use its reasonable endeavours to mitigate the costs and expenses referred to in clause 7.1. In its subcontractor/service provider contracts, Quotient Clinical must also use its best endeavours to negotiate the Inclusion of a requirement that these suppliers use their reasonable endeavours to mitigate any non-cancellable or non-refundable costs payable by Quotient Clinical.
- 7.3 The Customer shall make the payment set out in clause 7.1 within 30 days of invoice on presentation of Quotient Clinical's invoice for the same. Quotient Clinical's invoice must be accompanied by copies of relevant documentation supporting the invoiced sums.

# 8 Duration and Termination

- 8.1 This Agreement shall come into force on the Commencement Date and shall, unless terminated earlier pursuant to any of the provisions of this clause 8 (and subject to clause 8.11) below, remain in force until the Customer has received the final Research Output to be delivered by Quotient Clinical, and Quotient Clinical has received ail sums payable to it, under this Agreement and all Work Orders. For the avoidance of doubt, each Work Order shall come into force on the date that it has been signed by both parties and shall (subject to earlier termination in accordance with this clause 8 and to the provisions of clause 8.11) remain in force until the Customer has received the Research Output to be delivered by Quotient Clinical, and Quotient Clinical has received all sums payable to it, pursuant to that Work Order.
- 8.2 Either party may terminate this Agreement, and/or any Work Order (and the relevant Research), forthwith by giving notice in writing to the other party if the other party, (being a company) enters into liquidation or a provisional liquidator is appointed in respect of it, shall pass a resolution or suffer an order of a court to be made for its winding up, or if a receiver, administrator, administrative receiver or manager or similar officer is appointed in respect of the whole or any part of its assets, or if a notice of intention to appoint an administrator or an application for the appointment of an administrator shall be presented or filed in respect of it, or (being an individual or partnership) the other shall suspend payment or propose to enter into any composition with creditors or become unable to pay its debts (or have no reasonable prospect of doing so) or suffer a bankruptcy order or if anything analogous or similar to the above occurs to the other in any jurisdiction;
- 8.3 The Customer may terminate this Agreement and/or a specific Work Order (and the relevant Research), forthwith by giving notice in writing to Quotient Clinical, if Quotient Clinical is in material breach of any of its obligations under or in connection with this Agreement and/or a Work Order and (where the breach is capable of remedy) fails to remedy the same within 30 days of a request specifying the breach and requiring it to be remedied.
- 8.4 Quotient Clinical may terminate this Agreement and/or any Work Order (and the relevant Research), forthwith by giving notice in writing to the Customer, if the Customer is in material breach of any of its obligations under or in connection with this Agreement and/or a Work Order and (where the breach is capable of remedy) fails to remedy the same within 30 days of a request specifying the breach and requiring it to be remedied.

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- 8.5 Subject to clause 8.6, the Customer may terminate this Agreement or any Work Order (and the relevant Research) on giving Quotient Clinical not less than 14 days notice in writing.
  - On termination of any Work Order (whether by termination of the Agreement or by termination of that Work Order) by the Customer pursuant to clause 8.5, then the Customer shall;
    - (i) pay to Quotient Clinical:
      - (A) 50% of the QC Non-Cancellable Costs, if the Work Order is terminated between 90 and 61 days prior to the agreed date for dosing;
      - (B) 75% of the QC Non-Cancellable Costs, if the Work Order is terminated between 60 and 31 days prior to the agreed date for dosing;
      - (C) 100% of the QC Non-Cancellable Costs, if the Work Order is terminated less than 30 days prior to the agreed date for dosing;
    - (ii) pay to Quotient Clinical (in full without set off or deduction of any kind) any amounts (for work done) which Quotient Clinical has already invoiced to the Customer but which remain unpaid at the date of termination and/or which Quotient Clinical is entitled to invoice in accordance with the relevant Payment Schedule; and
    - (iii) pay to Quotient Clinical such tangible costs and expenses (excluding fixed operating costs) which :
      - (A) Quotient Clinical cannot avoid or mitigate pursuant to clause 8.8;
      - (B) do not constitute QC Non-Cancellable Costs; and
      - (C) have or will be directly incurred by Quotient Clinical in relation to the then current stage of the Work Order as a consequence of the termination and constitute non-cancellable sums which it is liable to pay third party subcontractors or service providers;

provided that any payments made in accordance with this clause 8.6 are contemplated in the Work Order and do not in aggregate exceed the aggregate of the amounts set out in the relevant Payment Schedule up to completion of the Work Order (less what has already been paid by Customer pursuant to the Payment Schedule).

- 8.7 On termination of any Work Order (whether by termination of the Agreement or by termination of that Work Order) by Quotient Clinical pursuant to clauses 8.2 or 8.4, then the Customer shall:
  - (i) pay to Quotient Clinical:
    - (A) 50% of the QC Non-Cancellable Costs, if the Work Order is terminated between 90 and 61 days prior to the agreed date for dosing;

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- (B) 75% of the QC Non-Cancellable Costs, if the Work Order is terminated between 60 and 31 days prior to the agreed date for dosing;
- (C) 100% of the QC Non-Cancellable Costs, if the Agreement is terminated less than 30 days prior to the agreed date for dosing;
- (ii) pay to Quotient Clinical (in full without set off or deduction of any kind) any amounts (for work done) which Quotient Clinical has already invoiced to the Customer but which remain unpaid at the date of termination and/or which Quotient Clinical is entitled to invoice in accordance with the relevant Payment Schedule; and
- (iii) pay to Quotient Clinical such tangible costs and expenses (excluding fixed operating costs) which :
  - (A) Quotient Clinical cannot avoid or mitigate pursuant to clause 8.8;
  - (B) do not constitute QC Non-Cancellable Costs; and
  - (C) have or will be directly incurred by Quotient Clinical in relation to the the neurrent stage of the Work Order as a consequence of the termination and constitute non-cancellable sums which it is liable to pay third party subcontractors or service providers,

provided that any payments made in accordance with this clause 8.7 are contemplated in the Work Order and do not in aggregate exceed the aggregate of the amounts set out in the relevant Payment Schedule up to completion of the Work Order (less what has already been paid by Customer pursuant to the Payment Schedule).

- 8.8 Quotient Clinical shall use its reasonable endeavours to mitigate the costs and expenses referred to in clauses 8.6 and 8.7. In its subcontractor/service provider, Quotient Clinical must also use its best endeavours to negotiate the inclusion of a requirement that these suppliers use their reasonable endeavours to mitigate any non-cancellable or non-refundable costs payable by Quotient Clinical.
- 8.9 The Customer shall make the payments and reimbursements set out in clauses 8.6 and 8.7 within 30 days of presentation of Quotient Clinical's invoice for the same. Quotient Clinical's invoice must be accompanied by copies of relevant documentation supporting the invoiced sums.
- 8.10 On termination of any incomplete Work Order (whether by termination of this Agreement or by termination of that Work Order) by the Customer pursuant to clauses 8.2 or 8.3, Quotient Clinical shall immediately refund all payments made by Customer in respect of the Work Order. The foregoing shall not be Customer's sole remedy in the event of such failure by Quotient and Customer shall retain its right to seek all other remedies available under law or equity.
- 8.11 Termination of this Agreement and/or any Work Order shall be without prejudice to all rights and remedies which have accrued thereunder prior to such termination. Any provision of this Agreement and/or any Work Order which expressly or by implication is intended to survive (including, without limitation, the provisions of clauses 1, 2.3, 2.6, 2.7, 2.8, 3.1, 3.3, 4.4, 4.5, 5, 6, 7, 8.6, 8.7, 8.8, 8.9, 8.10, 9, 10.2, 11, 12 and 13) shall survive the expiry or sooner termination of this Agreement or that Work Order (as applicable). For the avoidance of doubt, if this Agreement terminates, each Work Order shall terminate, but termination or expiry of one Work Order shall not of itself affect the continuation of another Work Order or (subject to clause 8.1 above) this Agreement.

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# 9 Indemnity

- 9.1 Customer confirms it accepts its obligations to provide compensation for Subjects in line with the ABPI Guidelines on Medical Experiments in non-patient Human Volunteers published in 1998 and ABPI Guidelines for Phase 1 Clinical Trials published in 2012 and any relevant guidelines referenced therein, including but not limited to the Guidance for Insurance and Compensation in the event of injury in Phase I clinical trials, and any further amendments to these Guidelines as appropriate.
- 9.2 The Customer shall indemnify and keep indemnified Quotient Clinical and shall pay such sums to Quotient Clinical as would keep Quotient Clinical's employees and Service Providers indemnified, from and against any and all losses, costs, expenses (including legal expenses), claims, damages and liabilities arising out of or in connection with any claim made by a third party which arises out of the performance of the Research and/or administration to, and/or consumption by, any Trial Subject of any Materials during the course of any Research PROVIDED:
  - (a) that the Customer shall not be liable pursuant to this clause 9.2 for any losses, costs, claims, expenses, damages or other liability to the extent that these are directly caused by:
    - the failure of Quotient Clinical or of any Service Provider to comply with this Agreement, the relevant Work Order, the relevant Clinical Protocol for the Research or to observe Good Clinical Practice or Good Manufacturing Practice, the Regulations or any other applicable laws;
    - (ii) any negligent act or omission or any breach of any law by Quotient Clinical or any Service Provider; and
  - (b) that as soon as reasonably practical following receipt by Quotient Clinical of a notice of any kind whatsoever of any claim or lawsuit which would fall under this clause 9.2, Quotient Clinical notifies the Customer in writing thereof and, subject to the Customer giving to Quotient Clinical such security as to costs and damages as Quotient Clinical may reasonably require, the Customer, and/or its insurers, shall take over and conduct the settlement and/or defence of such claim or lawsuit.
- 9.3 Subject to clause 11, Quotient Clinical shall indemnify and keep indemnified the Customer against all losses, costs, expenses (including legal expenses), claims, damages and liabilities arising out of any claim made by a third party which arises out of the administration to a Trial Subject of any relevant Materials during the course of Research to the extent that this is directly due to Quotient Clinical's failure to comply with the Clinical Protocol for the relevant Research or to observe Good Clinical Practice in administering the relevant Materials as part of that Research PROVIDED that as soon as reasonably practical following receipt by Customer of a notice of any kind whatsoever of any claim or lawsuit which would fall under this section 9.3 the Customer notifies Quotient Clinical in writing thereof, the Customer makes no admission or statement prejudicial to the claim in question and, subject to Quotient Clinical giving to the Customer such security as to costs and damages as the Customer may reasonably require, Quotient Clinical, and/or its insurers, shall take over and conduct the settlement and/or defence of such claim or lawsuit.

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# 10 Insurance

- 10.1 Quotient Clinical shall secure and maintain in full force and effect throughout the term of this Agreement appropriate insurance coverage for its responsibilities in connection with this Agreement.
- 10.2 The Customer shall maintain in force a no fault clinical trials insurance coverage policy with a reputable insurer to provide coverage to Trial Subjects sustaining bodily injury as a result of use of the Materials. Such cover shall provide for a minimum cover of AUD10 Million. Customer is willing to provide indemnity to Quotient Clinical in this regard as detailed in Clause 9, Indemnity and upon Quotient Clinical's request, Customer shall make available for Quotient Clinical's and/or Ethics Committee review, policy documents, certificates and any other relevant documents, as required, evidencing such insurance.

## 11 Limitation of Liability

- 11.1 Nothing in this Agreement or any Work Order shall exclude or restrict either party's liability for death or personal injury caused by that party's negligence, for fraudulent misrepresentation, for breach of any provision in clause 5 or 6 or to the extent that any restriction or exclusion of liability is prohibited bylaw.
- 11.2 Subject to clause 11.1, in no event shall a party be liable in contract (including under any indemnity), tort (including negligence), breach of statutory duty or otherwise howsoever to the other party for:
  - (a) any loss of profit, loss of business, loss of goodwill, loss of contracts, loss of revenues or loss of anticipated savings; or
  - (b) any increased costs or expenses; or
  - (c) any special, indirect, or consequential loss or damage of any nature whatsoever, whatever the cause thereof,

(collectively, "Consequential Losses") in each case arising out of or in connection with this Agreement or any Work Order provided that in the case of a claim by Customer under a Work Order in relation to a Major Quality Breach, Quotient will be liable for Consequential Losses but only to the extent of an amount not exceeding the Work Order contract price net of any refunds due to Customer by Quotient under clause 2.8 of this Agreement.

- 11.3 Subject to clause 11.1, the entire liability of Quotient Clinical to the Customer arising out of or in connection with a Work Order, whether arising from contract (including under any indemnity), tort (including negligence), or otherwise, shall not exceed three times the amount which is stipulated in the Proposal for that Work Order as to be paid by the Customer to Quotient Clinical.
- 11.4 Subject to clause 11.1 (and subject to and by virtue of clause 11.3) the total aggregate liability of Quotient Clinical to the Customer arising out of or in connection with this Agreement and/or any Work Orders, whether arising from contract (including under any indemnity), tort (including negligence), or otherwise, shall not, in any event, exceed three times the total of the amounts which are stipulated in the Proposals for ah Work Orders under this Agreement as to be paid by the Customer to Quotient Clinical.

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- 11.5 For the avoidance of doubt, if Quotient Clinical becomes liable to the Customer as a result of an act or omission in the course of or in relation to a particular Work Order including, without limitation any act or omission which constitutes a breach of a term of this Agreement) the Customer shall subject to clauses 11.1 and 11.2 only be entitled to make a claim against Quotient Clinical under the relevant Work Order referred to above and the limit at clause 11.3 will apply.
- 11.6 The Customer accepts that Quotient Clinical cannot act other than in accordance with the terms of any authorisation issued by the licensing authority for any Research and in accordance with the Regulations and all other relevant legal duties and obligations. Accordingly Quotient Clinical is not responsible for, and shall have no liability to the Customer for (provided that it or any Service Provider of it has not contributed in any way to Customer suffering), any delay, damage, liability or loss of or to the Customer (whether arising in contract, tort (including negligence) or otherwise) arising from the actions or failure to act of any licensing authority or ethics committee or as a result of Quotient Clinical complying with Its obligations under the Regulations or other legal duty or obligation including any obligation to provide notice or information to others regarding any Research and/or any obligation to safeguard the health and safety of any of its employees, the subject of any clinical trial or any other person who may be affected by any such trial,

# 12 Interpretation

- 12.1 Any references in this Agreement to clauses or schedules are to clauses of, or schedules to, this Agreement, and references in a schedule or part of a schedule to a paragraph are to paragraphs of that schedule or part of that schedule. The schedules shall have effect as part of this Agreement.
- 12.2 Headings shall be ignored in construing this Agreement and/or any Work Order.
- 12.3 References to a statute or statutory provision includes that provision as from time to time modified or re-enacted or consolidated whether before or after the date of this Agreement and any statutory instrument, order, by-law or other provision that may have been or may be made under it from time to time.
- 12.4 Unless the context otherwise requires, words imparting the singular shall include the plural and vice versa and reference to any masculine, feminine or neuter gender shall include the other genders.
- 12.5 A reference to a "person" or "persons" shall include companies, corporations, firms, unincorporated bodies of persons, local or other statutory authority and partnerships wherever and howsoever incorporated. The words "include", "including", or "includes" are to be construed as if they were immediately followed by the words "without limitation".
- 12.6 In the case of conflict or ambiguity, the order of precedence for this Agreement and the documents attached to or referred to in this Agreement shall be as follows:
  - (a) The Clinical Protocol
  - (b) the clauses of these terms and conditions;

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(c) the schedules to this Agreement

provided that, in the event of any conflict or inconsistency between a term of this Agreement and a term of a Work Order, the term of the Work Order shall (for the purposes of interpreting that Work Order) prevail.

- 12.7 All references to time in this Agreement and/or any Work Order are to UK time. A reference to "Business Days" are to any day other than a Saturday, Sunday or public holiday in England.
- 12.8 Unless the context otherwise requires, any reference in this Agreement or a Work Order to a "party" shall be to one of the parties thereto (and reference to "parties" shall be construed accordingly).

# 13 General

- 13.1 Quotient Clinical may upon written agreement from the Customer be entitled to sub-contract all or any of its obligations under this Agreement and/or any Work Order, at any time, to any person.
- 13.2 Neither party shall, without the prior written agreement of the other party assign, novate, transfer sub-contract or otherwise dispose of any of the Customer's rights or obligations arising under this Agreement and/or any Work Order.
- 13.3 Provided each party has, where reasonably practicable, put appropriate precautions in place enabling it to avoid the effect of a Force Majeure, neither party shall be liable for any failure to perform, or delay in performing, any of its obligations (other than payment obligations) if and to the extent that the failure or delay is caused by Force Majeure and the time for performance of the obligation, the performance of which is affected by Force Majeure, shall be extended accordingly.
- 13.4 This Agreement (together with all other documents to be entered into pursuant to it) sets out the entire agreement and understanding between the parties in connection with the subject matter thereof, and supersedes all proposals and Prior agreements, arrangements and understandings between the parties.
- 13.5 Each party acknowledges that in entering into this Agreement and/or any Work Order (and any other document to be entered into pursuant to it) it does not rely on any representation, warranty, collateral contract or other assurance of any person (whether party to this Agreement or otherwise) that is not set out in this Agreement or that Work Order (as applicable) or any document referred to in it. Each party waives all rights and remedies which, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance. The only remedy available to any person of this Agreement or that Work Order (or other assurance that is set out in this Agreement or a Work Order (or any document referred to in it) is for breach of contract under the terms of this Agreement or that Work Order (or elevant document) as applicable.
- 13.6 Except as expressly stated in this Agreement (or a Work Order, in which case such exception will only apply for the purposes of that Work Order) all conditions, warranties, stipulations and other statements whatsoever (except as to title to goods) that would otherwise be implied or imposed by statute, at common law, by a course of dealing or otherwise howsoever are excluded to the fullest extent permitted by law.

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- 13.7 The parties shall do any other acts and execute any other documents that are necessary in order to give full effect to the terms of this Agreement and/or any Work Order.
- 13.8 No variation of this Agreement or any Work Order shall be effective unless it is in writing and is signed by or on behalf of each of the parties.
- 13.9 The rights and remedies of the parties in connection with this Agreement and any Work Order are cumulative and, except as expressly stated in this Agreement or that Work Order as applicable, are without prejudice to and are not exclusive of any other rights or remedies provided by law or equity or otherwise. Except as expressly stated in this Agreement or any Work Order any right or remedy may be exercised (wholly or partially) from time to time.
- 13.10 Unless expressly stated elsewhere in this Agreement (or a Work Order), all notices to be given to a party under this Agreement (or that Work Order, as applicable) shall be in writing in English and shall be marked for the attention of the person, and delivered by hand or sent by first class prepaid post to the address detailed at the first page of this Agreement. A notice shall be treated as having been received:
  - (a) if delivered by hand between 9.00 am and 5.00 pm on a Business Day (which time period is referred to in this clause 13 as "Business Hours"), when so delivered; and if delivered by hand outside Business Hours, at the next start of Business Hours;
  - (b) if sent by first class post, at 9.00 am on the fifth Business Day after posting if posted on a Business Day and at 9.00 am on the seventh Business Day after posting in any other case; and

in proving that a notice has been given it shall be sufficient to prove that delivery was made, or that the envelope containing the notice was properly addressed and posted.

E-mailed notices are not valid for the purposes of this Agreement and/or any Work Order but this does not invalidate any other lawful mode of service.

- 13.11 The parties intend each provision of this Agreement and each Work Order to be severable and distinct from the others. If a provision of this Agreement or a Work Order is held to be illegal, invalid or unenforceable, in whole or in part, the parties intend that the legality, validity and enforceability of the remainder of this Agreement or Work Order (as relevant) shall not be affected.
- 13.12 Any person who is not a party to this Agreement (or a Work Order) cannot enforce any term of this Agreement (or that Work Order, as applicable) under the Contracts (Rights of Third Parties) Act 1999, but this does not affect any right or remedy of a third party which exists or is available apart from that Act.
- 13.13 This Agreement may be entered into in any number of counterparts and by the parties on separate counterparts, all of which taken together shall constitute one and the same instrument. However, this Agreement shall not come into force until each of the Customer and Quotient Clinical have signed at least one counterpart.
- 13.14 The validity, construction and performance of this Agreement and any Work Order shall be governed by and construed in accordance with the law of England and Wales. Each party irrevocably agrees to submit to the non-exclusive jurisdiction of the courts of England and Wales over any claim, dispute or matter arising under or in connection with this Agreement or a Work Order.

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13.15 In relation to all matters arising out of or in connection with this Agreement or a Work Order, each of the parties hereby:

- (a) waives any objections on the grounds of venue or forum non conveniens or any similar ground; and
- (b) consents to service of process by mail or in any other manner permitted by the relevant law.

Signed by the parties or their duly authorised representatives on the date of this Agreement

Signed by duly authorised for and on behalf of **Quotient Clinical Limited** 

SIMON A. LEE, CCO

e -

DIANNE ANGUS, COO

Signed by duly authorised for and on behalf of **Prana Biotechnology Ltd** 

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# Schedule 1

# TEMPLATE WORK ORDER (NUMBER [+])

This Work Order is entered into by and between Prana Biotechnology Limited ("Customer") and Quotient Clinical Limited, a company registered in England and Wales under number 02393366 whose registered office is at Newmarket Road, Fordham, Cambridgeshire, CB7 5WW ("Quotient Clinical") and is supplemental, and entered pursuant, to the Master Services Agreement dated [ $\bullet$ ] between the Customer and Quotient Clinical ("Agreement").

The parties hereby agree as follows;

# 1 Work Order

This document and its appendices constitute a "Work Order" under the Agreement. The terms and conditions set out in the Agreement (including, without limitation, the provisions of clause 11 of the Agreement) shall apply to this Work Order.

# 2 Services and Payment of Fees and Expenses

2.1 The specific services to be provided by Quotient Clinical, and the amount(s) to be paid by the Customer to Quotient Clinical in return, pursuant to this Work Order (together with the related timescales, invoicing dates, and invoicing and payment details) are set forth in the following appendices which shall for all purposes form part of this Work Order:

Appendix 1	Proposal
Appendix 2	Payment Schedule

2.2 [Quotient Clinical will act as the Legal Representative of the Customer for the purposes of the trial, study, and/or other services described in appendix 1 to this Work Order]\*

# 3 Term

This Work Order shall come into force on the date that it has been signed by or on behalf of both parties and shall remain in force in accordance with clause 8 of the Agreement.

\* To be deleted by Quotient Clinical as appropriate

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## 4 Amendments

No modification, amendment, or waiver of this Work Order shall be effective unless in writing and duly executed and delivered by each party to the other.

# 5 Signatures

Signed by the parties or their duly authorised representatives on the dates set out below

Signed by	)		
duly authorised for and on behalf of Quotient Clinical Limited	)		
Date			
Signed by	)		
duly authorised for and on behalf of	)		
Prana Biotechnology Ltd	) -		
Date	-		
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# Proposal

[+][Insert agreed proposal, deliverables, timeline and costing document]

Amount to be paid by the Customer: [•]

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## Appendix 2 (Work Order Number [•])

## Payment Schedule

	Payment Milestone – Invoicing Dates	Amount
1	Signature of Work Order	30%
2	First dosing day	20%
3	Last subject, last visit	30%
4	Database lock	10%
5	Dispatch of draft CSR	5%
6	Dispatch of final CSR	5%

The non-cancellable recruitment and screening, clinic and manufacturing labour costs for the Research are:

Study Period	Dates	Amount
1	[•]	£[•]
2	[•]	£[•]

Invoices will be addressed to: Name [+]

Name [•] Address [•] Phone [•] Fax [•] Email [•]

Payments will be made by wire transfer to:

Payments will be made by wire transfer to:

Account Bank Name Address	Quotient Clinical Ltd Ulster Bank Belfast City Office 1 BT1 5UB
Account No.	10669356
Sort Code	98-00-60
Swift Code	ULSBGB2B
IBAN No.	GB41ULSB98006010669356

Or such other account and/or payment method as Quotient Clinical may notify to the Customer for that purpose from time to time.

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#### Schedule 2

#### The Medicines for Human use (Clinical Trials) Regulations 2004

- For the purposes of the Regulations, Quotient Clinical agrees that it shall act as Legal Representative for the relevant Research throughout the duration of the Research in addition to the other services described in this Agreement and/or the Work Order provided that the Customer fulfils and continues to fulfil all its obligations to Quotient Clinical under this Agreement and the Work Order, including for the avoidance of doubt the obligation to pay all monies due to Quotient Clinical in accordance with the provisions of this Agreement and the Work Order.
- 2 For the purposes of this schedule 2 any word or phrase with a defined meaning in the Regulations shall be construed in this schedule in accordance with the meanings ascribed in the Regulations.
- 3 Quotient Clinical shall provide the Customer with a copy of all correspondence from the licensing authority relating to the relevant Research upon request from the Customer and will in any event provide a copy of any authorisation and any notice received from the licensing authority related to the Research within 2 Business Days of its receipt by Quotient Clinical.

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#### Work Order Number 1

This Work Order is entered into by and between Prana Biotechnology Limited, in Australia under number ACN 080 699 065 whose registered office is at Level 2, 369 Royal Parade, Parkville 3052, Victoria, Australia (**"Customer"**) and Quotient Clinical Limited, a company registered in England and Wales under number 05221615 whose registered office is at Trent House, Mere Way, Ruddington Business Park, Nottingham NG11 6JS (**"Quotient Clinical"**) and is supplemental, and entered pursuant, to the Master Services Agreement dated 12<sup>th</sup> December 2013 between the Customer and Quotient Clinical (**"Agreement"**).

The parties hereby agree as follows;

### 1 Work Order

This document and its appendices constitute a "Work Order" under the Agreement. The terms and conditions set out in the Agreement shall apply to this Work Order.

### 2 Services and Payment of Fees and Expenses

2.1 The specific services to be provided by Quotient Clinical, and the amount(s) to be paid by the Customer to Quotient Clinical in return, pursuant to this Work Order (together with the related timescales, invoicing milestones, and invoicing and payment details) are set forth in the following appendices which shall for all purposes form part of this Work Order:

Appendix 1	Proposal
Appendix 2	Payment Schedule
Appendix 3	Legal Representative

#### 3 Term

This Work Order shall come into force on the date that it has been signed by or on behalf of both parties and shall remain in force in accordance with clause 8 of the Agreement.

### 4 Amendments

No modification, amendment, or waiver of this Work Order shall be effective unless in writing and duly executed and delivered by each party to the other.

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# 5 Signatures

Signed by the parties or their duly authorised representatives on the dates set out below

Signed by duly authorised for and on behalf of **Quotient Clinical Limited** Date

Signed by duly authorised for and on behalf of **Prana Biotechnology Limited** Date

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) ) ) Geoffrey Kempler, CEO <u>12 December, 2013</u> Page 2 of 5

### Appendix 1 Work Order Number 1

"A Phase 1, Open-Label Study of the Absorption, Metabolism, Excretion and the Absolute Bioavailability of PBT2 in Healthy Male Subjects."

Customer Reference no.: QUOTIENT Reference no.: TBC QBR116882

# Proposal

Quotient's formal proposal reference "QBR116682 Prana Biotechnology Proposal ivMT\_ADME version 3" dated 9th December 2013 is attached here:



QBR116682 Prana Biotechnology Prop

The services to be provided by Quotient are detailed in sections 3, 6, 8, 9, 10, 11, 12 and 13 of the Proposal.

The division of responsibilities to be applied during provision of the services is detailed in section 7 of the Proposal.

The approximate timeline for study delivery is detailed in section 4 of the Proposal. A detailed Gantt chart will be provided at the point of signature. Once agreed, the Gantt chart will be incorporated into this Work Order

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### Appendix 2 Work Order Number 1

In consideration of the services to be provided, a fee of £498,903.00 (Four hundred and ninety eight thousand, nine hundred and three pounds) shall become payable by the Customer. Such fee to be paid in accordance with the following payment schedule:

### Payment Schedule

	Payment Milestone – Invoicing Dates	Amount	Value
1	Signature of Work Order	30%	£149,670.90
2	First dosing day	20%	£99,780.60
3	Last subject, last visit	30%	£149,670.90
4	Database lock	10%	£49,890.30
5	Dispatch of draft CSR	5%	£24,945.15
6	Dispatch of final CSR	5%	£24,945.15
	Т	otal 100%	£498,903.00

Pursuant to clauses 7.1, 8.6 and 8.7, the QC Non-Cancellable costs associated with recruitment, screening, manufacture and clinical conduct are:

Study Period	Dates	Amount
1	First Subject First Dose Period 1	£22,984
2	First Subject First Dose Period 2	£22,984

Invoices will be addressed to:

Name	Dr. Caroline Herd
Address	Prana Biotechnology Ltd,
	Level 2 369 Royal Parade,
	Parkvile, VIC 3052, Australia
Phone	+61 (0)3 9349 4906
Fax	+61 (0)3 9348 0377
Email	cherd@pranabio.com

Payments will be made by wire transfer to:

Account	Quotient Clinical Ltd
Bank Name	HSBC Bank PLC
Address	22 Central Avenue
	West Bridgford
	Nottinghamshire
	NG2 5GR
Account No.	81727109
Sort Code	40-35-19
Swift Code	MIDLGB22
IBAN No.	GB69MIDL40351981727109

Or such other account and/or payment method as Quotient Clinical may notify to the Customer for that purpose from time to time.

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#### Appendix 3

#### The Medicines for Human use (Clinical Trials) Regulations 2004

- For the purposes of the Regulations, Quotient Clinical agrees that it shall act as Legal Representative for the relevant Research throughout the duration of the Research in addition to the other services described in this Agreement and/or the Work Order provided that the Customer fulfils and continues to fulfil all its obligations to Quotient Clinical under this Agreement and the Work Order, including for the avoidance of doubt the obligation to pay all monies due to Quotient Clinical in accordance with the provisions of this Agreement and the Work Order.
- 2 For the purposes of this schedule 2 any word or phrase with a defined meaning in the Regulations shall be construed in this schedule in accordance with the meanings ascribed in the Regulations.
- 3 Quotient Clinical shall provide the Customer with a copy of all correspondence from the licensing authority relating to the relevant Research upon request from the Customer and will in any event provide a copy of any authorisation and any notice received from the licensing authority related to the Research within 2 Business Days of its receipt by Quotient Clinical.

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Change Order Form			
CHANGE ORDER NUMBER: 1	SPONSOR: Prana Biotechnology Limited		
DRUG NAME: PBT2	SPONSOR REFERENCE #: PBT2-102		
STUDY #: QBR116682 PROJECT MANAGER: Itesh Govan/Sue Sweet			
DATE OF REQUEST: 19 Mar 2014	PREPARED BY: Itesh Govan		
BRIEFLY DESCRIBE ORIGINAL ASSUMPTION AND NEW REQUEST BELOW:			
1. Prana has confirmed that they would like Quotient to sub-contract the monito	ring of the study and have agreed to use Jane Muir of Wirral Clinical Consultancy Limited.		
2. Prana has confirmed that they would like Quotient to perform the QP importat	ion and QP release of capsules (manufactured in Canada and labelled in Australia).		
3. Prana has confirmed that they would like to have the IV plasma samples from	Part 1 of the study tested for total radioactivity by AMS at Vitalea.		
IMPACT:			
1. Setting up a sub-contract agreement with Jane Muir.			
2. An additional 10 hours of QP resource on the assumption that all supporting	documentation requested by Quotient is supplied by Prana.		
3. Inclusion of these additional samples in the Work Order with Vitalea (samples were already being taken for other testing and costs have been received from Vitalea).			
TIMING: Effective immediately upon signature			
COST OF CONTRACT AMENDMENT:			
1. £8,250 for sub-contact with Jane Muir. This cost does not include travel expenses and any agreed additional activities (see attached proposal from Jane Muir), which will be handled as pass through costs.			
2. £1,375 for 10 hours QP resource.			
3. £20,585 for additional AMS testing at Vitalea.			
4.			
TOTAL = £30,210			
PAYMENT TERMS:			
100% on signature			
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# AMENDMENT:

This Change Order Form shall constitute a Contract Amendment to the Work Order Number 1 between Prana and Quotient Clinical Ltd effected on 12 Dec 2013 and shall apply only to the scope of services and revised payment schedule listed herein or attached hereto. In all other respects the terms and conditions of the Agreement shall remain in full force and effect and shall be applied to this Contract Amendment.			
SPONSOR APPROVAL:	QUOTIENT CLINICAL APPROVAL:		
Signature	Signature		
Name	Name SIMON A. LEE		
Title	Title CCO		
Date	Date 20 March 2014		

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Exhibit 8.1

# LIST OF SUBSIDIARIES

We have the following wholly-owned subsidiaries, both of which are currently inactive:

Prana Biotechnology Inc., incorporated in the United States

Prana Biotechnology UK plc, incorporated in the United Kingdom.

### 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 31, 2014

<u>/s/ Geoffrey P. Kempler</u>\* 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 ACTING CHIEF FINANCIAL OFFICER Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended

I, Phillip Hains, 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 31, 2014

<u>/s/ Phillip Hains</u> \* Phillip Hains Acting 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.

Exhibit 13.1

#### 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, 2014, 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 31, 2014

<u>/s/ Geoffrey P. Kempler</u>\* 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.

Exhibit 13.2

#### 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, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Phillip Hains, Acting 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.

<u>/s/ Phillip Hains</u>\* Phillip Hains Acting Chief Financial Officer

October 31, 2014

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

Exhibit 15.1

## 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) of Prana Biotechnology Limited of our report dated October 31, 2014 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers Melbourne, Australia October 31, 2014