Month	High US$	Low US$
July 2011	1.1029	1.0598
August 2011	1.1015	1.0461
September 2011	1.0725	0.9757
October 2011	1.0753	0.9388
November 2011	1.0565	0.9664
December 2011	1.0382	0.9862
January 2012	1.0685	1.0197
February 2012	1.0816	1.0610
March 2012	1.0793	1.0371
April 2012	1.0453	1.0262
May 2012	1.0342	0.9727
June 2012	1.0191	0.9675
July 2012	1.0526	1.0163
August 2012	1.0593	1.0301
September 2012	1.0579	1.0205

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

The following risks relate specifically to our business and should be considered carefully. Our business, financial condition and results of operations could be harmed by any of the following risks. As a result, the trading price of our ordinary shares and our American Depositary Shares, or ADSs, could decline and the holders could lose part or all of their investment.

Risks Related to Our Business

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

We are a development stage company at an early stage in the development of pharmaceutical products and our success is uncertain. Unless we are able to generate sufficient product revenue, we will continue to incur losses from operations and may not achieve or maintain profitability. As of June 30, 2012, we had an accumulated deficit of A$99.7 million. At this point we do not have any products that generate revenue. We will continue to incur losses from operations and we expect the costs of drug development to increase over the next years as more patients are recruited to our trials and potential commercialization draws near. In particular, we will continue to incur significant losses in carrying out clinical trials of Cvac necessary for regulatory approval. Because of the numerous risks and uncertainties associated with the development, manufacturing, sales and marketing of therapeutic products, we may experience larger than expected future losses and may never become profitable. Our current or any future product candidates may not be successfully developed, and if successfully developed, may not generate sufficient revenue to enable us to be profitable.

If we fail to become and remain profitable, or if we are unable to fund our continuing losses, our business will be harmed and the holders of our ordinary shares and ADSs could lose all or part of their investment. There is a substantial risk that we may not be able to complete the development of our current product candidates or develop other pharmaceutical products. We will rely on Cvac and our other product candidates to generate revenues for us in the future. It is possible that none of them will be successfully commercialized, which would prevent us from ever achieving profitability.

We will require additional financing in the future to sufficiently fund our operations and research.

We have been incurring losses and will continue to do so as we expand our drug development programs. Our actual cash requirements may vary from those now planned and will depend upon many factors, including: the continued progress of our research and development programs; the timing, costs and results of clinical trials; the cost, timing and outcome of submissions for regulatory approval; the commercial potential of our product candidates; our ability to increase manufacturing capabilities; and the status and timing of competitive developments.

We anticipate that as the trials for Cvac progress and its associated costs increase we will require additional funds to achieve our long-term goals of commercialization and further development of other product candidates. In addition, we will require funds to pursue regulatory applications, defend intellectual property rights, increase manufacturing capacity, develop marketing and sales capability and fund operating expenses. We intend to seek such additional funding through public or private financings and/or through licensing of our assets or other arrangements with corporate partners. However, such financing, licensing opportunities or other arrangements may not be available from any sources on acceptable terms, or at all. Any shortfall in funding could result in our having to curtail or cease our operations including our research and development activities, which would harm our business, financial condition and results of operations.

Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain requisite regulatory approvals for commercial sale.

Phase I and Phase II clinical trials are not primarily designed to test the efficacy of a product candidate but rather to test safety and to understand the product candidate's side effects at various doses and schedules. Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be repeated in later trials. Further, Phase III clinical trials may not show sufficient safety or efficacy to obtain regulatory approval for marketing. We may conduct lengthy and expensive clinical trials of our product candidates, only to learn that the product candidate is not an effective treatment or not sufficiently safe. A number of companies in the biotechnology industry have suffered significant setbacks in Phase III clinical trials, even after promising results in earlier trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could require that the clinical trial be redone or terminated. In addition, failure to construct appropriate clinical trial protocols could result in the test or control group experiencing a disproportionate number of adverse events and could require that a clinical trial be redone or terminated. The length of time necessary to complete clinical trials and to submit an application for marketing approval by applicable regulatory authorities may also vary significantly based on the type, complexity and novelty of the product candidate involved, as well as other factors. If we suffer any significant delays, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue the development of our products or product candidates or generate revenue and our business may be harmed.

If we do not obtain the necessary regulatory approvals we will be unable to commercialize our pharmaceutical products. Even if we receive regulatory approval for any product candidates, profitability will depend on our ability to generate revenues from the sale of our products or the licensing of our technology.

The clinical development, manufacturing, sales and marketing of our products are subject to extensive regulation by regulatory authorities in the United States, the United Kingdom, the European Union, Australia and elsewhere. These regulations vary in important, meaningful ways from country to country. Despite the substantial time and expense invested in preparation and submission of a Biologic License Application, or BLA, or equivalents in other jurisdictions, regulatory approval is never guaranteed. The U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the United States, the United Kingdom, the European Union, Australia and elsewhere, exercise substantial discretion in the drug approval process. The number, size and design of preclinical studies and clinical trials that will be required will vary depending on the product, the disease or condition for which the product is intended to be used and the regulations and guidance documents applicable to any particular product. The FDA or other regulators can delay, limit or deny approval of a product for many reasons, including, but not limited to, the fact that regulators may not approve our or our third-party manufacturer's processes or facilities or that new laws may be enacted or regulators may change their approval policies or adopt new regulations requiring new or different evidence of safety and efficacy for the intended use of a product.

Cvac is currently undergoing clinical trials, however, successful results in the trial and in the subsequent application for marketing approval are not guaranteed. If we are unable to obtain regulatory approvals we will not be able to generate revenue from Cvac or our other product candidates. Even if we receive regulatory approval for any product candidates, our profitability will depend on our ability to generate revenues from the sale of our product candidates or the licensing of our technology that will offset the significant and continuing expenditures required for us to advance our research, protect and extend our intellectual property rights and develop, manufacture, license, market, distribute and sell our technology and product candidates successfully.

Even if our product candidates receive regulatory approval, we may still face development and regulatory difficulties that may delay or impair future sales of our product candidates and we would be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our product candidates.

If we receive regulatory approval to sell Cvac or any other product candidate, the relevant regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses, manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping or impose ongoing requirements for post-approval studies. In addition, regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate

safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. If we discover previously unknown problems with a product or our manufacturing facilities or the manufacturing facilities of a contract manufacturer, a regulatory agency may impose restrictions on that product, on us or on our third-party contract manufacturers, including requiring us to withdraw the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend our regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities or terminating licenses to manufacture Good Manufacturing Practice grade material; or
- seize or detain products or require a product recall.

Any of the foregoing could harm the commercialization of our product candidates and our results and operations may be harmed. Likewise, any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize our products. In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action. If we are not able to maintain regulatory compliance, we might not be permitted to market our product candidates and our business could suffer.

We have limited manufacturing experience with our product candidates. Delays in manufacturing sufficient quantities of materials may negatively impact our business and operations.

Cvac differs from many therapeutic products in that it must be manufactured on a patient-by-patient basis, using the patients' own immune cells, and therefore cannot be mass produced and stockpiled. Should we obtain regulatory approval, we may not be able to manufacture sufficient quantities in a cost-effective or timely manner which would hinder the commercialization of the product and reduce or prevent potential revenues. We may need to develop additional manufacturing resources, enter into collaborative arrangements with other parties, or have third parties manufacture our products on a contract basis. We may not have access on acceptable terms to the substantial financing that would be required to scale-up production and develop commercial manufacturing processes. We may not be able to enter into collaborative or contractual arrangements on acceptable terms with third parties that will meet our requirements for quality, quantity and timeliness. Such delays and hurdles could harm our business, financial condition and results of operations.

To the extent we rely significantly on contractors, we will be exposed to risks related to the business conditions of our contractors.

We are a small company, with few internal staff and no capital facilities. As of June 30, 2012 we only had 26 employees. We rely on a variety of contractors to manufacture our products, to perform clinical testing and to prepare regulatory dossiers. Adverse events that affect one or more of our contractors could adversely affect us, such as:

- a contractor is unable to retain key staff that have been working on our business;
- a contractor is unable to sustain operations due to financial or other business issues;
- a contractor loses its permits or licenses that may be required to manufacture our products; or
- errors, negligence or misconduct that occur within a contractor may adversely affect our business concerns although we may not be directly responsible.

To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

An important element of our strategy for developing, manufacturing and commercializing our product candidates is entering into partnerships and strategic alliances with other pharmaceutical companies or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. We may not be able to negotiate alliances on acceptable terms, if at all. Although we are not currently party to any collaborative arrangement or strategic alliance that we believe is material to our business, in the future we may rely on collaborative arrangements or strategic alliances to complete the development and commercialization of some of our product candidates. Although we have no specific reason to believe that we will be at a

disadvantage when negotiating such collaborative arrangements or strategic alliances, our negotiating position will be influenced by our financial capacity at the relevant time to continue the development and commercialization of the relevant product candidate, as well as the timing of any such negotiations and the stage of development of the relevant product candidate. These arrangements may result in us receiving less revenue than if we sold such products directly, may place the development, sales and marketing of our products outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us. Collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our strategic partner/collaborators may devote to the product candidates;
- our strategic partner/collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

Our research and development efforts will be 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 obtained key man insurance for our chief executive officer and chief medical officer. We are not aware that any member of our senior management or key scientific personnel is contemplating ending their relationship with Prima BioMed. Competition among biotechnology and pharmaceutical companies for qualified employees is intense and we may not be able to attract and retain personnel critical to our success. Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel, manufacturing personnel, sales and marketing personnel and on our ability to develop and maintain important relationships with clinicians, scientists and leading academic and health institutions. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

Our research and development efforts will be jeopardized if we are unable to secure critical components and reagents necessary for manufacture of key components of Cvac.

A key component of Cvac manufacture is mononuclear cells (a type of blood cell) obtained from each patient, as Cvac is made specifically for each patient. To obtain mononuclear cells, we use a process called apheresis, which requires specially trained technicians using qualified processes on a COBE® Spectra machine from Terumo BCT. We have invested significant time and money into the training and quality control procedures for mononuclear cell collections. However, if we are unable to identify and train appropriate technicians in sufficient number, or if the COBE® Spectra becomes obsolete, or if kits for the COBE® Spectra are no longer supplied by the manufacturer, and we are unable to arrange for qualified substitutes, the continued development and any future commercialization of Cvac may be delayed.

Besides the patients' own cells, many reagents important to Cvac manufacture are common to all patients. Many of the key reagents are available from reputable commercial sources, produced under the appropriate level of quality control (e.g. GMP, ISO, etc.) and supplied with appropriate specifications and batch release documentation. We have assumed that our ongoing supply of these reagents will be available during further clinical development, that no further technology transfer from us is required and that lot-to-lot reproducibility can be assured.

Some key reagents important to Cvac manufacture are custom made for Prima BioMed, in particular the Cvac antigen (Mannosylated Fusion Protein or M-FP). We have scaled up manufacturing of M-FP and other key custom reagents and we have sufficient quantities stockpiled for our foreseeable development needs; however, it may be difficult to obtain the same or comparable custom reagents in the future.

If we are unable to secure critical reagents from our current suppliers the continued development and any future commercialization of our product candidates may be delayed if regulatory authorities require any comparability testing or bridging studies to be performed.

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

Any future success will depend in large part on whether we can obtain and maintain patents to protect our own products and technologies; obtain licenses to the patented technologies of third parties; and operate without infringing on the proprietary rights of

third parties. Biotechnology patent matters can involve complex legal and scientific questions, and it is impossible to predict the outcome of biotechnology and pharmaceutical patent claims. Any of our future patent applications may not be approved, or we may not develop additional products or processes that are patentable. Some countries in which we may sell our product candidates or license our intellectual property may fail to protect our intellectual property rights to the same extent as the protection that may be afforded in the United States or Australia. Some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, the United Kingdom, the European Union, Australia or elsewhere. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, the United Kingdom, the European Union or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection.

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, or third parties may in the future assert against us infringement claims regarding proprietary rights belonging to them. Such proceedings could result in the expenditure of significant financial and managerial resources and could negatively affect our profitability. Adverse determinations in any such proceedings could prevent us from developing and commercializing our products and could harm our business, financial condition and results of operations.

If we infringe the intellectual property rights of third parties, it may increase our costs or prevent us from the commercialization of our product candidates.

There is a risk that we are or may infringe other proprietary rights of third parties of which we are unaware. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. To date, we have not been involved in any such third-party claims and, except as stated above, we are not aware that our product candidates infringe the intellectual property rights of third parties. As a result of intellectual property infringement claims, or to avoid potential claims, we might be:

- prohibited from selling or licensing any product candidate that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- required to expend considerable amounts of money in defending the claim;
- required to pay substantial royalties or grant a cross license to our patents to another patent holder;
- required to redesign the formulation of a product so that it does not infringe, which may not be possible or could require substantial funds and time; or
- required to pay substantial monetary damages.

In March 2004, Cancer Vac (a wholly owned subsidiary of Prima BioMed Ltd) entered into an agreement with Canadian company Biomira Inc., (now known as Oncothyreon Inc.) regarding mucin peptide patents. These mucin peptide patents are owned by Imperial Cancer Research Technology Limited, an English company, and were licensed to Biomira. As part consideration for the agreement, Biomira became a shareholder of Cancer Vac. While the agreements could be interpreted that we would incur milestone and royalty obligations based on Cvac development and commercialization, we do not believe that Prima has any ongoing obligations to Oncotheryon under these agreements. The ICRT mucin peptide patents are expired in all countries except Canada and the United States. The ICRT patents expire in Canada and 2014 and there is very little likelihood Cvac would be commercialized in Canada prior to 2014. However, Cvac may infringe the mucin peptide patents if commercialized in the United States prior to April 24, 2018. We may be prevented by Oncothyreon, Inc. from commercializing Cvac in the United States prior to that date, or we may be required to obtain a license at considerable costs, if at all, from Oncothyreon Inc. if we attempt to commercialize Cvac in the United States prior to that date.

If we are unable to keep pace with technological change or with the advances of our competitors, our technology and products may become 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 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 non-competitive. Many of these competitors have greater financial and technical resources and manufacturing and marketing capabilities than we do, and have more experience in conducting clinical trials and obtaining FDA, Australia’s Therapeutic Goods Administration and other regulatory approvals. Our ability to further develop and commercialize our products may be adversely affected if our competitors were to succeed in obtaining regulatory approval for their products sooner than us.

Future sales of our products may suffer if they are not accepted in the marketplace by physicians, patients and the medical community.

There is a risk that Cvac or our other product candidates may not gain market acceptance among physicians, patients and the medical community, even if they are approved by the regulatory authorities. The degree of market acceptance of any of our approved products will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive products;
- our ability to provide acceptable evidence of safety and efficacy and our ability to secure the support of key clinicians and physicians for our products;
- cost-effectiveness compared to existing and new treatments;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payors;
- prevalence and severity of adverse side effects; and
- other advantages over other treatment methods.

Physicians, patients, payors or the medical community may be unwilling to accept, use or recommend our products which would adversely affect our potential revenues and future profitability.

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

Our product candidates may be rejected by the market due to many factors, including cost. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce healthcare costs may affect our future revenues and profitability. In Australia and certain foreign markets the pricing of pharmaceutical products is already subject to government control. We expect initiatives for similar government control to continue in the United States and elsewhere. The adoption of any such legislative or regulatory proposals could harm our business and prospects.

Successful commercialization of our product candidates 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 insurers and other organizations. Our product candidates may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis. Third-party payors are increasingly challenging the price of medical products and treatment. If third party coverage is not available for our products the market acceptance of these products will be reduced. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues lower than anticipated. If the prices for our product candidates decrease or if governmental and other third-party payors do not provide adequate coverage and reimbursement levels our potential revenue and prospects for profitability will suffer.

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

The testing, marketing and sale of therapeutic products entails an inherent risk of product liability. We face product liability exposure related to the testing of our product candidates in human clinical trials. If any of our products are approved for sale, we may face exposure to claims by an even greater number of persons than were involved in the clinical trials once we begin marketing, distribution and sales of our products commercially. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products and product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenues; and
- the inability to commercialize our products and product candidates.

If there is a claim made against us or some other problem that is attributable to our products or product candidates, our share price may be negatively affected. Even if we were ultimately successful in product liability litigation, the litigation would consume substantial amounts of our financial and managerial resources and may create adverse publicity, all of which would impair our ability to generate sales of our product candidates. We may incur substantial liabilities or be required to limit development or commercialization of our product candidates if we cannot successfully defend ourselves against product liability claims. Such

coverage may not be available in the future on acceptable terms, or at all. Even if we have adequate insurance coverage, product liability claims or recalls could result in negative publicity and force us to devote significant managerial and financial resources to those matters, and the commercialization of our product candidates may be delayed or severely compromised.

We rely on a number of third party researchers and contractors to produce, collect, and analyze data regarding the safety and efficacy of our product candidates. We have quality control and quality assurance in place to mitigate these risks, as well as professional liability and clinical trial insurance to cover financial damages in the event that human testing is done incorrectly or the data is analyzed incorrectly. If a claim is made against us in conjunction with the research testing activities, our share price may be negatively affected. We may be at risk of needing to redo testing at a significant cost. We could face additional liability beyond our insurance limits if testing mistakes were to endanger any human subjects. Liability claims due to errors or omissions in human testing may result in injury to our reputation in the eyes of scientists, doctors, regulators, and patients.

Risks Relating to Our Securities

Our stock price may be volatile and could decline significantly.

The market price of our ordinary shares historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. These fluctuations may be due to factors specific to us, to changes in analysts' recommendations and earnings estimates, to arbitrage between our Australian listed shares and our ADSs, to changes in exchange rates, or to factors affecting the biopharmaceutical industry or the securities markets in general. Market fluctuations, as well as general political and economic conditions, such as a recession, interest rate or currency fluctuations, could adversely affect the market price of our securities.

For example, during the last two fiscal years, the market price for our ordinary shares on the Australian Securities Exchange has ranged from as low as A$0.08 to a high of A$0.42. We may experience a material decline in the market price of our shares, regardless of our operating performance. Therefore, a holder of our ordinary shares or ADSs may not be able to sell those ordinary shares or ADSs at or above the price paid by such holder for such shares or ADSs. Price declines in our ordinary shares or ADSs could result from a variety of factors, including many outside our control. These factors include:

- the results of pre-clinical testing and clinical trials by us and our competitors;
- unforeseen safety issues or adverse side effects resulting from the clinical trials or the commercial use of any of our product candidates;
- regulatory actions in respect of any of our products or the products of any of our competitors;
- announcements of the introduction of new products by us or our competitors;
- market conditions, including market conditions in the pharmaceutical and biotechnology sectors;
- increases in our costs or decreases in our revenues due to unfavorable movements in foreign currency exchange rates;
- developments or litigation concerning patents, licenses and other intellectual property rights;
- litigation or public concern about the safety of our potential products;
- changes in recommendations or earnings estimates by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts;
- rumors relating to us or our competitors;
- additions or departures of key personnel;
- changes in third-party reimbursement policies; and
- developments concerning current or future strategic alliances or acquisitions.

Our ordinary shares may be considered a "penny stock" under SEC regulations which could adversely affect the willingness of investors to hold our ADSs.

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. During the fiscal year ended June 30, 2012, our ordinary shares traded on the ASX from low of A$0.09 to a high of A$0.32 per share. Under ASX listing rules our shares may not trade below A$0.001 per share. The low trading price of our ordinary shares may adversely affect the willingness of investors to hold our ADSs.

We may be a passive foreign investment company (PFIC) which would 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 currently a passive foreign investment company, or PFIC, which could result in a reduction in the after-tax return to a "U.S. Holder" of our ADRs and reduce the value of our ADSs. For U.S. federal income tax purposes, we will be classified as a PFIC for any taxable year in which (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.

The determination of whether we are a PFIC is made on an annual basis and depends on the composition of our income and the value of our assets. Therefore, it is possible that we could be a PFIC in the current year as well as in future years. If we are classified as a PFIC in any year that a U.S. Holder owns ADSs, the U.S. Holder will generally continue to be treated as holding ADSs of a PFIC in all subsequent years, notwithstanding that we are not classified as a PFIC in a subsequent year. Dividends received by the U.S. Holder and gains realized from the sale of our ADSs would be taxed as ordinary income and subject to an interest charge. We urge U.S. investors to consult their own tax advisors about the application of the PFIC rules and certain elections that may help to minimize adverse U.S. federal income tax consequences in their particular circumstances.

We have never paid a dividend and we do not intend to pay dividends in the foreseeable future which means that holders of shares and ADSs may not receive any return on their investment from dividends.

To date, we have not declared or paid any cash dividends on our ordinary shares and currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. Dividends may only be paid out of our profits. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors. Our holders of shares and ADSs may not receive any return on their investment from dividends. 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 the ADSs relative to the price of our ordinary shares.

The price of our ordinary shares is quoted in Australian dollars and the price of our ADSs will be quoted in U.S. dollars. Movements in the Australian dollar/U.S. dollar exchange rate may adversely affect the U.S. dollar price of our ADSs and the U.S. dollar equivalent of the price of our ordinary shares. In the last two years, the Australian dollar has as a general trend appreciated against the U.S. dollar. Any continuation of this trend may positively affect the U.S. dollar price of our ADSs and the U.S. dollar equivalent of the 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 ADSs could decline, even if the price of our ordinary shares in Australian dollars increases or remains unchanged.

As a SEC registrant, we are obligated to develop and maintain proper and effective internal controls over financial reporting. We may not complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common shares.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending June 30, 2013. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as, if we are an accelerated filer or a large accelerated filer as stipulated in Item 308(b) of Regulations S-K, a statement that our auditors have issued an attestation report on our management's assessment of our internal controls.

During the financial close process for the fiscal year ended June 30, 2012, we determined that the statement of cash flows for the fiscal year ended June 30, 2011 contained errors with respect to the calculation of proceeds from the issue from shares, share issue transaction costs, interest received and payments to employees and suppliers resulting in a reclassification of amounts between the financing and operating activities sections of the statement of cash flows. There was no impact on our cash or loss per share.

We determined that the restatement of our financial statements for the fiscal year ended June 30, 2011 was the result of internal control deficiencies. A material weakness, as defined under the standards issued by the United States based Public Company Accounting Oversight Board, or PCAOB, is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected and corrected on a timely basis. Therefore, a material weakness, as defined by the PCAOB, existed as of June 30, 2011 as we lacked the necessary technical accounting expertise to properly analyze and account for the increasingly complex financial agreements being reported in our financial statements. We have concluded that the steps described below designed to improve our financial reporting and internal controls have remediated this material weakness.

During fiscal 2012, we took the following steps designed to improve our financial reporting and internal controls: (1) the hiring of additional financial accounting staff, as we lessened our dependence on third-party contractors; (2) the retention of an international accounting firm to assist us on technical accounting matters related to material and complex transactions; and (3) the implementation of additional review procedures and controls over transactions and the financial close process.

We have not begun the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common shares to decline.

Risks Relating to Our Location in Australia

Currency fluctuations may expose us to increased costs and revenue decreases.

Our business is affected by fluctuations in foreign exchange rates. Currency fluctuations could, therefore, cause our costs to increase and revenues to decline. Our expenses will be denominated in Australian dollars, U.S. dollars and European euro. In the last two years, the Australian dollar has, as a general trend, appreciated against the U.S. dollar and European euro. . We conduct clinical trials in many different countries and we have manufacturing of some of our product candidates undertaken outside of Australia, which exposes us to potential cost increases resulting from fluctuations in exchange rates. In fiscal 2012, we suffered foreign exchange losses as a result of currency fluctuations of A$1.2 million. It is our policy to use forward exchange contracts to cover anticipated cash flow in the U.S. dollar and Euro for the next twelve months. This policy is reviewed regularly by directors from time to time.

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

We are incorporated in Australia and are subject to the takeovers laws of Australia. Amongst other things, we are subject to the Corporations Act 2001 (Commonwealth of Australia). Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares (including through the acquisition of ADSs) if the acquisition of that interest will lead to a person’s or someone else’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%. Exceptions to the general prohibition include circumstances where the person makes a formal takeover bid for us, if the person obtains shareholder approval for the acquisition or if the person acquires less than 3% of the voting power of us in any rolling six month period. Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our shares.

Rights as a holder of ordinary shares are governed by Australian law and our Constitution and differ from the rights of shareholders under U.S. law. Holders of our ordinary shares or ADSs may have difficulty in effecting service of process in the United States or enforcing judgments obtained in the United States.

We are a public company incorporated under the laws of Australia. Therefore, the rights of holders of our ordinary shares are governed by Australian law and our Constitution. These rights differ from the typical rights of shareholders in U.S. corporations. The rights of holders of ADSs are affected by Australian law and our Constitution but are governed by U.S. law. Circumstances that under U.S. law may entitle a shareholder in a U.S. company to claim damages may also give rise to a cause of action under Australian law entitling a shareholder in an Australian company to claim damages. However, this will not always be the case. Holders of our ordinary shares or ADSs may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the U.S., liabilities under U.S. securities laws. In particular, if such a holder sought to bring proceedings in Australia based on U.S. securities laws, the Australian court might consider:

- that it did not have jurisdiction; and/or

- that it was not an appropriate forum for such proceedings; and/or
- that, applying Australian conflict of laws rule, U.S. law (including U.S. securities laws) did not apply to the relationship between holders of our ordinary shares or ADSs and us or our directors and officers; and/or
- that the U.S. securities laws were of a public or penal nature and should not be enforced by the Australian court.

Holders of our ordinary shares and ADSs may also have difficulties enforcing in courts outside the U.S. judgments obtained in the U.S. courts against any of our directors and executive officers or us, including actions under the civil liability provisions of the U.S. securities laws.

As a foreign private issuer whose shares are listed on the NASDAQ Global 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 Global Market, we are permitted to follow certain home country corporate governance practices instead of certain requirements of The NASDAQ Marketplace Rules. As an Australian company listed on the NASDAQ Global Market, we may follow home country practice with regard to, among other things, the composition of the board of directors, director nomination process, compensation of officers and quorum at shareholders' meetings. In addition, we may follow Australian law instead of the NASDAQ Marketplace 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 filed with the U.S. Securities and Exchange Commission 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. Please see "Item 6. Directors, Senior Management and Employees – C. Board Practices" for further information.

Risks Related to an Investment in Our ADSs

Our ADS holders are not shareholders and do not have shareholder rights.

The Bank of New York Mellon, as depositary, registers and delivers our American Depositary Shares, or ADSs. Our ADS holders will *not* be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying our ADSs. Holders of our ADSs will have ADS holder rights. A deposit agreement among us, the depositary and our ADS holders, and the beneficial owners of ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. For a description of ADS holder rights, see "Item 12. Description of Securities Other than Equity Securities – D. American Depositary Shares." Our shareholders have shareholder rights. Australian law and our constitution govern shareholder rights. For a description of our shareholders' rights, see "Item 10. Additional Information – B. Memorandum and Articles of Association." Our ADS holders do not have the same voting rights as our shareholders. Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares. ADS holders may exercise voting rights with respect to the underlying ordinary shares only in accordance with the provisions of the deposit agreement. Under the deposit agreement, ADS holders vote by giving voting instructions to the depositary. Upon receipt of instructions, the depositary will try to vote in accordance with those instructions. Otherwise, ADS holders will not be able to vote unless they withdraw the ordinary shares underlying their ADSs. ADS holders may not learn of ordinary shareholders' meetings in time to instruct the depositary or withdraw underlying ordinary shares. If we ask for our ADS holders' instructions, the depositary will notify our ADS holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depositary will try, as far as practical, subject to Australian law and the provisions of the depositary agreement, to vote the shares as our ADS holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADS holders. We cannot assure our ADS holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their shares. This means that there is a risk that our ADS holders may not be able to exercise voting rights and there may be nothing they can do if their shares are not voted as they requested.

Our ADS holders do not have the same rights to receive dividends or other distributions as our shareholders.

Subject to any special rights or restrictions attached to a share, the directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash