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Company Information

Prima BioMed Ltd (ASX: PRR) (Prima) advises that it has prepared and lodged the attached information for the purpose of complying with continuous disclosure to the Australian market.

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About Cvac™ Ovarian Cancer Treatment

Cvac™ is Prima BioMed's core product. It is a vaccine therapy treatment for ovarian cancer sufferers that are administered post-surgery and post-chemotherapy to delay the relapse and control the metastases of the cancer. There is a large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate, and there are currently no maintenance-based therapy products commercially available.

The Company has commenced its Phase IIb Trial for Cvac™ with the US FDA and plans to commence a Phase III Clinical Trial for Cvac™ in Europe and US this year. The Phase IIb and Phase III Trials aim to further confirm the ability of Cvac™ to reduce the instance of relapse in ovarian cancer patients, control the metastases of the cancer and increase the life expectancy of patients.

Prima's ultimate goal is to commercialise Cvac™ into the multi-billion dollar global pharmacy oncology market.

Regulatory approval and commercialization of Cvac™ is the core focus for Prima.

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Business Overview

Background

Prima BioMed Ltd (Prima) is an Australian biotechnology company committed to the development and commercialization of new medical therapies with a particular focus on oncology. Key product candidates in development include Cvac™, an autologous dendritic cell vaccine for ovarian cancer, monoclonal antibodies for multiple tumour types, and an oral formulation for the Human Papilloma Virus, or HPV, vaccine.

Our mission is to be at the forefront of the fight against cancer by transforming the promise of science and biotechnology into therapies that have the potential power to restore health or even save lives of cancer patients. In everything we do, we aim to fulfil our mission to serve patients, from funding the next medical innovation to creatively working on patient treatments.

We have recently focused our pipeline on three projects, one clinical and two preclinical programs. We constantly monitor the competitive environment to identify new complementary product opportunities to acquire or in-license. We have also recently globalised our development strategy, moving manufacturing and clinical development of our lead product, Cvac™ into U.S. and European-based clinical trial centres. To complement this change, we expanded our Australia-based management team through the appointment of international representatives based in the United States and Europe.

Supporting all of our development initiatives is a comprehensive intellectual property portfolio of licensed granted patents and patent applications. Patents are applied for and prosecuted in all major markets of the world. Trademarks are similarly secured as required.

Our lead product candidate is Cvac™, a dendritic cell therapy, for which we are currently conducting a Phase IIb trial for the treatment of ovarian cancer. Cvac™ is designed to target the tumour antigen mucin-1 which is expressed at high levels on many different tumour types. Dendritic cells are immune cells that form part of the human immune system. Their main function is to process antigen material and present it on the surface to other cells of the immune system, thus functioning as antigen-presenting cells. An antigen is a substance/molecule that when introduced into the body triggers the production of an antibody by the immune system which will then kill or neutralize the antigen that is recognized as a foreign and potentially harmful invader. To date, clinical trials have demonstrated that Cvac™ is well tolerated and has shown clinical effects (as measured by CA-125 levels) in approximately 19% of patients with ovarian cancer that is in remission following initial treatment with chemotherapy or radiation therapy. The technology was developed and patented by scientists at the Austin Research Institute, or ARI, now the Burnet Institute, in Melbourne, Victoria, Australia.

In March 2010, we were granted Small and Medium Sized Enterprise, or SME, status by the European Medicines Agency, or EMA. The SME program is an EMA initiative

to address the needs of small and medium sized companies who are developing medicinal products in Europe. Companies with SME status can receive assistance, information and training from dedicated EMA employees. SME designated companies are also eligible for reduced or deferred fees associated with regulatory submissions, scientific advice and inspections.

In June 2010, we were granted Orphan Medicinal Product Designation for the Cvac™ ovarian cancer therapy vaccine in Europe. The European Orphan Medicinal Product designation is intended to promote the development of drugs that may provide significant benefit to patients suffering from rare diseases identified as life-threatening or very serious. Orphan Medicinal Product designation provides ten years of potential market exclusivity once the product candidate is approved for marketing for the designated indication in the European Union. Orphan Medicinal Product designation also allows for protocol assistance free of charge on clinical trials, a reduced Marketing Authorisation Application filing fee and the potential for grant funding.

We also have two preclinical product development programs. The first program targets the development of a humanized cripto-1 antibody as a potential therapeutic agent for the treatment of cancer. Preclinical development commenced in September 2010 with the goal, subject to technical success, of submitting an Investigational New Drug, or IND, or equivalent with the U.S. Food and Drug Administration, or FDA, in 2013. Cripto-1 is highly expressed by various tumour types and is considered an effective target for antibody therapy. The ARI has previously demonstrated anti-tumour activity with rodent derived cripto-1 antibodies in xenograft tumour models in mice. The second development program is for an oral vaccine formulation for HPV, which is the leading cause of cervical cancer. The research program's goal is to produce a widely available, cost effective oral cervical cancer vaccine in tablet form, thus making administration of the vaccine (that is currently injectable only) more broadly available and in particular accessible by the developing world.

Product Development Programs

Cvac™

Product Candidate

Cvac™ by dendritic cell therapy involves the manipulation of a patient's own dendritic cells (taken from white blood cells) to create, in the case of cancer, tumour-protein expressing dendritic cells that can then be injected back into the patient to, directly or indirectly, trigger cytotoxic (killer T cell) immune response to the protein leading to tumour regression. White blood cells are taken from the cancer patient and the appropriate cells extracted and grown into dendritic cells. The dendritic cells are then treated with mannan fusion protein, or MFP, a recombinant protein to elicit an immune response to mucin-1 once administered back to the patient. A recombinant protein is a protein that is derived from recombinant DNA, which is a form of artificial DNA that is created by combining two or more sequences that would not normally occur together through the process of gene splicing. Early clinical trials have shown that this

unique delivery of mucin-1, via dendritic cells helps to elicit a cytotoxic T cell response resulting in the death of the tumour cell. It is this form of immune response that has been considered potentially the optimal method for cancer vaccine development, providing targeted cells that can seek and destroy tumour cells bearing the antigen, mucin-1.

Cvac™ uses the patients' own dendritic cells primed by MFP. It is currently administered to the patients by intradermal injection in four locations on the skin on a schedule of monthly injections for up to three months and then a maintenance program of injections at twelve week intervals for a one year course of therapy.

Target Product Candidate Profile

Cvac™ is an immunotherapeutic approach to the treatment of ovarian cancer. The product's primary target population is ovarian cancer patients in remission post chemotherapy and surgery with the primary goal of improving the interval to relapse and overall survival. We do not anticipate that Cvac™ will be utilized as first line therapy, but as a maintenance therapy to prevent disease progression.

Market Opportunity

We believe Cvac™ has the potential to be developed for a variety of tumour types as mucin-1 is highly expressed by many tumours including breast, lung, colon, pancreas, kidney and ovarian cancer. The first target indication for Cvac™ in development is ovarian cancer.

Ovarian cancer is the most deadly of the gynaecological cancers due to the advanced stage of disease at time of diagnosis.

Competition

The existing treatments for ovarian cancer are surgery, chemotherapy, and radiation therapy. In some cases two or even all three of these treatments are used. These approaches are designed to debulk the tumour and then eradicate any remaining tumour cells. The key chemotherapeutic drugs used are platinum-based drugs such as cisplatin or carboplatin, and taxane drugs, such as paclitaxel. These drugs are all off patent and are readily available at relatively low cost. In the event of relapse, the patient is generally subjected to subsequent courses of chemotherapy and/or radiation therapy.

There are several products in clinical development for the treatment of ovarian cancer. These include new chemotherapeutic agents and products targeting the immune system such as vaccines and antibody therapies. Antibodies are forms of passive immunotherapy and offer greatest benefit when they influence tumour growth. Avastin, an antibody already approved for the treatment of colon cancer has recently completed a study in ovarian cancer patients in remission. There was no survival benefit of using the

drug and remission was prolonged on average just over three months. There is one competitive dendritic cell based technology under development by Dendreon that has completed a Phase I clinical trial targeting her-2/neu for breast cancer.

Several of the immunological approaches under development may compete with Cvac™ as immunological approaches are generally aimed at preventing relapse and metastases. New cytotoxic compounds are unlikely to compete with Cvac™ as they are generally used as acute first and second line therapeutic agents. These products are also likely to have significant side effects associated with them consistent with existing chemotherapeutic agents.

Potential Advantages

Cvac™ is being developed as a maintenance therapy. Maintenance therapy is a medical therapy that is designed to help a primary treatment succeed. We believe Cvac™ is most likely to be administered post surgery and chemotherapy to prevent relapse and spreading of the cancer. We believe the competitive advantage is created through two key areas, the therapeutic approach of pulsing dendritic cells to generate an immune response to an antigen on the tumour cell's surface, and the lack of toxicity of Cvac™. There are currently no marketed products for ovarian cancer patients in remission.

To date, the toxicity profile of Cvac™ has been favourable with no dose limiting toxicity as seen with cytotoxics. Cytotoxics are drugs capable of inducing the death of tumour cells, but are highly toxic to humans and have serious adverse side effects. Cvac™ is designed to be an active immunization approach compared to anticancer antibodies (passive immunization) and this could lead to a broader immune response which may assist a therapeutic response. Mucin-1 is expressed on over 90% of epithelial ovarian tumours and thus provides a target for the majority of ovarian cancers. Dendritic cell processing of antigens is immunostimulatory, or the active stimulation of the immune system) whereas many of the therapeutic antibodies produce an immune response to themselves, leading to tolerance and thus declining in effectiveness over time. Dendritic cell therapy is administered by intradermal injection which takes place in minutes whereas cytotoxics and antibodies are administered by intravenous infusion which is time consuming and needs nursing support. Cvac™ uses a recombinant mucin-1 that has cost advantages over therapeutic antibodies.

Clinical Development History

In 2001, a Phase Ib clinical trial in patients with advanced adenocarcinoma was initiated. Adenocarcinoma is a cancer of epithelia originating in glandular tissue. Epithelial tissue includes, but is not limited to, the surface layer of skin, glands and a variety of other tissue that lines the cavities and organs of the body. The trial was conducted at Austin Health, Melbourne, Australia. The aim of this trial was to demonstrate that the adoptive transfer of autologous antigen presenting cells that have

been cultured *ex vivo* with mannan-MUC1 (M-FP) vaccine could increase antigen presentation resulting in a superior immune response to MUC1 in patients with advanced adenocarcinoma.

In 2003, the Phase Ib safety trial of Cvac™ was completed. The trial enrolled 14 patients with various forms of advanced cancer. There were no adverse side effects recorded in any patients and all patients exhibited the desired immune response to the vaccine, demonstrating that the therapeutic approach had been successfully translated from the preclinical to the clinical setting. The results of this trial were published in *Clinical Cancer Research* in February 2006.

The Phase Ib clinical trial achieved all predefined objectives. All patients demonstrated mucin-1-specific T-cell responses within a 12 week period, and those monitored at 6 and 12 months demonstrated sustained immunity in laboratory tests. Three patients continued on treatment under the Special Access Scheme and no further data was collected. The vaccination procedure, using either fresh or frozen dendritic cells cultured *ex vivo* with Cvac™, was shown to induce T-cell immunity.

In July 2004, we commenced a Phase IIa trial of Cvac™ in ovarian cancer patients with progressive disease in Melbourne, Australia. The aim of this Phase IIa trial was to determine whether dendritic cell therapy with Cvac™ can lead to clinical responses or stabilization of disease, as determined by serum CA-125 in subjects with adenocarcinoma of the ovary. CA-125 is a biomarker to correlates to patient tumour burden. Cvac™ was delivered to subjects via 3 injections over a 10 week period, followed by booster injections every 10 weeks for a total of 7 treatments over 12 months.

In 2006, the Phase IIa Cvac™ trial was completed with the results reported in March 2007. Twenty-one of the 28 enrolled late stage patients with progressive ovarian cancer, demonstrated by rising CA-125 upon trial entry, were eligible to participate in the clinical efficacy evaluation. Cvac™ demonstrated a positive clinical response or stabilization of disease in four of the twenty-one patients (19%; CI 5.4 - 41.9%) based on changes in CA-125. Overall, Cvac™ was well tolerated by subjects. There were no serious adverse events that were definitely or probably related to Cvac™ treatment. There was one patient who experienced two serious adverse events (flu-like symptoms and abdominal pain) that were assessed as possibly related to Cvac™. There were no deaths on study that were attributed to Cvac™.

All subjects who were assessed as having stable disease remained stable at the end of the trial. Twenty-one of the 28 patients had progressed by the end of the study: either due to progression on the basis of CA-125, clinical progression or death. The median progression-free survival was 127 days. Fourteen subjects had died by the end of the study as determined by telephone contact with the subjects family or physician.

We subsequently held a pre-IND, meeting with the FDA to discuss plans for U.S. clinical trials of Cvac™. We were able to clarify requirements for the filing of an IND application which was subsequently submitted in July 2009 to evaluate the Cvac™ ovarian cancer therapy vaccine. The trial is to be managed by leading gynaecological oncologists, recruiting patients in the United States and Australia.

In May 2010, we entered into an agreement with a leading German institute, the Fraunhofer Institute for Cell Therapy and Immunology in Leipzig, Germany, to produce our Cvac™ cancer immunotherapy product for our European clinical trials. In July 2010, the first patient was enrolled in the Phase IIb trial for Cvac™, completing a significant milestone for Cvac™.

In September 2010, we received Orphan Drug Designation from the FDA for Cvac™ in the ovarian cancer indication.

While we prepare for further clinical studies of Cvac™, selective patient treatment for ovarian cancer patients using CvacTM continues in Australia, through the TGA's Special Access Scheme.

Clinical Development Strategy

In February 2010, we initiated under an IND application with the FDA a Phase IIb clinical trial in the United States and Australia. The study is a randomized, open-label trial evaluating the safety and efficacy of Cvac™ given as a single agent for epithelial ovarian cancer, or EOC, that is in first or second clinical complete remission.

A total of 60 patients will be recruited for the trial. As new manufacturing procedures have been developed since completion of the phase IIa clinical study the first six subjects enrolled to this study are to be treated in an open-label fashion with comparator analyses performed between clinical sites in the United States and Australia. An additional 54 subjects will be enrolled through an open-label, randomized fashion to compare efficacy and safety events of Cvac™ versus standard of care. Subjects randomized to the standard of care arm will not undergo leukopheresis but will be followed for progression and overall survival.

The rationale for this trial is based upon the observation of prolonged disease stabilization that was observed in the Phase IIa trial of Cvac™. EOC patients who are in remission after first or second-line chemotherapy are good candidates for an immunotherapy approach such as Cvac™ which offers an opportunity for a prolonged remission status. Therefore progression free survival is an appropriate measure of efficacy in the proposed randomised study for EOC patients who are in clinical complete remission. Additionally, the impact on overall survival is also being assessed

Primary objectives of the study are to confirm the safety of administering Cvac™ in EOC patients who are in first or second complete remission following platinum-based chemotherapy and to determine the effects of the vaccine on progression free survival. Secondary objectives are to determine overall survival for recurrent ovarian cancer subjects who receive Cvac™ after achieving remission in the first or second line setting and evaluation of host immunologic response to Cvac™ administration.

In February 2011, we announced that the first seven patients in the Phase IIb trial had completed the first treatment cohort with Cvac™.

In addition to the Phase IIb trial outlined above, a double blind placebo controlled Phase II/III study is being designed to explore progression free survival and overall survival in patients with ovarian cancer. This study will be conducted in multiple countries in Europe, and in the United States and Australia. In February 2011, we announced that we had reached agreement with the European Medicines Agency for the strategy and design of this study. The study should commence enrolling patients in the third quarter of 2011

Cripto-1 Therapeutic Antibodies

Product Candidates

Humanized therapeutic antibodies targeting the cripto-1 protein on cancer cells.

Target Product Profile

Specific cancer targets are yet to be identified due to the early stage of product development; however, we believe the most likely market will be solid tumours.

Market Opportunity

The market leaders in therapeutic antibodies for the treatment of solid tumours are Genentech Inc.'s colorectal, breast and non-small cell lung cancer treatment Avastin (bevacizumab) and the HER2+ breast cancer treatment Herceptin (trastuzumab).

Competition

We believe Biogen Inc. is our main competitor. Biogen is developing a cripto-targeting humanized monoclonal antibody with ImmunoGen Inc.'s cell-killing agent, DM4, attached. According to public statements by Biogen, this product candidate is currently in Phase I clinical testing.

Preclinical Development

The antigen cripto-1 is classified in the epidermal growth factor (EGF-CFC) family of proteins and is involved in the development and progression of various human carcinomas. The over-expression of cripto-1 on cancer cells relative to normal healthy cells suggests it contributes to cancer cell growth. In particular, cripto-1 expression has been detected in 50% to 90% of carcinomas of the colon, pancreas, stomach, gallbladder, breast, lung, endometrium and cervix. Cripto-1 also appears to have a role in the metastasis or migration of cancers.

In 2003, Oncomab entered into a Collaborative Research and Development Agreement with Medarex, Inc. to develop human antibodies to the cancer target cripto-1. The agreement provided for sharing of development costs and future revenue from the program and included a development plan to complete all activities required to submit an IND for a phase I clinical trial.

The ARI produced three rat monoclonal antibodies (mAbs) to a region unique to cripto-1. Binding of the mAbs to this region results in apoptosis, or cell death, in cell-based assays and the inhibition of tumour growth or eradication of tumours in mice. A manuscript describing the development of the rat antibodies to cripto-1 was published in *Cancer Research* in 2004.

The mAbs inhibit cancer cell growth in vitro, and this effect was greater with cytotoxic drugs such as 5-fluorouracil, epirubicin, and cisplatin. The anti-cripto mAbs prevent tumour development *in vivo* and inhibit the growth of established tumours of colon xenografts (a transplantation of colon cancer in mice) in immunocompromised mice. The mechanism of inhibitory effects of the cripto mAbs includes cancer cell apoptosis.

In August 2010, we announced the termination of the agreement with Medarex (now owned by Bristol Myer Squibb) to develop a human antibody to cripto-1 and an agreement with Bioceros, based in the Netherlands, to humanize the original rodent antibodies, previously developed by the ARI and tested by Oncomab as potential cancer therapeutics, as an alternative strategy to the development of a therapeutic candidate. A preclinical development program has been initiated with the view, if the program is successful, of filing an IND with the FDA or equivalent application in 2013.

Oral Vaccines

We embarked on a new development program late in 2009 to develop an oral delivery system for vaccines for cervical cancer. The project involves collaboration between us, The University of New South Wales under the leadership of Prof. Neil Foster and University of Queensland under the leadership of Prof. Ian Frazer.

Oral delivery of vaccines is attractive as it does not involve the fear and pain associated with parenteral injection which often leads to poor patient compliance and compromised therapeutic effects. The advantages of oral delivery include the benefits of prolonging drug action thus reducing side effects, improved patient compliance maximizing the therapeutic outcome, improved storage options making delivery to developing markets possible and potential cost effectiveness. Despite these benefits few orally administered vaccines exist. There are several reasons for the current lack of a generic technology for oral vaccine delivery including:

- harsh conditions in the gastrointestinal tract resulting in vaccine degradation and reduced half life;

- inefficiencies in the absorption and presentation to appropriate cells of the immune system often requires administration of large doses; and
- recognition of the vaccine antigens as food/flora resulting in oral tolerance of vaccines instead of eliciting protective immune responses.

To eliminate or ameliorate these problems a controlled release formulation for vaccines would be desirable. The overall aim of this program is to develop novel techniques for the preparation of vaccines with controlled release characteristics – in particular those suitable for oral delivery. In this program the feasibility of utilizing dense gas anti-solvent techniques for the encapsulation of vaccines with a stimulus responsive biocompatible/biodegradable polymer will be investigated. The aim is to produce a vaccine formulation that is entirely coated in a stimulus responsive biocompatible/biodegradable polymer, and to engineer the formulation such that the release of the vaccine conforms to a desired release profile.

We have initiated a three year development program to obtain proof of concept for an oral HPV vaccine. Initially multiple formulations will be created using Bovine Papilloma Virus before translating the research to HPV. Proof of concept will require equivalent immunogenicity to the parenteral HPV vaccine in animal models, prior to undertaking a human development program. We believe at this time that we will seek a development partner for the vaccine.

Regulatory Authorities

United States

Government oversight of the pharmaceutical industry is usually classified into pre-approval and post-approval categories. Most of the therapeutically significant innovative products marketed today are the subject of New Drug Applications, or NDAs, or Biologics License Applications, or BLAs. Preapproval activities, based on these detailed applications, are used to assure the product is safe and effective before marketing.

In the United States, The Centre for Biologics Evaluation and Research, or CBER, is the FDA organization responsible for vaccines, blood and biologics evaluation and approval. Before approval, the FDA may inspect and audit the development facilities, planned production facilities, clinical trials, institutional review boards, and laboratory

facilities in which the product was tested in animals. After the product is approved and marketed, the FDA uses different mechanisms for assuring that firms adhere to the terms and conditions of approval described in the application and that the product is manufactured in a consistent and controlled manner. This is done by periodic unannounced inspections of production and quality control facilities by FDA's field investigators and analysts.

Federal Food, Drug and Cosmetic Act and Public Health Service Act

Prescription drug and biologic products are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, safety, efficacy, labelling, storage, record keeping, advertising and promotion of such products under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, and their implementing regulations. The process of obtaining FDA approval and achieving and maintaining compliance with applicable laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with applicable FDA or other requirements may result in refusal to approve pending applications, a clinical hold, warning letters, civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of the product from the market. FDA approval is required before any new drug or biologic, including a new use of a previously approved drug, can be marketed in the United States. All applications for FDA approval must contain, among other things, information relating to safety and efficacy, stability, manufacturing, processing, packaging, labelling and quality control.

Biologic License Applications (BLAs)

The FDA's BLA approval process generally involves:

- completion of preclinical laboratory and animal testing in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin in the United States;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations; and
- submission to and approval by the FDA of a BLA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot guarantee that any approvals for our product candidates will be granted on a timely basis, if at all. Preclinical tests include laboratory evaluation of toxicity and immunogenicity in animals. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Our submission of an IND may not result in FDA authorization to commence clinical trials. A

separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, covering each medical centre proposing to conduct clinical trials must review and approve the plan for any clinical trial before it commences at that centre and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice, or GCP, regulations, which include requirements that all research subjects provide informed consent and that all clinical studies be conducted under the supervision of one or more qualified investigators.

For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase I: Trials are initially conducted in a limited population to test the product candidate for safety and dose tolerance.

- Phase II: Trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the initial efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase III clinical trials.

- Phase III: These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites. Generally, replicate evidence of safety and effectiveness needs to be demonstrated in two adequate and well-controlled Phase III clinical trials of a product candidate for a specific indication. These studies are intended to establish the overall risk/benefit ratio of the product and provide adequate basis for product labelling.

- Phase IV: In some cases, the FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the product’s safety, purity and potency after BLA approval. Such post-approval trials are typically referred to as Phase IV clinical trials.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. Concurrent with clinical studies, sponsors usually complete additional animal studies and must also develop

additional information about the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Moreover, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical trials, along with the aforementioned manufacturing information, are submitted to the FDA as part of a BLA. BLA's must also contain extensive manufacturing information. Under the Prescription Drug User Fee Act, or PDUFA, the FDA agrees to specific goals for BLA review time through a two-tiered classification system, Standard Review and Priority Review. Standard Review is applied to products that offer at most, only minor improvement over existing marketed therapies. Standard Review BLAs have a goal of being completed within a ten-month timeframe, although a review can take a significantly longer amount of time. A Priority Review designation is given to products that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes the FDA to review a BLA is six months. It is likely that our product candidates will be granted Standard Reviews. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

The FDA may deny approval of a BLA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or additional pivotal Phase III clinical trials. Even if such data are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we do. Once issued, product approval may be withdrawn by the FDA if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, Risk Evaluation and Mitigation Strategies, or REMS, and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Products may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labelling or manufacturing processes or facilities, approval of a new or supplemental BLA may be required, which may involve conducting additional preclinical studies and clinical trials.

Other U.S. Regulatory Requirements

After approval, products are subject to extensive continuing regulation by the FDA, which include company obligations to manufacture products in accordance with GMP, maintain and provide to the FDA updated safety and efficacy information, report adverse experiences with the product, keep certain records and submit periodic reports, obtain FDA approval of certain manufacturing or labelling changes, and comply with FDA promotion and advertising requirements and restrictions. Failure to meet these obligations can result in various adverse consequences, both voluntary and FDA-imposed, including product recalls, withdrawal of approval, restrictions on marketing, and the imposition of civil fines and criminal penalties against the BLA holder. In addition, later discovery of previously unknown safety or efficacy issues may result in restrictions on the product, manufacturer or BLA holder.

We, and any manufacturers of our products, are required to comply with applicable FDA manufacturing requirements contained in the FDA's GMP regulations. GMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet GMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We, and any third-party manufacturers, are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting products for uses or in patient populations that are not described in the product's approved labelling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

Changes to some of the conditions established in an approved application, including changes in indications, labelling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase IV testing, risk mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

European Union

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, we must submit and obtain authorization for a clinical trial application in each member state in which we intend to conduct a clinical trial. After we have completed our clinical trials, we must obtain marketing authorization before we can market our product. We may submit applications for marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. If a member state objects to the approval, an arbitration process is initiated and the final decision is made by the European Commission on the basis of an opinion of the Committee for Proprietary Medicinal Products, or CHMP. The mutual recognition procedure may be used more than once for subsequent applications to other member states in relation to the same product candidate.

The European Medicines Agency, or EMA, is a decentralised body of the European Union located in London. The EMA is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. The EMA is involved in the scientific evaluation of medicines that fall within the scope of the centralized procedure. However, other medicines that do not fall within this scope are marketed in the European Union either in individual member states, in accordance with their national authorisation procedures, or in multiple member states through the decentralised or mutual-recognition procedures. The EMA only becomes involved in the assessment of such medicines when they have been referred to the EMA due to a

disagreement between two or more member states about the authorisation or use of the medicine, or due to some other issue that requires resolution in the interest of protecting public health.

Australia

In Australia, the relevant regulatory body responsible for the pharmaceutical industry is the Therapeutics Goods Administration, or TGA. Blood, blood components, plasma derivatives, tissue and cellular products, and tissue and cell based derivatives are regulated under the Therapeutic Goods Act 1989. In May 2010, the TGA began a 12month process to implement the framework for regulation of blood products. Although this framework is still being defined, it is expected to harmonize with EMA and FDA guidance.

Third-Party Payor Coverage and Reimbursement

Although none of our product candidates has been commercialized for any indication, if they are approved for marketing, commercial success of our product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels.

Manufacturing and Raw Materials

Cvac™

Manufacture of the Cvac™ vaccine requires a number of manufacturing processes to produce both raw materials and the final product. Manufacture of the Mucin-1 fusion protein conjugated to oxidised mannan, or MFP, a key starting material for Cvac™, is done by a qualified contract manufacturer in line with the principles of current Good Manufacturing Procedures. MFP is produced using a combination of commercially available raw reagents and cells from a working cell bank generated and owned by Prima BioMed. Supply of raw materials is reliable and the standard operating procedures used to produce the fusion protein are documented in master batch records. We believe the technology and know-how for MFP production can be readily transferred to another contract manufacturing organisation to produce the novel fusion protein as we own the know-how and recombinant protein sequences. Several organisations have been approached and could provide our manufacturing requirements.

The manufacture of Cvac™ is conducted on a patient by patient process and requires the use of fresh blood cells. It is currently necessary to establish country-specific centralized manufacturing to ensure product can be transported within acceptable time frames between the patient and the manufacturing sites. These are critical operational windows from patient to site, and vice versa, of less than 24 hours. Since the process must be performed for each individual patient, it is not possible to mass produce and stockpile the product in one location. It is a core requirement to have sufficient facilities, materials and staff available regionally to provide each patient product. Thus for the clinical trials of Cvac™, the manufacturing of the cells for injection has been contracted to Cell

Therapies Pty Ltd in Australia, Fraunhofer Institute for Cell Therapy and Immunology in Germany, and Progenitor Cell Therapy LLC in the United States. We have entered into manufacturing contracts with each of these parties which are described below. We believe these three organizations have sufficient capacity and regionally based coverage to address the clinical trial requirements for patients in Australia, Europe and the United States. Standard Operating Procedures for the production of Cvac™ have been produced and are closely aligned between processing facilities (minor adjustments may be required due to variations in equipment or facilities). Comparability testing between sites is also undertaken to ensure consistency of product manufacture across the three sites.

Currently we are undertaking a feasibility study to determine when automation of the Cvac™ manufacturing process should be implemented. Execution of this aspect of manufacturing will enable approval of the automated process by regulators and allow Prima BioMed to be ready for the potential commercialization and scale up of the Cvac™ production in a time and cost effective process.

We may not be able to secure such processes or facilities for Cvac™ in a timely manner for potential commercialization of Cvac™. We are evaluating expansion of the facilities of existing partners and/or engagement of new manufacturing facilities within or outside of the existing territories. We may also establish our own manufacturing facilities in order to address increased manufacturing requirements or to provide product to locations not currently accessible from the existing facilities.

Cell Therapies Pty Ltd

In October 2009, Cancer Vac entered into a Manufacture Agreement with Cell Therapies Pty Ltd, the commercial manager of the Peter MacCallum Cancer Centre's Centre for Blood Cell Therapies. Under this agreement, Cell Therapies will undertake all tasks required to assume manufacturing responsibility for the Australian arm of Cancer Vac's Phase IIb trial for Cvac™, and to maintain overall support for such trial program, including support as requested for the Unites States arm of such trial. Cancer Vac is required to pay Cell Therapies a monthly facility fee (A$78,000 per month for the initial terms of the agreement) and to reimburse, on a costs plus basis, certain costs incurred by Cell Therapies in performing the services. The initial term of this agreement is twelve months and may be extended by mutual agreement of the parties. This agreement has been extended by the parties following the initial term for an additional 36 months. Either party may terminate this agreement without cause upon advance notice, or immediately if such party reasonably determines the trial is not scientifically or ethically viable, or for the uncured material breach or bankruptcy of the other party.

Fraunhofer Institute for Cell Therapy and Immunology

In March 2010, Prima BioMed entered into an Agreement on the Tasks and the Division of Responsibilities in Contract Manufacturing of Investigational Medicinal Products with Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e. V.,

as legal entity for Fraunhofer Institute for Cell Therapy and Immunology IZI, or FhG/FhI. Under this agreement, FhG/FhI will provide manufacture and related services in support of Cvac™'s clinical trials in Europe, including technology transfer, application for manufacturing authorisation, comparability trials, and manufacturing of Cvac™ for clinical trials in Europe. The estimated total cost under this agreement is €1,271,000. Unless terminated earlier, this agreement will expire upon the completion of all services set forth therein. Either party may terminate this agreement without cause upon advance notice, or for the other party's uncured material breach.

Progenitor Cell Therapy LLC

In May 2009, Prima BioMed entered into a Services Agreement with Progenitor Cell Therapy, LLC. Under this agreement, Progenitor Cell Therapy will provide manufacture and related services in support of Cvac™'s clinical trials in the United States. Prima BioMed is required to make monthly payments to Progenitor Cell Therapy for the services, the amount of which varies from stage to stage of the project but is estimated to be approximately A$1.7 million. In addition, Prima BioMed will make certain fixed payments to Progenitor Cell Therapy upon completion of certain tasks (up to a total of A$62,000), and will reimburse, on a costs plus basis, certain costs incurred by Progenitor Cell Therapy in performing the services. Unless terminated earlier, this agreement will expire upon the completion of all services set forth therein. Prima BioMed may terminate this agreement without cause upon advance notice, and either party may terminate this agreement for the other party's uncured material breach.

Cripto-1

The cripto-1 antibody program involves the generation of humanised antibodies for treatment of cancer. The rat antibodies utilized as the source material for the humanisation program are stored frozen at the Burnet Institute (former ARI) in Melbourne, Australia and at Bioceros' facilities in the Netherlands. The project is classified as early stage research and development and there is no guarantee that commercial product will be generated.

Intellectual Property

Pivotal to the development and commercialization of our product candidate portfolio is intellectual property protection for the underlying technology and the product candidates. We currently hold exclusive worldwide licenses to five patent families from the Burnet Institute (formerly the ARI) and exclusive license rights to three patents from Biomira. The Burnet patents are being prosecuted worldwide in major market jurisdictions to maximize market coverage and underpin future incomes from commercialization and/or licensing agreements.

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 matters in biotechnology are highly uncertain and involve complex legal and factual questions. 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 Prima BioMed can obtain on some or all of its licensed inventions or prevent us from obtaining patent protection either of which could harm our business, financial condition and results of operations. Since patent applications are not published until at least 18 months from their first filing date and the publication of discoveries in the scientific literature often lags behind actual discoveries, we cannot be certain that we, or any of our licensors, were the first creator of inventions covered by pending patent applications, or that we or our licensors, were the first to file patent applications for such inventions. Additionally, the grant and enforceability of a patent is dependent on a number of factors that may vary between jurisdictions. These factors may include the novelty of the invention, the requirement that the invention not be obvious in the light of prior art (including prior use or publication of the invention), the utility of the invention, and the extent to which the patent clearly describes the best method of working the invention. In short, this means that claims granted in various territories may vary and thereby influence commercial outcomes.

While we intend to seek patent protection for its therapeutic products and technologies, we cannot be certain that any of the pending or future patent applications filed by the company, or licensed to us, will be approved, or that Prima BioMed will develop additional proprietary products or processes that are patentable or that we will be able to license any other patentable products or processes. Prima BioMed 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 the company or licensed to us, or design around the patents owned or licensed by us, or that any patents owned or licensed by us will provide us with competitive advantages.

Furthermore, we cannot be certain that patents held by third parties will not prevent the commercialization of products incorporating the technology developed by us or licensed to us, or that third parties will not challenge or seek to narrow, invalidate or circumvent any of the issued, pending or future patents owned or licensed by us.

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

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

Patent Portfolio

The following table presents our portfolio of patents and patent applications, including their status (as of May 23 2011) and a brief description of their respective inventions.

Patent Family	Title	Status	Expires
CANCERVAC			
Family 1			
Mannan fusion	Composition of matter patent - Mucin-Mannan conjugates, antigen carbohydrate compounds, or mucin-1 derived antigens and their use in immunotherapy.	Granted in Australia, Canada, Japan (x2), U.S. (x3), UK, Italy, France, Germany, Ireland.	2014
Family 2			
Mimics	Mucin -1 mimicking peptides and their use in cancer immunotherapy.	Granted in Australia, New Zealand, U.S., Japan, UK, Italy, France, Germany, and Switzerland. Application pending in Canada.	2016
Mucin -1 mimicking peptides and their use in cancer immunotherapy. Family 3			
Ex vivo cell therapy	Method of producing dendritic cells pulsed with MFP (family 1).	Granted in Australia, Austria, Belgium, Denmark, France, Germany, Italy, Ireland, Japan, Luxemburg, Spain, Sweden, Switzerland, Netherlands, and UK. Applications pending in the U.S. and Canada.	2018
Family 4			
Non-VNTR regions	New immunogenic regions of Mucin-1 and their use in cancer immunotherapy.	Granted in Australia and the U.S. Applications pending in Europe, Canada, and Japan.	U.S.: 2014 ROW: 2021
Biomira license patents	Human mucin core protein, antibodies and probes.	Granted in the U.S. (3 patents) and Canada.	2015
ONCOMAB			
Family 1			
Cancer Antibodies	Therapeutic cancer antibodies targeting cancer antigen, cripto-1.	Granted in Australia, China, New Zealand, South Korea, and the U.S. Applications pending in Canada, , Europe, Japan and the U.S.	2022

Material Contracts Related to Intellectual Property and Commercialization Rights
Cancer Vac

ARI License Agreement

In May 2001, a License Agreement between the Burnet (then the ARI) and its wholly-owned subsidiary Ilexus Pty Ltd and Prima BioMed and Cancer Vac Pty Ltd was executed. The agreement was amended in August 2005 and the amended rights applied retroactively to May 2001. The agreement provides Cancer Vac with the exclusive worldwide rights to conduct research and development and for the commercialization of the background technology, improvements to the background technology and research results arising from Cancer Vac's own development programs in respect of the background technology for the purposes of developing and commercializing *ex vivo* based mannan adjuvant based therapeutics for the treatment of cancer. The rights extend for the duration of the patents/patent applications and include the right to sublicense, sell the assets or merge the company. In return, the Burnet receives a single digit royalty on any income received by Cancer Vac through the commercialization of the background technology, improvement or research results.

Unless terminated earlier, this agreement will continue in force for the duration of the patents/patent applications. Either party may terminate this agreement upon written notice to the other party for the other party's uncured material breach, bankruptcy or cessation of business.

Biomira License Agreement

In March 2004, a License and Development Agreement was executed between Prima BioMed, Cancer Vac Pty Ltd and Biomira Inc. A Deed of Variation was executed in February 2007. The 2004 agreement provided Cancer Vac with exclusive rights for the use of mucin-1 in *ex vivo* therapy for the treatment of cancer and provided Biomira with an option to elect to secure commercialization rights for CvacTM. In February 2007, Biomira elected to forego their option to commercialise CvacTM thus Cancer Vac retains full commercialization rights in respect of CvacTM and freedom to operate in regard to mucin-1 under the existing license. The agreement is a sublicence of Cancer Research Technology Limited, or CRTL, whom has granted Biomira a licence over mucin-1 antigen technology.

The sublicense permits Cancer Vac to use, develop, market, promote, distribute and sell CvacTM for the treatment of cancer worldwide. It was established in the interest of forming an arrangement allowing the development and commercialization of CvacTM for delivery via *ex vivo* dendritic cells.

The term of the sublicense granted remains in force on a product-by-product and country-by-country basis until the later of:

- the patent claims in a given territory expire; or
- the expiration of exclusivity periods of a given product in a given country, where exclusivity period is defined as secured by either patent protection or extension, or a regulatory marketing exclusivity such as orphan drug status etc.

We have certain milestone obligations (up to a total of US$8.5 million) and royalty obligations (from middle single digit to middle teens) to Biomera as CvacTM continues development and if it is commercialized. Cancer Vac has the right to grant one or more sub-licenses outside of North America without the prior consent of Biomira and CRTL.

Unless terminated earlier, the Biomira agreement will continue in force on a product-by-product and country-by-country basis until the expiration of all relevant patents and exclusivity periods covering the product. Either party may terminate this agreement upon written notice to the other party for the other party's uncured material breach, bankruptcy or cessation of business.

Oncomab

ARI License Agreement

In November 2002, a License Agreement between the ARI and its wholly-owned subsidiary Ilexus Pty Ltd and Prima BioMed and Oncomab Pty Ltd was executed. The agreement was amended in August 2005 and the varied rights applied retroactively to November 2002. The agreement provides Oncomab with the exclusive worldwide rights to conduct research and development and commercialization of the background technology, improvements to the background technology and research results arising from Oncomab's own development programs in respect of the background technology for the purposes of developing and commercializing cripto-1 antibodies for the diagnosis and treatment of cancer. The rights extend for the duration of the patents/patent applications and include the right to sublicense, sell the assets or merge the company. In return, the ARI receives a single digit royalty on any income received by Oncomab through the commercialization of the background technology, improvement or research results.

Unless terminated earlier, this agreement will continue in force for the duration of the patents/patent applications, and in the case of non-patented technology, until the later of the date the last patent expires or March 26, 2021. Either party may terminate this agreement upon written notice to the other party for the other party's uncured material breach, bankruptcy or cessation of business.

Bioceros Research and Development Partnership Agreement

In August 2010, Prima BioMed and Bioceros B.V. (the Netherlands) entered into a Research and Development Partnership Agreement for the development of cripto-1 therapeutic antibodies. Prima BioMed has provided access to its cripto-1 intellectual property to Bioceros to allow it to develop a potential therapeutic antibody to cripto-1. Bioceros has provided access to its intellectual property in respect of antibody production and manufacturing processes and techniques. Collectively the parties aim to generate a potential therapeutic antibody with certain pre-clinical research and development responsibilities undertaken by Bioceros. Prima BioMed has an option to buy out Bioceros' interest in the program. If Prima BioMed timely exercises the option,

we will pay Bioceros a buyout amount that is calculated based on the development costs incurred by Bioceros, and this agreement will terminate upon the exercise of the option. If Prima BioMed does not exercise the option, the parties may jointly develop and commercialize the product developed from the program pursuant to a joint venture agreement, in which case this agreement will terminate upon the execution of the joint venture agreement. The financial provisions of the joint venture agreement would allow for sharing of the development costs and commercialization returns based on pre-agreed terms and respective contributions to the overall program, with Prima Biomed bearing the majority of the development costs and receiving the majority of the commercialization returns.

This agreement will continue in force indefinitely until terminated pursuant to its terms. Either party may terminate this agreement for certain technical failure, the other party's bankruptcy or uncured material breach, or certain force majeure event affecting the other party. In addition, either party may also terminate this agreement within certain time period if Prima BioMed's option expires unexercised.

Oral Vaccines

NewSouth Innovations Collaboration Research Agreement

In December 2009, Prima BioMed entered into a Collaborative Research Agreement with NewSouth Innovations Pty Ltd, the commercial entity of the University of New South Wales. The purpose of the agreement is to conduct a research program for the development of oral vaccines and includes an option for Prima BioMed to commercialize the outcomes of the research program. NewSouth Innovations will conduct the research program with both parties providing any required background intellectual property under a non-exclusive royalty free license for the purposes of conducting research. The research program is funded by Prima BioMed and an Australian Research Council, or ARC, Linkage Grant awarded in 2009. Prima BioMed has the option during the research project term and for six months post completion of the term to secure an exclusive license to the project intellectual property for the purposes of commercializing the project intellectual property on pre-agreed terms. If we timely exercise the option, we will have certain milestone obligations (up to a total of A$10 million per application licensed) and royalty obligations (high single digit to low double digit) to NewSouth Innovations. In addition, if we grant sublicenses under our license from NewSouth Innovations, we will pay NewSouth Innovations a portion of any upfront payments we receive from any such sublicensees.

This agreement has expired on 1 January, 2011, and our option will expire on 1 July, 2011.

A. Organizational Structure

We established four subsidiaries in Australia, as we initially conducted research and development activities via our subsidiaries:

- Cancer Vac Pty Ltd (wholly-owned, for the development of CvacTM ovarian cancer therapy);
- Oncomab Pty Ltd (wholly-owned, for the development of monoclonal antibodies);
- Panvax Pty Ltd (wholly-owned, for the development of vaccine technology); and
- Arthron Pty Ltd (99.99% owned, for the development of anti-inflammatory therapies).

Commencing July 2010, we no longer conduct our research and development activities via our Australian subsidiaries. As a result, all of the Australian subsidiaries are currently inactive.

In October 2009, Prima BioMed Europe Limited, a 100% owned subsidiary of Prima BioMed Ltd was incorporated in the United Kingdom. This subsidiary is inactive. In April 2010, Prima BioMed USA Inc, a 100% owned subsidiary of Prima BioMed Ltd was incorporated in the United States. In May 2011, Prima BioMed GmBH, a 100% owned subsidiary of Prima BioMed Ltd was incorporated in Germany and also in May 2011, Prima BioMed Middle East FZLLC a 100% subsidiary of Prima BioMed Ltd was incorporated in the United Arab Emirates. These subsidiaries were established to allow us to conduct commercial and clinical operations in Europe, the United States and the UAE.

B. Property, Plants and Equipment

We own computer equipment, office furniture and laboratory equipment, the major item being a Cobe Spectra that is being used for manufacturing CvacTM.