

Developing the world's first Ovarian Cancer Therapeutic Vaccine

Investor Presentation May 2011





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The statements in this presentation regarding the future and commercial prospects of Prima including statements regarding the efficacy of CVac™, the timetable and success of clinical trials and the potential market for CVac™ are forward looking and actual results could be materially different from those expressed or implied by such forward looking statements as a result of various risk factors. This presentation contains certain "forward-looking statements". Forward looking words such as, "expect", "anticipate", "believe", "likely", "intend", "should", "could", "may", "plan", "will", "forecast", "estimate", "target", "aim" and other similar expressions are intended to identify forward-looking statements. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this presentation are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions.



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Overview of the Placement

Placement offer size

- Approximately \$18 million placement to sophisticated and professional investors
 - Up to 64.3 million shares offered
 - Representing approximately up to 7.9% of issued share capital

Placement offer price

- Fixed offer price of \$0.28 per share
 - 16.4% discount to Prima's closing price
 - 18.8% discount to Prima's 5-day VWAP

Timing

- Book opens at 10am, Wednesday, 25 May 2011
- Book closes at 5pm, Wednesday, 25 May 2011
- Settlement and Allotment on Tuesday, 31 May 2011

Ranking

- The new shares issued pursuant to the Placement and the SPP (New Shares) will rank equally with Prima's existing shares

Underwriting

- The placement will not be underwritten

Use of proceeds

- Funds raised will be used by the Company for its ongoing development of the Cvac™ immunotherapy ovarian cancer vaccine*, including its Phase III clinical trials, and also to provide working capital for the company

Note: Investors should refer to the risk section (Appendix I) before making any investment decision

** The effectiveness of the vaccine is still subject to the outcome of further testing*

CellTherapy - A new paradigm for the treatment of cancer





Overview of the Share Purchase Plan

Eligible shareholders

- Open to eligible Australian and New Zealand shareholders registered at the record date of Tuesday, 24 May 2011

SPP offer

- Subscriptions may be up to a value of approximately \$15,000 in Prima shares

Size

- Raising approximately \$20 million before costs, with the ability to accept applications in excess of that amount

SPP offer price

- SPP offer price to be equal to the Placement price of \$0.28 per share

Timing

- SPP offer opens Friday, 3 June 2011
- SPP offer closes 5pm (AEST) Friday, 24 June 2011

Other

- No brokerage or transaction costs
- Further details will be sent to eligible shareholders shortly



Indicative timetable

Key dates - Placement

Announcement and trading halt	Wednesday, 25 May 2011
Book opens	10am, Wednesday, 25 May 2011
Book closes	5pm, Wednesday, 25 May 2011
Prima shares re-commence trading	Thursday, 26 May 2011
Placement settlement and allotment date	Tuesday, 31 May 2011
New Placement shares commence trading	Wednesday, 1 June 2011

Key dates - SPP

Record Date for determining entitlement to participate in SPP	Tuesday, 24 May 2011
SPP offer materials despatched to eligible shareholders	Monday, 30 May 2011
SPP offer opens	Friday, 3 June 2011
SPP offer closes	5pm, Friday, 24 June 2011
Settlement of SPP shares	Wednesday, 29 June 2011
Allotment of SPP shares	Thursday, 30 June 2011
New SPP shares commence trading	Friday, 1 July 2011



About Prima Biomed

Prima BioMed (ASX:PRR) is a biotechnology company focused on **developing new oncology therapies**

Ovarian cancer has one of the lowest survival rates of all gynaecological cancers. CVac™ may address the huge unmet medical need for treatment of ovarian cancer

Prima's extensive **intellectual property portfolio** originates from the Austin Research Institute, Melbourne, Australia(now the Burnett institute)

The Company's **strategy is to commercialize CVac™**

The addressable market for CVac™ could exceed A\$1.5 billion per indication*

Other products in the development pipeline at an earlier stage of development include:

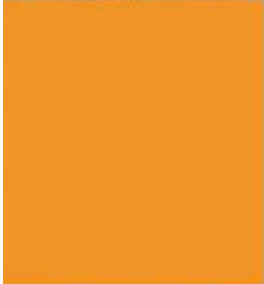
- Oral HPV vaccine** created using dense gas technology
- Humanized monoclonal antibody targeting Cripto-1

* Morgan Joseph and Roth Capital

**The effectiveness of the vaccine is still subject to the outcome of further testing

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Executive Leadership

- **Mr Martin Rogers, CEO**
 - Extensive business management experience and scientific background
- **Mr Ian Bangs, CFO**
 - CFO and company secretary for several publicly traded ASX companies
- **Dr Neil Frazer, CMO**
 - Former Glaxo, 25 years drug development experience including 10 FDA approvals
- **Amy Brewer, US Project Manager**
 - Has several years of pharmaceutical project management at SPRI (contract research organisation)
- **Dr Sharron Gargosky, SVP CVac™ Program**
 - 3 previous successful Orphan Drug approvals with FDA
- **Mr Matthew Lehman, COO**
 - Has experience in execution of over 100 clinical trials

CVac™ - Lead Program*



- CVac™ is an autologous, dendritic-cell (DC) based therapy or cancer vaccine**
- CVac™ is currently in the clinic with a third clinical study ongoing
- Results from phase I (9 evaluable patients) and phase IIa (21 evaluable patients) trials were very promising
- Ongoing phase IIb (60 patients) and upcoming phase III (800 patients) trial may provide further proof of concept for global registration
- If CVac™ progresses to full commercialisation, CVac™ could capture a significant share of the multi-billion dollar ovarian cancer treatment market

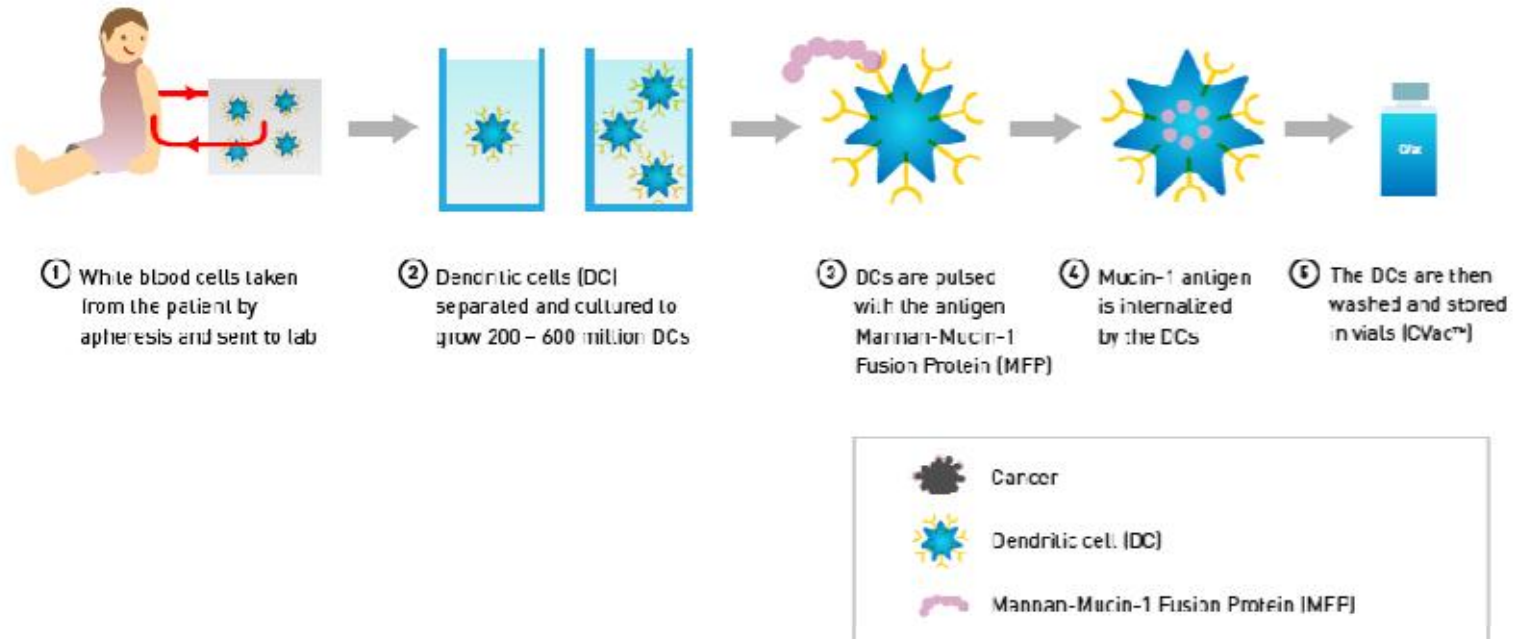
**Please refer to risk section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision*

*** The effectiveness of the vaccine is still subject to the outcome of further testing*



How CVac™ Works*

Manufacturing of CVac

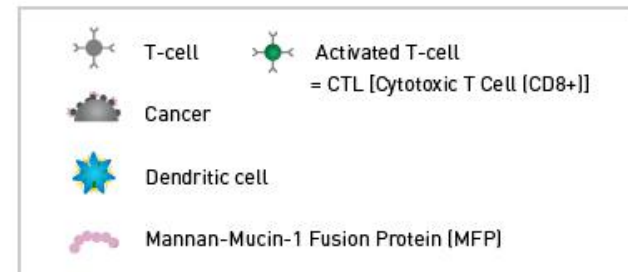
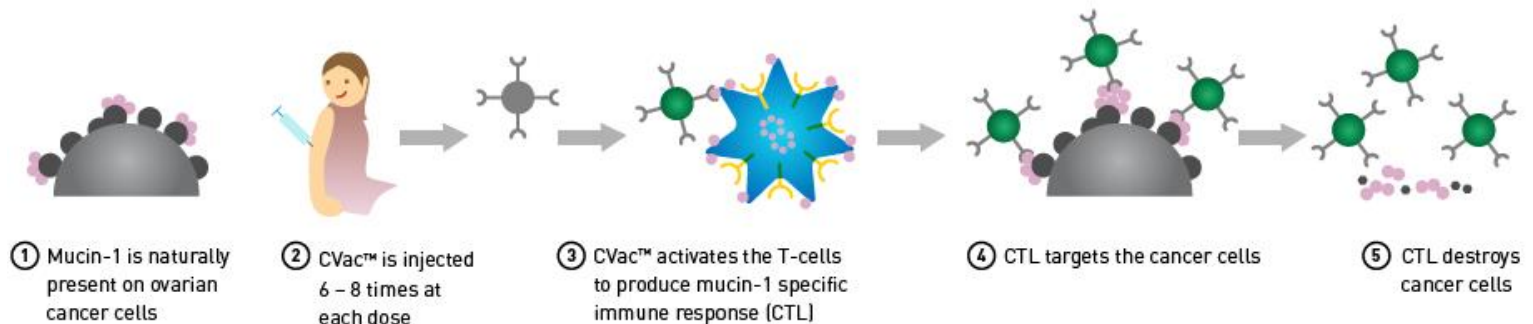


**Based on initial clinical trials only, and is subject to further trials and testing. Please refer to risk section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision*

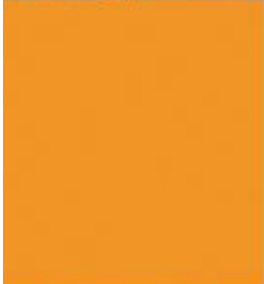


How CVac™ Works*

Mechanism after injection



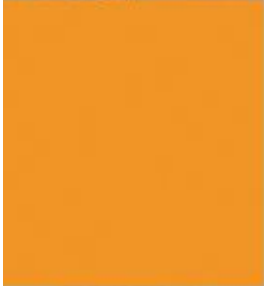
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Demand for CVac™

- The global market size for ovarian cancer therapy was estimated to be **US\$3.6bn in 2010***
- Each year **73,000 women** are diagnosed with ovarian cancer in the US, Europe, Australia and Japan and **318,000 women globally***
- Since ovarian cancer is generally diagnosed at a late stage, only 20-30% of patients with late stage disease survive for 5 years*
- A maintenance style treatment like CVac™ would be the first of its type in the market and the company has potential to achieve market penetration within the first year

** Thomson Business Intelligence, Ovarian Cancer Therapeutics Industry Analysis 2007*



Demand for CVac™

- Median progression free survival after optimal surgery and chemotherapy is only 22 months
- Non-toxic nature of CVac™ will make it attractive for the oncologist to prescribe
- **Analysts reviewing the market based on Dendreon Corp. forecasts predict the market size could be greater than US\$1.5Bn per indication***
- Subject to the outcome of additional clinical trials, CVac™ may have an indication in several additional mucin-1 positive cancers

**Morgan Joseph and Roth Capital*

CVac™ - Lead Program



- CVac™ could revolutionize treatment for tumors that over-express mucin-1*
- Ovarian cancer, the first target, has the highest mortality of all gynecological cancers
- Drugs used for treatment of ovarian cancer have not changed in over a decade
- CVac™ has the potential to alter the treatment paradigm by prolonging periods of ovarian cancer remission with very low toxicity potential



**Based on initial clinical trials only. Please refer to risk section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision*



Clinical Evidence to date Demonstrates Disease Modification*

- **Phase Ib - CVac™**
 - 14 patients (9 evaluable) with terminal cancer (3-6 months life expectancy), broad range of adenocarcinomas including renal, breast, ovarian, fallopian tube, colon, lung and oesophageal
 - Objectives:
 - Primary: assess toxicity
 - Secondary: assess anti-tumor efficacy, immune response and procedure feasibility

**Based on initial clinical trials only. Please refer to risk section (Appendix I), in particular risk 3, as to the status and significance of clinical trials before making any investment decision*



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Clinical Evidence to date Demonstrates Disease Modification

- Results:
 - No treatment related toxicity
 - All 14 patients produced desired cellular immune response
 - Patient's cells were successfully cryopreserved
 - Of 9 evaluable patients, 4 had stable disease during the assessment period of one year
 - 2 patients received ongoing therapy for >40mths



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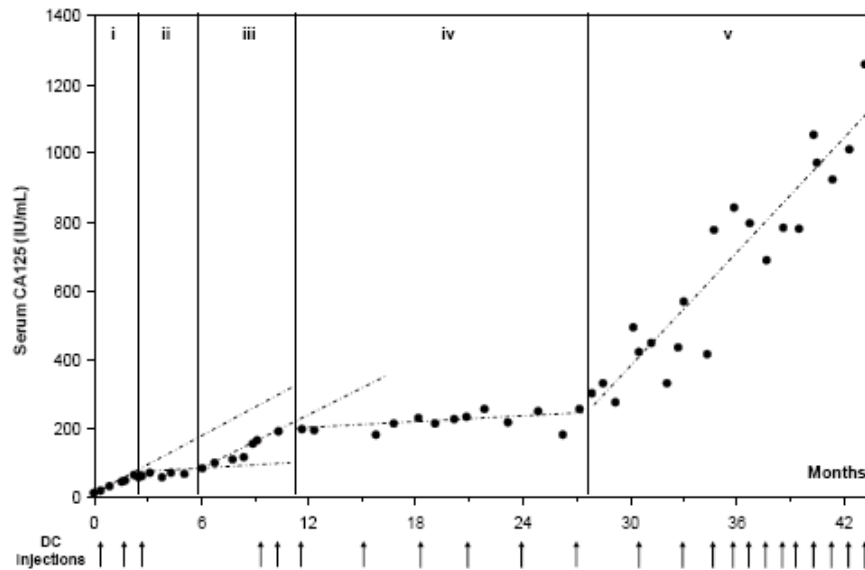
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Why target Ovarian cancer?

Cvac™ targets ovarian cancer, a disease with a very low five year survival and late stage detection

Example: Stage III ovarian cancer patient

- Incurable recurrent disease, diagnosed by elevated CA125 marker
- CVac™ treatment demonstrates stabilization of CA125, initially for 4mths, then for a further 18mths post further injections of CVac™



Stable disease

4mths

18mths

Phase IIa Trial Demonstrates* Disease Stabilization



CVac™ results – 21% of patients responded to therapy

- **Protocol:** Enrolled 28 patients (21 evaluable) with incurable ovarian cancer (life expectancy at least 6 months), and rising CA125 levels defined as at least 25% over baseline within one month confirming rapidly progressing disease. Patients had received multiple courses of chemotherapy/ radiotherapy
- Patients received 3 injections of CVac™ over a ten week period, followed by 4 injections at 10 week intervals
- **Objectives:**
 - **Primary:**
CA125 response or stabilization in at least 15% patients
 - **Secondary:**
Disease progression-free survival, immune response and safety

**Based on initial clinical trials only. Please refer to risk section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision*

Phase IIa Trial Demonstrates* Disease Modification



CVac™ results – 21% of patients responded to therapy (CA-125 reduction or prolonged stabilization) and 47% of patients had disease stabilization (CA-125 remained stable)

- **Results**

- No Cvac™ therapy-related toxicity
- Ovarian tumors respond to therapy with CA125 reduction or stabilization
- Progression Free Survival averaged 127 days (95% confidence limits 96 to 219 days)

**Based on initial clinical trials only. Please refer to risk section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision*



Clinical Trial Program*

- **Phase I and IIa** (30 evaluable patients) trials indicate CVac™ could be a strong candidate for treatment of ovarian cancer patients in remission and for other MUC-1 over-expressing tumors
- **Ongoing Phase IIb** trial (60 patients) for ovarian cancer patients after successful 1st or 2nd line therapy is recruiting patients in USA and Australia in order to:
 - Assure comparability of multiple manufacturing centers
 - Confirm safety and tolerability established in earlier trials
 - Compare CVac™ to standard of care in terms of progression-free survival (PFS)
 - Confirm host immunologic response to CVac™ therapy

**Based on initial clinical trials only. Please refer to risk section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision*



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CVac™ - Phase III Study design

- **Phase III** trial for **ovarian** cancer patients in remission planned to commence by 3rd Quarter 2011 (Europe, USA, Australia):
 - 800 patients randomized, double-blinded, well-designed efficacy trial
 - Definitively establish survival benefit – progression free survival (PFS) and overall survival (OS)
 - Assess quality of life and pharmacoeconomic parameters
 - Expected to support marketing authorizations globally
 - Interim data analysis set for Q4 2012-Q1 2013
 - Final data set for Q4 2013 – Q1 2014
 - Event driven study giving the interim analysis to allow flexibility to adjust for registration end point



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Value Drivers – Key Prima Biomed Attributes

- If proven clinically successful CVac™ could address a major global unmet medical need
- Depth and experience in management for drug approval
- Global ovarian cancer treatment market estimated to be worth US\$3.6b in 2010, and Cvac™
- FDA accepted the Investigational New drug (IND) application in 2009
- Phase IIb study (60 patients) recruited first patients Q3 2010 and is expected to complete in Q3 2011



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Value Drivers – Key Program Attributes

- Phase IIb trial leadership from prestigious Fred Hutchinson Cancer Centre in Seattle and Stanford Medical Centre in the USA <http://www.investorcalendar.com/IC/CEPage.asp?ID=163542>
- **Progressing clinical studies of world's first ovarian cancer vaccine*, CVac™**
- Pursuing global fast-track commercialisation
- Phase III study (800 patients) to be conducted in Europe, US and Australia and New Zealand commencing recruitment by Q3 2011
- Full patient recruitment for the phase III study (800 patients) expected by Q4 2012

Please refer to risk section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision

** The effectiveness of the vaccine is still subject to the outcome of further testing*

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Value Drivers – Key Program Attributes

- Highly experienced scientific advisory team including Prof. Ian Frazer, co-inventor of Merck/CSL's cervical cancer vaccine, Gardasil™
- Experienced pharmaceutical sector expert Dr Neil Frazer appointed Chief Medical Officer to oversee CVac™ clinical trials
- Prima BioMed Ltd has a pipeline of earlier stage oncology products which are under investigation
- Company in solid financial position*

** Based on cash position and current cash burn*

Note: Refer to risks section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision

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Clinical Leader Opinions

Further commentary is available from key opinion leaders

- Dr. Jonathan Berek, MD
 - Stanford Medical Centre, Head of Women's Cancer Centre
<http://www.investorcalendar.com/IC/CEPage.asp?ID=163542>
- Prof. Ian Frazer, MD
 - University of Queensland, Diamantia Centre for Immunology
- Dr. Heidi Gray, MD
 - Fred Hutchinson Cancer Centre, University of Washington



Anti-Cripto-1 Mab (early development)

- Prima has raised various murine and human monoclonal antibodies (Mabs) recognizing the EGF-CFC family member named Cripto-1
- Human Cripto -1 is a M_r 36,000 molecule. Cripto-1 is also an oncogenic growth factor that is involved in cancer cell proliferation and metastasis
- The Mabs inhibit tumor growth *in vitro* of most cancers of the breast, colon, lung, stomach and pancreas but only exhibit a weak reaction with normal tissues. The effects of the cripto-1 Mab were greater in the presence of cytotoxic drugs such as 5-fluorouracil, epirubicin, and cisplatin

Plan of Action:

1. Update with Anti-Cripto-1 Mab – 3Q 2011
2. Preclinical studies to support an IND and human trials – 2013

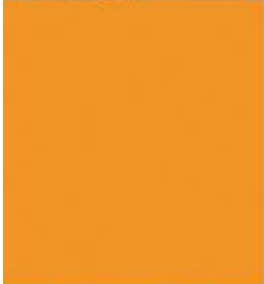


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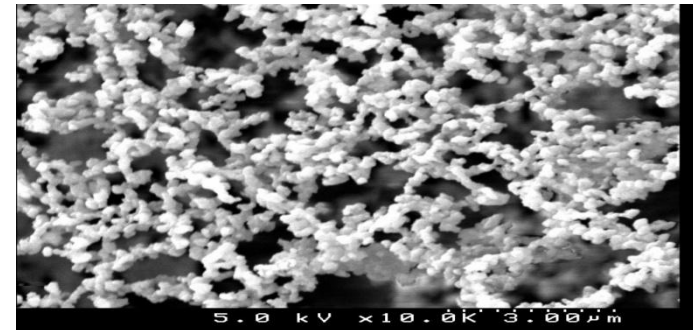
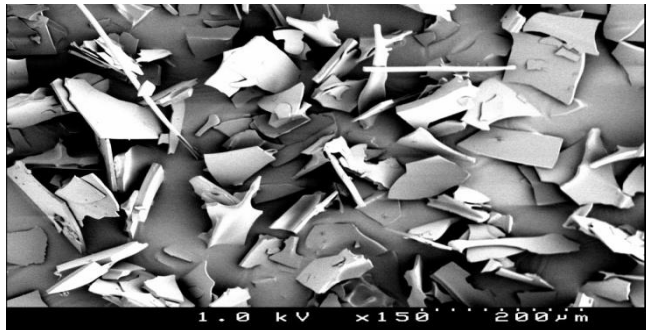


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Oral HPV Vaccine*

- Prima has partnered with Prof. Ian Frazer and Prof. Neil Foster to use **dense gas** technology to attempt to formulate of an oral HPV vaccine
- The technology reformulates large, irregular particles into smaller, consistent sizes, allowing for higher bioavailability at lower doses of a drug and encapsulation for oral dosing
- Studies with Eudragit® coated lysozyme completed and feasibility studies with ovalbumin are ongoing. Animal studies to evaluate immunogenicity will occur in Q3 2011



Using dense gas technology (lysozyme framework) reduced the particle size seventy-fold and produced a much more regular shape.

** The effectiveness of the vaccine is still subject to the outcome of further testing*



Newsflow

- Phase IIb randomized phase Feb 2011 (**complete**)
- Regulatory agreement on phase III completed Scientific Advice with European Union* (**complete**)
- Potency assay expected to be qualified Q2-Q3 2011
- European license for Manufacturing Q2-Q3 2011
- Phase III study recruitment commencement (800 patients) Q3 2011
- FDA meeting for registration study review Q3 2011
- Update Cripto 1 progress Q3-Q4 2011
- Oral HPV vaccine progress update Q3-Q4 2011



**Please refer Prima Biomed announcement dated 21 February 2011 for further details*

Note: Please refer to risks section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision



Conclusions

- There is a major unmet medical need for new therapies for ovarian cancer
- CVac™ has the potential to transform the treatment of ovarian cancer in remission. Results are subject to successful outcomes of Phase II & Phase III trials*
- CVac™ may also have potential to treat other mucin-1 over-expressing tumours. Examples include breast, colorectal, lung, gastric and pancreatic cancers
- The pivotal Phase III study has been designed to seek global registration in key markets for Cvac™
- Prima BioMed has recruited top tier advisers with a track record of successful commercialization

**Please refer to risks section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision*



Conclusions

- Solid financial position*
- Strong management team
- Pipeline of early stage research with other cancer treatment technologies
- If successful may provide considerable investment return in the foreseeable future



** Based on cash position and current cash burn, refer to slide 31, Corporate Snapshot*

Note: Refer to risks section (Appendix I) , in particular risk 3, as to the status and significance of clinical trials before making any investment decision

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Corporate Snapshot

Issued Capital

ASX Code: PRR (Australian Stock Exchange)

Shares: 818.8M

Listed Options: 91.5M (Exercisable at \$0.02 on or before 31 Dec 2011)

Total Issued Securities: 910.3M

Price & Capitalisation

Share Price: \$0.34 (24/5/11)

2011 high: \$0.42 (11/4/11)

Mkt. Cap(diluted) **\$304.9M**

Cash Position: **\$16.0M (current average cash burn \$0.9M/month FY11Q1-Q3)**

Board of Directors

Ms Lucy Turnbull AO

Chairman

Mr Albert Wong

Deputy Chair

Mr Martin Rogers

Chief Executive Officer

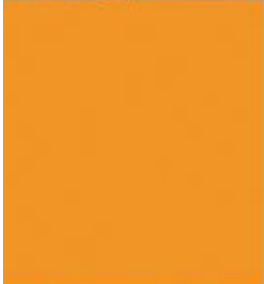
Dr Neil Frazer

Chief Medical Officer

Dr Richard Hammel

Non-Executive Director





Appendix I - Risks



Key risks in relation to Prima

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, could decline and the holders could lose part or all of their investment.

1. 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 December 31, 2010, we had an accumulated deficit of A\$68 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 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.

2. We will require substantial 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 substantial 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.





Key risks in relation to Prima (cont...)

3. 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.





Key risks in relation to Prima (cont...)

4. 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, labelling, 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.





Key risks in relation to Prima (cont...)

5. 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 patient's 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.

6. 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, 2010 we only had four employees. Accordingly, 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.

7. 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.





Key risks in relation to Prima (cont...)

8. 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 are currently in the process of obtaining key man insurance for our chief executive officer, chief operating 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.

9. Our research and development efforts will be jeopardized if we are unable to secure critical reagents necessary for manufacture of key components of our ovarian cancer vaccine*.

The initial component of CVac manufacture is common to all patients regardless of disease indication. A number of 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. These reagents include:

- Cytokines for cell processing: rHuGM-CSF (Global Rx) and rHuIL-4 (Gentaur);
- Antibiotic free AIM-V media (Invitrogen) for cell processing;
- FITC-mannan (Chemicon) for DC phenotyping; and
- Various antibodies for DC phenotyping.

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



** The effectiveness of the vaccine is still subject to the outcome of further testing*



Key risks in relation to Prima (cont...)

10. 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; 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.

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

There is a risk that we are or may infringe the 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 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.





Key risks in relation to Prima (cont...)

12. 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.

13. 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 payers 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.





Key risks in relation to Prima (cont...)

14. 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 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 analyse 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

15. 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 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\$0.05 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 may not be able to sell those ordinary shares at or above the price paid by such holder for such shares. Price declines in our ordinary shares 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.





Risks relating to our securities (cont...)

16. We may be a passive foreign investment company (PFIC) which would subject our U.S. investors to adverse tax rules.

Holders of our ordinary shares 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 ordinary shares and reduce the value of our ordinary shares. 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 ordinary shares, the U.S. Holder will generally continue to be treated as holding ordinary shares 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 ordinary shares 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.

17. We have never paid a dividend and we do not intend to pay dividends in the foreseeable future which means that holders of shares 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 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.





Risks relating to our location in Australia

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

Our business may in the future be affected by fluctuations in foreign exchange rates. Currency fluctuations could, therefore, cause our costs to increase and revenues to decline. The majority of our expenses will continue to be denominated in Australian dollars although we will also be expending cash in other denominations, including U.S. dollars and European euros. In the last two years, the Australian dollar has as a general trend appreciated against the U.S. dollar. If this trend continues, this may have a positive effect on any costs which we incur in the U.S. but may have an adverse effect on our revenues sourced from the U.S. We cannot anticipate whether this trend will continue in respect of the U.S. dollar. The exchange rates of the Australian dollar to the European euro have fluctuated over the same period. In circumstances where the Australian dollar devalues against either or both of the U.S. dollar or the European euro, this may have an adverse effect on our costs incurred in either the U.S. or the European Union (as applicable) but may have a positive effect on any revenues which we source from the U.S. or the European Union (as applicable). The same principles apply in respect of our costs and revenues in other jurisdictions. In addition, 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. To date, we have not suffered any material foreign exchange losses as a result of currency fluctuations.

19. 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 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 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. 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 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 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 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.





Glossary

- **Dendritic cell** - White blood cells that instruct the immune cells on what foreign thing (antigen) they should attack. They eat what they identify to be foreign substances in the blood then process (degrade) antigen into small peptides, place the peptides that indicate the characteristics of an antigen on their surface, and present the antigen to T cells so as to produce the appropriate immune system response. The class of cells called antigen presenting cells also includes dendritic cells or dendritic macrophages
- **Cancer Vaccine /Autologous** - A vaccine that has been developed to target a cancer molecule to either prevent cancer (prophylactic vaccine) or treat existing cancer (therapeutic vaccine). CVac is a cancer vaccine.
- **Immunotherapy** – A treatment that seeks to make use of the immune system so as to manage a disease condition.
- **CA125** - A tumour marker that is indicative of ovarian cancer.
- **CD4+ cells** - White blood cells that assist in the body's immune response by helping B cells create antibodies. CD4+ cells receive the antigen of foreign cells from the MHC Class II molecules on Antigen Presenting Cells.
- **CD8+ cells** – White blood cells that assist in the body's immune response by killing foreign cells, which is why CD8+ cells are also called Cytotoxic T-Lymphocytes or Killer T-cells. CD8+ cells receive the antigen of foreign cells from the MHC Class I molecules on Antigen Presenting Cells.
- **Cell therapy** - The process of introducing new cells into a tissue in order to treat a disease. CVac is a cell therapy in that it introduces an MFP into the body to generate an anti-cancer immune response.
- **Cisplatin** – A platinum-containing chemotherapy drug first approved by the FDA in 1978. In conjunction with Taxol, it is the current standard for ovarian cancer treatment.
- **Progression free survival** – The period of time in which a patient in a clinical trial for a cancer therapy experiences no worsening of their cancer after being administered the treatment.
- **MUC-1** – A mucin that Cancer Vac's Mannan Fusion Protein targets. MUC-1 is of interest to cancer researchers because a wide variety of tumour cells, including those from breast, colon, prostate, pancreatic and lung cancers, not only overproduce mucin, and in particular MUC-1, but seem to produce a variety that is poorly glycosylated.
- **Antigen** - The 'bad guy' substance that stimulates the immune system to respond to the perceived threat.
- **T-cell receptors** – Receptors on the surface of Helper T lymphocytes that recognise the combined MHC Class II and peptide epitope and then pass the word on to create the appropriate B lymphocytes.
- **T Lymphocytes** – White blood cells that are responsible for killing cells infected by viruses, in the case of 'Cytotoxic T cells', and inducing B lymphocytes to produce antibodies, in the case of 'Helper T lymphocytes'.
- **Phase III** – A clinical trial in humans to test efficacy in a large sample. Phase III is used for product registration
- **IND** – Short for Investigation New Drug, an FDA designation of a drug that has been approved for clinical trials in the US.
- **Statistical significance** - The probability, measured by the 'p-value', that an observed outcome of an experiment or trial is due to chance alone. Generally p-values below 0.05 are taken as markers of statistical significance
- **Event Driven Study** - Phase III study where the timing is determinant on the outcome of progression free survival





Contact

Martin Rogers
Chief Executive Officer
Prima BioMed Ltd

E: martin.rogers@primabiomed.com.au
P: +61 2 9276 1242
M: +61 428 268 357

www.primabiomed.com.au

