



# PRIMA BIOMED INVESTOR UPDATE

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## Message from the CEO

Welcome to the third issue of the Prima BioMed Investor Update for 2011. I am delighted to report on what has been another period of strong growth for the Company and our plans for the CVac™ immunotherapy ovarian cancer vaccine.



We continue to remain focused on our late stage trials of CVac™, and since the last Investor Update we have achieved a number of milestones on this front.

In September, the Company announced that it had completed full patient enrolment for the 60 patient CVac™ Phase IIb Trial. This trial is being conducted in five premier sites in Australia and 15 sites across the US.

We are now well underway with preparations for our major clinical trial, which has been named CANVAS (CANcer VAccine Study). Patient enrolment into CANVAS is due to commence by the end of the year. This will be a large, multi-centre trial of 800 patients, and details of our preparations for the trial are provided in this Investor Update.

It also gives me great pleasure to announce that we recently formally launched our partnership with The City Hospital in Dubai Healthcare City (DHCC) to make the CVac™ commercially available in the Middle East region.

The significance of this is that represents the first commercialisation of CVac™ anywhere in the world, and allows us to provide treatment for cancer patients in the Middle Eastern and begin generating revenues.

It has also been a busy period for the company on the corporate front.

Prima was recently added to the Standard & Poor's S&P/ASX 300 Index for the first time. We are delighted with our inclusion in the index and view it as a strong validation of the company's continued growth, which will assist in promoting Prima's exposure within the Australian equity market.

The company has also been awarded a EUR 4.1 million grant by the German state of Saxony to help fund the CVac™ clinical program in Europe.

I would like to conclude by thanking all our loyal shareholders for their continued support through what has been a difficult time in investment markets.

**Martin Rogers**  
Chief Executive Officer

## Update on CANVAS

The company is now very much down to the 'business end' in the development process for the CVac™ ovarian cancer vaccine.

The company continues in its preparations for its major late-stage trial, which it has formally named CANVAS (CANcer VAccine Study).

CANVAS will be a multinational, multi-centre, randomised, double-blinded, placebo-controlled trial of CVac™ as a maintenance treatment for epithelial ovarian, primary peritoneal, or fallopian tube cancer in complete remission. The trial will be an 800 patient trial, of women in complete remission after completing first-line treatment for ovarian cancer.

### The trial's goals are to;

- definitively establish that CVac™ is able to extend the time in remission
- extend overall life expectancy, and
- improve quality of life for patients.

Patient enrolment for CANVAS is due to commence by the end of the year. Based on expected recruitment rates, full patient enrolment should be complete by about Q1, 2013.

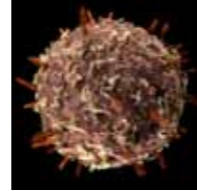
The Company recently completed a successful progress meeting with the US Food and Drug Administration for CANVAS. The meeting followed the granting of Scientific Advice for the European component of CANVAS by the European regulator, in February.

The trial has been finalised based on feedback from these regulator meetings, and advice from Prima's scientific and clinical advisory boards.

Also, CVac™ manufacturing facilities in Melbourne and Leipzig, Germany, have been inspected by the respective regulators. Manufacturing authorisation has now been granted in Germany (see p.2 of Investor Update) and a decision from the Therapeutic Goods Administration in Australia is due soon.

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## Manufacturing Authorisation for CVac™ granted in Germany

The Company achieved a major milestone in its plans for the European component of CANVAS in October when its European manufacturing partner, the Fraunhofer Institute for Cell Therapy and Immunology IZI, received manufacturing authorisation to produce CVac™ in Germany.

The authorisation was given under the German Drug Act and was provided after a successful Good Manufacturing Practices (GMP) inspection by Landesdirektion Leipzig, in consultation with the Paul-Ehrlich-Institut.

It covers the complete CVac™ manufacturing for testing in clinical trials.

**‘Manufacturing Authorisation is a key component of the regulatory application to commence the CANVAS trial in Europe’.**

GMP inspection and subsequent manufacturing authorisation is a prerequisite to production of any medicinal product intended for human administration in Europe.

The process is governed by European Directives and the German Drug Act and includes checking that all stages of manufacture and quality control are carried out in accordance with the principles of GMP.

The manufacturing authorisation was only provided once the regulator was assured that manufacture and testing had been carried out according to the required science and technology standards.

Prima placed a major emphasis on manufacturing quality in its Manufacturing Authorisation process, and the authorisation is a key component of its regulatory application to commence the CANVAS trial in Europe.

## Patient enrolment for Phase IIb Trial complete

In recent times Prima has also made great progress on its Phase IIb Trial for CVac™. In September it reported that it had completed full patient enrolment for the 60 patient trial.

Patient enrolment commenced in July 2010, and in February this year the Company advised that the trial’s first patient cohort (seven patients) had successfully completed the first treatment with the vaccine, with no therapy-related adverse effects.

Based on this positive result, the Data Safety Monitoring Board confirmed that the trial was safe to proceed, and the remaining patients were enrolled into the trial.

The company has been delighted at the uptake and response to the enrolment process, and was particularly pleased that enrolment was completed in such a short period of time.

The Phase IIb Trial is being conducted in five premier sites in Australia and 15 sites across the US. The trial design is a randomised and open label trial, comparing patients who are in remission (after 1st and 2nd line active treatment with CVac™) against observed standard of care.

### The trial will aim to confirm;

- manufacturing comparability of multiple sites,
- the potency assay,
- the safety of CVac™, and
- compare disease progression between CVac™ and the control group

The trial will also seek to augment the promising efficacy data generated by previous studies, including the Phase IIa pilot study of 28 patients, completed in 2007.

## Prima included in Standard & Poor’s S&P/ASX 300 Index

Corporately, the company continues to perform strongly.

After an extremely successful capital raising earlier in the year, it is well funded to pursue its late stage trials, and it continues to attract widespread investor interest.

One notable achievement has been its inclusion in Standard & Poor’s S&P/ASX 300 Index for the first time. The inclusion was effective from 19 September, and was part of Standard & Poor’s September quarterly review.

The S&P/ASX 300 Index is comprised principally of the 300 largest and most liquid stocks listed and traded on the Australian Stock Exchange.

Prima’s inclusion in the index is a sign of the company’s growing reputation and presence in the investment community. The company sees it as a strong validation of its clinical programs, and it will also assist in promoting the Company’s exposure within the Australian equity market.

Inclusion in the S&P/ASX 300 Index is based on certain criteria regarding listing, size and liquidity, and Prima is delighted to have been included in the Index for the first time.

Standard & Poor’s is the leading provider of market indices in Australia. The S&P/ASX 300 Index is designed to address investment managers’ needs to benchmark against a portfolio characterised by sufficient size and liquidity. It is a component of the Australian indices that can be utilised as building blocks for portfolio construction.

**‘Prima’s inclusion in the index is a sign of the company’s growing reputation and presence in the investment community’.**

## Commercialisation of CVac™ in Middle East

The company’s main goal is to commercialise the CVac™ immunotherapy ovarian cancer vaccine in major health care markets across the globe – and provide a new treatment option for ovarian cancer patients and deliver significant returns for its shareholders.

It recently achieved a major step towards this goal with the confirmation of the formal launch of its partnership with The City Hospital in Dubai Healthcare City (DHCC) to make CVac™ commercially available in the Middle East region.

It is the first commercialisation of CVac™ anywhere in the world, and allows the Company to provide treatment for cancer patients in the Middle Eastern region and generate revenues in a growing health care market.

The company expects to be in a position to commence the first sales of CVac™ in DHCC before the end of 2011.

The program was officially launched on October 23, at a ceremony to mark the third anniversary of The City Hospital. It came after Prima announced in May that it had been granted approval for the marketing and distribution of CVac™ in DHCC.

It is an important pilot commercialisation program for CVac™, and the company will also look at the potential to expand the application of CVac™ in the region, to treat other mucin-1 positive tumours.

### Therapeutic Apheresis program

At the same time, Prima also launched a Therapeutic Apheresis program with The City Hospital. It will provide a treatment to remove harmful proteins, chemicals or cells in blood that cause disease. This will be the first time a service of this type has been offered in Dubai.



Prima Chairman Lucy Turnbull, CEO Martin Rogers and Chief Operating Officer Matthew Lehman with Prima staff and Fraunhofer staff at Fraunhofer Institute in Leipzig (Germany).



Prima CEO Martin Rogers, Chief Operating Officer Matthew Lehman and Chairman Lucy Turnbull (L-R) at the Fraunhofer Institute.



Dr. Schmiedeknecht, Ms Turnbull and Mr Rogers (L-R) at clean rooms at Fraunhofer IZI.

## Additional information on Prima and CVac™

Please see below two links from the Prima company website that provide additional information on CVac™.

Webcast of a recent Experts Conference Call;  
[www.investorcalendar.com/IC/CEPage.asp?ID=163542](http://www.investorcalendar.com/IC/CEPage.asp?ID=163542)

A short video which provides an overview of how the CVac™ vaccine works in practice;  
[www.primabiomed.com.au/movies/movie\\_3.php](http://www.primabiomed.com.au/movies/movie_3.php)

## EUR 4.1 million grant for CVac™ in Europe

In another positive step in the preparation for the CANVAS trial, the Company was awarded a major grant to help fund the CVac™ clinical program in Europe.

In August, it was awarded a EUR 4.1 million grant by the German state of Saxony.

The grant came from a merit-based research and development grant program which was designed to provide funding for specific projects which demonstrate the potential to further economic development in Saxony.

The grant was provided by the State Ministry for Higher Education, Research and the Arts of Saxony.

Prima and the Fraunhofer Institute of Cell Therapy and Immunology (Fraunhofer IZI) submitted a joint proposal for the grant, to cover the costs of CVac™ materials and manufacturing, plus staffing costs in Saxony and some clinical procedure costs of the European component of CVac™'s trial process.

The company was delighted at being successful in the grant process, and that the German authorities had assessed that its clinical program merited the funding.

Prima and Fraunhofer will be reimbursed for eligible costs as they are incurred during the project. Funds under the grant are provided by the European Union and the state of Saxony.

### For further information please contact:

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## Forward looking statement

Any forward looking statements in this newsletter have been prepared on the basis of a number of assumptions which may prove incorrect and the current intentions, plans, expectations and beliefs about future events are subject to risks, uncertainties and other factors, many of which are outside Prima Biomed Ltd's control. Important factors that could cause actual results to differ materially from any assumptions or expectations expressed or implied in this newsletter include known and unknown risks. As actual results may differ materially to any assumptions made in this newsletter, you are urged to view any forward looking statements contained in this newsletter with caution. This newsletter should not be relied on as a recommendation or forecast by Prima Biomed Limited, and should not be construed as either an offer to sell or a solicitation of an offer to buy or sell shares in any jurisdiction..

## Prima BioMed – Fast Facts

### Listings

Australian Securities Exchange (ASX)

ASX Code: PRR

Issued Capital - Ordinary shares  
1.011B

### (Listed) Options

54.1M (exercise price \$0.02 on or before 31 Dec 2011)

Market Capitalisation (fully diluted)  
A\$202.3M (@ 27/10/11)

### Cash Position

51.1m (@ 21/10/11)

## Board

Ms Lucy Turnbull	Non-executive Chairman
Mr Albert Wong	Non-executive Deputy Chairman
Mr Martin Rogers	Managing Director and Chief Executive Officer
Dr Neil Frazer	Executive Director and Chief Medical Officer
Dr Richard Hammel	Non-executive Director

## Senior Management

Ian Bangs	Chief Financial Officer
Matthew Lehman	Chief Operating Officer
Dr Sharron Gargosky	Senior Vice President, CVac™ Program
Marc Voigt	General Manager, European Operations
Vanessa Waddell	Business Development and Intellectual Property Manager
Larisa Chisholm	Intellectual Property Manager
Dr Hind Al Saadi	General Manager, Middle East