# Investor Update



Edition
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11



CEO Matthew Lehman

# Message from the CEO

Welcome to the first issue of the Prima BioMed Investor Update for 2014. We have had a great start to 2014 here at Prima BioMed and are excited to share some news with you.

### Clinical Trial Update

As recently announced, we reached an important milestone in the development of CVac with the commencement of our amended phase 2 CAN-004 clinical trial in Europe. Prima is now actively recruiting patients from 16 different sites across Europe, with further sites due to commence recruitment later this month. The amended phase 2 CAN-004 clinical trial will include a total of 210 epithelial ovarian cancer patients in remission after second-line treatment. The primary endpoint is Overall Survival (OS), while the secondary endpoints include progression-free survival, and tolerability and quality of life assessment. We continue to explore the CVac immune profile through specialised immune monitoring testing.

In September last year, based on the top-line data from the CAN-003 trial of CVac we adjusted the focus of the ongoing CAN-004 clinical trial. These amendments received approval from a number of regulatory agencies in Europe which allowed for the amended CAN-004 trial to re-commence.

We have also advanced a 40 patient pilot trial of CVac for resected pancreatic cancer to assess signals in OS.

### CAN-003 data to be presented at ASCO

We are pleased that the final progression free-survival (PFS) data was accepted for oral presentation by Dr Heidi Gray at the 2014 American Society for Clinical Oncology (ASCO) Annual Conference on 31st May 2014 in Chicago. ASCO is among the world's largest annual scientific events in the oncology community. We are excited about the opportunity at ASCO to update the medical community on our progress with CVac. Dr Gray will also provide an update on overall survival from CAN-003. Prima will make a market announcement regarding the CAN-003 data on 14th May 2014 to coincide with the release of this data contained in the ASCO abstract. A further market announcement will also be made shortly after Dr Gray's presentation at ASCO.

### Neopharm Licence

In February, Prima entered into an exclusive Licence Agreement with Neopharm Group; the first commercial transaction for our CVac technology. The licence permits Neopharm to seek registration approval for CVac as a cell-based immunotherapy for ovarian cancer and then exclusively market and supply CVac in Israel and Palestine.

This demonstrates a high level of confidence in our development program and CVac's commercial potential. Under the terms of the agreement, Neopharm will reimburse Prima for commercial manufacturing costs of CVac and net profits from CVac sales will be shared equally between Prima and Neopharm. Prima BioMed retains the right to out-license CVac in the rest of the world and we regularly discuss potential partnership opportunities with companies.

### Financial update

As reported in our Appendix 4C for the quarter ended 31 March 2014, we had A\$26.74 million in cash and term deposits, which included an R&D tax refund from the Australian Federal Government of approximately A\$1.6 million received in March.

We have made good progress in reducing our cash outflows. This has been partly achieved by consolidating the majority of our manufacturing into our German facility in collaboration with the Fraunhofer Institute, following grant funding from the Saxony Development Bank.

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## Message from the CEO

### New Board Appointments

In February, Pete Meyers joined the company as a Non-Executive Director. Pete brings to the Prima BioMed Board significant experience in U.S. capital markets and in advising healthcare companies. He is currently the Chief Financial Officer of TetraLogic Pharmaceuticals Corporation, and prior to that was Co-Head of Global Healthcare Investment Banking at Deutsche Bank in New York, having also held various senior investment banking positions at Dillon, Read & Co. and Credit Suisse First Boston. Also in February, we farewelled our retiring Non-Executive Director, Dr Richard Hammel and thanked him for his over eight years of service on Prima's Board.

### American Depository Receipt (ADR) Activity

Over the past year there has been a significant increase in the issuance of American Depository Receipts ("ADRs") in Prima's NASDAQ listed ADR program. As of March 2014, 3.7 million

ADRs have been issued and are outstanding, compared to only 109,711 ADRs outstanding in March 2013.

#### Outlook

Our focus remains firmly on continuing to develop the CVac program, with our highest priority being the phase 2 CAN-004 trial. With our dedicated team of highly experienced clinicians in the emerging field of cancer immunotherapy, we now have a clear, data-driven clinical development plan for CVac in second-remission ovarian cancer. We are excited about the opportunity to deliver patients a product that has less toxicity than conventional cancer treatments and can extend their overall survival.

As always, I would like to thank you for your ongoing support of Prima BioMed and our development of CVac. We remain in a fundamentally strong position and I look forward to reporting on further progress in the months ahead.

Matthew Lehman | Chief Executive Officer

## Prima strengthens the Clinical Advisory Board

In March 2014, Prima BioMed appointed three new members to its Clinical Advisory Board (CAB). This follows the appointment of Dr Bradley J. Monk as Chair of the CAB in February this year. Each new board member is a highly accomplished physician and preeminent leader in the field of gynaecological cancer. These three newly joined members will be working together with existing member of CAB: Dr. Berek, Dr. Goh and Dr. Kuhn. Their summary biographies are included below.

The principal role of the CAB is to advise on the design and implementation of Prima BioMed's clinical trials. The three new European appointments bring substantial relevant European experience to the CAB and coincide with the imminent start of the Company's amended phase 2 CAN-004 clinical trial in Europe.

The Company engages with the CAB through frequent board meetings as well as ad hoc liaison with its Chief Technology Officer, Sharron Gargosky.



### Prof. Pujade-Lauranine, MD, PhD

Prof. Pujade-Lauranine established the French GINECO Group, which is devoted to clinical research in gynecologic cancer. He is the head of the Women Cancers and Clinical research Department at Hôpitaux Universitaires Paris Center, site Hôtel-Dieu, AP-HP in Paris, France and Professor of Medical Oncology at University Paris Descartes.



### Prof. Christian Marth, MD, PhD

With 25 years of activity in clinical gynecologic oncology and translational research, Prof. Christian Marth is Head of the Department of Obstetrics and Gynecology at Innsbruck Medical University. He is also the president and founder of the Austrian Association for Gynecologic Oncology, and president elect of the European Network of Gynecological Trials Group (ENGOT).



### Prof. Ignace Vergote, MD, PhD

Prof. Ignace Vergote is Head of the Department of Obstetrics and Gynecology and Gynecologic Oncology at the Catholic University of Leuven, Belgium. He was Chairman of the European Organization for Research and Treatment of Cancer (EORTC) Gynecologic Cancer Group from 1997 to 2003, and is now the chairman of its Protocol committee.



### Dr Bradley J. Monk, MD, FACS, FACOG

Dr Monk is Professor in the Department of Obstetrics and Gynecology at the University of Arizona College of Medicine, Professor at the Creighton University School of Medicine, and Director of the Division of Gynecologic Oncology at St. Joseph's Hospital and Medical Centre in Phoenix.

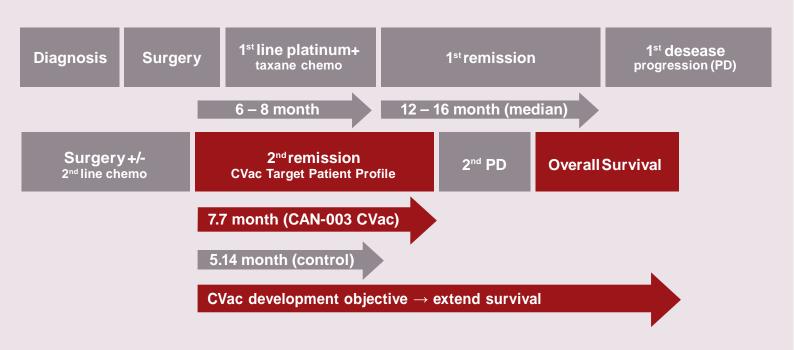


# CVac target patient profile: maintenance after second line chemotherapy

Prima's CAN-003 protocol succeeded in helping to identify a potentially focussed, optimal Target Patient Profile (TPP): maintenance (or consolidation) treatment of platinumsensitive epithelial ovarian cancer in remission after recurrence. The clinical development objective of CVac is to extend the overall survival (OS) and progression-free survival (PFS) of patients in this indication.

Twenty patients who attained complete remission after their second recurrence who participated in the CAN-003 trial, showed significant improvement in progression-free survival when treated with CVac. The next step in clinical development is the completion of a 210-patient randomised, standard-of-care controlled trial in this patient population to confirm what we saw in the smaller number of patients from CAN-003. This CAN-004(2) protocol commenced enrolment in April.

# CVac's place in ovarian cancer management



Ovarian cancer is the seventh most common cancer in women worldwide in terms of new cases diagnosed (238,719 in 2012) and including previously diagnosed patients based on the 5 year prevalence data (586,624 in 2012), the sixth most common in women worldwide.(GLOBOCAN 2012 database <a href="http://globocan.iarc.fr/Pages/fact\_sheets\_population.aspx">http://globocan.iarc.fr/Pages/fact\_sheets\_population.aspx</a>).

Most patients with ovarian cancer achieve complete clinical remission after optimal debulking surgery and platinum-based chemotherapy. However, data from the National Cancer Institute suggest around 80% will relapse despite high response rates to first-line treatment, and undergo

subsequent lines of chemotherapy. Generally, the progression free interval between treatments becomes shorter with each relapse, and the patient eventually dies from the disease. The ability to increase the progression free intervals between remission windows would have a significant benefit to a patient's quality of life and would potentially lead to longer overall survival.

CVac is intended as a maintenance therapy for ovarian cancer patients in complete second remission to increase quality of life and extend overall survival and progression free intervals. There is a high unmet medical need for such treatments.



A patient's journey with CVac

# Sarah's story: CVac blood cell collection



This is the second installment in our case study of a patient's journey with CVac. We continue our journey with "Sarah", a hypothetical patient who is enrolled in the CANVAS clinical trial and learn about her experience of the mononuclear cell (MNC) blood collection process. In the last newsletter we learned about her diagnosis of ovarian cancer, her family's support and her decision to enroll in the CVac clinical trial - this is her journey.

I had been accepted for the CVac clinical trial – my blood was healthy after surgery, my tumor was Mucin 1 positive and should respond to

CVac and I met all the trial criteria. Now I was ready for the procedure called MNC collection. MNC is the scientific term for mononuclear cells. These are my immune cells that will become part of my personalised CVac vaccine.

Karen, the study coordinator, explained that I would need to go to a trial-approved blood collection center since the staff there have been trained in the blood collection process. They would explain what will happen and check my veins and general health. We found a date that would work. I wanted my husband with me. I was nervous about the process and asked him to take time off work to be with me.

My doctor wrote the referral letter to the Peter MacCallum Cancer Centre. The week before my procedure, I went to the blood collection center where a nurse explained the collection process and paperwork that I had to fill out. I filled out another consent form (by now I was getting pretty experienced with reading and understanding these and felt quite comfortable) and a questionnaire (like I used to fill out when I donated blood). There is so much paperwork in hospitals and this seemed to be particularly true for clinical trials.

As we talked about the blood collection process, I asked so many questions, I was sure the nurse would become tired of me! But she patiently answered even the smallest technical details of what would happen. The unit director then checked my veins to see if I could have the collection in my arms or if I would need a catheter in my neck.

Finally, when the day came and I went through the process – it really was okay and compared to surgery and the preparation, it was very straightforward.

I had a needle inserted in each arm so the tubes could transfer my blood. One tube took the blood out and put it into a machine that separates my cells. The blood that was not used was returned through another tube into my other arm. Up to 10–15L of my blood was circulated in order to collect 200mL (20floz) of the cells. The whole process was conducted in a sterile environment to reduce the risk of infection.

The blood they didn't use was warmed up before it went back into my arm so I wouldn't get cold. I was told that some people have a side effect with the blood diluter given with the blood circulation but that it is corrected with a calcium carbonate tablet, which I took. I didn't experience any side effects. The process took about four hours. I had to sit or rest in a bed for the whole time. So I watched TV and chatted but I couldn't move around much.

That same day they shipped my blood to the manufacturer to make my CVac vaccine. I try not to worry if I will get a placebo or CVac – I just hope that I can help others eventually by participating in the trial.



## **Q&A** with Dr Bradley J. Monk

Dr Bradley J. Monk (MD, FACS, FACOG) is Chair of the Prima BioMed Clinical Advisory Board. He is one of the most recognised and experienced researchers in ovarian cancer today and shares some of his thoughts about immunotherapy and CVac.

**Q.** What attracted you to join the Prima BioMed CAB? **A:** A considerable part of my career has been devoted to clinical research into gynaecological cancer.

Maintenance therapy for ovarian cancer after second line treatment is a significant unmet medical need with an addressable market of more than 25,000 patients annually in major global markets.

Prima BioMed is one of the leading companies in developing an immunocellular treatment with its CVac technology and it is great to be working alongside some of the most esteemed researchers and clinicians in our field.

# Q. What are the advantages of immunotherapy for ovarian cancer?

A: The scientific community is confident that immunotherapy will play an important role in the future treatment of ovarian cancer

Immunotherapy is a safer and potentially more effective treatment as it stimulates the patient's natural immune system to locate and kill malignant cancer cells.

Ovarian cancer is one of the cancers where immunology would be most effective in treating patients and CVac is well tolerated with a very acceptable side effect profile, as demonstrated by Prima BioMed's early clinical trials.

I am excited to be part of the CVac clinical trial program and help guide the product though development.

# Q. How significant is the development of CVac for the treatment of other cancers?

**A:** The approval of CVac would potentially be a major breakthrough for the treatment of cancers related to the Mucin 1 protein, such as ovarian, pancreatic, breast and lung cancer.

Prima BioMed will soon be initiating a 40 patient trial to assess the feasibility of CVac therapy for resected pancreatic cancer, the CAN-301 protocol.

Available data strongly supports immunotherapeutic approaches to treating pancreatic cancer and with more than 80% of patients expected to have Mucin 1 overexpressing cancer cells, the target of CVac, the addressable market is estimated to be 17,000 patients annually. Therefore results of this trial could be very significant.

# Lucy Turnbull meets Saxony's Minister of State in Leipzig, Germany

In April, Prima BioMed Chairman, Lucy Turnbull and CFO Marc Voigt met with Saxony's Minister of State for Science and the Fine Arts, Prof. Sabine von Schorlemer at the Company's CVac manufacturing facility in Leipzig, Germany.

In collaboration with the Fraunhofer Institute for Cell Therapy and Immunology ("Fraunhofer"), Prima BioMed will manufacture CVac for all European clinical trial sites from the Leipzig facility. The facility will also be the centre for administering all its European clinical trials for Ovarian and Pancreatic cancer.

The Saxony Development Bank in Germany provided Prima BioMed and the Fraunhofer jointly with a grant of

nearly EUR 8 million to co-fund the development of CVac.

Lucy Turnbull said: "Based on funding by the Free State of Saxony we are able to advance the development of therapy candidate CVac in the amended phase 2 clinical trial on a Europe-wide scale."

Sabine von Schorlemer commented: "We are proud that we were able to attract internationally active companies such as Prima BioMed to BIO CITY LEIPZIG and to successfully support them. The positive development of Prima BioMed will also raise the international profile of Saxony as a high-technology location."



Picture of Lucy, Minister Prof. von Schorlemer, Dr Feist (Member of German Parliament), Marc Voigt, CFO



Lucy and Marc with the Prima team in Leipzig



# Company calendar and upcoming catalysts

Prima has enhanced its website to keep shareholders abreast of all upcoming company events. Check out the Company Calendar for regular updates.

6 MAY 2014	Conference call for Third Quarter
31 MAY 2014	2014 ASCO conference in Chicago: presentation on CAN-003 data by Heidi Gray, MD
31 MAY 2014	Goldman Sachs reception at ASCO
25-28 JUNE 2014	2014 WAGO Annual meeting, Truckee, California

# Follow Prima's progress

Prima BioMed is dedicated to maintaining consistent and clear communications with our investors. In addition to our quarterly newsletter, we encourage our shareholders to continue following Prima's progress in a number of ways:

### Quarterly conference calls

Prima's management holds quarterly conference calls to review our operational and financial results. Details of the calls and accompanying webcasts are announced to the ASX and posted on our website. Recordings and transcripts of these calls are also maintained on our website.

### www.primabiomed.com.au

The company website is a treasure trove for those in search of details about our company, our management team, and archived information. We encourage everyone to check it out regularly.

### www.clinicaltrials.gov

Prima registers all of our clinical trials, and the details of enrolling doctors, on the ClinicalTrials.gov website, a service of the United States National Institutes of Health. This register is the largest such repository of clinical trial information around the world.

### Twitter

twitter.com/PrimaBioMed

### Facebook

www.facebook.com/PrimaBioMed

### LinkedIn

http://us.linkedin.com/company/prima-biomed-ltd

### Prima BioMed - Fast Facts

### Listings

Australian Securities Exchange (ASX), NASDAQ, Deutsche Börse

#### Stock Codes

ASX: PRR, NASDAQ: PBMD,

Deutsche Börse: ISIN: US74154B2304 (as of 31 March 2014)

### **Issued Capital - Ordinary shares**

1.23B (approximate as of 31 March 2014)

### **Issued ADR's**

3.7M (approximate as of 31 March 2014)

### **Market Capitalization**

A\$50.38M (approximate as of 31 March 2014)

### **Cash Position**

A\$26.74M (approximate as of 31 March 2014)

### **Board of Directors**

Ms Lucy Turnbull, AO Non-executive Chairman

Mr Albert Wong Non-executive Deputy Chairman

Mr Matthew Lehman Managing Director and

Chief Executive Officer

Dr Russell J Howard Non-executive Director

Mr Pete A Meyers Non-executive Director

## **Senior Management**

Dr Sharron Gargosky Chief Technical Officer

Mr Marc Voigt Chief Financial Officer

Ms Deanne Miller General Counsel and

Company Secretary

www.primabiomed.com.au