



# PRIMA BIOMED INVESTOR UPDATE

EDITION 3  
MARCH 2011

## Message from the CEO

*Welcome to the first issue of the Prima BioMed Investor Update for the new year.*



*2011 looms as an exciting year for the Company, as we continue to make progress with our development plans for our headline clinical program, the CVac™ immunotherapy ovarian cancer vaccine.*

*The year ahead will see the Company focused on the late stage clinical trials for CVac™. Our Phase IIb trial, with the US Food and Drug Administration, is currently underway, and plans are well advanced for a Phase III trial, under the authority of the European regulator, the European Medicines Agency.*

*Details of the progress on both these trials is provided in this issue of your Investor Update.*

*We are also preparing for the Company's listing on the NASDAQ exchange in the United States. The NASDAQ ticker is PBMD and we look forward to being able to confirm a listing date in the near future.*

*The Company has generated strong interest from US based investors, and the NASDAQ listing will give US investors an opportunity to capitalise on this interest, and invest directly in the Company. It will represent a significant milestone, and I would like to thank all those involved for their tireless work on the listing process.*

*Also, in this issue of your Investor Update, we introduce a new contributor to the team, Dr Sharron Gargosky, Senior Vice Preside of CVac™ Program.*

*Dr Gargosky is a strong advocate of women's health issues, and we are delighted to welcome her contribution to the Prima BioMed Investor Update.*

*In this issue she will provide some of her insights into ovarian cancer and the need for new treatment options.*

*Also included in this issue is a centre-piece which provides an excellent graphical representation of how the CVac™ vaccine actually works.*

*Welcome to 2011 and I look forward to sharing the positive progress of your Company throughout the year.*

**Martin Rogers**  
**Chief Executive Officer**

## Company prepares for NASDAQ listing

The Company is pleased to report that its expects its planned listing on the NASDAQ Exchange in the USA to be finalised in the near future. Over the past 18 months, the Company has attracted an increasing level of support and interest from the US market.

This has been generated, in part, by the success of NASDAQ-listed company Dendreon, which last year successfully completed the commercialisation of its Provenge vaccine product, for the treatment of prostate cancer.

Prima BioMed uses similar technology in its CVac™ ovarian cancer vaccine, and this has helped whet the appetite of US investors for Prima's potential to achieve a similar result.

Against this backdrop, the Company announced plans to list on the NASDAQ Global Market last September. Prima has submitted all required documentation ahead of its listing and its management team has been actively marketing the Company to US institutional investor groups.

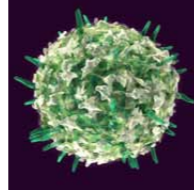
Prima's listing on the NASDAQ will be a Level II ADR compliance listing, and as a result the Company will have dual listings of its securities on both the Australian Securities Exchange (ASX) and NASDAQ.

NASDAQ is the largest electronic screen-based equity securities trading market in the US, and the aim of the NASDAQ listing is to provide a structure that better meets the needs of both Prima's Australian and US investors, and to provide increased liquidity for Prima's shares.

The listing process is being managed by Bank of New York Mellon and US broking house National Securities Corporation. The NASDAQ listing will come at a significant point in the development of the Company's CVac™, and the timing of the listing will offer US investors an outstanding opportunity to share in this growth phase of the Company.

## In this Issue

- Prima prepares for NASDAQ listing
- Scientific Advice Agreement reached for Phase III Trial
- Dr Sharron Gargosky's column
- Initial Phase IIb Trial patient group completes first CVac™ treatment
- About the CVac™ Phase III Trial



## Scientific Advice Agreement for Phase III Trial

The Company continues to make strong progress on its late stage clinical trials for CVac™.

The commencement of a Phase III Trial in Europe will be a key focus for Prima in 2011, and preparations for this are well advanced.

Prima recently completed a key milestone in the trial preparation, with an Agreement being reached for the strategy and design of the Phase III Trial for CVac™.

The Agreement comes after the European regulator, the European Medicines Agency (EMA), advised that Scientific Advice for the Phase III Trial had successfully been completed.

Scientific Advice was completed after the review of extensive data on the trial strategy, design and endpoints was completed.

Evaluation of patient needs, the CVac™ dosing regimen, plus manufacturing and safety data from past clinical and pre-clinical data was compiled in order to allow the regulator to make a positive determination on the strategy and design of the upcoming trial.

The Scientific Advice is a significant milestone in the development timeline for CVac™'s global registration. Prima can now move forward and begin preparations for patient enrollment into the trial.

**See page 6 for more details on the CVac™ Phase III Clinical Trial.**

## Early termination of Spring-Tree funding facility and additional \$2.5M placement

In January Prima announced that it had reached an agreement with US investment fund SpringTree for the early termination of the convertible loan funding facility SpringTree had provided Prima.

Prima entered into the funding agreement with Spring-Tree in July 2009, and since that time they have provided Prima in the order of \$12.2 million to continue its work to develop and commercialise the CVac™ immunotherapy ovarian cancer vaccine.

SpringTree has agreed to waive the termination fee that would have otherwise been due under the funding agreement. The termination will take effect no later than on 29 March 2011.

With Prima's pending listing on the NASDAQ, and the anticipated increase in exposure and interest from US investors it is expected to deliver, both Prima and SpringTree agreed that the early termination was in the best interests of shareholders.

Prima has enjoyed a very strong working relationship with SpringTree, and the funds they have provided have proved invaluable to Prima over a key phase of its development timeline for CVac™.

### SpringTree to make additional one-off \$2.5M investment in Prima

In addition, to the agreement on the early termination of the funding facility, SpringTree has agreed to make a further, one-off, \$2.5 million investment in Prima. This will be made up of a placement of \$1.25 million in Prima (at 20 cents per share) and \$1.25 million by way of a convertible security. Full details of this investment was provided in an ASX announcement of 10 January 2011.

## Dr Sharron Gargosky's column



Prima is delighted to welcome the Company's Senior Vice President of CVac™ Program, Dr Sharron Gargosky, as a new contributor to your Investor Update.

In this issue she provides some of her insights into ovarian cancer and the need for new treatment options.

### Ovarian cancer facts

Ovarian cancer is one of the most insidious cancers, and has a high morbidity rate.

In Australia, three women are diagnosed with ovarian cancer every day, and there is no early detection test. This means that when most patients are diagnosed, the cancer is already

at an advanced stage.

More than 1200 women are diagnosed with ovarian cancer in Australia each year and 800 women will die from the disease. At the moment, only 40% of women with ovarian cancer will be alive five years later.

### Treatment

Current treatment usually involves surgery and chemotherapy, and, less often, radiotherapy.

The first treatment is usually *surgery*, called a laparotomy. This is also the main way a diagnosis of ovarian cancer is confirmed. In a laparotomy, as much of the tumour as possible is found and removed.

Most patients will also require *chemotherapy*. This aims to attack cancer cells and slow or stop their growth. Chemotherapy works best when the tumour is small and the cancer cells are actively growing. Chemotherapy can also damage some healthy cells in the body and cause a range of side effects.

*Radiotherapy* is also occasionally used as a treatment option. Special x-rays are aimed at the site of the cancer, which damage the DNA in the cancer cells and kills them. Radiotherapy also has side effects.

### Alternative treatment options

The high morbidity rate of ovarian cancer, coupled with a limited range of treatment options and associated side effects, makes finding viable alternative treatment options a high priority.

Work in the field of immunotherapy treatments – using the body's own cells to provide a defense mechanism – has made strong progress in recent years. Prima BioMed is to be commended for its work in developing an immunotherapy vaccine for ovarian cancer.

Typically, such treatments won't offer a cure for a cancer, but provide a complementary treatment option to mainline treatments (like surgery and chemotherapy) to delay the spread of the cancer and improve patients' quality of life.

There is a clear medical need for viable, widely available such treatments for ovarian cancer.

Statistics and information for this article have been gathered from Ovarian Cancer Australia.

## A word from Prima's Scientific Advisory Board Chairman, Professor Ian Frazer



***'I continue to be excited and encouraged by the outstanding work being done by the Prima team in developing this immunotherapy technology for ovarian cancer and its work on other major diseases. Their commitment to providing a commercially available, alternative treatment option for ovarian cancer patients is highly commendable.'***

Professor Ian Frazer,

Australian of the Year 2006

Prima BioMed Scientific Advisory Board Chairman

### CVac™ - A 'Focused Cancer Killer'

This issue of your Investor Update has been

expanded to include a double-page centrepiece, titled 'Focused Cancer Killer', which provides an excellent graphical representation of how the CVac™ ovarian cancer vaccine actually works.

It shows a roadmap of the vaccine in action; >> from the body's own key cells being engaged, >> to the cells being selectively harvested from the patient's blood to make the vaccine, and finally >> to the vaccine being administered to the patient and the activated cells targeting the tumour cells

The centre-piece also provides answers to a number of frequently asked questions on CVac™, and provides some key statistics on ovarian cancer, which help highlight the need for new, alternative treatment options.

## Experts Conference Call

The Company recently hosted an Expert's Conference call to provide an update on CVac™'s clinical trials, the unmet medical need of ovarian cancer patients and relevance for the medical oncology profession.

The Call featured Dr Jonathan Berek from Stanford Medical Centre, Prima's chief medical officer Dr Neil Frazer and Jason Kolbert head analyst from National Securities.

The Webcast of the Conference Call is available on the Prima website at the following link;  
<http://www.investorcalendar.com/IC/CEPage.asp?ID=163542>

**STATISTICS**

Ovarian cancer represents the **6<sup>th</sup>** most commonly diagnosed cancer among women worldwide.

It causes **more deaths** per year than any other cancer of the female reproductive system

It is the **5<sup>th</sup>** leading cause of cancer death among women globally

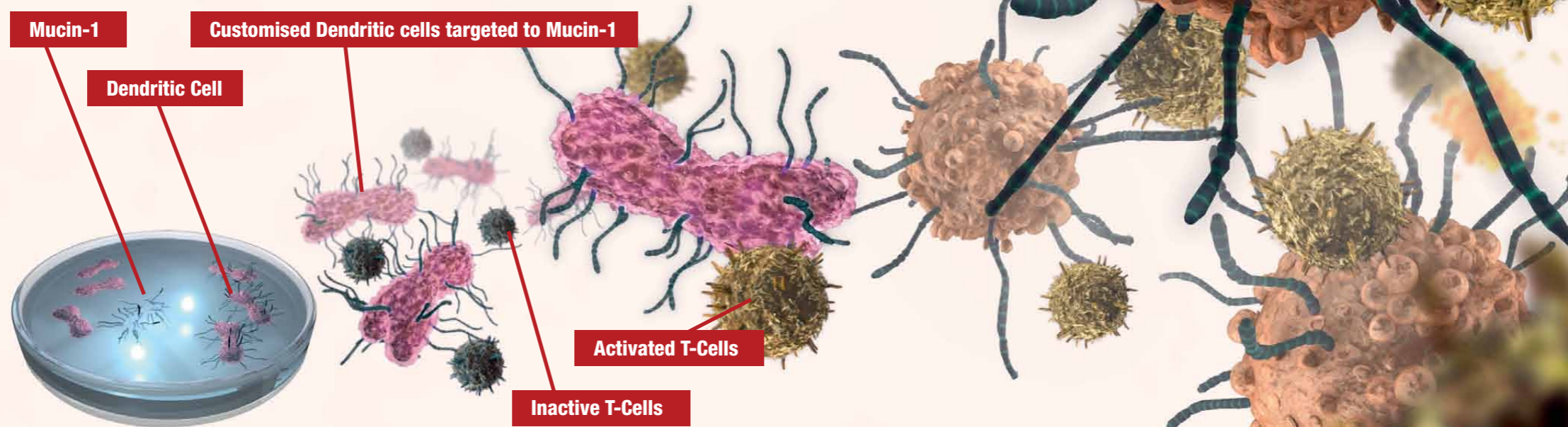
Only **3** out of **10** women with ovarian cancer live more than five years

**FOCUSED CANCER KILLER**

Ever since the days of William Coley in New York, who pioneered in the year 1893 the use bacterial injections in an attempt to stimulate the immune system to fight cancer, physicians have attempted to harness the awesome power of the human immune system to fight tumours. Dr. Coley's patient lived for an additional twenty six years, and his tumour vanished. Such a success should have led to more and more sophisticated cancer immune therapies, but physicians chose the route of toxic chemotherapy, and harmful radiation to destroy rampaging tumours. Killing fast dividing cells by damaging their DNA seemed swifter than waiting for the body to mount a massive immune system attack

on the tumour. In April of 2010, Dendreon Corporation became the first company in history to get Food and Drug Administration approval in the United States for Provenge, a product consisting of patients own cells, primed to target PAP a protein found in high quantities in prostate tumour cells. Giving patients their own cells to boost the immune system proved an effective therapy, and patients lived on average 4.1 months longer than those given a sham treatment. Many new therapies are in development to target tumours, and an Australian company Prima Biomed Ltd is in the lead to develop a therapy for ovarian cancer that uses the patient's own cells to tackle their tumours.

**Fighting Cancer with a Vaccine** Illustration by brandlovers.de



**THE KEY CELLS**

The immune system is primed to find "foreign" proteins and to send killer cells to destroy them. The cells that find the foreign protein are antigen presenting cells, and dendritic cells are a key antigen presenting cell. The antigen presenting cell then picks up some of the bad protein, and shows it to T cells. The T cells then know what protein to find, and they kill any cell carrying that protein.

**VACCINE THERAPY**

Therapy involves selectively harvesting cells from the patient's blood that can be matured into dendritic cells. These dendritic cells are then customised to the foreign protein or cancer antigen called mucin-1. The mucin-1 targeted dendritic cells are the treatment or in the case of PrimaBio-Med, CVac™.

**TARGETING THE TUMOUR**

When the cells are injected back into the patient's skin, they find T cells and show them the antigen. Activated T cells then hunt down tumour cells displaying Mucin-1 and destroy them.

**FREQUENTLY ASKED QUESTIONS**

**HOW IS CVAC™ DIFFERENT FROM OTHER IMMUNE THERAPIES FOR CANCER?**

In the case of Provenge®, the vaccine targets prostate cancer only. The cells are injected into a vein, whereas CVac™ is injected under the skin where it finds T cells in large numbers. Other immune therapies may take a sample of the patient's tumour, killing it and returning it to the patient in the hopes that the body will start treating the tumour as an invader, and attack it. Yet other therapies simply boost the whole immune system, running the risk that other tissues will be damaged by attack by T cells.

**WHAT OTHER TUMOURS ARE BEING TARGETED BY VACCINE THERAPY?**

There are many immune therapies in development for cancers, and many have shown promise during early development. Another company, Merck KgA, is developing a vaccine against Mucin-1, but in their case, they target lung and breast cancer. The vaccine is called Stimuvax™ and in early studies, patients lived 17 months longer on average than patients receiving a placebo.

**WHY DOES THE BODY NOT RECOGNIZE TUMOUR CELLS AS ABNORMAL BEFORE IT GETS THE VACCINE?**

Tumour cells have escaped the normal patrolling T cells and hide in the background. It is only when the vaccine is given, and many new T cells are recruited to hunt down the tumour, then it can no longer remain undetected with such a focused attack.

**DO VACCINES WORK TO PREVENT CANCER?**

They may do in the future. However, each vaccine tends to be targeted at one tumour type, and we would all have to receive thousands of vaccines to try to prevent any type of tumour from developing.



## About the Phase III Trial

The Phase III Trial for CVac™ will be conducted on a 750 patient population in a double-blind, placebo-controlled study (randomized 1:1) of CVac™ vs Standard of Care.

It will be conducted across multiple sites in Europe, US and Australia. This will include the world renowned Charite University Hospital in Berlin, Bonn University, both in Germany, Stanford Medical Centre in the United States and the Austin Hospital in Melbourne, Australia.

The trial will run concurrently with the Phase IIb Clinical Trial, which is currently underway, under the authority of US Food and Drug Administration.

The CVac™ Phase III Trial is designed to deliver statistically powered endpoints for progression free survival, and also for overall survival.

The patient population will be randomised to the CVac™ treatment arm vs a standard of care observation arm.

The objective of the trial is to further confirm the ability of CVac™ to reduce the instance of relapse in ovarian cancer patients, control the metastases of the cancer and increase the life expectancy of patients. Patient quality of life and patient immunological markers will also be measured.

If statistical endpoints are successfully reached it is the Company's hope that CVac™ would become the world's first ovarian cancer immunotherapy treatment and, in so doing, provide a new paradigm for patients and oncologists globally.

**'... it is the Company's hope that CVac™ would become the world's first ovarian cancer immunotherapy treatment and, in so doing, provide a new paradigm for patients and oncologists globally'.**

## Initial Phase IIb Trial patient group successfully completes first CVac™ vaccine treatment

The Company has been delighted with the progress of its Phase IIb Trial for CVac™ to date.

We recently reported a major milestone in the trial; that the initial patient group had successfully completed its first treatment with the CVac™ immunotherapy vaccine and that, importantly, no safety data concerns had been expressed by the Data Safety Monitoring Board.

This represents a significant achievement for the Company, and the progression of its clinical trials. It not only marks the treatment of the first group of trial patients, but it also paves the way for the enrollment of the balance of patients into the Phase IIb Trial.

Patient enrollment into the randomised component of the trial will now proceed. This will include a further 54 pati-

ents. This patient cohort will be tracked on either standard of care versus treatment with CVac™ (CAN-003 is versus standard of care. CAN-004 is versus placebo.)

The initial patient group, which comprised seven patients who met the Phase IIb Trial's eligibility criteria, completed their first injection of the CVac™ vaccine and were then monitored for a period of (at least) 28 days to assess any treatment-related adverse effects.

Prima was delighted to report to the market that this patient group did not suffer any therapy related adverse effects. As a result, the Data Safety Monitoring Board advised that the Phase IIb Trial was safe to proceed.

Its positive verdict was based on a detailed review of patients' safety laboratory measures of blood, serum and urine chemistry, vital signs, and any reported study agent effect.

Further information on the Phase IIb Trial will be released on the ASX as it becomes available.

**'It not only marks the treatment of the first group of trial patients, but it also paves the way for the enrollment of the balance of patients into the Phase IIb Trial'.**



## Planned upcoming activity

The Company is entering an extremely active phase in its development plans for CVac™, and also its other clinical programs. Following is an overview of some of the key pieces of upcoming Company activity to anticipate.

Event	Indicative timeline*
Potency Assay qualified for Phase IIb Clinical Trial	Q1, 2011
Fast Track Status for Phase IIb Clinical Trial expected to be granted by FDA	Q2, 2011
Phase IIb Clinical Trial completing enrollment	Q3, 2011
Phase III Clinical Trial commences enrollment	Q3, 2011
Initial data for Oral HPV vaccine received	Q3, 2011

\* The timelines listed above are indicative only, and are designed to provide a guide on timing of key upcoming events. The actual times of delivery of these events is subject to change and may vary depending on a number of internal and external factors

The above represents some of the major upcoming events scheduled for 2011. For details of all material information releases from Prima, please refer to the Company's ASX announcements during the course of the year.

## Strengthening the Prima team – New CFO appointed



Prima prides itself on the calibre of people it attracts to the Company. It has assembled a world-class clinical team and management team, and is delighted to welcome the latest addition to the team, the Company's new CFO Ian Bangs.

Ian has more than 25 years experience in senior finance positions with companies across a range of diversified industries. With the continued strong growth in Prima's business, he will play a key role in the Company's corporate management team. He has previously been Chief Financial Officer and Company Secretary for a number of ASX-listed companies, including LandMark White Limited and IFC Capital Limited.

He also spent 10 years as the CFO of the Regent Hotel in Sydney. Ian has expertise in the day to day financial and administrative operations of businesses, together with their statutory reporting and compliance obligations. He has a Bachelor of Commerce degree and is a Fellow CPA.

### For further information please contact:

**Mr Martin Rogers**  
 Chief Executive Officer  
 Prima BioMed

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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 Code: PRR

Issued Capital - Ordinary shares  
 774.6M

(Listed) Options  
 102.1M (exercise price \$0.02 on or before 31 Dec 2011)

Market Capitalisation (fully diluted)  
 A\$201.4M (@ 14/02/11)

Cash Position  
 A\$14.4M (@ 31/12/10)

## 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

Matthew Lehman	Chief Operating Officer
Dr Sharron Gargosky	Senior Vice President, CVac™ Program
Vanessa Waddell	Business Development and Intellectual Property Manager
Larisa Chisholm	Intellectual Property Manager