



# PRIMA BIOMED INVESTOR UPDATE

EDITION 1  
SEPTEMBER 2010

## Message from the CEO

*"I am pleased to bring you the first issue of the Prima BioMed Investor Update. Shareholders and followers of the Company would be aware that over the past year we achieved significant progress in our goal to develop and commercialise our headline cancer treatment product, the CVac™ immunotherapy vaccine for ovarian cancer.*



*During this period, the Company initiated its Phase IIb Trial for CVac™ with the US Food and Drug Administration (FDA) and began preparations for a CVac™ registration study, to be conducted in Europe. We also appointed a number of key clinical and management personnel to the team to help drive the trials process, and attracted strong financial backing which has allowed the Company to pursue the development of CVac™ with significant confidence.*

*But this is no time to reflect on achievements to date. The Company continues to work diligently on progressing the trials process for CVac™, as we move into a critical phase where over the next 12 months we will be running our Phase IIb and registration study concurrently. This represents an exciting period for the Company and we look forward to sharing this with you via our Investor Updates.*

*In this first issue, we provide an overview of the CVac™ program and introduce you to some of the key members of our management team, as well as offer an outlook for the Company over the coming 12 months. Also, at Prima we believe strongly that how we conduct our business is as important as the business itself, and with this in mind we have formulated a number of key values by which the Company measures itself and these are included in this Investor Update.*

*We are excited by the potential for CVac™ to provide a commercially available treatment option for ovarian cancer patients globally, and thank all our investors for their support as we continue on this journey."*

*Martin Rogers  
Chief Executive Officer*

## An Introduction to CVac™ Cancer Vaccine

The CVac™ immunotherapy cancer vaccine involves the manipulation of a patient's own dendritic cells to create (in the case of cancer) tumour-protein expressing dendritic cells that are then injected back into the patient to trigger a cytotoxic immune response to the protein, leading to tumour regression.

Dendritic cells are a subset of white blood cells whose primary role is to educate the immune system to recognise infection and cancer. When the dendritic cell encounters foreign material it generates a recognition signal and triggers the immune system to respond by activating another subset of blood cells called cytotoxic or killer T cells. These cells then respond by killing the foreign material.

Manipulating the dendritic cells outside the patient's own body allows the cells to overcome the evasive mechanisms of the tumour, and the immune system is educated to recognise and fight the tumour.

At Prima BioMed the tumour antigen being targeted is called mucin-1. This is a molecule expressed by a variety of tumours including breast, ovarian, prostate, lung and colon cancers. Mucin-1 is expressed by normal tissue in the body but changes conformation on tumour cells so the immune response will be specific to the tumour tissue and will not damage normal tissue.

We also use a proprietary immune adjuvant called mannan (oxidised mannose). Mannan assists in activating the immune system and ensures preferential expression of the production of killer T cells that will target mucin-1.

*Continued on page 3.*

## Company Mission and Values

### Our Mission

Prima BioMed strives to be at the cutting-edge in the fight against cancer by transforming the promise of science and biotechnology into therapies that have the power to restore health and save lives of cancer patients. In everything we do, we aim to fulfill our mission to serve patients by funding the next cutting-edge medical innovation to creatively working on patient treatment delivery.

### Our Values

#### Medical Innovation

Our success depends on superior scientific innovation, integrity and continuous improvement in all aspects of our business through the application of the scientific method in medical innovation for cancer treatments. We see the scientific method as a multi-step process that includes designing the right experiment, collecting and analyzing data and rational decision making. It is a logical, open and rational process. Applying the scientific method in all parts of the organisation is expected and highly valued. Funding the next level of medical innovation is part of this value.

#### Think and Win

We compete against time, past performance and industry rivals to rapidly achieve high quality results in cancer treatment. Winning requires taking risks and thinking. We cannot be lulled into complacency by previous achievements. Though we compete intensely to win, we maintain high ethical standards and demand integrity in our dealings with partners and each other.

#### Create Value

We provide value by focusing on the needs of patients and improving the lives of those suffering from cancer. Prima BioMed creates a work environment that provides opportunities for staff members to reach their full potential. We strive to provide shareholders with superior long-term returns while balancing the needs of patients, staff and shareholders.

#### Be Ethical

It may appear normal to behave ethically particularly for a cancer treatment company but it is in difficult times and challenges we are mindful in applying the highest ethical standards to our products, services and communications.

#### Trust and Respect Each Other

Every job at Prima Biomed is important and every Prima Biomed staff member is important. We attract diverse, capable and committed people and provide an environment that fosters inclusion,

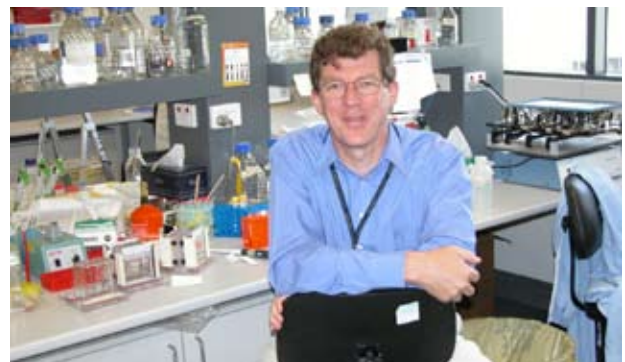
respect, individual responsibility and values diversity. Trust is strengthened through personal initiative, proactive thinking, transparency and by obtaining quality results rapidly.

#### Ensure Quality

Quality is a cornerstone of all of our activities from manufacturing processes, clinical trial work and communication. We seek the highest quality information, decisions and people. We produce high quality products and services. Quality is woven into the fabric of everything we do.

## A message from the Company's Scientific Advisory Board Chairman

*"I am extremely encouraged by the progress being made by the Company in developing and commercialising CVac™ as a potential treatment option for ovarian cancer patients in the global multi-billion oncology pharmacy market. CVac™ makes use of a new paradigm in cancer treatment, utilising the body's own immune system to fight cancer. CVac™ is a therapy vaccine treatment which is intended to be administered post-surgery and post-chemotherapy to delay relapse and control metastases. There is currently a large unmet medical need for new treatments for ovarian cancer, which has a very high morbidity rate, and development of CVac™ as part of a treatment program for patients is extremely exciting for the company.*



*Prima BioMed Scientific Advisory Board Chairman, Professor Ian Frazer*

## CVac™ cancer vaccine in action

A short video which provides an overview of how the CVac™ vaccine works in practice for ovarian cancer patients is available at the Company website. Just access the following link to view the video; [www.primabiomed.com.au/movies/movie\\_3.php](http://www.primabiomed.com.au/movies/movie_3.php).

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## An Introduction to CVac™ Cancer Vaccine

Dendritic Cell Therapy offers a number of advantages over other practiced and experimental treatments for cancer. Firstly, by targeting a protein that sits on tumour cells in a form not on normal cells, the side effects are minimal which is in stark contrast to cytotoxic agents (chemotherapy) which kill cells indiscriminately.

Secondly, the process activates the immune system to recognise the tumour and once the immune system is activated it will continue to fight the tumour, unlike antibody based therapies that need to be administered at frequent intervals to have their effect on tumours.

Dendritic cells can be isolated from a cancer patient and manipulated to trigger recognition of a cancer by T cells. Isolation of the dendritic cells from the blood takes place via a process not dissimilar to donating blood, called leukapheresis.

Once the dendritic cells have been removed from the patient they are then manipulated in the laboratory to express a tumour associated protein or antigen. These cells are then injected back into the cancer patient where they activate the killer T cells to fight the tumour.

## Meet our management team

In each issue of our Investor Update we will provide profiles of members of our senior management team. In this first issue we feature our most recent addition to the team, Dr Sharron Gargosky and our Chief Operating Officer Matthew Lehman.

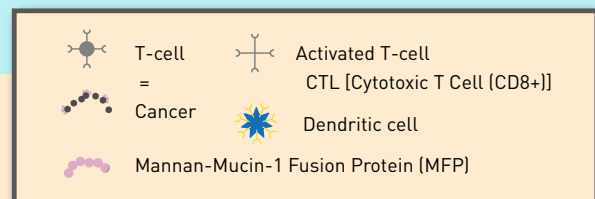
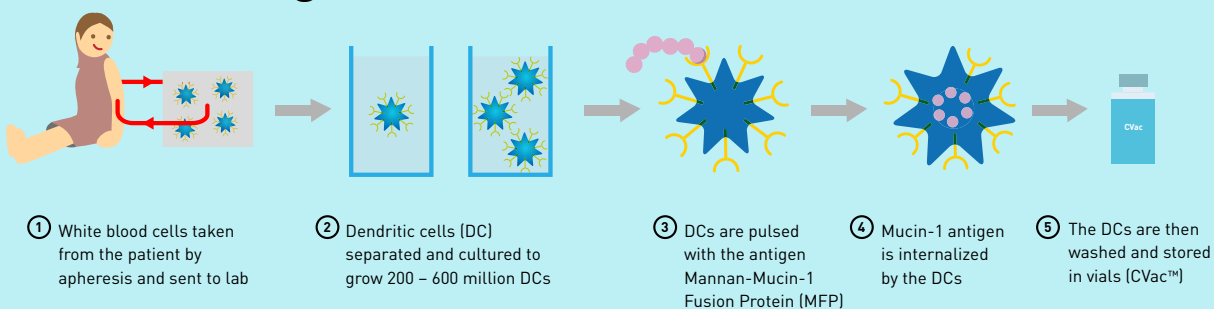
### Dr Sharron Gargosky, Senior Vice President, CVac™ Program

Dr Gargosky has been in the pharmaceutical industry for more than 15 years and has worked in senior roles in many different therapeutic areas - endocrinology, hepatology, diagnostic, and metabolic. Importantly Dr Gargosky has spearheaded three US FDA Orphan Drug approvals.

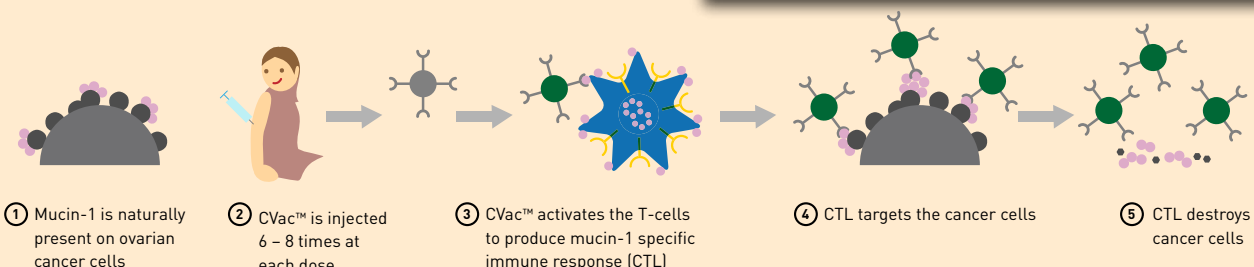
At Ucyclyd Pharma she managed the approval of orphan drug products (Ammonul®) and the development of a NCE (New Chemical Entity). At Medicis Pharmaceuticals she managed the successful BLA (with the US FDA) submission for Reloxin®, and as Vice President of Business Development at Diagnostic System Laboratories she was responsible for business expansion through the evaluation and implementation of new growth opportunities and patent portfolio management.

Dr Gargosky's other previous positions include Clinical Director for Pharmacia, and Assistant Research Professor in the Endocrinology Division at Oregon Health State University. Dr Gargosky has a PhD from Adelaide University and completed a post-doctoral fellowship at Stanford University in California.

## Manufacturing of CVac™



## Mechanism after injection



## Meet our management team

### Mr Matthew Lehman, Chief Operating Officer

Mr Lehman has strong experience in clinical research, development programs and obtaining drug approval. He has specific expertise in clinical development strategies, operations and in-outsourcing.

Prior to joining Prima Biomed Mr Lehman was chief operating officer for SPRI Clinical Trials in Europe, where he managed a team of 60 staff and 50 consultants in all areas of clinical operations. Over the past nine years he has been involved in approximately 150 clinical programs in a variety of roles.

In his role with Prima, Mr Lehman is based in Berlin, Germany and plays a key role in leading the Company's research and development plans, and clinical trials for the CVac™ ovarian cancer therapy vaccine in Europe.

Mr Lehman has a Master of Science from Columbia University in New York, and a Bachelor of Arts, Political Science and History from the University of Louisville, Kentucky, USA. He is also a member of the European Business Association and Association for Clinical Research Professionals.

## Prima BioMed – Fast Facts

<b>Listings</b>	Australian Securities Exchange
<b>ASX Code</b>	PRR
<b>Issued Capital</b> (30 August 2010)	719,475,645
<b>(Listed) Options</b> (30 August 2010)	116,406,444
<b>(Market Capitalisation)</b> (9 September 2010)	A\$75.6M
<b>Cash Position</b> (30 June 2010)	A\$15.6M+A\$17.5M converting note with Spring Tree Global Investors

### Board

Mr Albert Wong, Non-Executive acting Chairman  
 Mr Martin Rogers, Managing Director and CEO  
 Dr Neil Frazer, Executive Director, Chief Medical Officer  
 Dr Richard Hammel, Non-Executive Director

### Senior Management

Mr Martin Rogers, Chief Executive Officer  
 Dr Neil Frazer, Chief Medical Officer  
 Mr Matthew Lehman, Chief Operating Officer  
 Dr Sharron Gargosky, Senior Vice President, CVac™ Program  
 Ginny Raymond, Clinical Affairs Director  
 Vanessa Waddell, Business Development and Intellectual Property Manager  
 Larisa Chisholm, Intellectual Property Manager

## Outlook for the next 12 months

The upcoming 12 months promises to be another period of rapid development for the Company, with the progression of the late stage trials for CVac™ being a key priority and focus. The following is an overview of some of the key milestone points to look out for during this period.

### Orphan Drug status for CVac™ with FDA and Fast Track Application for CVac™ with FDA.

Both these represent significant points in the development of CVac™ and will help ensure that the commercialisation of CVac™ is achieved in a timely and efficient manner. The Company hopes to secure FDA Orphan Drug status for CVac™ and also submit its Fast Track Application for CVac™ with the FDA by the end of 2010.

Orphan Drug status provides incentives to encourage companies to pursue cures and treatments for rare diseases, such as ovarian cancer. These include; fast tracking, research support, eligibility for protocol assistance and possible exemptions in regulatory fees. Orphan Drug status also provides the exclusive rights to the cure or treatment for a specific condition for an extended period of time post its commercial approval, and the provision of tax benefits.

**CVac™ registration study in Europe.** The Company is already engaged in preparations for its registration study for CVac™. In the first half of next year it aims to secure regulatory authorisation for the trial and then initiate the Phase III Trial. The first component of this is to have the EU approve the license of the manufacture of CVac™, and then the Company will be able to move forward into patient recruitment for the trial.

Commencement of the Phase III trial in Europe will be a major point in CVac™'s development, as from this point on trials will be run concurrently by the FDA and in Europe. The goal will be to achieve a larger data outcome in a shorter period of time.

We look forward to keeping you up to date with these and other developments in the months ahead.

### For further information please contact:

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**Chief Executive Officer**

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