

# INVESTOR UPDATE

by  **PRIMA BIOMED**

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9



CEO Matthew Lehman

## Message from the CEO

*On behalf of all of us at Prima, we wish you a happy New Year. It has been a busy holiday period for the Company and it does not look to slow down anytime soon.*

*We continue to monitor and collect patient data on the CAN-003 trial. In the second half of this calendar year, we look forward to the final analyses of this phase 2 study. This is a critical catalyst in the ongoing development of CVac for ovarian cancer.*

*For the CANVAS trial, we have recently received regulatory approvals in many European countries including Belgium, Bulgaria, Belarus, Lithuania, Latvia, Ukraine, Poland, and Germany. We are also pleased to report that the first patients have been dosed in the US and Australia for this study. Thanks to Marta Schilling and the team for this milestone.*



First dosing in USA/AU

*In addition to the ovarian cancer program, we look forward to initiating additional pilot studies of CVac in additional cancer targets pending appropriate funding. With our significant investment in manufacturing and logistics capacity, and the positive signals we are receiving from the immune monitoring data, we think it is very sensible to maximize the potential application of our product. During the coming months, we will be able to share a lot more about the Company plans for starting and funding these plans.*

*I would like to thank our investors for their ongoing support of Prima. While we still have a lot to do, we have been able to make great advances with our research programs and we are getting closer to our end goal of bringing efficacious and less toxic treatments to cancer patients.*

*I wish all of you a great 2013 and I look forward to keeping in touch as we meet our milestones this year.*

**Matthew Lehman**  
Chief Executive Officer

## A patient's CVac journey – a new series

Beginning in 2013, your Shareholder Newsletter will introduce a new series which will take shareholders on an in-depth journey of a patient in the clinical trials of CVac.

Each quarter will concentrate on a specific aspect of the trial process. Through this series, we aim to provide a close-up look at what patients go through in CVac's clinical programs and an overview of the trial process from a patient's perspective.

The following topics will be covered;

- 2Q CY 2013 – Cancer diagnosis and screening for eligibility
- 3Q CY 2013 – Cell collection and logistics management
- 4Q CY 2013 – CVac Manufacturing and quality control process
- 1Q CY 2014 – Dosing and how CVac works in the body
- 2Q CY 2014 – Patient follow up and monitoring

## Prima Investor days & Conference calls

In early February, Prima's management held a number of public investor days in major cities throughout Australia. These days have provided shareholders and other followers of the Company a first hand opportunity to hear the latest on the progress of Prima's clinical programs for CVac and its other initiatives, and the opportunity to participate in Q&A sessions with management.

Details of investor days and the presentation are available at Prima's website.

The Company will also conduct quarterly conference calls throughout the year to help keep shareholders up to date with its activities and operations.

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*Dr Richard Hammel*

## Q & A with Dr Richard Hammel

Dr Richard Hammel is the longest serving director of Prima BioMed, having joined the board in 2005. Dr Hammel is an industry veteran of 30 years and was a

founding partner of ProPharma International Partners, a pharmaceutical/biotechnology consulting firm which provides a range of services, from business to financial and product development. He has previously held senior management positions with Glaxo Pharmaceuticals, Connetics Corporation as Vice President for Commercial Development, and Matrix Pharmaceuticals Inc. as Vice President of Business Development, Sales and Marketing.

Dr Hammel has also held several positions at Glaxo Inc, including Director of Professional Affairs, Director of New Business Development, and Director of Marketing Services.

**Q: 2012 was a year of considerable change for Prima BioMed; can you provide some insights from your perspective on the change within the Company?**

**Answer:** *I have watched this Company continuously grow and improve over the past seven years, and have been very pleased with the recent additions to the management team and the focus and refinement of the business strategy. Just a few years ago, Prima had a number of research programs in different technology areas and as we have continued into development, we have now concentrated our efforts on the most promising of these technologies. The directors see substantial value in the cancer immunotherapy space with a couple of products, such as Provenge® and Yervoy®, now reaching the market. More products are entering late phase trials, and there is increasing interest from bigger pharma and biotech companies.*

*We believe that CVac and the immune cell technology will drive our growth. Importantly, our management team has developed along with our technology and clinical trials. Our executive leadership brings significant*

*industry experience in the fields that Prima needs to succeed - immunotherapy for oncology, clinical development, manufacturing, corporate finance, and business development.*

**Q: What are the Company's plans for CVac?**

**A:** *We are very pleased with CVac for its potential applicability in a number of cancer types. The scope of our global manufacturing know-how and our intellectual property position sees us well placed to drive further development. One important point to note is the side effect profile seen thus far in trials of CVac. The safety and tolerability of CVac may give us an attractive complementary treatment to more traditional therapies with higher toxicity.*

*Our plan for CVac is to maximize the value of the product through optimization of a cost effective and global manufacturing platform, advancing in late phase global clinical trials for ovarian cancer, and commencing pilot trials of CVac in other cancer types that over express mucin 1 pending appropriate funding.*

**Q: In more detail, can you discuss the manufacturing technology platform?**

**A:** *We like to consider this manufacturing platform as the long-term driver of value at Prima. Certainly, we are very interested in the efficacy of CVac for ovarian cancer and other cancer targets - there will be a lot of data coming out in 2013 and beyond on this front. Additionally, our manufacturing platform provides us with multiple opportunities for further value creation. It puts us in a position of strength to negotiate potential partnerships for CVac and we can also look at other immunotherapy products to bring into Prima's pipeline. Our global manufacturing capacity gives us a significant competitive advantage and we look to consolidate our position as a leader in this space.*

## Evaluating T cell responses in CVac patients

# Why Prima is undertaking intracellular cytokine staining (ICS) of T Cells

T cells are a subtype of lymphocytes (a white blood cell) essential for human immunity. They protect the body against infections and cellular abnormalities. T cells are produced in the bone marrow and migrate to the thymus where they are matured, hence their name T cells (or T lymphocytes). Once T cells are matured and have acquired their cell surface protein expression (e.g. CD4 or CD8 protein) they circulate in the blood and are present in lymph nodes. T cells contribute to your immune defenses in two major ways. Some help regulate the complex workings of the overall immune response, while others are cytotoxic and directly contact infected cells and destroy them.

### Helper T cells (CD4+)

Helper T cells are needed to activate many immune cells, including B cells and other T cells. They help other white blood cells of the immune system during an infection. They also activate CD8+ T cells and antigen presenting cells. Helper T cells are also known as CD4+ T cells as they express the CD4 protein on their surface. CD4+ T cells become activated by recognizing a small fragment of a foreign molecule which is expressed on the surface of antigen presenting cells (such as dendritic cells).

### Cytotoxic T cells (CD8+)

Cytotoxic T cells, sometimes called killer T cells, are also known as CD8+ T cells as they express the CD8 protein on their surface. CD8+ T cells are activated and then kill cells by recognizing a small fragment of the virus or cancer which is expressed on the surface of antigen presenting cells (such as dendritic cells). CD8+ T cells are the main defense cells against viruses and cancer cells.

Prima BioMed is evaluating the types of T cell response induced by CVac with a technique called intracellular cytokine staining (ICS). Both the CD4+ and CD8+ T cells secrete certain types of cytokines called lymphokines or interleukins. These types of cytokines have many purposes, including serving as a messenger among T cells, facilitating activation of additional T cells to mount an immune re-

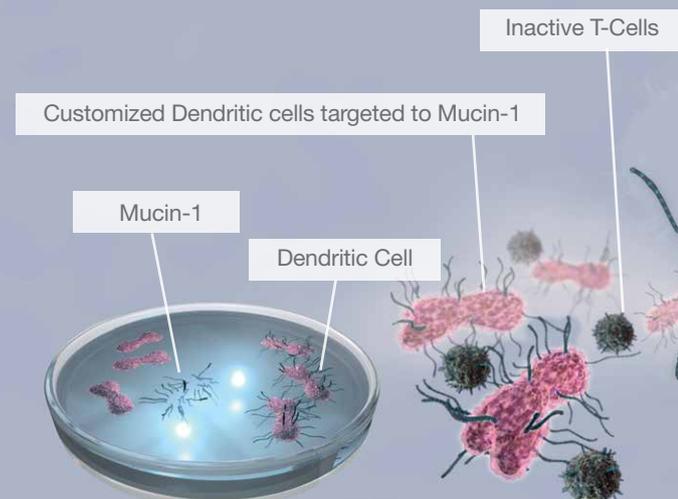
sponse, and direct action in the killing of cancer cells. Cytokines work by binding to specific receptors on target viral or cancerous cells, and they recruit many other cells and substances to the field of action. Some cytokines recruit the CD8+ killer T cells to the site of the cancer, which then contain potent cytokines and chemicals to kill cancer cells on contact.

### How CVac and dendritic cells interact with T cells

CVac is made of a patient's own dendritic cells exposed in a laboratory to a specific antigen mucin 1. When CVac is injected into a patient, the dendritic cells present the mucin 1 antigen to T cells, which activates them to start an initial immune response. As the CD4+ and CD8+ T cells start the immune response, the cytokines they illicit can then trigger activation of additional T cells to the site of the cancer cells.

By evaluating the types and intensity of cytokine responses by intracellular cytokine staining, Prima intends to more fully understand how CVac is working in a patient's body.

Illustrations by brandLOVERS.de





Marta Schilling

## Meet the Prima team - Marta Schilling, VP of Manufacturing

Marta Schilling joined the Prima team in November of 2011 as Vice President of Manufacturing. Marta has over 25 years of experience spanning corporate

research and development, clinical trials, product development, customer training and support and cGMP cell therapy manufacturing.

Based on the West Coast of the US, prior to joining Prima BioMed, Marta was the Technical Director – Projects at Progenitor Cell Therapy’s West Coast Facility where among other cell therapy projects, she was a key project team member overseeing the manufacture of CVac for the USA CAN-003 and CAN-003X clinical studies.

Prior to joining PCT, Marta was the Associate Director of the Cell Processing Laboratory at IDM Pharma where she was instrumental in setting up the cGMP manufacturing facility and systems as well as being scientifically involved

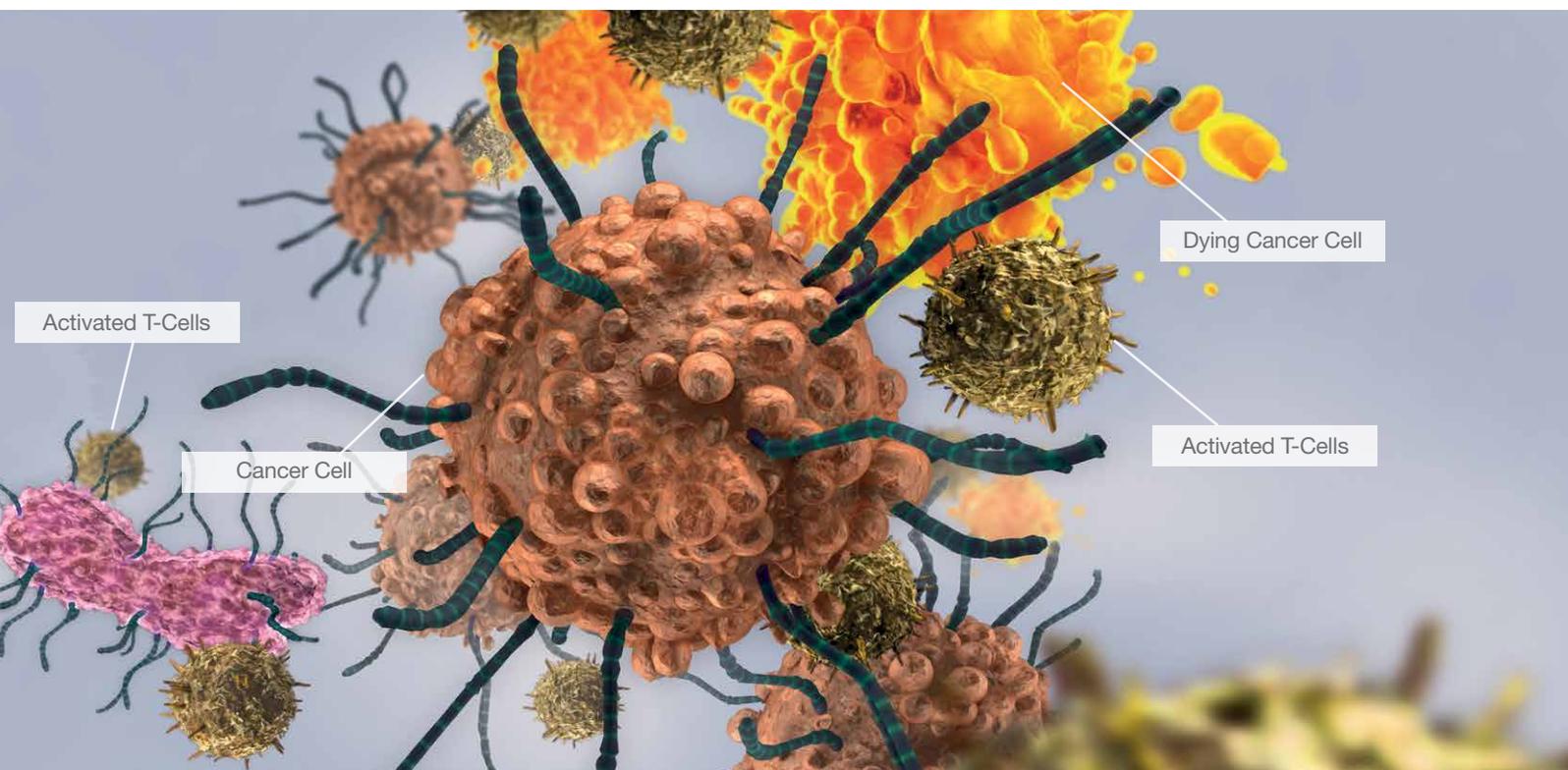
in process improvements for producing autologous dendritic cell vaccines for Phase I/II clinical trials.

Previously she had a long career at Baxter Healthcare and later Nexell Therapeutics where she was involved in the research, development and customer support of the Isolex® CD34 Cell Selection System and the CytoMate® Cell Washer Device. Her responsibilities included product improvements of these cellular therapy devices. She brings this valuable experience to the Prima team as we look to the future for potential new process optimizations.

Ms Schilling was awarded her Bachelor of Science degree in Medical Technology, specializing in Hematology, from the University of Vermont.

Marta is passionate about her work and feels privileged to be a part of the Prima team bringing the promises of immunotherapy to help cancer patients fight their disease using their own cells.

*Fighting cancer with a vaccine*



## Company Calendar

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

<b>11-12 FEB 2013</b>	<i>The BIO CEO &amp; Investor Conference, New York City, USA</i>
<b>11-13 MAR 2013</b>	<i>ISBiotech, Virginia, USA</i>
<b>11-13 MAR 2013</b>	<i>BIO-Europe Spring, Barcelona, Spain</i>
<b>22-25 APR 2013</b>	<i>BIO International Convention, Chicago, USA</i>
<b>22-25 APR 2013</b>	<i>19th International Society for Cellular Therapy, Auckland, New Zealand</i>

<b>Q1 - 2013</b>	<ul style="list-style-type: none"> <li>• <i>Last patient enrolled on CAN-003X</i></li> <li>• <i>CANVAS first Data and Safety Monitoring Board meeting</i></li> <li>• <i>EU CANVAS start</i></li> <li>• <i>Half-year report</i></li> </ul>
<b>Q2 - 2013</b>	<ul style="list-style-type: none"> <li>• <i>Announce pilot trials of CVac in new cancer targets</i></li> </ul>
<b>Q3 - 2013</b>	<ul style="list-style-type: none"> <li>• <i>Final immune monitoring data (intracellular cytokines and mucin 1 antibody) from CAN-003</i></li> </ul>
<b>Q4 - 2013</b>	<ul style="list-style-type: none"> <li>• <i>CAN-003 final progression-free survival data</i></li> <li>• <i>Final CAN-003X dosing</i></li> </ul>

## Stay in touch with Prima

To stay in touch with our activities and progress, check out Prima on Twitter, Facebook, and on LinkedIn

 **Twitter**  
<https://twitter.com/PrimaBioMed>

 **Facebook**  
<https://www.facebook.com/PrimaBioMed>

 **LinkedIn**  
<http://us.linkedin.com/company/prima-biomed-ltd>

 Future issues of the Prima investor newsletter will be available by email only. If you wish to continue to receive the investor newsletter in hard copy please email; [enquiries@primabiomed.com.au](mailto:enquiries@primabiomed.com.au)



*Frozen samples*

## 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), NASDAQ, Deutsche Börse

### Stock Codes

ASX: PRR, NASDAQ: PBMD,  
Deutsche Börse: ISIN: US74154B2304

### Issued Capital - Ordinary shares

1.066B

### Market Capitalisation

A\$117.2M (@ 11<sup>th</sup> of Feb 2013)

### Cash Position

A\$28M (approximate as of 31<sup>st</sup> Dec 2012)

## Board

<b>Ms Lucy Turnbull, AO</b>	Non-executive Chairman
<b>Mr Albert Wong</b>	Non-executive Deputy Chairman
<b>Mr Matthew Lehman</b>	Managing Director and Chief Executive Officer
<b>Mr Martin Rogers</b>	Non-executive Director
<b>Dr Richard Hammel</b>	Non-executive Director

## Senior Management

<b>Dr Sharron Gargosky</b>	Chief Technical Officer
<b>Mr Marc Voigt</b>	Chief Financial Officer
<b>Dr Neil Frazer</b>	Chief Medical Officer
<b>Ms Deanne Miller</b>	General Counsel and Company Secretary
<b>Ms Marta Schilling</b>	VP of Manufacturing

[www.primabiomed.com.au](http://www.primabiomed.com.au)