

Prima BioMed Ltd.

Shareholder Briefing

15 June 2012



Matthew Lehman
*Chief Operating Officer
& CEO Designate*

(ASX:PRR, NASDAQ:PBMD)



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Agenda

- Intros to Prima and management M. Lehman
- Recent accomplishments & updates M. Lehman
- CVac safety & CAN-003X N. Frazer
- CVac development S. Gargosky
- Looking forward M. Lehman
- Questions & answers

Prima BioMed: Introduction

Legal form	Public listed company	• <i>Mission: developing novel and high-value personalized bio-therapeutic products with a focus in cell therapy for oncology.</i> • <i>Lead product: CVac™ is made of autologous dendritic cells pulsed with mannan-mucin-1 fusion protein. In advanced clinical development for ovarian cancer.</i> • <i>CVac potential: mucin-1 is also present in other cancers such as breast, colon, pancreas, lung and stomach.</i> • <i>Technology: global platform (formulation, manufacturing, regulatory, distribution) for development of personalized bio-therapeutics</i>
Active since	2001	
Headquarters	Sydney, Australia	
Shares	1,065 million	
Market cap (13 Jun 2012)	~AU\$ 126 million ~US\$ 125 million ~EUR 100 million	
Headcount	~20	



Prima BioMed is a world leader in the development of personalized bio-therapeutics

Senior Management Introduction

Neil Frazer

- Chief Medical Officer
- Physician with 26 years in industry
- Led development programs in US & EU

Matthew Lehman

- Chief Operating Officer & CEO Designate
- 12 years in industry clinical development
- Hundreds of clinical programs

Sharron Gargosky

- Chief Technology Officer
- PhD biochemist with 18 years in industry
- Responsible for several FDA approvals

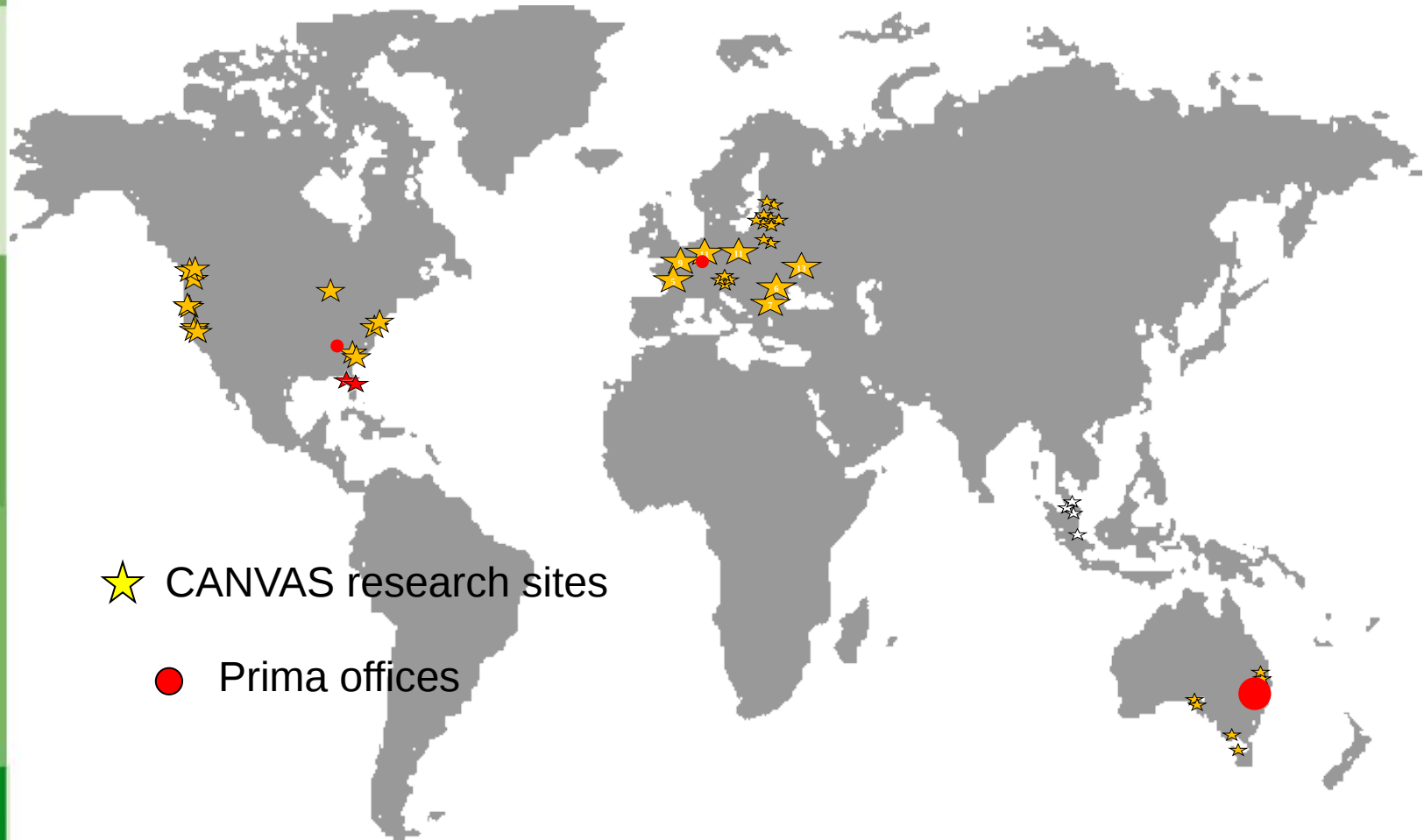
Marc Voigt

- Chief Business Officer
- Corporate development in biotech for 15 years
- Led investment and partnering for several assets

Ian Bangs

- Chief Financial Officer & Company Secretary
- 25 years in senior financial positions
- Company secretary and CFO for a number of ASX companies

Prima BioMed: Global Footprint



Cell Therapy - A new paradigm for the treatment of cancer

Prima BioMed: Key Strengths

- ✓ **Management team** with a proven product development and commercial track record in oncology
- ✓ Clear development plan for **CVac™** in **ovarian cancer** with an opportunity to expand CVac in other cancer indications
- ✓ Significant commercial opportunities to treat patients in remission
- ✓ Broad **intellectual property** position for CVac (patents, process know-how, orphan status in USA and EU)
- ✓ **Strong technology** and **global platform** for development of personalized bio-therapeutic products (cell therapy, immunology)
- ✓ **Liquid stock** on the Australian Securities Exchange (ASX:PRR); American depository receipts (1 ADR: 30 shares) listed on NASDAQ (NASDAQ: PBMD) and Deutsche Börse.
- ✓ **Solid financial position** and unencumbered programs allow flexibility to leverage future development opportunities

Prima's technology & platform

- ❖ **Cryopreserved cell formulation** → minimizes cell collections (leukapheresis procedures) from patients and reduces cost
- ❖ **Intradermal injections** → maximises delivery of maturing dendritic cells to drain to lymph nodes and migrate to tumor cells
- ❖ **Automated logistics** → labeling with bar codes and digital management of the entire supply chain minimizes errors and optimizes use of human resources and facilities
- ❖ **Cell collection expertise** → 40+ qualified and trained cell collection centers worldwide to provide material for high-quality products
- ❖ **Global breadth** → experience in tech transfers, comparability protocols, and regulatory licensing of manufacturing facilities in Australia, USA, and Germany
- ❖ **Mucin 1 multiple opportunities** → mucin 1 is overexpressed on numerous other cancer types; Prima has a unique immunogenic sequence and companion diagnostic to move in other indications
- ❖ **New product opportunities** → when supported by data and financing, at the right time, Prima has the opportunity leverage company strengths with new products

Recent Accomplishments & Business Updates



US & German ADR Listings

- SEC process in US significant validation of transparency & compliance of the business
- In line with Prima's strategy of global visibility and operations
- Important step to facilitate larger and institutional investors in USA and Europe
- Expect to increase interest and liquidity in the stock over time – especially behind *clinical trial data that drives US analysts*

Dubai Operations

- Was an interesting opportunity for a pilot commercialization project
- The initial assumptions of the business case were too optimistic
- Too challenging to reliably treat patients and too long to achieve profitability in Dubai to continue the business
- CVac and Prima can come back to the region at a more appropriate time

Cripto-1

- Embryonic gene implicated in carcinogenesis; re-expresses at high levels in several human tumor types.
- Interesting target for potential antibodies
- Prima tested 3 antibodies generated at the Burnet Institute (Melbourne)
- Strong binding to Cripto-1; however, no detectable direct killing of cancer cells
- While it is still an interesting target, potential applications would require substantial early phase research work – *not Prima's focus*

CVac™

- EUR 4.1 million grant from Saxony, Germany supports European development
- CAN-003 study completed recruiting 63 patients in 3rd quarter 2011
- CANVAS trial commenced recruitment in 1st quarter 2012; Australia & US sites open
- Major advances in control & scale-up of manufacturing, distribution, supply chain

CVac Intellectual Property

- ✓ Licensed patents and unique mucin 1 sequence demonstrated to stimulate high levels of immune activity in nonclinical and clinical studies
- ✓ Composition of matter patent on Cvac and other key antigens
- ✓ Method patent for processing DCs with the antigen
- ✓ Orphan status (in ovarian cancer) in USA and EU
- ✓ Protection under biosimilars legislation
- ✓ Immense process and logistics know-how

CVac development and IP has established Prima's leadership position in personalized bio-therapeutics

CVac Potential Market

- **Target Patient Profile:** Stage III/IV epithelial ovarian cancer patients who are in complete remission after optimal debulking surgery and platinum & taxane containing chemotherapy = **New Market**
- Annual incidence of EOC in Australia & “major markets” (USA, Japan, UK, Germany, France, Italy, Spain) ~61,283 p.a. (2010)
- 70-75% diagnosed in late stage ~44,400 p.a.
- 70-80% of those patients are mucin 1 positive and achieve remission ***~33,300 p.a. (Total estimated present market size in Australia & major markets)***
- CVac potential market share & price depends on:
 - Competitive products for maintenance of remission – currently there are none in advanced development
 - Clinical trial results (quantification of benefit)
 - Negotiations with payors & health plans (e.g. PBS)

CVac™

Safety & CAN-003X Study



Neil Frazer, MB ChB
Chief Medical Officer

(ASX:PRR, NASDAQ:PBMD)



Why Cvac should be well tolerated

- Autologous dendritic cell approach
 - Comprised of a patient's own cells
 - Normal Mucin 1 is produced by cells lining body tissues exposed to the outside world, and only at their tips that line these organs (airways, gut, mouth and others)
 - Killer T Cells do not normally enter these “tubes”
- Killer T Cells target abnormal Mucin 1
- Intradermal route is inherently a safe way to deliver the dendritic cells to optimize migration to lymph nodes

CAN-001 and CAN-002 safety

- Studies recruited patients with rapidly progressing disease
- Studies did not have an arm with patients who did not receive CVac
- Multiple courses of chemotherapy, surgery and radiation therapy for all patients
- Cvac was very well tolerated
- Adverse events recorded were almost always associated with the disease, not Cvac
- Investigator assessment: some injection site reactions (similar to mosquito bites), rare temporary flu like illness related to Cvac

Safety Profile in CAN-003

- Independent safety reviews by a safety monitoring board to date support progression of the study
- Serious adverse events (for example requiring time in hospital) are uncommon, and almost always considered disease related
- One death (cerebral hemorrhage) in a patient in the “standard of care” arm while on study, obviously unrelated to CVac
- Pain on injection and/or injection site reaction (mild) in 7 of 36 patients receiving Cvac
- Full safety analysis anticipated after completion of dosing of all CAN-003 patients

CAN-003X

- Newer protocol only for CAN-003 patients
- Allows patients who progress during the CAN-003 study to:
 - receive CVac for the first time (if they had been in the standard-of-care arm), or
 - continue to receive a full course of Cvac if they had not completed the course on CAN-003
- The study is ongoing and one death due to disease progression has occurred
- Data outcomes:
 - Explore safety of combining CVac with standard chemotherapy
 - Additional data for overall safety

CVac™

Development for ovarian cancer



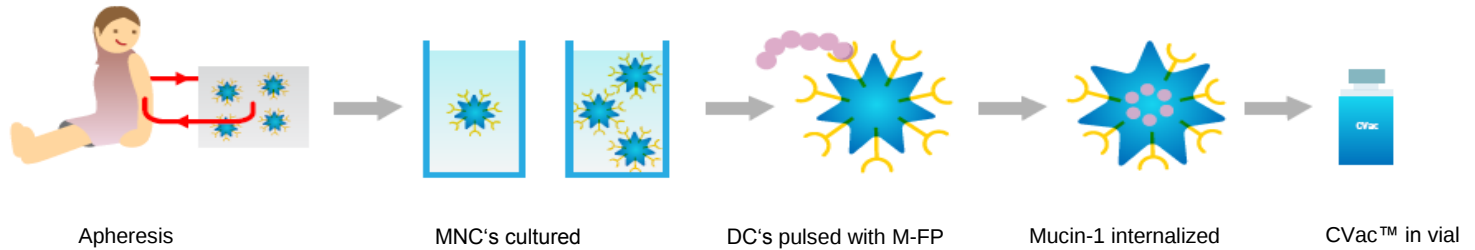
Sharron Gargosky, PhD
Chief Technology Officer

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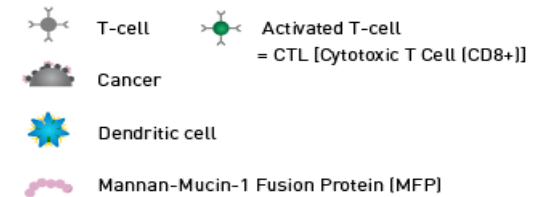
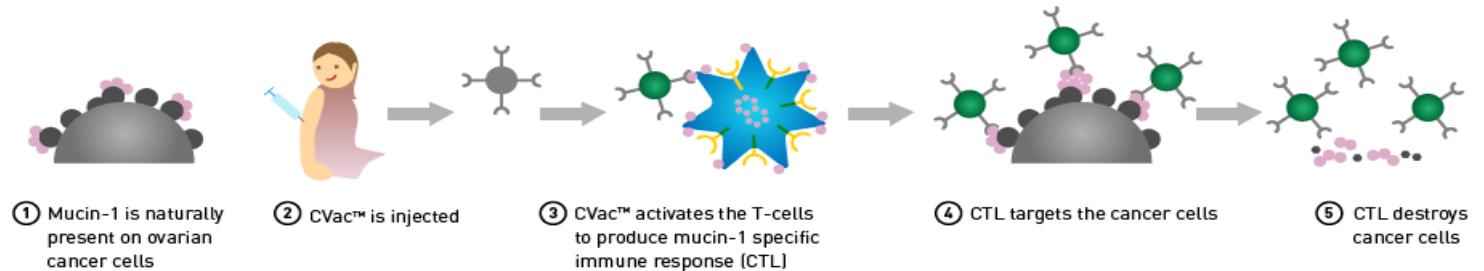


CVac overview

Manufacturing of CVac



Mechanism after injection



Mucin 1 Immunotherapy

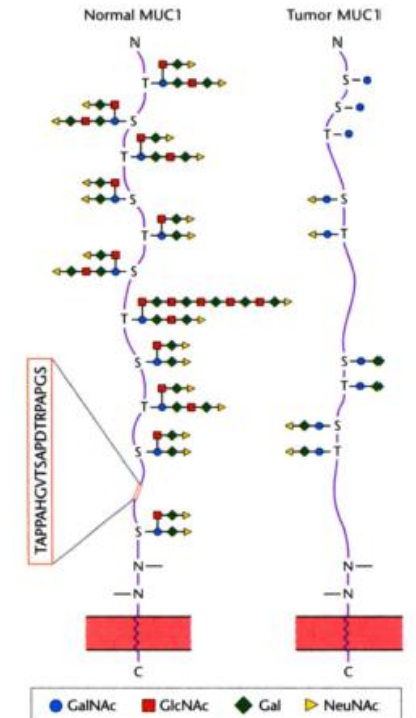
Objective - stimulation of the immune system to target and destroy tumors, leaving normal tissue undamaged

Mucin1 selected as the target for immunotherapy

Up to a 40-fold increase in the amount of mucin1 present in cancer cells compared with normal cells

Alteration in cellular distribution of mucin1 in cancer cells, with mucin1 being found ubiquitously throughout the cell rather than at the secreting pole

May also be an alteration in the structure of mucin1 such that new carbohydrate and peptide epitopes, which are not detected in normal tissues, are exposed – i.e. “naked” protein is exposed



Differences in the structure of the mucin MUC1 expressed by normal and tumor cells. Normal MUC1 (left) has more complex O-linked sugar chains than tumor MUC1 (right), which has simpler (and fewer) sugar chains. The tandem repeat sequence of 20 amino acids is exposed in the under-glycosylated tumor MUC1 but not in normal tissue MUC1.

CAN-001 Study

- 10 patients with terminal cancer (3-6 months life expectancy), broad range of adenocarcinomas including renal, breast, ovarian, fallopian tube, colon, lung and oesophageal
- Objectives:
 - Primary: assess toxicity
 - Secondary: assess anti-tumour efficacy, immune response and procedure feasibility
- Results:
 - No treatment related toxicity
 - ***All patients produced desired cellular immune response***
 - Patient's cells could be successfully cryopreserved

CAN-002 Study

- Protocol:
 - 28 patients (21 evaluable) enrolled ovarian cancer and rising CA-125 levels (>25% over baseline within one month)
 - Patients received 3 injections of CVac™ at one-monthly intervals, followed by 4 injections at 10 week intervals
 - 9 of 21 evaluable patients received 3+ doses
- Objectives:
 - Primary: disease response as defined by CA-125
 - Secondary: safety
- Results Summary:
 - 4 of 21 evaluable patients responded (19%) to CVac™ (stabilization or reduction in CA-125 level from baseline)
 - All 4 of the responding patients had received 3+ doses (i.e. 44% response in this group of 9)
 - CVac™ well tolerated; no therapy-related toxicity

CAN-003 Study

- Protocol:
 - 63 epithelial ovarian cancer patients enrolled in complete remission after successful 1st or 2nd line chemotherapy
 - 36 randomized to CVac™; 27 to observation standard of care
- Objectives:
 - Primary: progression free survival (PFS) as defined by CA-125
 - overall survival (OS)
 - prove biological activity by intracellular cytokine staining (ICS)
 - establish comparability between 2 global manufacturing sites
 - confirm safety of CVac in patients in remission
- Results:
 - Manufacturing comparability established
 - CVac well tolerated to date; no therapy-related toxicity
 - Dosing complete for all patients in 4th quarter 2012
 - Within the next 1-2 months, Prima will outline a calendar for full data release planned over the next year (ICS, PFS, OS)

CANVAS - CAN-004 Study

CANVAS(**CAN**cer **VA**ccine **S**tudy) is multinational, multi-center, randomized, double-blinded, placebo-controlled for a robust analysis

- ❖ Stage III/IV patients eligible after optimal debulking
- ❖ 1000 patients randomized 1:1 CVac:placebo to obtain 800 evaluable patients
- ❖ Patients must be in complete clinical and radiologic remission after chemotherapy to continue to dosing
- ❖ 6 doses in 44 weeks
- ❖ Dosing start as soon as possible (~2-3 weeks after chemo)
- ❖ About 120-130 centers globally (USA, Australasia, Europe)
- ❖ First patient in Q1 2012
- ❖ Last patient in expected by Q1 2014

Data Points & Development Milestones

- ✓ Manufacturing
- ✓ Intracellular cytokine staining (ICS) to add knowledge of biologic mechanism of action
- ✓ Companion screening test
- ✓ Safety confirmation
- ✓ Establish CVac effects on progression free survival
- ✓ Establish CVac effects on overall survival
- ✓ Collect pharmacoeconomic and quality of life data

Manufacturing milestones

- Qualification and training of cell collection centers worldwide
- Validation of automated scheduling and logistic management software
- Comparability and scale-up of 3 global production centers
- Validation of quality control measure
- Finalization of product specifications

Intracellular Cytokine Staining

- ICS is a method to see if CVac, after administration, induces a T cell response specific to mucin 1
- Validation of CVac's mechanism of action (how it is expected and intended to work biologically)
- Data would be a key point for Prima to go into exploratory studies in other cancer types that overexpress mucin 1

Companion Screening Tool

- CVac is intended to target mucin 1 overexpressing tumor cells
- Important for efficacy and commercial reasons to only treat patients with mucin 1 overexpressing tumors
- Prima has developed a mucin 1 screening test in collaboration with Fraunhofer Institute in Germany
- Plan to approach development partners to help validate the test for commercial use

Progression Free Survival

- The time between when a patient responds to 1st line therapy and is in remission until the tumor comes back (relapse)
- Extending the time in remission can confer significant improvement in quality of life, reduces the burden on the medical system by deferring further medical intervention, and may indicate an improvement in later overall survival
- Median time in remission for our target patients group is about 16-20 months
- Goal is to obtain a “clinically meaningful” improvement in this time

Overall Survival

- “Gold standard” of cancer research
- Most objective measure of efficacy
- Some weaknesses:
 - Can be confounded due to multiple treatments
 - Much longer time point to observe
- Secondary objective of CVac trials is to obtain an improvement in overall survival of patients

Quality of Life

- For regulators and payors, quality of life is of increasing importance
- Goal is to assess the patient's ability to work and live a normal standard of life
- Key point of any future pricing negotiations with health plans
- Goal of CVac is to also improve life *quality*

Looking forward



CVac catalysts - next 12 months

- Data catalysts (all subject to exact timing of patient outcomes):
 - CAN-003 final safety analysis
 - CAN-003 intracellular cytokine staining data (ICS)
 - CAN-003 progression-free survival data
 - CAN-003 overall survival data
- Development catalysts:
 - Comparability with 3rd manufacturing center (Europe)
 - All blood collection centers globally qualified and approved
 - All CANVAS sites globally initiated
 - Initiation of exploratory trial in new cancer indication(s) – pending confirmatory biological activity from ICS

Corporate Strategy

1. Enhance **business development**:

- Identify assets and technology complimentary to Prima's existing advantages to develop additional products in an expanded pipeline
- Review a variety of arrangements that maximize potential upside – acquisitions, collaborations, licenses
- Expand CVac development to other cancers pending data and financing
- Marc Voigt recently appointed as CBO

Corporate Strategy

2. Incremental **research innovation**:

- Identify optimal patient populations
- Support development of portfolio products
- Improve product manufacturing processes
- Lower costs of production and delivery

Corporate Strategy

3. Expand internal **resource capacity**:

- Focus in San Francisco – a key area for hiring in our field
- Review production and laboratory capacity
- Enhance value of the company
- Add security to supply chain
- Maximize control over programs
- Support increased development activity

Corporate Strategy

4. Execute **development plans**:

- Data will be the main driver for future growth in company value
- Data establishes safety, efficacy, and commercial viability of our products
- Data is the basis for global regulatory approvals & physician use
- Focus on data quality
- Focus on data integrity

As Dr. Frazer says . . .



... everyone else bring data



(the US FDA's unofficial motto)