

# Prima BioMed Ltd

*CEO report to the Annual General Meeting of shareholders*



*Matthew Lehman, CEO  
15 November 2013  
Radisson Blu Hotel, Sydney*

ASX:PRR; NASDAQ:PBMD; ISIN:US74154B2034



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# Cancer vaccines have great potential

For Drew Pardoll, Director of the Cancer Immunology Program in Johns Hopkins University's Sidney Kimmel Comprehensive Cancer Center:

**. . . the real excitement lies with cancer vaccines. 'Their stock is very low right now, but they are going to come roaring back'**

*- Nature Reviews Drug Discovery, Vol 12, July 2013*

# The market for cancer immunotherapies is enormous



Citi Research  
Equities

22 May 2013 | 52 pages

Drugs (Citi)  
Europe | United Kingdom

## Immunotherapy – The Beginning of the End for Cancer.

### Transforming Cancer into Chronic Disease. Winners and Losers

- Immunotherapies—\$35bn potential/annum, will likely become the treatment backbone in up to 60% of cancers over the next 10 years compared with <3% today. The current explosion in all ongoing approaches (including checkpoint agents, vaccines and cell therapy) to utilise the immune system to seek and destroy cancer cells marks a watershed, analogous to the impact of HIV drugs transforming life expectancy in HIV,

■ Industry Overview



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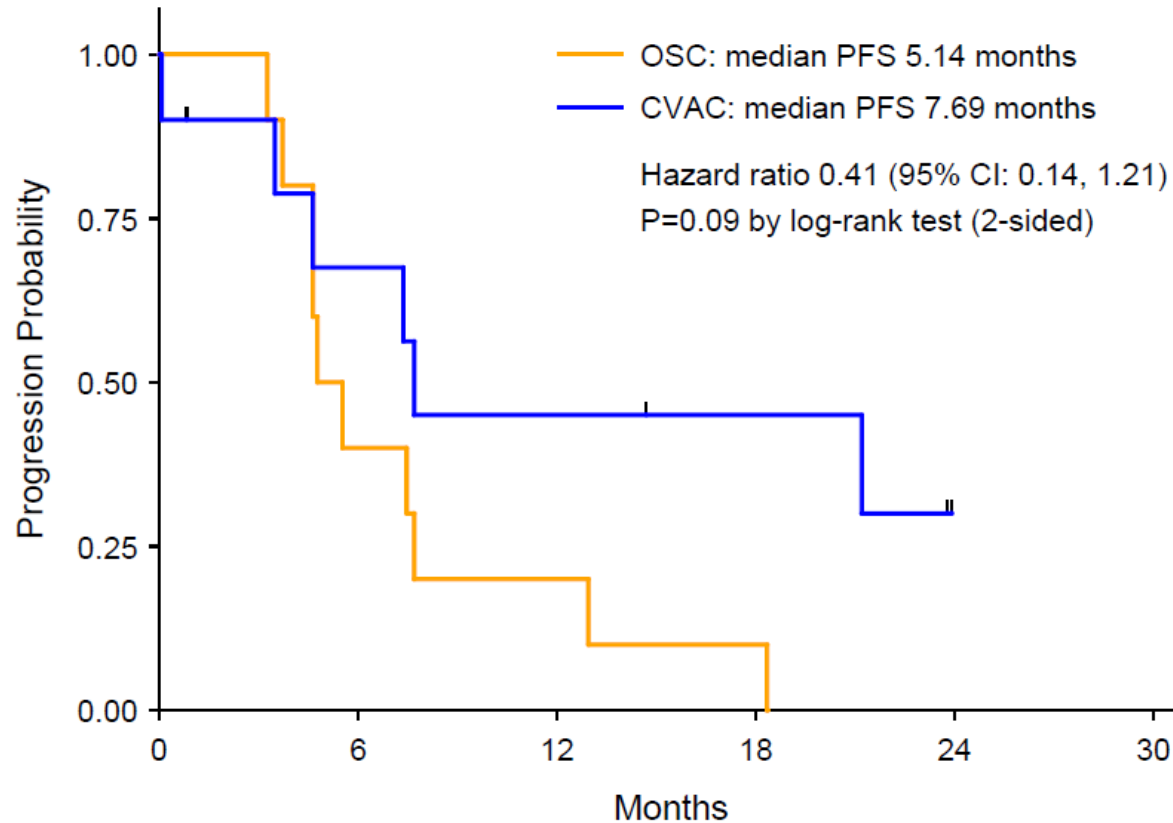
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# **CVAC™ OVARIAN CANCER COMMERCIAL OPPORTUNITY**

# Compelling signal from CAN-003

## Improving progression-free survival (PFS)



OSC	6/10	2/4	1/2	1/1	0/0
CVAC	3/10	2/6	0/4	1/3	0/0

## Ovarian cancer – second remission

**“80%-85% of patients tend to undergo second line therapy or maintenance therapy.**

**Therefore, a large group of patients seeking for second line is a significant sales driver for second line treatment drugs in the ovarian cancer market.”**

Global Data’s 2011 report

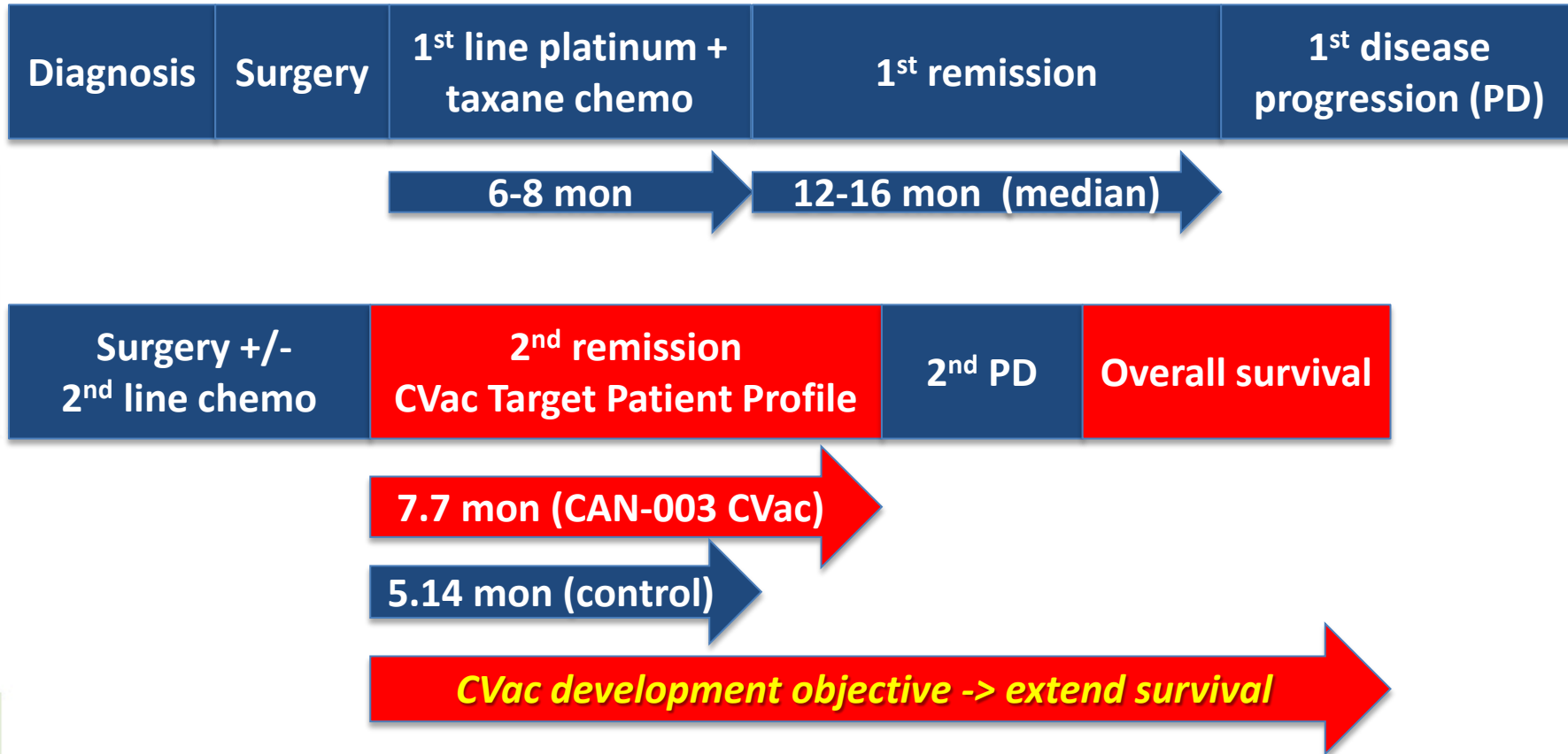
“Paclitaxel (Ovarian Cancer) – Analysis and Forecasts to 2020”

## Addressable market: 2<sup>nd</sup> remission ovarian

- Annual incidence of ovarian cancer 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 platinum sensitive ~33,300 p.a.
- ***70-80% continue through second line ~25,000 p.a.***



# CVac's place in ovarian cancer treatment



# Comparative ovarian cancer deal



## Merck and Endocyte Enter Exclusive Worldwide Agreement to Develop and Commercialize Phase III Cancer Candidate Vintafolide (EC145)

WHITEHOUSE STATION N.J. & WEST LAFAYETTE, Ind.--(BUSINESS WIRE)-- Merck, known as MSD outside the United States and Canada, (NYSE: MRK) and Endocyte Inc. (NASDAQ: ECT), today announced that they have entered into an agreement to develop and commercialize Endocyte's novel investigational therapeutic candidate vintafolide (EC145). Vintafolide is currently being evaluated in a Phase III clinical trial for platinum-resistant ovarian cancer, (PROCEED trial) and a Phase II trial for non-small cell lung cancer (NSCLC); both studies are also using Endocyte's investigational companion diagnostic agent, etarfolatide (EC20).

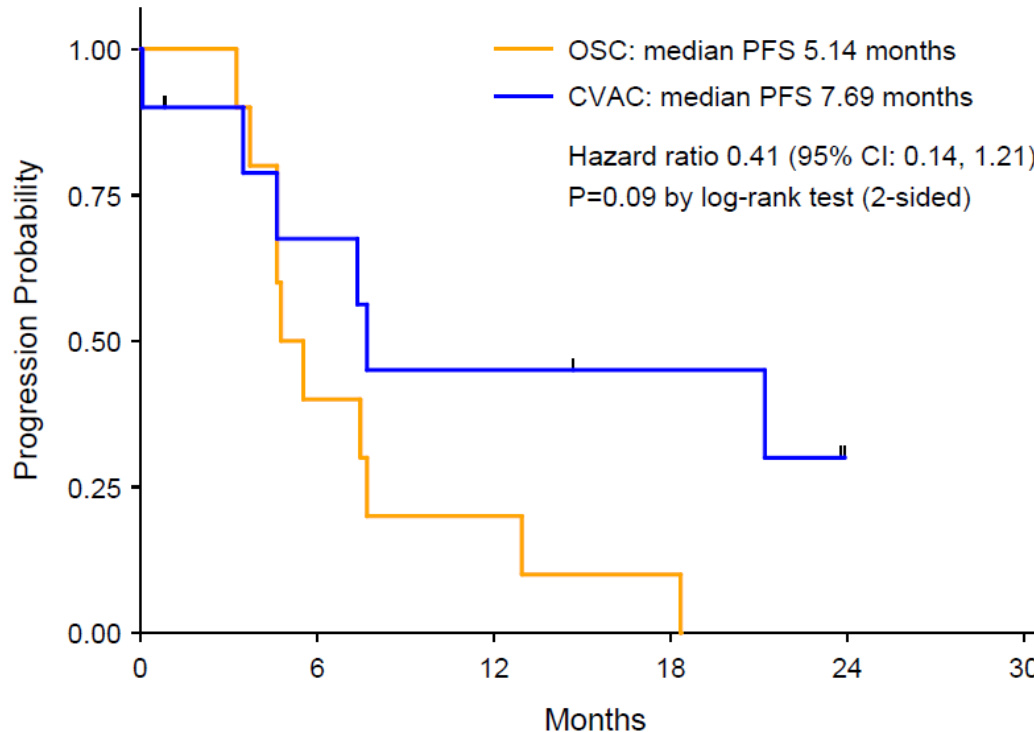
"Vintafolide is a promising and innovative late-stage cancer drug candidate. In addition to pursuing the lead indication of platinum-resistant ovarian cancer, Merck plans to further evaluate its potential for treatment of multiple other cancer types," said Peter S. Kim, executive vice president and president Merck Research Laboratories. "This agreement underscores our strategy of building a portfolio of oncology therapeutics that employ a companion diagnostic to facilitate selection of those patients most likely to respond to treatment."

Under the agreement, Merck, through a subsidiary, will gain worldwide rights to develop and commercialize vintafolide. Endocyte will receive a \$120 million upfront payment and is eligible for milestone payments of up to \$880 million based on the successful achievement of development, regulatory and commercialization goals for vintafolide for a total of six cancer indications. In addition, if vintafolide receives regulatory approval, Endocyte will receive an equal share of the profit in the United States (U.S.), as well as a double-digit percentage multiple on sales of the product in the rest of the world. Endocyte has



# **CVAC™ CLINICAL PATHWAY IN OVARIAN CANCER**

# Prima has compelling clinical data & a clear development path



*50% increase in median PFS for ovarian cancer patients in second remission*

*Extended time in remission for the best responders to CVac*

OSC	6/10	2/4	1/2	1/1	0/0
CVAC	3/10	2/6	0/4	1/3	0/0

Data from CVac CAN-003 protocol  
 PFS: progression free survival



# What did we learn from CAN-003?

- Strong PFS signal in second remission epithelial ovarian cancer patient population
- Positive mucin 1-specific T cell response in CVac treated patients
- We have chosen Overall Survival (OS) as primary endpoint:
  - Clear regulatory (FDA) direction
  - Overall Survival was the endpoint for commercially approved cancer immunotherapies (Yervoy, Provenge)

# Consequently, we modified our CAN-004 ovarian cancer protocol

- No new enrollment of 1<sup>st</sup> remission patients; patients currently enrolled will continue on CVac or placebo
- New patient group for analysis:
  - 210 patients in second remission
  - 1:1 randomization CVac vs. control group (observation only)
  - Primary endpoint = Overall Survival (OS)

***Goal -> robust standard for proof of clinical concept***



**CVAC™ RESECTED PANCREATIC CANCER  
COMMERCIAL OPPORTUNITY  
& PILOT TRIAL**

# Addressable market: resected pancreatic cancer

- Annual incidence of pancreatic cancer in “major markets” (USA, Japan, UK, Germany, France, Italy, Spain) ~99,000 p.a.
- ~20% suitable for surgical resection ~20,000 p.a.
- 80-95% of those survive surgery **~17,000 p.a.**



# CAN-301: A pilot pancreatic cancer trial

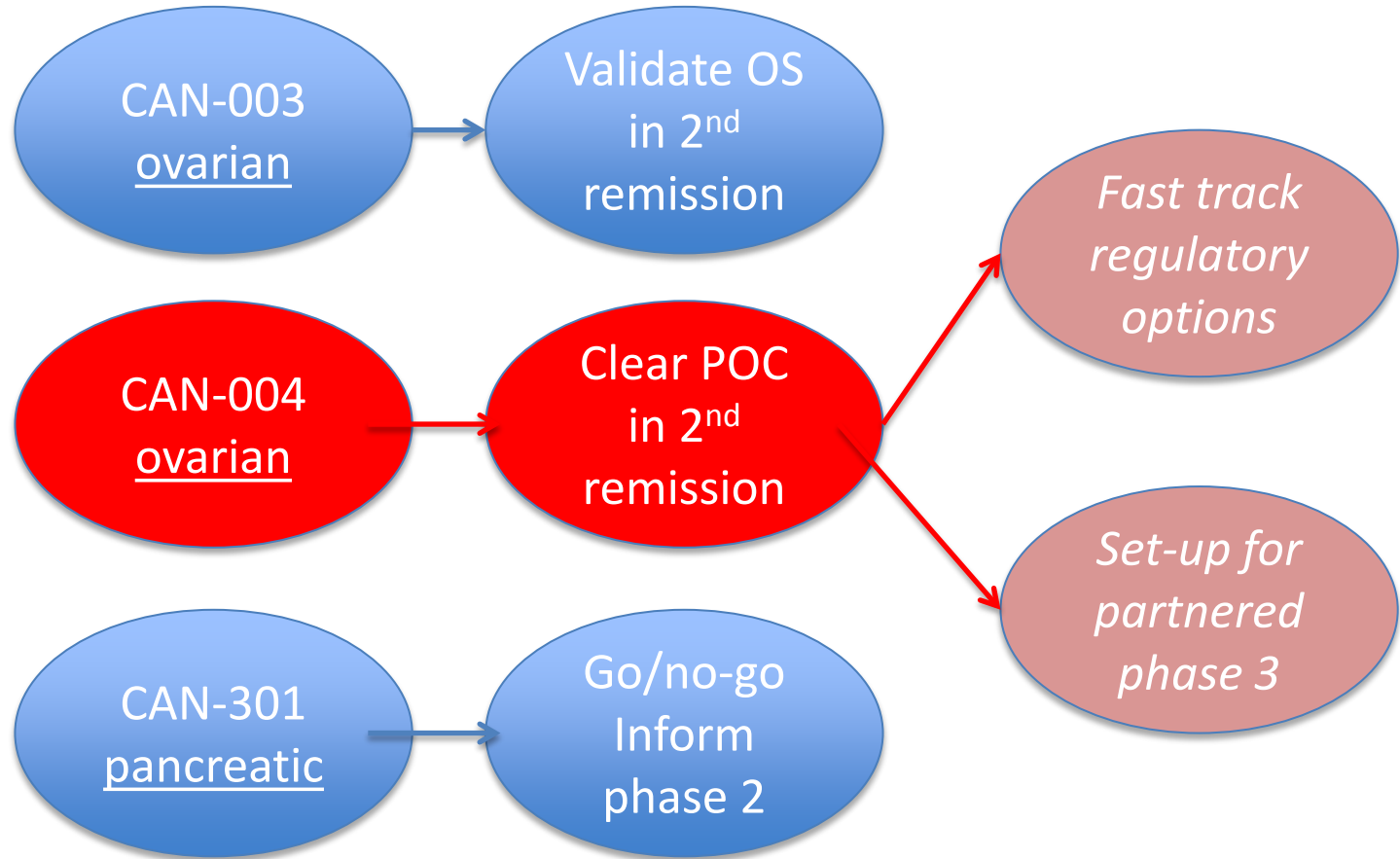
- 40 resected pancreatic cancer patients
- Single-arm pilot trial
- Endpoints:
  - Overall survival
  - Immune response
  - Safety

***Goal -> data to add value to the CVac franchise & drive go/no-go decision on further clinical trials in pancreatic cancer***



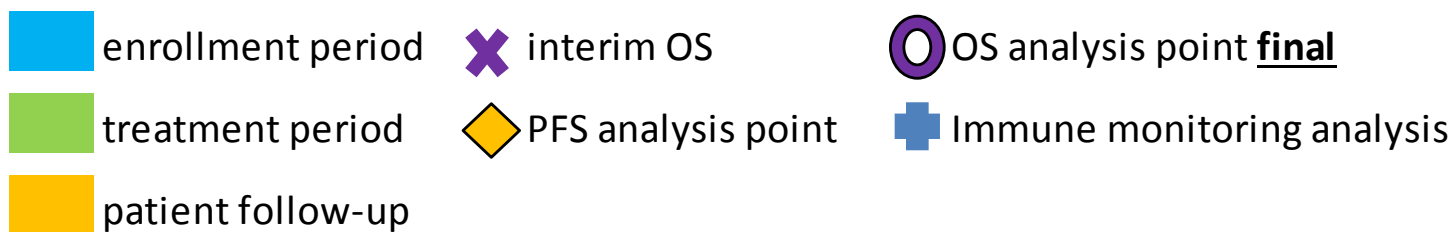
# CVAC™ DEVELOPMENT OBJECTIVES

# 3 Priority Clinical Trials -> Objectives



# Clinical Data Catalysts

Clinical Trial Protocols	Quarter (Calendar year basis)																	
	2013		2014				2015				2016				2017			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
CAN-003	◇					×		○										
CAN-003X			×			×												
CAN-004 (1)					×		◇		×		+	◇	×					×
CAN-004 (2)								×		◇		×		+	○			
CAN-301								×				◇	×	○	+			



*Exact timings dependent on regulatory reviews  
& timing of clinical events (i.e disease progression and deaths)*



**STRONG FUNDAMENTALS  
& EXCITING OUTLOOK**

# Partners & advisors



## **Professor Ian Frazer AC, FRS, FAA, Chair of Scientific Advisory Board**

CEO of Translational Research Institute; internationally renowned co-creator of technology for cervical cancer vaccines; cancer immunotherapy researcher at University of Queensland Diamantina Institute

## **Jonathan S. Berek, MD, MMS, Chair of Clinical Advisory Board**

Established and directs the Stanford Women's Cancer Center, renowned expert in gynecologic oncology, especially the immunology and immunotherapy of gynecologic malignancies, group chair and PI of the Cooperative Ovarian Cancer Group, part of premiere international consortium, Gynecologic Cancer Intergroup



## **Holbrook Kohrt, MD, PhD, Senior Clinical Advisor**

Assistant professor at Stanford University Medical Center; investigator on a number of NIH and industry sponsored oncology trials and has published extensively in the fields of cancer immunology and immunotherapy.



# Budget for updated clinical plan

## Key changes in the updated operational plan:

- 50% decrease in per-patient clinical costs due to protocol changes
- \$1.5 million p.a. reduction in manufacturing costs & internalization of expertise
- Continued management & reduction of corporate overhead expenses

# An exciting future built from strong fundamentals

- Strong scientific collaborators and advisors
- Cash position \$31 million (30 Sept. 2013)
- Estimated 2+ years of cash reach
- Important CVac data catalysts in 2014, 2015, 2016
- Leadership position in the emerging field of cancer immunotherapy
- Evaluation of value accretive business development transactions