## Prima BioMed Ltd

The leader in developing personalized immunocellular therapeutics

Investor presentation February 2013



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### **Investor Update**

- 1. Company strategy
- 2. CVac clinical development
- 3. Manufacturing & technology
- 4. Business development
- 5. Investor relations
- 6. Business matters



# **Company Strategy**

- ✓ Consolidate our leadership position in the development of immunocellular therapeutics for cancer
- Continued investment in our technology, operational platform, and product development to further increase value
- ✓ Be "best-in-class" in 5 key areas of our business:
  - Human resources
  - Asset portfolio
  - Quality processes
  - Product development
  - Infrastructure
- Longer term monetize our assets through commercial partnerships or licenses & continued investment to remain the leaders in immunocellular therapeutics for cancer in order to maximize shareholder value



# **CVac clinical development**

Phase	Protocol	Population	Patients
1	CAN-001	Terminal cancer adenocarcinoma (breast, ovarian, fallopian tube, colon, lung, oesophageal)	10
2	CAN-002	Ovarian cancer patients with no further treatment options	28
2	CAN-003	Ovarian cancer patients in remission after 1st or 2nd line therapy	63
2	CAN-003x	Ovarian cancer patients who have progressed on CAN-003	9
2/3	CAN-004	Ovarian cancer patients in remission after 1st line surgery and chemotherapy	800 (est)



# **CVac clinical building blocks**

CAN-004 top line data (2015)

**CAN-003X** case data (2014)

Start new indications (2013)

**CAN-003 final data (2013)** 

CAN-003 interim data (2012)

CAN-002 data (2007)

CAN-001 data (2005)



# CAN-001 & CAN-002

- Demonstrated the technological feasibility of CVac production in Australia
- Demonstrated the safety of CVac in a small population
- Demonstrated that CVac can stimulate an immune response in cancer patients
- Indications of clinical efficacy in late stage ovarian cancer patients



### **CAN-003 outcomes to date**

- Manufacturing comparability between Australia and US established
- CVac safety profile continues to be attractive
- Interim immune monitoring data (intracellular cytokine staining) indicates a mucin 1 specific t-cell response
- Interim progression free survival data show encouraging trends



# **CAN-003 upcoming data**

- 3Q CY13 Full immune monitoring profile of 63 patients over multiple time points during and after dosing
- 4Q CY 13 Final protocol analysis of progression free survival and first evaluation of overall survival
- Goal to evaluate the clinical endpoints & to explore the relationship between immune response and clinical outcome



#### CAN-003X

- Small extension trial for patients who progress during the CAN-003 trial
- Evaluate longer-term safety of CVac & interactions with other therapeutic agents
- 9 patients enrolled. Closed for further enrollment



# CAN-004 (CANVAS) status

- Approved by regulators in 9 countries (including Australia, USA, Belgium, Bulgaria, Belarus, Lithuania, Poland, Ukraine and Germany)
- Ethics committee approvals in 14 countries
- 46 cell collection centers inspected & trained; 28 activated to start the trial (26 Jan 2013)
- 14 clinical centers activated by Prima and allowed to recruit patients
- 26 patients consented to participate (30 Jan 2013); 23 patients have met study criteria and have been randomized
- 3 patients have been dosed (1 Feb 2013)



# **CANVAS** goals

- ✓ Validate and plan for a commercial-ready manufacturing process in 3 global regions
- ✓ Validate a companion Mucin 1 diagnostic test
- Confirm acute and longer-term safety and tolerability of CVac in a larger patient population
- ✓ Establish CVac efficacy by PFS and/or OS
- ✓ Investigate CVac impact on quality of life factors
- ✓ Exploration of biomarkers and immune monitoring analysis
- Support potential marketing approvals pending data outcomes



# **CANVAS** considerations

- Learning from previous industry experience in commercial scale-up and manufacturing challenges
- Careful scale up of global manufacturing for the largest autologous cell therapy trial undertaken
- Harmonization of global regulatory demands for a comparable product (blood collection, cell culture media, manufacturing specifications)
- Learning from recent data in cancer immunotherapy (Provenge<sup>®</sup>, Yervoy<sup>®</sup>, Stimuvax<sup>®</sup>)
- Analyzing CAN-003 immune monitoring and clinical efficacy data (sample size, endpoint)



### **CANVAS** expectations

- Start recruitment in Europe early 2013
- Significant scale up of clinical centers and patients through 2013
- Recruitment complete 2<sup>nd</sup> half of 2014 Prima is controlling the rate of recruitment carefully and will keep everyone informed
- Top line data approximately 2015 pending recruitment and rate of progression events

CANVAS is a major investment and we always ensure quality, safety, and data integrity



# **CVac in new indications**

- Prima believes the interim immune data demonstrate the activity of CVac and believes it has potential applications in addition to ovarian cancer
- Plan to initiate 2-3 pilot trials in additional cancer targets in 2Q CY 2013 pending the appropriate funding
- Goal is to expand the potential clinical applications for CVac and the commercial attractiveness of the franchise



# Manufacturing & technology milestones

- Scale up and characterization of M-FP
- Product comparability in 3 global facilities
- Automated logistics management
- Customization & validation of shipping materials and cold supply chain
- Securing & obtaining regulatory approval of supply chain of starting production materials



#### **CVac manufacturing building blocks**

**Commercial ready production (2016)** 

Manufacturing validation (2014-15)

Manufacturing scale-up (2013-14)

Aus-USA-Germany comparability (2012)

**Tech transfer to Germany (2011)** 

Aus-USA comparability (2010)

Tech transfer to USA facility (2009)

**Professional manufacturing Australia (2006)** 

**Production** feasibility (2004)



#### **CVac manufacturing overview**

#### http://primabiomed.com.au/movies/movie\_5.php



# Manufacturing & technology plans

- Long term planning for commercial scale up own facilities or partnership
- Expand cell collection network
- Continuous improvement & efficiency in logistics management
- Optimize production processes
- Enhance quality control testing significant area for cost reduction and intellectual property assets



# **Business development plan**

- Bring in complementary technologies that can benefit from Prima's expertise:
  - Antigen targets in addition to mucin 1
  - Immune cell products for clinical development
- Partner products in late stage development for commercialization:
  - Robust clinical proof of concept
  - Clear regulatory pathway
  - Scalable commercially viable manufacturing platform



### **Investor relations**

- Committed to consistent and clear communication about the development of the business and our programs
- Continuation of quarterly shareholder newsletters
- Initiation of quarterly conference calls starting with the December 2012 half year report in a few weeks



#### **Business matters**

- NASDAQ ADR program:
  - poor trading liquidity and increased expense for accounting and compliance
  - increased awareness in the US and higher level of transparency because of SEC
  - Prima will evaluate this program in 2013
- Frankfurt/XETRA ADR listing:
  - nominal expense
  - directly tied to the NASDAQ ADR listing



#### **Business matters**

- Finances:
  - A\$ 28 million in cash as of 31 December 2012
  - Cash burn of approximately A\$ 5 million per quarter
  - Cash support expected from Australian R&D tax credit,
     Saxony Development Bank and bank interest
  - CANVAS increased recruitment could moderately accelerate cash burn from the current projection
  - Managing cash need for additional CVac indications or new products



#### **Business matters**

- Pending investment projects:
  - Pilot CVac trials in additional cancer indications
  - Manufacturing optimization
  - Potential addition of new clinical products
- Monitoring capital needs:
  - Grant and subsidy programs
  - Raising capital from placement of new shares
  - Longer term outlicensing/partnering/monetizing Prima's products and technology



#### **Investment thesis**

- Leadership position in an emerging field of immunocellular therapeutics for cancer
- Significant market potential to help cancer patients with less toxic therapies and benefit shareholders
- Discipline of <u>continuous improvement</u> in our technology and manufacturing for improved quality and cost effectiveness
- Lead product with important <u>near term</u> development catalysts and <u>long term</u> market growth potential
- Opportunity to leverage current technology and assets to <u>deepen our product pipeline</u>
- Global team & resources maximizes market potential



#### **Company catalysts & milestones**

Indicative timing	Event	
2Q CY 2013	Announce pilot trials of CVac in new cancer targets	
3Q CY 2013	CAN-003 immune monitoring (ICS) final data	Continuous
4Q CY 2013	CAN-003 progression-free survival final data and initial overall survival data	<ul><li>improvement</li><li>Quality</li></ul>
2H CY 2014	CANVAS recruitment complete	production
CY 2014	Mucin 1 M-FP (antigen) manufacturing validation	
CY 2014	Mucin 1 screening test validated	<ul> <li>Cost efficiency</li> </ul>
CY 2014	CVac manufacturing scale-up (600+ patients)	enciency
2H CY 2015	Top line CANVAS data	
CY 2015	CVac manufacturing validation	
CY 2015/16	Data - pilot trials of CVac in additional indications	
CY 2016	Establish commercial-ready CVac production	

