



## Prima BioMed Ltd

### Overview

**Recommendation:** Long Term Speculative Buy

**Investment:** Prima Biomed Ltd

**ASX Code:** PRR

**Market Cap:** \$24.6m

**12 Month Performance:** +1300%

**Technical Note:** The stock price has been finding support at the 50% retracement level of the recent trading range. On Friday the share price pushed off from this level, the stock is very favourably positioned to move higher in the future.

### About the investment

Prima Biomed's lead product CVac™ ovarian cancer vaccine treatment, if successful will become a second-line and maintenance based therapy to existing ovarian cancer treatments.

Currently, there is only one proven treatment for Ovarian cancer—Taxol, should patients relapse (which often occurs within a short time frame) this leaves medical oncologists with no choice but to treat patients with another round of Taxol. This is poor medical practice, but there is no alternative and this is where CVac™ is used as a second-line and maintenance based therapy.

### The need

Each year 318,000 women are diagnosed with ovarian cancer and 75,000 women are diagnosed in developed markets (within countries where patients can afford medical treatment) with ovarian cancer in the US, Europe, Australia and Japan alone. Of these 75,000 women, only 10% - 20% survive beyond 5yrs.

### The potential

By 2010 the global chemotherapeutic ovarian cancer treatment market is estimated to be worth US\$3.6b. Prima Biomed aims to capture conservatively 10% of this market or US\$360m. This doesn't include ongoing maintenance use of the vaccine or a predicted preference of the non toxic benefits of CVac™ versus the side effects of chemotherapy (nausea, hair loss etc).

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Currently the market cap of Prima Biomed is only \$24.6m (the cancer vaccine peer for prostate cancer Dendreon (DNDN.NSD) is US\$2b plus), should the company be successful with CVac™ then there is significant upside potential for this investment.

**Insight** - US FDA approval of drugs has declined from 53 in 1996 to 18 in 2007 leaving a glut of blockbuster drugs coming off patents in the following years. Major pharmaceutical companies are in desperate need of new multi-billion dollar block buster drugs. This means, Prima Biomed could become a takeover target.

Of recent the Obama administration has established a new FDA commissioner, Margaret Hamburg and a new associate commissioner Joshua Sharfstein along with an increased budget for the FDA. This change of board is positive for Prima as it allows a faster and more proactive drug approval process.

### **Investment Vehicles**

- Direct investment through the ASX (Code: PRR)
- Company listed options expiring 31st Dec 2011 with a strike of \$0.02 (Code: PRRO)

### **How To Invest**

Contact Kinetic Securities on 1300 306 114 (Sydney office) or 1300 664 045 (Gold Coast office)

## **Investment Information**

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### **About CVac™**

CVac™ is intended to be a second line maintenance based therapy vaccine to ovarian cancer. The promising factor about CVac™ is the approach taken to attack tumour cells—the current approach for treating ovarian cancer includes surgery, chemotherapy and radiation whereas CVac™ uses the patient's own immune system to fight tumour cancers. This new approach excites the scientific and medical community. For this reason Prima has established a world-class following of medical professionals that are taking an active interest and role in helping with the development and commercialisation of this drug.

The CVac™ treatment is a 6 day process which starts by collecting the patient's blood, separating dendritic cells, multiply these cells in a cell therapy laboratory and are then activated. Once this process is complete, these cells are then injected back into the patient to assist the immune system in the production of mucin-1 cells which attack the tumours.

Recently there has been positive results in phase I trials where all 14 patients generated an immune response halting tumour growth for more than 3 years. Phase II trials are said to have exceeded internal hurdles and have excited the scientific community.



### **Meet Rosalie Martin**

More than 2 years after successful treatment of CVac™, Rosalie is living a healthy life completely free of cancer today.

Remember that currently only 10% - 20% of women survive beyond five years - currently. Ovarian cancer is an insidious and painful disease with no current treatment available. The topic of ovarian cancer is close to most people that either know someone or are related to someone that suffers from this debilitating and terminal illness.

The vaccine creates hope and considerably improves the quality of life for CVac™ patients by boosting their immune system.

### **How does Cvac™ work**

Dendritic cell therapy is currently being utilised in Prima's CVac™ program, a completed Phase II clinical trial in ovarian cancer.

To learn more about how this process works, view this short movie from Prima;  
[http://www.primabiomed.com.au/images/PrimaBioMed\\_web.mov](http://www.primabiomed.com.au/images/PrimaBioMed_web.mov)

### **The future of Prima Biomed Ltd**

The company has recently secured \$12m to advance the commercialisation of CVac™. Currently Prima Biomed is in the final stages of its commercialisation timeline and will commence its stage IIb/III pivotal clinical trial with the US FDA mid year before seeking FDA approval to licence the product for commercial use.

Once licensed for commercial use Prima Biomed can begin tapping the potential US\$3.6b market for ovarian cancer.

When you consider that this treatment may also be applied to other solid tumour cancers with high levels of mucin-1 target, the market size potential of CVac™ rises 5 or 10 times this US\$360m figure. Pancreatic, breast, lung and kidney solid tumour cancers are characteristically high in the target mucin-1 protein.

This scalability and safety profile of CVac™ is a key feature of the treatment which in our view makes it an attractive target for a large pharmaceutical company.

### **Other Prima Biomed investments**

Prima Biomed has three other non-core assets:

- Oncomab Pty Ltd (monoclonal antibody for the anti-cancer Cripto-1), 100% ownership
- Anthron (Trillium Therapeutics Inc), 7% stake worth approx AUD\$3m
- Panvax Pty Ltd, 100% ownership

The company is currently in negotiations with interested parties to divest these assets which could contribute significantly to the company's balance sheet.

### **Investing in Prima Biomed**

There are two avenues to invest in Prima BioMed.

1. Purchase shares in the company on the Australian Stock Exchange (Code: PRR). The stock last traded at \$0.07 (8th of May 2009)
2. Purchase company listed options which expire on the 31st of December 2011 with a strike price of \$0.02

Considering the potential long term nature of this investment, it is recommended investors opt for direct share investment.

### **The Prima Story So Far**

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There are two components to the recent share price movements in Prima Biomed share price. Firstly, the company announced on March 11 that it had secured a \$12 million equity draw down facility from Fortrend to support registration trials of CVac™. The net effect of this arrangement is that it has enabled Prima to approach other potential investors on a more confident basis, demonstrating that a key risk with the company (funding) is essentially underwritten.

Secondly, and perhaps much more significant for Prima, has been the massive increase in Dendreon's share price, which increased by 702% in the same period. Like Prima, Dendreon has been developing a cancer immune-therapy, named Provenge, but targeted at prostate cancer. Dendreon said that its treatment increased overall survival times in a just completed 512 patient Phase III study, at the urology conference in New York.

Dendreon was confident enough to say that Provenge "significantly prolongs survival". It would appear that the result is the validation sought for many years by immunotherapy developers that cancer vaccines not only stabilize disease but increase survival. This is very bullish for Prima. Prima has to its advantage Orphan Drug Designation for ovarian cancer which means it will be fast tracked through the FDA and have a 7 year patent extension in US and 10 year patent extension in Europe.

Until recent board and management changes at Prima with the appointment of Martin Rogers and Ata Gokyildirim, Prima Biomed was a company in a parlous condition lacking direction and cash. Now it is focused and financed to take advantage of the multibillion dollar oncology drug market.

## **Phase IIb/III Clinical Trial Plan for Cvac™**

Prima Biomed has made significant progress towards filing an Investigational New Drug application for CVac™ with the FDA. The company has been guided by Professor Ian Frazer from the **University of Queensland**, who is noted for his co-invention with Jian Zhou of the cervical cancer vaccine Gardasil (**Merck/CSL**). Frazer has provided, along with several other interested parties, in-kind support for the next stages of clinical development of CVac™. Other members of the Prima scientific team include Dr Bruce Loveland, who was involved with the Phase I and Phase II trials of CVac™ and Dr Cassian Yee and Dr Heidi Gray from the **Fred Hutchinson Cancer Research Center** in Seattle.

Interestingly Prima Biomed now looks set to follow positively in the path of Dendreon and benefit from the questions posed to Dendreon by the FDA regarding manufacturing of autologous immunotherapy's, with a clearer pathway mapped out. Prima will also be using the same manufacturer that Dendreon has used.

## **Management**

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### **Mr Martin Rogers (CEO) Director since 16 November 2007**

Mr Rogers, has a science and corporate consultancy background with a focus on the incubation of business ideas and the establishment of both internal ventures and external partnerships, including finance concept origination for the likes of Macquarie Bank. Mr Roger's role with Prima Biomed will be to strengthen business development, its investor relations and to assist the Company with seeking corporate opportunities. Mr. Rogers holds a bachelor of Chemical Engineering and a bachelor of Computer Science from the University of NSW.

### **Mr Ata Gokyildirim (Non-Executive Chairman of the Board) Director since 20 December 2007**

Mr Gokyildirim has extensive merchant banking experience and recently Mr Gokyildirim founded a marketing and distribution business for the pharmaceutical industry in Turkey and the Middle East. He has vast experience in helping restructure companies in need and deliver substantial shareholder returns from these reforms.

### **Richard Hammel, Ph.D (Non-Executive Director) Director since 24 January 2005**

Dr. Hammel is the founding partner with ProPharma International Partners in San Francisco, USA. ProPharma is a pharmaceutical/biotechnology consulting firm providing a range of business, financial and product development services. He previously held senior management positions with Connetics Corporation (Vice President for Commercial Development), Matrix Pharmaceuticals Inc. (Vice President Business Development, Sales and Marketing) and held several positions at Glaxo Inc (Director, Professional Affairs; Director, New Business Development; and Director, Marketing Services). Dr Hammel is widely recognised in the US, Europe and Japan for his extensive 26 years expertise in the commercialisation and licensing in emerging and developing biotechnology companies.

**Prof. Ian Frazer (Scientific Adviser)**  
**Adviser since 19 March 2008**

Professor Ian Frazer is a leading cancer/oncology and immunology expert. His wealth of experience includes his well known work on the development of the world's first cervical cancer vaccine Gardasil™ in 2006 which is now available worldwide, manufactured by Merck & Co and distributed in Australia by CSL Ltd. Professor Ian Frazer is the president of the Cancer Council, was named Australian of the Year 2006, and is a recipient of the Florey Medal named in honour of Australian Nobel laureate Howard Florey.

## Financials

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<b><u>Income Statement</u></b>	<b><u>2008</u></b>	<b><u>2007</u></b>	<b><u>2006</u></b>	<b><u>2005</u></b>
Revenue	\$57,940	\$156,122	\$3,876,910	\$1,068,386
Research & Development	-\$70,146	-\$974,404	-\$2,759,775	-\$3,654,903
Corporate Administration	-\$1,362,404	-\$1,503,626	-\$2,373,210	-\$1,921,888
Net Loss	-\$1,887,378	-\$3,139,034	-\$4,357,874	-\$7,145,520

<b><u>Balance Sheet</u></b>	<b><u>2008</u></b>	<b><u>2007</u></b>	<b><u>2006</u></b>	<b><u>2005</u></b>
Total Current Assets	\$1,181,255	\$704,281	\$3,391,930	\$7,817,981
Total Non-Current Assets	\$1,639,995	\$3,653,996	\$3,967,994	\$1,313,231
Total Assets	\$2,821,250	\$4,358,277	\$7,359,924	\$9,131,212
Total Current Liabilities	\$187,817	\$261,091	\$1,026,317	\$774,543
Total Non-Current Liabilities	-	\$17,116	\$17,009	\$13,568
Total Liabilities	\$187,817	\$278,207	\$1,043,326	\$788,111
Net Assets	\$2,633,433	\$4,080,070	\$6,316,598	\$8,343,101

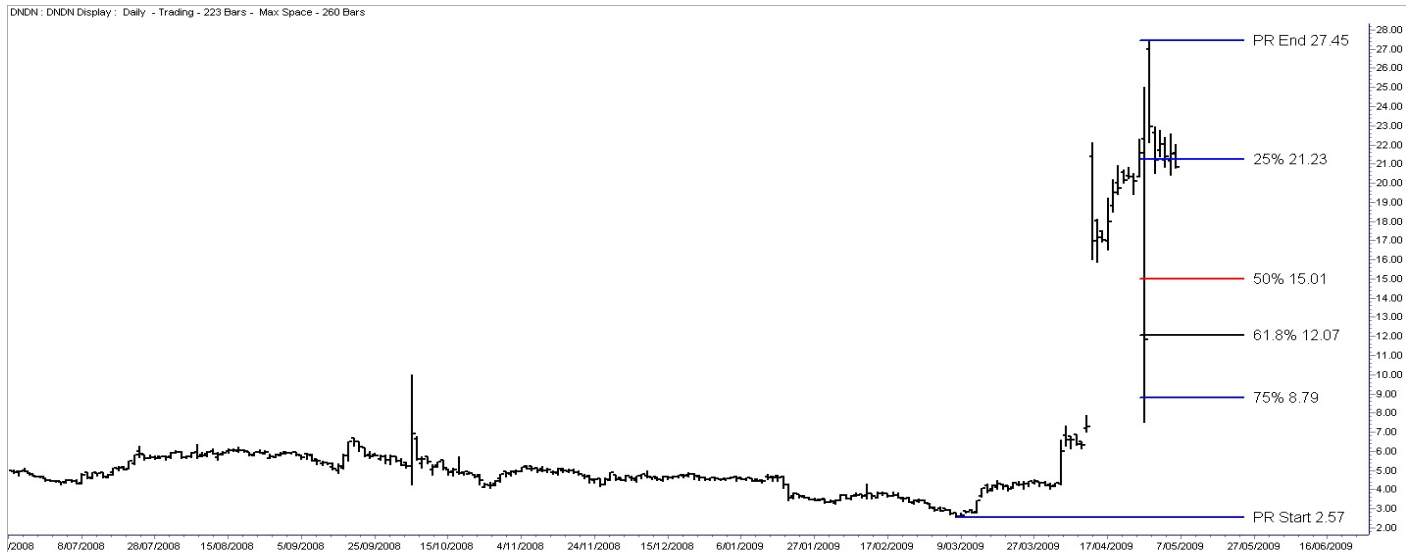
<b><u>Cash Flow Statement</u></b>	<b><u>2008</u></b>	<b><u>2007</u></b>	<b><u>2006</u></b>	<b><u>2005</u></b>
Net Operating Cash Flows	-\$1,554,336	-\$3,329,338	-\$5,051,642	-\$4,734,789
Net Investing Cash Flows	-\$4,571	-\$9,417	\$749,914	-\$8,687
Net Financing Cash Flows	\$1,985,386	\$799,186	\$19,925	-\$546,294
Net Increase / (Decrease) in Cash	\$426,479	-\$2,539,569	-\$4,321,653	\$4,748,230
Cash and Cash Equivalents Year End	\$1,098,259	\$671,780	\$3,211,349	\$7,533,002

# Dendreon Corp

## The Dendreon Story

Dendreon (DNDN)—a NASDAQ listed health care company is developing a similar technology to Prima but with a focus on prostate cancer. Dendreon has paved the way for this technology through the US Food and Drug Administration which will assist with slipstreaming the process of CVac™ through US FDA trials.

More importantly Dendreon recently released results of its phase III trial of Provenge with extremely positive results which resulted in the share price rallying 966% from low to high, DNDN is currently trading at USD\$19.24 a share!



## Prima BioMed - holding 50% retrace level

After rallying 1300% in the last 12 months, the price of PRR is resting around the 50% level of this trading range. Often stocks will form major lows on this 50% level. If PRR can continue to consolidate and hold above \$0.06 in the near future, then the stock could be positioned to move significantly higher in the future. PRR is approximately 2 – 3 years behind DNDN, with some positive trials and a FDA approval, PRR has huge potential upside.



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### **Kinetic Securities Pty Limited**

(ABN 83 120 225 149)

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- 2 This SFSG is supplementary to the Financial Services Guide issued by Kinetic Securities Pty Limited on 6<sup>th</sup> March 2009 and is to be read with that FSG.
- 3 This SFSG is dated 9 May 2009.
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