

Prima Biomed (ASX:PRR)

CVac™ a treatment for ovarian cancer...

Wise-owl.com has been commissioned to produce this report.

US Gap analysis has been received for CVac™. Prima Biomed is on track to submit a US Food and Drug Administration (FDA) Investigational New Drug (IND) application.

Phase IIa trial results exceeded expectations. CVac™ demonstrated a positive clinical response or stabilisation of disease in 4 of 21 patients with ovarian cancer. The strength of this result is highlighted by the condition of the patients who all suffered chronic, progressing, late stage ovarian cancer and exhausted all treatment options.

Ovarian cancer has a large unmet need. Each year 73,000 women are diagnosed with ovarian cancer in the US, Europe, Australia and Japan. The size of this market was valued at US\$2.1b in 2007, and estimated to grow to US\$3.6b by 2010. Prima Biomed has announced that CVac™ would initially target 10% of this market. Sadly, 70% of patients diagnosed with ovarian cancer are stage 3 or 4, where the 5 year survival rate is only 10-20%. A lack of treatment options could soften regulatory hurdles for Prima Biomed.

The market capitalization of US listed peer Dendreon Corporation (NASDAQ: DNDN) points to valuation upside. Dendreon Corporation, is conducting phase III trials of a cell therapy comparable to Prima Biomed's CVac™ and has a diluted market capitalization of ~US\$530m vs a current ~AUD\$5m market capitalisation for Prima Biomed.

Structural changes in the pharmaceutical sector to favour biotech. Large pharmaceuticals are in growing need of block buster drugs as a flurry of patents reach expiry and the US FDA has cut back on approvals for new treatments. 'Big Pharma' (multi billion dollar pharmaceutical companies) are expected to bolster product pipelines through the acquisition of treatments from smaller biotechs'.

A divestment strategy could reinvigorate Prima Biomed. Three non-core assets are open to divestment, namely Onocomab, Arthron and Panvax. In our view the NPV of the sale of these assets could potentially be made at a price that is a multiple of Prima Biomed's current market capitalisation.

This is a high risk play. Biotechnology firms are by nature risky propositions. Technical, timing and funding risks must be considered by investors. Prima Biomed's products are still under development, and may not reach commercialisation. Patents for the flagship CVac™ treatment expire in 2018 assuming no patent extensions or regulatory approved marketing exclusivity. However the risk to potential reward of PRR is attractive.

12 Month Target: Under evaluation

13-04-2008

Initiating Coverage

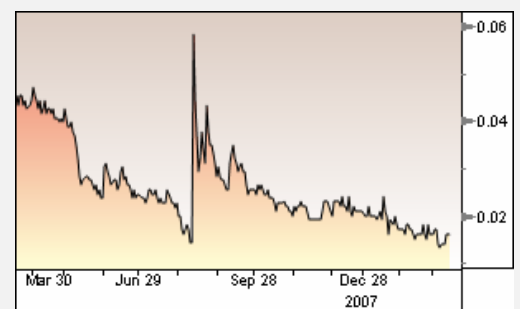
Risk Rating: Very High
Snr Analyst: Simon Guzowski
 (02) 8198 7245

Management Team

N-Exec Chairman	Mr. Ata Gokyildirim
N-Exec Director	Mr. Martin Rogers
N-Exec Director	Dr. Richard Hammel

Share Data

Sector	Biotechnology
Market Cap	\$3.29m
Fully Diluted Cap	\$4.86m
Shares on issue	299.1m
Options on issue	155.2m
Avg. Daily traded value	\$22k



Prima Biomed Ltd, Daily Chart

1. Gap analysis received

Prima Biomed is on track to submit a request for a preIND meeting with the US FDA.

Prima Biomed has received a Gap Analysis report from clinical research organisation PharmaNet Inc for its lead product, ovarian cancer treatment CVac™. Prima Biomed is now using this to Gap Analysis report to plan and formulate a submission to the US FDA for a preIND meeting.

“CVac™ trains the immune system to attack a cancer”

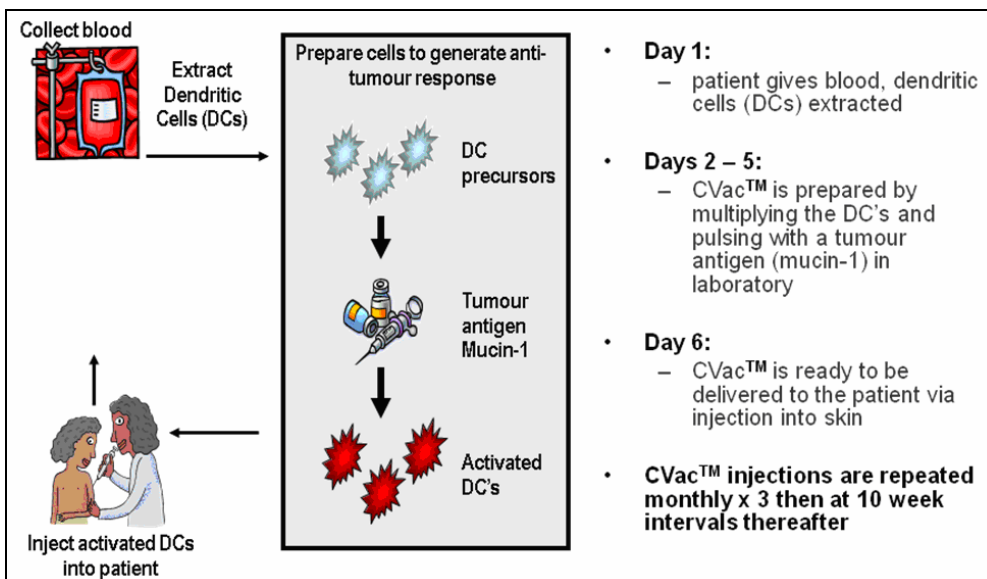
2. Lead treatment CVac™ ready to advance

Prima owns CancerVac Pty Ltd. CancerVac holds license to the IP required to develop CVac™ a cell therapy for the treatment of ovarian cancer. Under the CVac™ treatment, cells are administered to a patient to provoke an immune response that attacks the tumour. This is a promising new approach to cancer treatment yet to be commercialised. To date treating cancer has relied on aggressive methods like surgery, chemotherapy and radiation. The scientific community views cell based treatments as a potential new paradigm in complementary treatments for solid tumour cancer.

Prima Biomed’s CVac™ treatment works like a vaccine that uses a patients own dendritic cells to stimulate the patient’s immune system. The process involves extracting blood cells from a patient, expanding these cells in culture, fusing them with the mucin-1 target protein, and reinjecting these cells back into the patient. The dendritic cells then ‘present’ the mucin-1 cancer protein to the patient’s immune system, helping the immune system to specifically target cancer cells expressing mucin-1 which are prolific on the surface of many cancers.

“CVac™ is potentially scalable, making it an attractive proposition for big pharma”

The mucin-1 protein is also common on pancreatic, prostate, kidney, breast, colon and lung cancer cells. This dramatically opens the market potential for CVac™ to be applied to a variety of cancer types down the track, which is a large draw card for big pharma looking to bolster pipelines of scaleable treatments.



3. Positive Phase I and Phase II results for CVac™

Phase I trials were conducted in 14 patients with a variety of advanced malignant tumours. Impressively, the treatment generated an immune response in all 14 patients which included two outstanding survival accounts where tumour growth was halted for more than 3 years.

These results were a strong lead into phase II trials specifically focused on advanced ovarian cancer. Phase II trials were conducted on a group of 21 patients, all of whose CA125 levels (a biomarker for disease activity) were increasing. The rising CA125 levels that made patients eligible for participation in the trial demonstrated that their already advanced stage II and III ovarian cancers were progressing or growing.

The treatment consisted of 3 CVac™ injections in the first 10 weeks, followed by injections every 10 weeks after this to a total of 7 injections.

Phase IIa trial results exceeded internal hurdles.

4. Pipeline of news flow lined up for CVac™

Over the next 6 – 9 months, Prima Biomed's core focus is to align the future development of CVac™'s phase IIb and phase III trials with the requirements of the US drug regulator US Food and Drug Administration (FDA).

Prima Biomed has selected US based Clinical Research Organisation PharmaNet Inc to evaluate the existing clinical data package for CVac™ and assess its alignment to US requirements.

Now that the GAP analysis report has been received, Prima Biomed will begin preparations for a pre-IND meeting with the FDA as the first milestone in the US development process. Pending the outcome of the pre-IND meeting, Prima will then consider whether to file an Investigation New Drug (IND) application with the FDA to seek clinical trial approval. Obtaining FDA approval of CVac™'s development program would widen the potential market for CVac™ and partially de-risk the project, making it a more valuable asset for partnering, out-licensing, or sale.

Alternatively, should sufficient funding be in place Prima Biomed could pursue a phase IIb or phase III trial.

5. Large target market for CVac™

The global market size of ovarian cancer was valued at US\$2.1b in 2007, and is estimated to become US\$3.6b by 2010. Each year 73,000 women are diagnosed with ovarian cancer in the US, Europe, Australia and Japan, of which only 20% survive beyond 5 years.

A maintenance style treatment like CVac™ would be a first and initially aim to take US\$360m or approximately 10% of this ovarian cancer market in 2010. With sufficient funding, commercialisation could be as close as 6 years away on an achievable best case scenario.

When you consider that this treatment may also be applied to other solid tumour cancers with high levels of the mucin-1 target, the market size

“Pancreatic, breast and kidney solid tumour cancers are high in the mucin-1 protein targeted by CVac™”

“Targeting a large unmet need”

potential of CVac™ rises to 5 or 10 times this US\$360m figure. Pancreatic, breast 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 make it an attractive target for a large pharmaceuticals.

6. Development will be assisted by three factors

- An absence of effective treatments for advanced ovarian cancer.
- Blood components classification from the Australian Therapeutic Goods Administration.
- Structural shifts in the pharmaceutical sector.

Ovarian cancer presents a large unmet medical need that is frequently detected at a late stage. 70% of patients diagnosed with the disease are stage 3 or 4, where the 5 year survival rate is only 10-20%.

As an immunotherapy, CVac™ currently falls under the Australian Therapeutic Goods Administration (TGA) blood components classification, and as such may be eligible for some exclusions from the TGA's registration procedure for new drugs. This could accelerate commercialisation and marketing in Australia. Assuming that no changes are made to existing regulations. CVac™ uses a patient's own dendritic cells which have the function of presenting foreign proteins to the immune system. This in turn can deliver an immune response that attacks the cancer.

Structural shifts in the pharmaceutical sector may also assist commercialisation. The US FDA approved only 18 drugs last year, substantially less than the 53 drugs approved in 1996. As a result pharmaceuticals may now shift their focus to drugs that treat rare diseases or diseases that lack treatment options as they are likely to receive easier approval.

A lack of new drug approvals, combined with a glut of block buster drugs coming off patent highlights that large pharmaceutical companies are in need of fresh block busters simply to maintain the status quo. With uninspiring internal pipelines, 'Big Pharma' is increasingly looking to biotech firms to grow their treatment pipelines. This is shifting the balance of negotiating power back into the hands of those developing new treatments.

7. Share Price Catalysts

- Release of GAP analysis by Pharmanet Inc for CVac™.
- PreIND meeting with the FDA.
- Filing an Investigation New Drug (IND) application with the FDA.
- Obtaining FDA approval of a CVac™ clinical development program .
- Prepare for phase IIb CVac™ trials.
- Securing funds via a divestment or capital raising to further develop CVac™.
- Dendreon Corporation phase III interim results due for release in 2H 2008 and final results late 2009.
- Potential 'Big Pharma' takeover target.

“Big pharma is on the hunt for new products that can bolster development pipelines”

“Newsflow over the short to medium term to drive share holder value”

8. Dendreon Corporation points to value in Prima Biomed

The most comparable peer to Prima Biomed is US listed Dendreon Corporation. Dendreon is conducting a phase III trial of Provenge, a cell therapy targeting prostate cancer which is a similar therapeutic approach to Prima Biomed's CVac™. Phase II results have suggested that Provenge can extend the life span of a prostate cancer patient by an average of 4 months.

Dendreon Corp is also developing a cancer vaccine called Neuvence which has completed phase I trials. Dendreon Corp has a cash balance of US\$120m, and an additional US\$130m funding package on offer from Azimuth Opportunities Ltd.

So what is all this worth? Dendreon Corp has market capitalization of US\$400m, however should the Azimuth Opportunities funding be taken up, which is probable, the market capitalisation will rise to circa US\$530m. While Australian biotechnology firms have consistently traded at a discount to their US peers, the market capitalisation of Dendreon Corp at US\$530m does contrast spectacularly to that of Prima Biomed's market capitalisation of AUD\$4.8m.

Dendreon Corporations flagship asset Provenge is at a more advanced stage of development and also enjoys a larger target market than Prima Biomed's CVac™, however CVac™ does offer several theoretical advantages over Provenge. CVac™ may offer a survival advantage however this is yet to be confirmed by a pivotal trial.

Ovarian cancer is considered a more dire need than prostate cancer. Patients diagnosed with prostate cancer have both higher rates of survival and a longer expected lifespan than patients diagnosed with ovarian cancer.

Prima Biomed may also benefit from a clearer path to FDA approval. As Prima Biomed is developing a closed circuit treatment, it may be able to sidestep many of the challenges Dendreon faced as it sought FDA approval.

9. Funding remains a challenge

Securing the funds required to further develop its pipeline of therapies has been the Achilles heel of Prima Biomed. At the very least funding is required to obtain FDA approval of a CVac™ development program, which would be an important step in triggering a re-rating in the stock. Funds may be raised from a trade sale of non core assets and/or a capital raising, the former being more probable in our view.

10. Divestment of non-core assets to lift cash levels

Prima Biomed has 3 non-core assets that are divestment candidates, Onocomab Pty Ltd, Anthron and Panvax. Any cash generating divestment would be viewed as positive as it would drive further development of lead treatment CVac™.

“Dendreon Corp is developing a similar therapy and trades at a market capitalisation of US\$530m”

“Prima Biomed's CVac™ has theoretical advantages over Dendreon Corps technology”

10.1. Oncomab Pty Ltd

Also known as Anti-Cripto antibodies, divestment of this asset could be the biggest win for Prima Biomed. This 100% owned subsidiary is developing a patented technology with partner firm Medarex Inc.

Anti-Cripto is a treatment based on antibodies that inhibit tumour growth. The target tumour protein is cripto-1 which occurs in a variety of solid tumours and leukaemias. Xenograph models of cancer and animal tests have demonstrated anti-tumour activity for this pre-clinical treatment. Confidentiality agreements with Medarex Inc mean that news flow is scarce from Oncomab.

10.2. Arthron Pty Ltd

Arthron is a 99.99% owned Prima Biomed subsidiary with a holding of 1.2m shares in Trillium Therapeutics Inc. Prima Biomed currently has this company valued on its books at AUD \$2.98m.

Arthron was developing an arthritic treatment which lacks fit with Prima Biomed's focus on oncology. The treatment targets the FcyRIIa receptor, which is central to the activation of the autoimmune cascade which is responsible for inflammation and joint damage that causes rheumatoid arthritis. While the intellectual property has been sold, Prima still holds a 7% equity stake which could rise to 19% with milestones in private Canadian company Trillium.

10.3. Panvax Pty Ltd

A 100% owned subsidiary developing DCtag™. This is a vaccine adjuvant based on 'nanoparticles' of polystyrene or alternatively a biodegradable material designed to assist the immune system to make a stronger response to vaccines. Divestment will be challenging as interest reportedly lies in the biodegradable particle which currently lacks a formal proof of concept and large scale manufacturing of nanoparticles remains technically challenging. It is most likely that this asset will be divested to the inventor who may use it to pursue government research grants to further development.

“Prima Biomed is divesting non-core assets to increase cash reserves and realise shareholder value”

11. Legacy shareholders remain on the registrar

Prima Biomed has not achieved market darling status over recent years and has left many shareholders sitting on a capital loss. This shareholder base does pose some risk as they may sell into share price strength.

In our view, the new management team which is now in place is steering Prima Biomed in a positive direction that is clearly focussed on driving shareholder value.

Should management achieve their divestment objectives, US FDA IND approval, and a partnering or outright sale of CVac™ a re-rating for shareholders from current levels is evidently possible. While Prima Biomed is undoubtedly a high risk play, the size of the potential upside from current levels make the 'risk to reward' proposition attractive in our view.

11. Management

Two fresh board members from Super Structure Services, Ata Gokyildirim and Martin Rogers have joined Prima Biomed with an aim to reinvigorate the business. The chairman of Super Structure Services has taken an interest of 21m shares or 8.76% in Prima Biomed.

**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 recently joined Super Structure Services as an executive to help restructure companies in need and deliver shareholder returns from these reforms.

**Mr Martin Rogers (Non-Executive Director)
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.

**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 world wide, 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.

11. Patents

Patent Family CVac™	Status	Expiry
Family 1 Mannan Fusion	Granted in Australia, USA (x2), Japan, UK, Italy, France, Germany, Ireland; application pending in Canada, USA and Japan.	2014
Family 2 Mimics	Granted in Australia, New Zealand, USA, UK, Italy, France, Germany, Switzerland; application pending in Canada and Japan.	2016
Family 3 Ex vivo cell therapy	Granted in Australia; applications pending in the USA, Europe, Canada and Japan.	2018
Family 4 Non-VNTR regions	Granted in Australia and the USA; applications pending in Europe, Canada, and Japan.	US: 2014, AUS: 2021
Biomira licensed patents	Granted in the US.	2014 - 2018
Oncomab		
Family 1 Cancer Antibodies	Granted in Australia, New Zealand and USA. Applications pending in Canada, Europe, Japan, South Korea and China	2022
Panvax		
Family 1 DCtag™	Granted in Australia, New Zealand (x2), South Africa and Singapore; application pending in Australia, USA, Canada, Europe, Japan, China, India, Israel, South Korea.	2021
Family 2 Mixed Beads	PCT Application filed in Australia. Application abandoned in Feb 2007 due to lack of commercial interest	

12. Historic Financials

Income Statement	2007	2006	2005
Revenue	\$156,122	\$3,876,910	1068386
Research & Development	-\$974,404	-\$2,759,775	-3654903
Corporate Administration	-\$1,503,626	-\$2,373,210	-1921888
Net Loss	-\$3,139,034	-\$4,357,874	-7145520

Balance Sheet	2007	2006	2005
Total Current Assets	\$704,281	\$3,391,930	\$7,817,981
Total Non-Current Assets	\$3,653,996	\$3,967,994	\$1,313,231
Total Assets	\$4,358,277	\$7,359,924	\$9,131,212
Total Current Liabilities	\$261,091	\$1,026,317	\$774,543
Total Non-Current Liabilities	\$17,116	\$17,009	\$13,568
Total Liabilities	\$278,207	\$1,043,326	\$788,111
Net Assets	\$4,080,070	\$6,316,598	\$8,343,101

Cash Flow Statement	2007	2006	2005
Net Operating Cash Flows	-\$3,329,338	-\$5,051,642	-\$4,734,789
Net Investing Cash Flows	-\$9,417	\$749,914	-\$8,687
Net Financing Cash Flows	\$799,186	\$19,925	-\$546,294
Net Increase / (Decrease) in Cash	-\$2,539,569	-\$4,321,653	\$4,748,230
Cash and Cash Equivalents Year End	671780	3211349	7533002

13. Capital Structure

Issued Shares

299,079,913

Options

Number	Expiry	Exercise Price	ASX Code
139,693,305	31-Dec-11	\$0.02	N/A
5,000,000	30-Sep-08	\$0.12	PRRAA
5,250,000	02/29/2009	\$0.20	PRRAY
1,000,000	26-Feb-09	\$0.30	PRRAC
2,000,000	31-Dec-09	\$1.25	PRRAE
300,000	6-Aug-10	\$0.20	PRRAK
2,000,000	20-Oct-10	\$0.01	PRRAD

Total

454,323,218

The Bulls & The Bears



The Bulls Say

- US FDA IND approval of ovarian cancer treatment could drive a significant re-rating in Prima Biomed.
- CVac™ phase IIa trials exceed expectations.
- CVac™ targets ovarian cancer which is a large unmet need.
- Each year 73,000 women are diagnosed with ovarian cancer in the US, Europe, Australia and Japan, sadly survival rates are under 20% after 5 years.
- New Non-Executive directors are focused on driving shareholder returns in the year ahead.
- Ample news flow potential over 2008, including CVac™ milestones, possible divestments and the release of Dendreon Corporation phase III interim results for Provogen.
- Thin development pipelines and a flood of blockbuster drugs coming off patent will encourage 'Big Pharma' to partner with or purchase technology from smaller biotechnology firms.
- Dendreon Corporation is developing a comparable treatment to CVac™ and boasts a market capitalisation of ~US\$530m, suggesting valuation upside for Prima Biomed.
- Key treatments have patents in place.



The Bears Say

- Individualised nature of the treatment may limit sales to wealthier markets.
- Funding must be secured to progress clinical trials.
- Credit market turmoil will make it more difficult for listed companies to source funding. Prima Biomed has a cash balance of AUD \$1.8m and a cash burn rate of AUD \$1.2m.
- Divestments may not generate the expected upfront cash and milestone payments.
- Trials may not achieve required efficacy or safety hurdles to warrant further development in phase III trials.
- If interim results from Dendreon Corporation's phase III trials for Provenge are not favourable it will reduce investor appetite for cell based therapies such as CVac™.
- Timing risks exist as patent expiry for the flagship CVac™ treatment is 2018, however this may be extended.
- Options with a strike of 2c may create resistance at the 2c level.

Wise-owl.com recommendation system

Care has been taken to define the level of risk to return associated with a particular company. Our recommendation ranking system is as follows:

Spec Buy

We forecast strong earnings growth or value creation that may achieve a return well above that of the broader market. These companies also carry a higher than normal level of risk.

Buy

Companies with 'Buy' recommendations have been cash flow positive for some time and have a moderate to low risk profile. We expect these to outperform the broader market.

Hold

A sound well managed company that may achieve market performance or less, perhaps due to an overvalued share price, broader sector issues, or internal challenges.

Sell

Risk is high and upside low or very difficult to determine. We expect a strong underperformance relative to the market and see better opportunities elsewhere.

Valuation

No recommendation as a valuation only report has been requested.

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