

20 May 2011

Prima Biomed (PRR)

A powerful Australian cell therapy

Analyst

Stuart Roberts 612 8224 2871

Authorisation

Steve Goldberg 612 8224 2809

Recommendation

Spec Buy

Price

\$0.34

Target (12 months)

\$0.75

Prima Biomed is developing CVac, a cellular therapy which commences Phase III for ovarian cancer in mid-2011 and which is similar to Dendreon's recently FDA approved Provenge cancer vaccine. We expect CVac to be on the market by 2014 or 2015, with the product now on a clear pathway to accelerated regulatory approval. Spec. Buy recommendation maintained with new target price 75 cents (was 60 cents).

Expected Return

Capital growth **121%**

Dividend yield **0%**

Total expected return **121%**

Company Data & Ratios

Enterprise value **\$260.6m**

Market cap **\$276.7m**

Issued capital **813.7m**

Free float **100%**

12 month price range **\$0.08-\$0.42**

GICS sector

Healthcare Equipment and Services

This note updates our 31 May 2010 note on Prima Biomed

Ovarian cancer is a significant market opportunity

Prima Biomed (PRR) is moving to late stage clinical trials of CVac, a 'cellular therapy' or 'cancer vaccine' for the treatment of various cancers, beginning with ovarian cancer. CVac performed well in this indication in a Phase IIa clinical trial for which data reported in March 2007. In the US\$2-3bn market for ovarian cancer, existing treatments have a small level of efficacy. This is the main opportunity for CVac, however we also see the potential for the therapy to be applied to other cancers such as breast, kidney and pancreatic.

CVac has performed well in the clinic

CVac performed well in Phase IIa in terms of disease-free survival as well as reduction in cellular markers of the disease. We see the Phase IIb trial, now nearing the end of recruitment, and the shortly-to-commence Phase III trial as providing further indications of efficacy and bringing CVac to market in Europe and the US by 2014 or 2015.

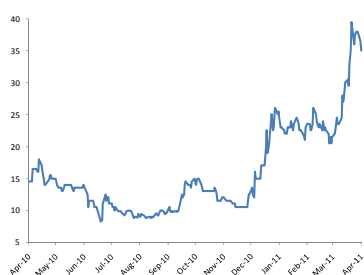
PRR is a well-managed company

We have a high regard for PRR's management led by CEO Martin Rogers. We like the commercial approach that the company has taken towards realising value from the quality science behind CVac.

New target price 75 cents per share

We now value PRR on the basis of bringing CVac to market by itself rather than via partnering. Our new 75 cent target price for PRR is at the lowpoint of our base case \$0.77 / optimistic case \$1.02 per share probability-weighted DCF valuation range and reflects the progress the company has made towards Phase III for CVac. We think that the current market capitalisation of Dendreon (Nasdaq: DNDN), US\$5.6bn, is indicative of the potential of PRR. Dendreon's Provenge cellular therapy, which is similar to PRR's, gained FDA approval in April 2010 and CMS reimbursement in April 2011.

Absolute Price



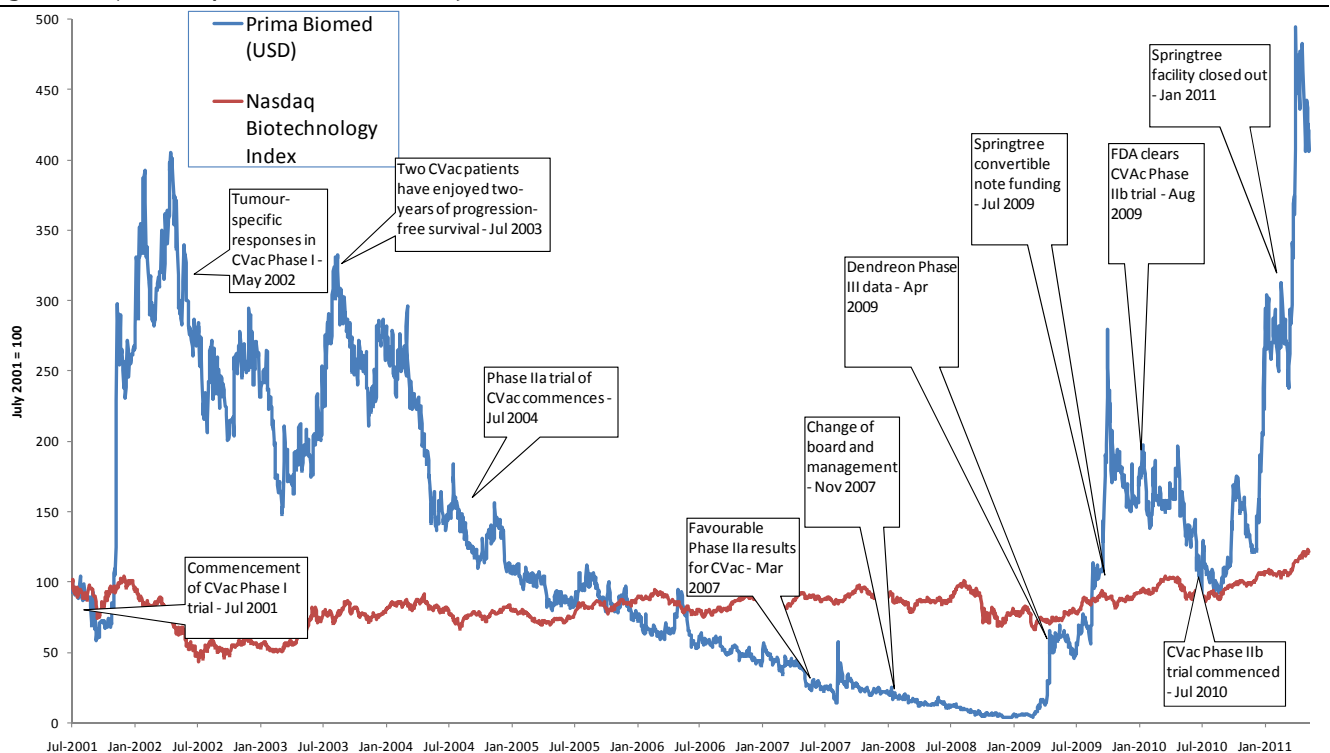
SOURCE: IRESS

Disclosure of Interest: Southern Cross Equities earned a fee of 2.0 million options exercisable at 25 cents by May 2015 for preparing our initiation report on PRR in October 2009.

Prima Biomed – A powerful Australian cell therapy

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Figure 1 - Major developments for PRR since July 2001



SOURCE:PRR, SOUTHERN CROSS EQUITIES, NASDAQ

"It is important to remember that the success of recent antibody products for lymphoma and breast cancer did not happen overnight. Rather, those successes were 20 years in the making. In this regard, for cancer immunotherapy, which is T-cell based, this similar anniversary is not yet upon us but it is getting close. The next few years are critical to this emerging field and likely to be full of promise, surprises and even success." – David Weiner and Jong Kim, *Cancer vaccines: is the future now?*, Expert Review of Vaccines, October 2002.

Nine reasons to own PRR

1. **PRR's CVac technology performed well in Phase IIa**, with a number of responders to the product being registered in late-stage ovarian cancer patients.
2. **Ovarian cancer is a large market of unmet medical need.** We estimate that the ovarian cancer market is worth US\$2-3bn, with around 70,000 new diagnoses per year in the US, Europe and Japan but only a 20% five year survival rate using the existing standard of care, which is chemotherapy using the Bristol-Myers Squibb drug Taxol. We argue that the clinical data for CVac to date gives the potential for the technology to eventually become the standard of care. CVac was granted Orphan Drug designation for ovarian cancer in Europe and the US in 2010, providing certain market-related benefits.
3. **CVac can be used for other cancer indications**, with the technology having performed clinically against kidney cancer and also being theoretically useful against pancreatic, breast and lung cancer.
4. **There is now a clear pathway to Phase III and regulatory approval.** CVAC's Phase IIb trial commenced in mid-2010 and it is now merging into an 800-patient Phase III, to be conducted mainly in Europe from mid-2011. Ordinarily a drug or medical device requires two Phase III trials before it can apply for FDA approval. However PRR's guidance from the FDA is that CVac IIb and III trials will be sufficient for this product. We expect this Phase III to help put CVac on the market by 2014 or 2015.
5. **The nearness of commercial revenues from CVac warrants a higher market cap for PRR.** We think that the current market capitalisation of Dendreon (Nasdaq, DNDN), US\$5.6bn, is indicative of the potential of PRR. Dendreon gained FDA approval for Provenge, a cellular therapy similar to CVac but for prostate cancer, in April 2010. The product gained CMS reimbursement in April 2011.
6. **Dendreon has helped pioneer the regulatory pathway for CVac.** Dendreon has worked with the FDA to develop the protocols that would allow a cellular therapy such as CVac to be approved for clinical use.
7. **PRR is a well-managed company.** We have a high regard for PRR's management led by CEO Martin Rogers. We like the commercial approach that the company has taken towards realising value from the quality science behind CVac.
8. **There is potential for PRR to realise value from non-core assets**, namely the Oncomab cancer antibody technology, some early stage know-how related to an orally available HPV vaccine, and a 7% shareholding in Trillium Therapeutics, a privately held Canadian biotech company which holds technology related to a PRR-developed rheumatoid arthritis drug target. We have allowed no value for these projects.
9. **Our new target price is 75 cents per share.** We now value PRR on the basis of bringing CVac to market by itself rather than via partnering. Our new 75 cent target price for PRR (was 60 cents) is at the lowpoint of our base case \$0.77 / optimistic case \$1.02 per share probability-weighted DCF valuation range. It reflects the progress the company has made towards Phase III for CVac.

We expect a pivotal trial for CVac to start in mid 2011

The success of Dendreon, a US\$5.6bn cap company, bodes well for PRR

We value PRR at \$0.77 base case and \$1.02 optimistic case

Valuing PRR and realising that value

Our valuation of PRR

We value PRR on the basis of CVac alone. To attempt a valuation of PRR we took CVac and assumed no value for the other projects currently housed within PRR or the company's 7% stake in the privately held Canadian biotech company Trillium Therapeutics¹.

A model based on PRR bringing CVac to market by itself. With PRR now close to initiating its own Phase III trial of CVac we have decided to value the company using a scenario where it brings CVac to market by itself². Our probability-weighted DCF valuations contain the following assumptions:

- only European and US sales, with near-simultaneous approvals in 2015;
- a sales curve based on sales levels reached at the point of maximum sales growth in year 3 (US\$1.5bn for base case and US\$2bn for optimistic case³);
- a product life of around 14 years post approval;
- 80% gross margins;
- Cost of field force of around US\$40m, rising 5% pa.

We valued the resulting cash flows using a 20% discount rate⁴, a 30% tax rate, and a 0.8 AUD/USD exchange rate. And we also assumed a ~50% chance of success from now to regulatory approval, and allowed a 3% royalty to a US company called Oncothyreon, which has similar technology (see below for details).

We assume a A\$60m capital raising to fund CVac's Phase III trial

We assume a further \$60m capital raising. The forthcoming Phase III trial is expected to cost around US\$45m. We assumed a capital raising of around \$60m at a ~20% discount to the current market price to fund this as well as the other PRR programmes and overhead over the next four years. We understand PRR is listing on Nasdaq from later this year partly to access US institutions for such a raising.

Target price \$0.75. Our CVac valuation plus our assumption of increased dilution resulted in our valuing PRR at base case \$0.77 per share and optimistic case \$1.02 per share. Our new 75 cent 12-month target price sits at the lowpoint of this range.

Strong potential upside. We regard the current market capitalisation of Dendreon on Nasdaq of US\$5.6bn as indicative of the potential upside from CVac.

What to expect over the next twelve months

The rest of 2011 will likely feature some good news flow for PRR:

¹ This privately-held Toronto-based company (www.trilliumtherapeutics.com) bought PRR's Arthron project, which covered a rheumatoid arthritis target called FcγRIIa, in October 2005. We expect it will be some years before PRR can recover its investment via an IPO of Trillium- all of that company's programmes are at the pre-clinical stage, and North American biotechs generally don't tend to go public until the later stages of clinical development. That said, Trillium continues to work on various projects related to cancer and inflammatory disorders, and gained fresh venture capital funding from a number of Canadian institutions in late 2008. Around that time Trillium filed for an IND for its lead compound, TTI-1612, a drug for the prevention of necrotizing enterocolitis and the treatment of interstitial cystitis. The company is also working on rheumatoid arthritis and cancer drugs related to an immunoregulatory molecule called CD200. Trillium continues to work on an FcγRIIa -specific monoclonal antibody, however it appears that AstraZeneca has decided not to pursue further development on a small molecule to the target. For more on Trillium and Arthron see our 30 October 2009 PRR note.

² In our previous note we assumed out-licensing after Phase IIb.

³ We assume that an effective cellular therapy potentially doubles the ovarian cancer drug market.

⁴ In May 2010 we used 25% but feel that CVac's progress through Phase IIb and towards Phase III warrants a slightly lower rate.

We expect strong news flow for the rest of 2011

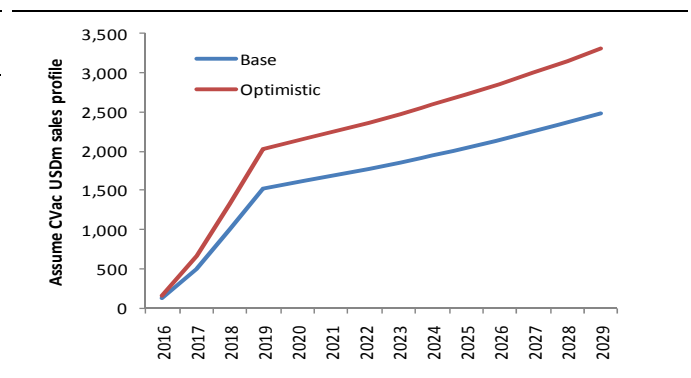
- The company’s Nasdaq listing, which is likely to be well received given the strong following for Dendreon on The Street;
- Completion of enrolment for the CVac Phase IIb trial;
- Qualification of CVac’s ‘potency assay’;
- Granting of a manufacturing license by the EMA, allowing Prima to make CVac for trial purposes in Germany;
- Commencement of Phase III for CVac;
- Progress in humanising the Cripto antibodies;
- Progress in developing the oral HPV programme.

Figure 2 - Our valuation of PRR

	Base case	Optimistic case
Value of CVac (\$m)	819.1	1,110.9
Cash as at 31/3/2011 plus cash to be raised	76.1	76.1
Cash from options (\$m)	12.7	12.7
Total diluted value (\$m)	907.9	1199.8
Total diluted shares	1175.8	1175.8
Value per diluted share	\$0.77	\$1.02
Valuation midpoint	\$0.90	
Share price now	\$0.340	
Upside to midpoint	164%	

SOURCE: SOUTHERN CROSS EQUITIES

Figure 3 - Assumed sales profile for CVac



SOURCE: SOUTHERN CROSS EQUITIES ESTIMATES

The path to 75 cents per share

We see four other factors continuing the current re-rating of PRR stock beyond 2011:

- 1) **Recognition of the near-term nature of the story.** With PRR to enter Phase III shortly we believe sentiment on the stock will strengthen, since investors tend to like late stage biotech opportunities;
- 2) **Progress on recruitment to the trial.** As new patients are recruited into the Phase III trial, we expect confidence to build regarding PRR’s ability to meet timelines for trial completion;
- 3) **Recognition of the importance of cellular therapy.** As data grows on the effectiveness of Provenge and other cellular therapies compared to older kinds of medicine, PRR is likely to benefit from increased acceptance of its approach by biotech-focused investors⁵;
- 4) **Public awareness of ovarian cancer.** As a disease specific to women with a relatively low five-year survival rate, ovarian cancer and prospective treatments for it attracts media attention from time to time, particularly when high profile women are diagnosed or die from the disease⁶. This may help focus public attention on the prospects for CVac’s clinical success.

⁵ The stem cell company Mesoblast (ASX: MSB), which we cover, is also a beneficiary of this phenomenon. In a 17 May 2010 note on MSB we commented ‘We see the FDA approval of Provenge... as illustrative of the potential opportunity for MSB from MPCs...The dendritic cell priming element of Provenge represents a form of autologous cell therapy not dissimilar to what MSB had been doing with MPCs before it started allogeneic use of MPCs. With multiple large market applications of the Dendreon technology available beyond prostate cancer, we see the current US\$5.9bn market cap for Dendreon pointing to the potential boom the market foresees in cellular therapy in an environment where the FDA is comfortable with the regulatory oversight it has developed for cellular therapy products’.

⁶ There is a Wikipedia article entitled *List of women with ovarian cancer*.

Why CVac is valuable technology for PRR

PRR's principal asset is its CVac technology, which covers an immunotherapy for the treatment of various cancers and is currently being focused on ovarian cancer. We argue in this note that CVac is potentially worth >A\$800m to PRR depending on the outcome of upcoming clinical trials.

What is an immunotherapy and what is CVac?

An immunotherapy is any medical treatment that enables an element of the human immune system, including the patient's own immune system, to go after disease-causing agents in the body. CVac is one such immunotherapy. The CVac product is a sugar called mannan conjugated to a common cell surface marker often overexpressed on cancer cells called MUC-1. Doctors give the mannan/MUC-1 combination to a patient *ex vivo*, that is, outside of the body. They take a blood sample from the patient, and draw out from that sample 'dendritic cells', which are cells in the immune system that help to direct an immune response. These dendritic cells, after their exposure to mannan/MUC-1, are then able to direct the attention of the patient's immune system to the cancer. For more on immunotherapy and on the technical background of CVac, see Appendixes II and III of this report.

Why is CVac potentially so valuable?

We see three reasons why CVac can become a highly valuable technology for PRR:

- 1) **Immunotherapy is the wave of the future in cancer treatment.** These days cancer is largely treated by surgery, chemotherapy and radiotherapy. This is brutal on the patient in terms of the side effects, and generally fails to deal with the cancer for very long. Immunotherapy can potentially solve these problems because the immune system, with its high level of specificity, can zero in on cancer cells that surgeons, drugs and X-rays can't reach.
- 2) **Immunotherapy has become a reality thanks to Dendreon.** Until recently cancer immunotherapy had largely been theoretical, with no serious late stage results in the clinic. That changed in April 2009 when an American biotech company called Dendreon⁷ announced positive Phase III data on the survival advantages of its immunotherapy, called Provenge, in prostate cancer. This not only proved that it was possible to target the immune system to attack cancer, it also demonstrated that an immunotherapy could be a 'company maker'. Dendreon gained FDA approval for Provenge in April 2010, and is now selling the product at a >US\$100m annual rate. This is likely to continue growing thanks to CMS's decision to cover the therapy in April 2011. Dendreon's market capitalisation is now US\$5.6bn. We argue in this note that CVac represents a similar therapeutic approach to Provenge with similar potential.
- 3) **CVac has generated the Phase II data indicating the potential for success.** In March 2007 PRR announced the results of a Phase IIa clinical trial in late stage ovarian cancer patients, which the company and the trial investigators regarded as a statistical success and indicative of its prospects in a larger and different clinical setting.

Dendreon's Provenge cell therapy has paved the way for PRR's CVac product

⁷ Nasdaq: DNDN. Seattle, Washington. www.dendreon.com.

What the CVac Phase II data told us.

A favourable response rate. In CVac's Phase IIa trial, 21 late-stage ovarian cancer patients were studied for the duration of response and the period in which they were disease-free, based on measurement of CA125, a biochemical marker that oncologists traditionally use in following the progression of ovarian cancer. Of the 21 patients, four registered a positive clinical response or stabilisation of disease, for a 19% response rate. This may not seem like much, but was actually quite an achievement because:

- 1 **The patients were late stage** - having failed other therapies, their CA125 levels were rising rapidly by the time they enrolled, which meant that any response rate above 10% was considered remarkable;
- 2 **The response, when it happened, was long-lasting**, ranging from 27 weeks to 44 weeks, which was significant given the low life expectancy of the patients enrolled⁸. We understand the average progression free interval was 127 days⁹;
- 3 **Around half of the patients notionally gained some benefit.** The 19% response rate was for those patients where CA125 went down or only rose slowly. Another five patients registered some response to the vaccine for shorter periods, suggesting that around half of all patients gained some benefit from the vaccine;
- 4 **There were no safety issues as measured by 'serious adverse events'.** This suggests CVac can deliver on being a gentler form of cancer therapy than chemo or radiotherapy;
- 5 **Other cancer products have had lower response rates.** Provenge's Phase II response rate, as measured by a reduction in biomarker levels, was 16%¹⁰. This subsequently translated into strong Phase II data on progression free intervals and overall survival. It's also worthwhile considering the example of Tarceva, a Roche drug for the treatment of non-small-cell lung cancer¹¹. That product enjoyed US\$1.3bn in worldwide sales in 2010. A typical response rate for Tarceva as a lung cancer monotherapy is in the order of 10-20%.

Half of all late stage ovarian cancer patients gained some benefit from CVac in Phase IIa

Ovarian cancer is an attractive market for PRR

Ovarian cancer, while less common than other cancers, is a difficult disease to treat:

- There were an estimated 21,880 new cases of ovarian cancer in the US in 2010 while 13,850 women died of the disease¹²;
- There are few existing treatments for ovarian cancer beyond drug therapy with taxol and carboplatin/cisplatin, the latter two being harsh chemotherapy drugs, the former not so harsh but chemo nonetheless. Also, ovarian cancer tends to become resistant to this regimen after a while;
- There is currently no maintenance therapy available for ovarian cancer, while CVac would be able to prescribe this in a non-toxic form. It is poor medical practice for the oncologist to prescribe taxol and carboplatin/cisplatin after it has failed on the patient;

⁸ Seven enrollees died before they could be treated, while only two of the 28 lived to receive 7 CVac injections.

⁹ 95% confidence interval.

¹⁰ In a Phase I/II trial in 19 patients 3 out of 19 saw levels of PSA (Prostate Specific Antigen) falling >50% after Provenge treatment. Ref: Small EJ, et al. J Clin Oncol 2000;18(23):3894-903.

¹¹ See www.tarceva.com.

¹² Source: Cancer Facts and Figures 2010, American Cancer Society.

- The current five-year survival rate post diagnosis for the disease is relatively poor, at only 46%. Two-thirds of all ovarian cancer is detected once the disease has started to metastasise, where five-year survival is only 30%¹³;
- Probably US\$2-3bn pa is spent on ovarian cancer in the industrialised world even though the survival figures are not great. We think an effective cancer vaccine indicated for ovarian cancer can potentially double this market given the healthcare economics involved. For us, this has suggested CVac revenue quickly rising to US\$1.5-2bn in the event of clinical success;
- There are few new drugs in the late stage of the pipeline that are intended primarily for this disease¹⁴.

CVac has been granted Orphan Drug status in Europe and the US

Prima's product is an Orphan Drug. CVac received Orphan Drug designation for ovarian cancer from the EMA in June 2010 and from the FDA in September 2010. In the US an Orphan Drug is one treating a disease affecting less than 200,000 patients, which would ordinarily limit the attractiveness of the market for drug developers. In the US designation as an Orphan Drug brings with it seven years of marketing exclusivity after approval and 50% tax credits for clinical trial expenses. In Europe an Orphan Drug gets 10 years market exclusivity and tax reductions.

PRR doesn't face intellectual property issues for CVac

PRR owns 100% of the technology, without intellectual property issues and with only a modest royalty payable. In March 2004 PRR licensed the CVac technology for use outside Australia and New Zealand to a Canadian company called Biomira, which was developing a similar technology to PRR¹⁵. That agreement was altered in February 2007 with PRR taking back the international rights in return for a modest royalty on sales. This helped clear up the intellectual property space around MUC-1 and consequently we have no concern about patent litigation in the event of CVac's clinical trial success. Biomira is now Oncothyreon, a company we profile below.

There are no royalties payable to the Burnet Institute. As a result of previous deals with the Austin Research Institute, which took equity in PRR, the company has no royalty obligations to the Burnet Institute, into which the Austin was merged in 2006.

Why Dendreon is a good comparable for PRR

Dendreon is obviously further down the road to commercialisation than PRR, as indicated by its US\$5.6bn market capitalisation, however we argue that the comparison is a valid one and also an indicator of a potential future market capitalisation for PRR much greater than the current one. We say this for three reasons:

- 1) **The treatment approach is similar.** Provenge is, like CVac, an *ex vivo* dendritic cell therapy, the difference being CVac uses mannan/MUC-1 as the

PRR could be the 'next Dendreon'

¹³ Source: Cancer Facts and Figures 2010, American Cancer Society – average five-year survival rate across all cancers and detection stages is more like 68%. Many cancer authorities regard the five-year survival rate for ovarian cancer as less than 20%. For example, a National Cancer Institute document from 1997 entitled *New Directions in Ovarian Cancer Research* states that "...70 percent of women with ovarian cancer are not diagnosed until the disease is advanced in stage. The 5-year survival rate for these women is only 15 to 20 percent".

¹⁴ Avastin, the Roche/Genentech antibody drug which has been successful in colon cancer, had shown promise against ovarian cancer but in 2005 Genentech halted trials after 11% of patients developed perforations in their stomach and intestines.

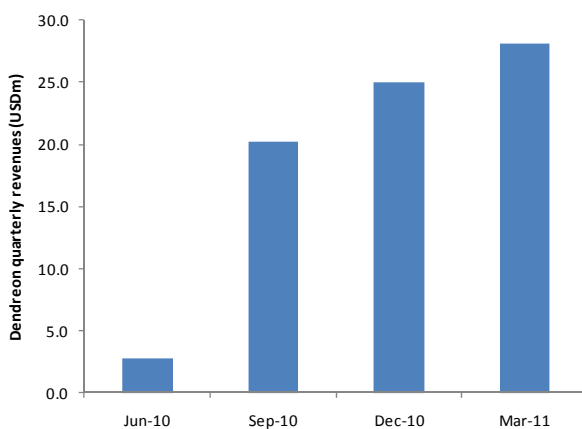
¹⁵ Biomira was developing a product called BLP25, which was MUC-1 wrapped up in liposomes. The fact that the two companies were playing with MUC-1 was potentially an intellectual property issue for PRR, but the Melbourne company, by generating such favourable early stage data with its *ex vivo* product - BLP25 is by contrast *in vivo* because liposomes won't crumble under pressure like mannan - had put itself in a favourable position vis-a-vis the Canadian company. Biomira had enabled its product by licensing technology from Imperial College London (see US Patent 6,222,020).

stimulating agent whereas Provenge is prostatic acid phosphatase conjugated to GM-CSF¹⁶.

- 2) **The survival data seems achievable.** In the Phase III data released in April 2009 Provenge extended survival in patients in the last stages of the disease by a median of 4.1 months¹⁷. Given what we know about CVac this kind of survival data seems achievable in ovarian cancer.
- 3) **CVac can be administered intradermally,** whereas Provenge is an intravenous treatment. This gives CVac a net advantage in terms of ease of administration and, importantly, a theoretical efficacy advantage, since subcutaneous administration would likely speed delivery of dendritic cells to the lymph nodes.

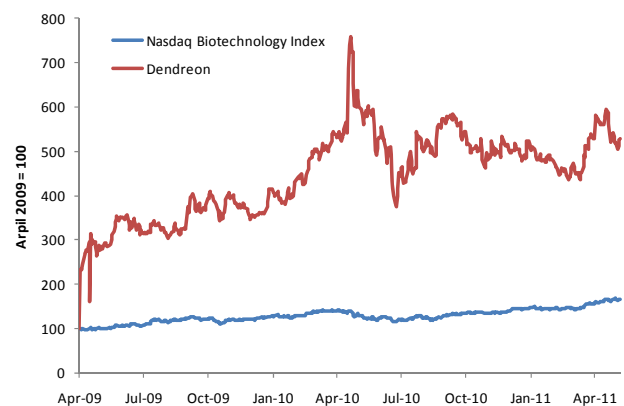
CVac can be administered intradermally, whereas Provenge is an intravenous treatment

Figure 4 - Dendreon has been growing revenue from Provenge



SOURCE: DENDREON

Figure 5 - Wall Street has loved Dendreon since the April 2009 Overall Survival data



SOURCE: NASDAQ

CVac provides a potentially large payoff

In addition to Dendreon, we see a number of other companies against which PRR is likely to be compared in the event of clinical success:

Geron, while best known for its work on stem cell therapies, is also working on vaccines targeting telomerase, the enzyme which seems to give cancer cells their survival advantage over ordinary cells. Dendritic cell approaches have been important in this effort although Geron's partner, Merck & Co., is trying a different approach.

CEL-SCI. This company has developed a cancer vaccine called Multikine, which is a mixture of cytokines that simulate the body's healthy immune response. A Phase III trial in head and neck cancer commenced in December 2010.

Celldex. This company's lead product is Rindopepimut, a vaccine that targets EGFRvIII, which in turn is a mutated version of a growth factor receptor that appears in various cancers. Rindopepimut has worked well in glioblastoma, a brain cancer, and has generated positive Phase II results in this indication. The product was licensed to Pfizer in 2008 but Pfizer handed it back in September 2010 in spite of the good data.

¹⁶Prostatic acid phosphatase is a chemical expressed by prostate tissue that is overexpressed in prostate cancer, while GM-CSF is an immunostimulatory agent. GM-CSF is Granulocyte Colony Stimulating Factor, a cytokine that stimulates growth of a kind of white blood cells known as the granulocyte (so called because it contains granules of toxic chemicals that are poisonous to microbial invaders in the body) and another kind called the macrophages, being white blood cells that can ingest dead tissues.

¹⁷ 31.7% of the patients on Provenge were still alive at the three-year mark, compared with 23% of those on placebo.

Generex. This company’s vaccines are built around its ‘Antigen Express’ technology, where a fragment of the MHC class II called “li-key” is combined with peptide of interest to enhance presentation of this peptide to the immune system. Generex has conjugated li-key with Her2/neu, a protein overexpressed in various cancers¹⁸, to create a potential cancer vaccine. The technology is in Phase II in breast cancer.

Figure 6 - PRR comparables

Company	Location	Code	Market cap (USDm) ¹⁹	Website
Dendreon	Seattle, WA	Nasdaq: DNDN	5,619	www.dendreon.com
Geron	Menlo Park, Ca	Nasdaq: GERN	608	www.geron.com
Oncothyreon	Seattle, WA	Nasdaq: ONTY	169	www.oncothyreon.com
CEL-SCI	Vienna, Va	Nasdaq: CVM	129	www.cel-sci.com
Celldex	Needham, Ma	Nasdaq: CLDX	109	www.celldextherapeutics.com
Agenus	Lexington, Ma	Nasdaq: AGEN	110	www.agenusbio.com
Generex	Toronto, On	Nasdaq: GNBT	64	www.generex.com

SOURCE: SOUTHERN CROSS EQUITIES, GOOGLE FINANCE

PRR appears undervalued compared to comparable companies

Agenus. This company’s Prophage technology involved taking a sample of the patient’s tumour, isolating heat shock proteins from them, and using these as a personalised cancer vaccine. This technology has registered some clinical success in renal cell carcinoma and in glioma, a brain cancer.

Oncothyreon. This company, which used to be called Biomira (mentioned above regarding CVac’s IP position), is currently in Phase III with its MUC-1 immunotherapy, called Stimuvax, in non-small-cell lung cancer and in breast cancer. Oncothyreon partnered Stimuvax to Merck KGaA²⁰ in 2001, which was converted to a full license in 2007, while manufacturing rights were granted to Merck KGaA in late 2008. In March 2010 the FDA placed a clinical hold on the Stimuvax trials due to a trial subject developing encephalitis. The non-small cell lung cancer hold was lifted in June 2010, but the hold remains for breast cancer. With regard to PRR we think Oncothyreon is particularly worth paying attention to:

- *The data for lung cancer has been favourable* – In a 171 patient Phase IIb trial for which final survival results were announced in April 2006 median survival for treated patients was 30.6 months versus 13.3 months for the controls.
- *We understand Phase III data will be available close to the end of 2011* - Success for Merck KGaA and Oncothyreon in this trial will also be favourable for PRR given the validation it will provide for the use of MUC-1 as an antigen generating an anti-cancer immune response.

¹⁸ Particularly breast cancer – the Roche/Genentech antibody drug Herceptin targets this molecule.

¹⁹ As at 19 May 2011.

²⁰ ie ‘German’ Merck, based in Darmstadt, Hesse (Xetra:MRK, www.merck.de), a completely different drug company to Merck & Co, based in Whitehouse Station, New Jersey.

CVac enters Phase III in 2011

Phase IIb is set to generate data soon

Trial recruitment to complete by June 2011. In July 2009 PRR filed its IND application with the FDA to conduct a 60 patient Phase IIb clinical trial of CVac in the US. The FDA cleared the trial within 30 days, which is the agency's minimum turnaround time²¹, and after around a year's worth of tech transfer activity²² the first patient was enrolled in July 2010. The trial appears to have proceeded quickly since then, with PRR expecting recruitment for the trial to be complete by the end of June 2011. We are encouraged about the Phase IIb progress for five reasons:

- 1) **PRR knows what the FDA wants.** Since the trial is being conducted under an IND, it's reasonable to say that PRR has a good idea what the FDA expects in an approvable immunotherapy. CVac's Phase IIa trial had not been conducted under an IND, and we understand that the data collected in that trial currently differs from what the agency now requires²³;
- 2) **The trial is being run out of 'The Hutch'.** Seattle's Fred Hutchinson Cancer Research Center²⁴, known locally as 'The Hutch', is one of the world's premier cancer research and treatment facilities and a leader in immunotherapy research. Dendreon's clinical work was also centred at the Hutch. That this site was a clinical trial site raised the chances that the 60 patients would be recruited swiftly, which they were;
- 3) **There is the potential for near term data on CVac efficacy.** The IIb trial vaccinates patients every four weeks for 24 weeks, followed by booster injections every eight weeks until week 48. The aim of the trial will be to generate superior data on Progression Free Survival compared to standard of care. We understand that PRR has included in the IIb trial protocol an 'interim data point' in which the company can look at the data to see if the trial is sufficiently powered. We expect that interim data, if any, could be available within a year of first dose, that is, around July 2011;
- 4) **Dendreon has done the hard work on regulatory issues.** We noted above that Dendreon gained approval for Provenge in April 2010. We regard Dendreon's travails with Provenge as helping make the regulatory pathway smoother for CVac and other competing immunotherapies currently in development. Dendreon initiated its pivotal trials for Provenge expecting that the product could be approved by the FDA using 'Time to Progression' as the key endpoint²⁵. When the pivotal data came through the Time to Progression data was not statistically significant even though Survival data for the treated patients was. However Survival had not been pre-specified as an endpoint. Consequently when Dendreon first filed for Provenge approval in 2007, the FDA demanded another trial, this time with Survival as the endpoint. That data didn't come through until April 2009. PRR with CVac, having observed these issues, have agreed with the FDA on Progression Free Survival and Overall Survival as endpoints for the IIb trial. In the meantime the Dendreon experience has helped the FDA develop its thinking in terms of

Phase IIb interim data could be available shortly

²¹ See NCT01068509 at www.clinicaltrials.gov.

²² Which is standard for a new therapy like PRR's.

²³ Dr Joyce Frey-Vasconcells, former US FDA Director of Cell and Gene Therapy, consulted to PRR on this filing.

²⁴ See www.fhccr.org.

²⁵ That is, time between treatment and when disease symptoms show up, when measured in patients that were initially asymptomatic.

what it expects from cancer vaccine trials, as evidenced by the fact that in September 2009 it released a guidance paper headlined *Clinical Considerations for Therapeutic Cancer Vaccines*;

- 5) **The patient population will be easier to work with.** PRR indicated at the time of the Phase IIa results that its next trial of CVac would be in a 'healthier patient population' (ie patients at an earlier stage of disease) where it was reasonable to expect the response rate to be greater. Consequently in this trial patients will have to be in remission and have only gone through one or two rounds of chemotherapy, raising the likelihood that the immune system can generate a response against cancer as it re-occurs²⁶. We think this will ultimately lead to better data from the trial.

Phase III to start shortly

There is now a clear pathway to Phase III and regulatory approval. While recruitment for the IIb trial will be complete by June 2011, PRR is also preparing for an 800-patient Phase III trial to be conducted in Europe, US and Australia that will commence in Q3 2011²⁷. Ordinarily a drug or medical device requires two Phase III trials before it can apply for FDA approval. However PRR's guidance from the FDA and EMA is that CVac IIb and III trials will be sufficient for this product. Consequently the first patient dosage for Phase IIb, which happened in mid-2010, can be considered commencement of 'pivotal' trials for CVac.

CVac's pivotal yield's interim data late in 2012. As with Phase IIb, the Phase III trial of CVac will only recruit patients in remission, and will randomise the patients to either CVac or standard of care, measuring the months in which the patients enjoy Progression Free Survival as well as Overall Survival. PRR expects to be able to do an interim analysis of the data by late 2012 or early 2013, with the final data set in late 2013 or early 2014. We expect that regulatory filings with the EMA and FDA would follow, on a six-month review timeframe. This could lead to marketing approval by late 2014 with commercial launch in 2015.

Phase III is bigger than we had previously estimated. In May 2010 we suggested that CVac's Phase III trial would be 200 patients costing US\$15m. Since that time PRR's advisers have crafted a trial four times as big, but only costing around three times as much (ie US\$45m) due to greater efficiencies. The principal reason for the change was to better power the trial, reducing the potential for clinical failure due to lack of statistical significance. It's also worth noting that:

- PRR is better placed this year to raise the necessary capital than it was in May 2010, due to the larger market cap (it was A\$97m at that time);
- There is flexibility built into the trial to change the subject numbers. If Progression Free Survival and Overall Survival are compelling at the interim analysis time point in late 2012, less patients may need to be recruited and a faster time to market could result.

Christmas 2012 could be a good one for PRR shareholders

²⁶ The thinking here is that the less chemo, the better the immune system functions as the T-Cell cycle is intact.

²⁷ Scientific Advice for this trial was granted by the EMA in February 2011.

Strong leadership

We have a high regard for the leadership team at PRR, which has rebuilt the company from a point in November 2007 where its core projects were not expected to recover commercially.

CEO Martin Rogers, has helped incubate technology for UNSW and also has valuable experience as an entrepreneur and as a private investor in his own right. We find Rogers very commercial in his approach. Rogers has helped build the team that filed the CVac IND and is now working on the Phase IIb and Phase III trials. He has also been instrumental in rebuilding Australian clinician support for CVac.

Chief Operating Officer Matt Lehman, who joined the company in January 2010 and will work from Germany, brings extensive experience in the clinical trial process, having previously been COO for SPRI Clinical Trials, an international contract research organisation. He has worked in over 100 clinical research programs and helped with drug approvals in Europe and US.

Chief Medical Officer Dr Neil Frazer has worked in Europe and in the US conducting Phase I-IV studies, which have led to product registrations in Europe and the US. Prior to joining PRR Neil was with GSK with 10 FDA approvals he personally worked on over 25 years.

The Prima Board has the mix of skills needed to build the company. In addition to Rogers and Neil Frazer it features **Chairman Lucy Turnbull**, an investment banker and lawyer by background who was formerly Lord Mayor of Sydney, **Albert Wong**, the Sydney stockbroker, and **Dr Rick Hammel**, an American adviser to various pharmaceutical ventures.

Professor Ian Frazer, the University of Queensland immunologist who is famous as the co-inventor of Merck & Co's Gardasil HPV vaccine, brings considerable credibility to PRR as Chairman since early 2008 of the company's Scientific Advisory Board. Not only does Frazer have a high regard in the scientific community for the farsightedness of his research, but his favourable attitude towards the commercialisation of science, as demonstrated through UQ's licensing of the Gardasil intellectual property in the mid-1990s, bodes well for PRR in a commercial sense. Frazer is a household name in Australia, having been Australian of the Year in 2006.

Head of CVac clinical programmes Dr Sharron Gagorsky, who joined the company in mid-2010, brings 18 years of biotech and pharma experience doing R&D with companies like Hyperion Therapeutics and Medicis. She has worked with several companies that have received FDA approval for Orphan Drugs.

Vanessa Waddell, who is PRR's Melbourne-based Business Development and Intellectual Property Manager and who has been with PRR since 2001, helps bring valuable commercial focus to the science. She has both a science degree and an MBA, and over the years has helped shepherd the PRR projects since their early inception in the lab. She has also been responsible for building key relations both with the labs as well as with commercial partners.

**PRR's SAB Chairman,
Professor Ian Frazer,
was Australian of the
Year in 2006**

The risks

Biotechnology is risky

The stocks of biotechnology companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character. Since most biotechnology companies in Australia fit this description, the speculative moniker also applies to the entire sector. The fact that biotechnology's intellectual property base lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology ought to be regarded. Investors are advised to be cognisant of this risk before buying any Australian biotech stock including PRR.

PRR is not without risk

We see six major risks specifically related to PRR as a company and a stock:

- 1 **Clinical risk** – While we are satisfied with the existing data on CVac, there is the risk that PRR's ovarian cancer trial could fail in terms of not outperforming placebo with statistical significance.
- 2 **Trial structuring risk** – There is the risk that the Phase III trial in ovarian cancer could be incorrectly structured to generate the kinds of data that regulators are looking for. For example, the trial could measure the wrong endpoints or test the patients through too short a period of follow up.
- 3 **Timing risk** – There is the risk that PRR could take much longer to organise and conduct the pivotal CVac trial than the roughly four years we have postulated in this note.
- 4 **IP risk** – There is the risk that PRR could find itself locked in dispute over patent infringement.
- 5 **Burn rate** – As at March 2011 PRR had around \$16.1m cash, having burned around \$740,000 per month through 2010. It has raised \$59m in equity capital since 2001 but the CVac pivotal will cost around US\$45m, which will have to be financed by new equity.
- 6 **'SpringTree risk'** - In July 2009 PRR entered into an agreement in relation to a A\$25.5 million convertible loan facility from the New York-based SpringTree Global Investors²⁸, an alternative asset management company. The SpringTree facility provided A\$700,000 per month to PRR with those funds converting to PRR ordinary shares at a 10% discount to market²⁹. In addition to the shares issued to pay for this drawdown, at a 10% discount to 5-day VWAP, PRR also had to issue one five-year option exercisable at 150% of 20-day VWAP for every new share. In all, the facility yielded PRR A\$14.7m before it was closed out in March 2011. By that time PRR had issued 152.7 million shares and 40.7 million options to SpringTree³⁰ and since SpringTree has not gone substantial on the PRR register, we estimate that it has sold on-market at least 111.3 million shares. Moreover the options are progressively being exercised. There is the risk that SpringTree will continue to be a seller of PRR stock.

The CVac pivotal will cost around US\$45m

²⁸ See www.springtreegi.com. PRR's facility is with the SpringTree Special Opportunities Fund.

²⁹ That this facility was helpful at the time is suggested by the fact that PRR's share price was only 7.1 cents. PRR had just filed its IND for the CVac Phase IIb.

³⁰ This included 15 million shares and options as an establishment fee for the facility.

Appendix I – PRR’s capital structure

The stock. Currently Prima Biomed is only traded on the ASX. In September 2010 the company announced that it intended to establish a Level II ADR listing on Nasdaq (that is, for quotation on Nasdaq rather than for capital raising on it, which is Level III), however this has yet to take place. The ratio is 30:1 (Aus:US).

Major shareholders. There have been no substantial shareholders of PRR since June 2010.

Liquidity. A strong feature of PRR is its liquidity. Between July 2009 and April 2011 the stock traded on all but two days on which the ASX was open for business, with average daily turnover of \$1.66m.

Figure 7 - PRR’s current capital structure

Shares (ASX Code PRR)	813,747,746		Price (c)	34.0
Shares that may result from the conversion of options	147,760,547	(15.4% of total)	Undiluted cap (\$m)	276.7
Total diluted shares	961,508,293		F.D. Cap (\$m)	326.9
Options schedule	Number	Exercise price	Expiry date	Cash
PRRO - Listed options	94,521,552	\$0.020	31-Dec-11	1,890,431
SpringTree options ³¹	16,238,995	\$0.215	11-Jan-15	3,488,603
PRRAC – Unlisted options	2,500,000	\$0.250	6-May-15	625,000
PRRAL – Unlisted options	34,500,000	\$0.194	27-Dec-13	6,700,000
Total	147,760,547	\$0.0860	07-Nov-12	12,704,034

SOURCE: PRR. NOTE – THE EXERCISE PRICE AND EXPIRY DATE OF THE SPRINGTREE AND PRRAL OPTIONS ARE AVERAGES. 2,000,000 OF THE PRRAC OPTIONS ARE HELD BY SOUTHERN CROSS EQUITIES.

Figure 8 - PRR’s capital raising history

Previous raisings	Capital raised (\$m)	Price	Shares issued	% of current shares on issue	Note
Jul-01	3.5	\$0.20	17,500,000	2.2%	Placement
Nov-01	2.8	\$0.42	6,549,047	0.8%	Placement
Nov-02	3.3	\$0.45	7,252,112	0.9%	Placement
Aug-03	2.7	\$0.37	7,360,000	0.9%	Placement
Aug-03	3.5	\$0.37	9,419,603	1.2%	Placement
Oct-04	10.0	\$0.12	83,400,000	10.2%	Placement
Nov-06	1.0	\$0.05	20,000,000	2.5%	Placement
Oct-07	2.0	\$0.02	99,026,638	12.2%	1 for 2 rights issue
Dec-08	0.2	\$0.01	39,600,000	4.9%	SPP
Jun-09	0.2	\$0.07	2,357,112	0.3%	SPP
Jun-09	1.5	\$0.03	57,692,307	7.1%	Placement
Dec-09	11.3	\$0.14	80,401,244	9.9%	SPP
Feb-10	2.5	\$0.14	17,602,741	2.2%	SPP shortfall
Aug-09 - Mar-11	14.7	\$0.10	152,011,073	18.7%	SpringTree convertible note funding
Total	59.0	\$0.098	600,171,877	74.8%	

SOURCE: PRR. NOTE – THE SPRINGTREE FUNDING REPRESENTS AVERAGE PRICES, WITH SHARES ISSUED MONTHLY FROM 2009 TO 2011.

PRR has raised \$59m in 14 major capital raisings at an average 10 cents per share since 2001

³¹ In total Springtree was granted 40.7 million options exercisable at an average 14.8 cents with average exercise date January 2015 under the convertible note funding facility. As at May 2011 Springtree had exercised 24.5 million options at an average 10.4 cents per option. It retained 16.2 million options exercisable with an average exercise price of 21.5 cents and an average expiry date of January 2015.

Appendix II - Immunology basics

To understand PRR, you have to understand a little immunology. On stock exchanges around the world there are hundreds of biotechnology companies listed, and many of them are seeking to develop **immunotherapies**, that is, treatments that seek to make use of the immune system so as to manage a disease condition. The reason isn't too hard to figure out. The body comes ready-made with its own, usually highly effective, mechanisms for the removal or destruction of aberrant cells. If immunologists can devise ways to harness this highly complex system so as to treat diseases that chemicals or surgery have been unable to deal with, then huge markets await the successful development of the resulting technologies. Like, for example, the US\$10-20bn market for cancer treatments, or the US\$10bn spent on treatments for **autoimmune diseases** like rheumatoid arthritis, where the immune system is attacking the patient's body rather than infection or cancer cells. Let's take a moment to understand the basic parts of the immune system before moving onto look at PRR's effort to tap into the huge payoffs available for successful immunotherapies.

Dendritic cells are the 'orchestrators' of the immune system

What is the immune system? The immune system is basically a collection of various white blood cells, where each kind of cell has a specialised function that contributes towards dealing with the **antigen**, that is, the 'bad guy' substance that the immune system is designed to recognise as foreign. The job of the immune system as a whole is to first recognise the antigen and then mobilise to either remove the antigen-bearing cell from the body or outright kill that cell. Physically, an antigen is generally a foreign protein of some sort, on which the immune system recognises molecular 'signatures' or 'motifs' called **epitopes**. The antigen or epitope can be recognised by the immune system in a number of different ways but eventually the **dendritic cells**, the so-called orchestrators of the immune system, will come into play. Also called antigen-presenting cells, dendritic cells eat what they identify to be foreign cells they encounter (which is why they're also called 'dendritic macrophages' – *phagein* being the Greek verb 'to consume') and place the chopped up proteins, called peptides (that is, strings of the amino acids that go to make up proteins) indicative of the characteristics of an antigen on their surface. These are then presented to **T cells** so as to produce the appropriate immune system response. T cells come in two varieties - **Cytotoxic T cells**, also called Killer T cells, whose job is to kill cells bearing the antigen they have processed, and **Helper T cells**, one of whose jobs is to help another group of cells called the **B cells**. This brings us to the fact that the immune system has two basic 'arms' – the cellular arm, handled by the Cytotoxic T cells, and the humoral arm, which is the province of the B cells. The latter cells are responsible for the production of **antibodies**, that is, Y-shaped molecules that can attach themselves to antigens with exquisite specificity, enabling the effect of the antigen-bearing cell to be neutralised and the cell itself to be removed from the body. The neutralisation happens because once an antibody has bound to an antigen, the resulting **immune complex** is engulfed by cells such as **neutrophils** and **macrophages** which then send out hormones called **cytokines**, whose role, broadly speaking, is to signal to the rest of the immune system that more help is needed to deal with a substance in the body that is 'foreign', and to direct that response. This storm of cytokines is called **inflammation**. When inflammation creates a situation where the immune system attacks cells that should rightly regard as 'self' rather than foreign 'non-self'³², or alternatively generates an immune response that is inappropriate or too powerful, the result is

³² The result of which can be that tissue becomes 'inflamed', which is to say, red and sore.

**Immunotherapy is
the wave of the
future in disease
treatment**

inflammatory diseases such as rheumatoid arthritis and/or asthma. These diseases are areas of strong research interest because of the difficulty of turning the inflammation off, whereas with cancer or infectious diseases, where sometimes the relevant antigen is missed or doesn't register strongly enough with the immune system, the aim of the game is to turn inflammation up, often through the use of **adjuvants** designed to boost an immune response to the antigen of interest.

Harnessing the immune system to treat disease. What immunologists who work on disease treatments want to do is harness all or part of this system so as to treat disease. So far, their greatest achievement in this regard has been the **monoclonal antibody** drugs. Monoclonal antibodies are so-called because the antibodies in the drug formulation have been cloned from one individual antibody that researchers found to be particularly specific for a certain target antigen in the body. So, for example, the Biogen Idec drug Rituxan³³, for the treatment of a B cell cancer called Non-Hodgkin's Lymphoma, works because in that disease the B cells overexpress an antigen called CD20, to which the antibody that makes up Rituxan is specific. Monoclonals have gone some way towards achieving a 'magic bullet' approach to disease treatment. However immunologists today are wondering if one can't go a step further and induce the patient's own immune system to produce the required antibodies or T cells. This brings us to the province of vaccines. With a vaccine one seeks to administer an antigen to a vaccine subject and get that subject's immune system to respond to it, so that when the immune system meets the 'real thing' it can mount the appropriate response. This is what happens when one gets immunised against various infectious diseases, via so-called prophylactic vaccines, however the next frontier for vaccines is **immunotherapeutic vaccines**, those that can induce a patient's own immune system to attack a disease already in place in the body.

What is PRR's particular immunotherapy? CVac involves priming a cancer patient's dendritic cells so that their immune systems can recognise the cancer antigen and attack the cancer cells. We detail the background to CVac in Appendix III of this note.

³³ See www.rituxan.com.

Appendix III – Background on CVac

CVac is MUC-1 plus mannan. A day before Christmas 1993, the Austin Research Institute's then Director, Professor Ian McKenzie³⁴, a scientist whose research expertise crosses several different fields³⁵, filed a provisional patent application over some *Antigen carbohydrate compounds and their use in immunotherapy*³⁶. What the McKenzie team had done in work leading up to this application was conjugate a substance called MUC-1 to a sugar called mannan. The 'MUC' in MUC-1 is a mucin, that is, a protein/sugar combination often to be found in epithelial cells, that is, cells that cover organ surfaces. As the number '1' indicates, there are several other mucins known in biology. MUC-1 is of interest to cancer researchers because a wide variety of tumour cells, including those from breast, colon, prostate, pancreatic and lung cancers, not only overproduce mucin, and in particular MUC-1, but seem to produce a variety that is light on the carbohydrate. This aspect of MUC-1 suggested to McKenzie et. al. the possibility of a cancer immunotherapy. The issue was how to persuade the immune system to regard mutant MUC-1 as foreign and dispose of cells carrying it.

The technology needs to get to the dendritic cells. The McKenzie team reckoned that combining antigens from mutant MUC-1 with mannan represented a potential solution, in that the resulting MFP, that is mannan fusion protein, would get the attention of the immune system's dendritic cells. Work in animal models demonstrated this assumption to be broadly correct, in that MFP would bring forth a killer T cell response to the mutant MUC-1 that the McKenzie team was able to identify as coming from the dendritic cells. The mechanism of action involved receptors for mannose, the basic constituent of mannan, on the surface of dendritic cells. The dendritic cells, while taking in mannan, also took in the MUC-1 to which it was conjugated in MFP. The dendritic cells then proceeded to express MUC-1 antigens designed for Killer T cells to pick up.

CVac works because, like Provenge, it is an *ex vivo* therapy

The big breakthrough was *ex vivo* therapy. From 1998 ARI researchers were injecting MFP into late stage cancer patients, but without the kind of results they had hoped for. The reason, it would seem, is that mannan breaks down rapidly in the blood, so that MUC-1 wasn't being delivered to the patient's dendritic cells in the quantities required. Consequently by 2001, when the technology was licensed into a PRR subsidiary called Cancer Vac, the focus of MFP development had switched to *ex vivo*, that is, out of the body, therapy. Here, instead of injecting the MFP into the patient, the McKenzie team sought to draw blood out of the patient, extract the dendritic cells from that blood through a process called apheresis, expose the cells to MFP, and then return them to the body. That way, the doctors could ensure that the dendritic cells to be found in the blood were suitably 'primed' by MFP to generate T cells specific to MUC-1 once the cells were back inside the patient.

Success in Phase I. After that change of tack the next three and a half years saw steady progress for MFP. A Phase Ib trial in ten patients, which started in July 2001, generated an encouraging interim result in May 2002. *Ex vivo* priming of dendritic cells using MFP, PRR reported at the time, had produced tumour-specific immune response in the first eight patients treated, with two yet to complete treatment. Moreover those patients showing the immune response had

³⁴ He retired from this post at the end of 2002, in favour of Mark Hogarth, who was the principal scientist behind the Arthron project that PRR later vended into Trillium Therapeutics.

³⁵ He is perhaps best known for his work in cancer antibodies such as the anti-Cripto-1 antibodies that are the basis of Oncomab.

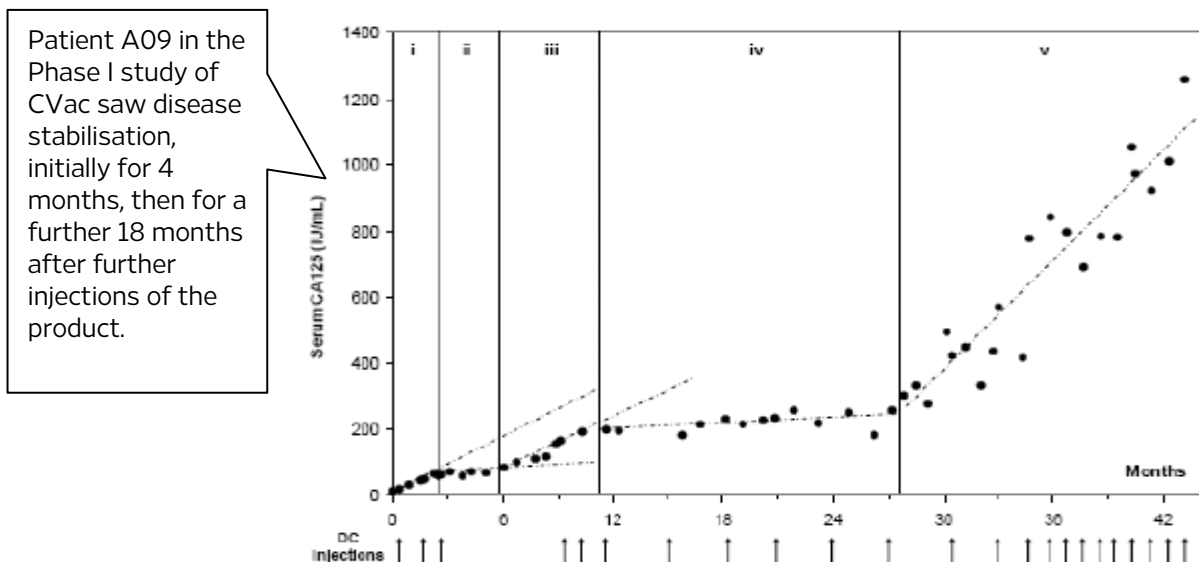
³⁶ See WO/95/18145, priority date 24 December 1993.

done so without experiencing treatment-related toxicity. An October 2002 announcement confirmed that the other two patients had enjoyed a similar experience. Then came an extension of Phase Ib, where two out of the ten patients who had not seen any progression of their cancer continued to receive treatment, in a trial to test the effect of cryopreservation, that is, freeze-storage, of patient cells so as to reduce the number of cell collections. In July 2003 PRR announced that two patients - one with kidney cancer and the other an ovarian cancer sufferer - had reached the two year mark without any further progression in their tumours³⁷. For two patients in the small sample on which the technology was trialled to have their cancer checked by *ex vivo* dendritic cell priming using Cancer Vac's approach was remarkable, and good reason for PRR to start gearing up for a Phase II trial of the technology. PRR was encouraged as well by the finding that even when dendritic cells were cryopreserved those cells were still able to work therapeutically without loss of activity when they came out of the refrigerator. The results of the trial were published in February 2006 in the journal *Clinical Cancer Research*³⁸.

Even when dendritic cells are cryopreserved the cells retain therapeutic activity

Why PRR chose ovarian cancer as a focus for Phase II. In April 2004 a Phase IIa trial of *ex vivo* dendritic cell priming therapy in 20 ovarian cancer patients obtained ethics approval. Recruitment for the trial, to be undertaken in Melbourne, commenced in around June 2004 and completed in 2006 with favourable data being reported in March 2007. PRR chose ovarian cancer because it was one of the two cancers that seemed to have the best response in the Phase I trial, and also because ovarian cancer is such a grim disease. Which is to say, there are few existing treatments for ovarian cancer beyond drug therapy with taxol and cisplatin, and the current five-year survival rate post diagnosis for the disease is relatively poor, at only 46%.

Figure 9 - The data on disease stabilisation in ovarian cancer is interesting



SOURCE: CLINICAL CANCER RESEARCH JOURNAL

³⁷ As at May 2010 these patients are, as we understand it, still alive.

³⁸ See Clin Cancer Res. 2006 Feb 1;12(3 Pt 1):869-77.

Appendix IV – PRR pipeline projects

Oncomab (PRR 100%) – the next Herceptin?

A potential cancer antibody. The Oncomab project centres on an antibody to a cancer target called Cripto-1. With approved cancer antibody drugs growing in commercial importance, Oncomab remains potentially valuable. That said, little progress has been made on the project over the last eight years.

Figure 10 – Cancer antibodies are big business

Brand name	Generic name	US\$m worldwide sales 2010	Indication	Company
Rituxan	rituximab	6,095	leukaemia / lymphoma	Roche / Biogen IDEC
Herceptin	trastuzumab	5,206	breast cancer	Roche
Avastin	bevacizumab	6,195	lung and colon cancer	Roche
Erbitux	cetuximab	1,731	colon cancer / head and neck cancer	Bristol-Myers Squibb / Merck KgaA
Vectibix	panitumumab	288	colon cancer	Amgen

SOURCE: SOUTHERN CROSS EQUITIES

Oncomab potentially represents another Herceptin

Background to Oncomab. The biomedical world has known about Cripto-1 ever since 1990, when researchers at America's National Cancer Institute found this molecule to be overexpressed on cells from a wide range of epithelial cancers³⁹. It was named 'Cripto' because it didn't seem to be related to known proteins and signalling pathways in cells. Cripto was, however, subsequently found to be a member of the family of EGF-related growth factors. In other words, too many Cripto-1 molecules on the surface of a cell and that cell will get too many signals to grow and divide, and the result is cancer. The famous Herceptin drug of Roche/Genentech, for the treatment of breast cancer, works to block a receptor called Her2/neu specific for an EGF, that receptor being overexpressed on breast cancer cells. It occurred to Ian McKenzie around 2000 that antibodies specific to Cripto-1 could be quite powerful as a therapy in a number of cancers. By 2001 the McKenzie lab had managed to raise a number of antibodies to Cripto-1 that were effective in destroying colon and prostate cancer tumours in animal models.

Oncomab has been effective against a variety of cancers. McKenzie and colleagues collected their antibodies by injecting into laboratory rats a peptide made up of the 17 amino acid portion of Cripto-1 that was understood by other scientists to set the protein apart from other members of the EGF family. The team then screened the antibodies against two colon cancer cells lines and a breast cancer line, and picked out three, codenamed C3, C4 and C13, that seemed to do the best inhibition job on the cancer cells. McKenzie et. al. found that their antibodies worked best when targeted against colon and breast cancers (with inhibition in the order of 70-95%) as well as cancers of the lung, pancreas and stomach, and that, further, the antibodies were able to sensitise the cancer cells to standard chemotherapy drugs such as 5-fluorouracil and cisplatin. That, in itself, was very satisfactory news because it was an indication that anti-Cripto antibodies would fit in well with existing, and trusted, drug therapies. But even more exciting were the results obtained when the anti-Cripto monoclonal antibodies, on their own, were injected into mice in which tumours had been

³⁹ See U.S. Patent 5,256,643 of October 1993, entitled *Human cripto protein*.

established. Against both a prostate cancer called DU145, in the case of C4, and a colon cancer called LS174T, with C13, there was a dramatic 80%-or-so drop in tumour size for the treated mice. This work was eventually published in the American journal *Cancer Research*⁴⁰, but long before this McKenzie et. al. had also done another study on Cripto-1 to satisfy itself that it was only cancer cells that expressed that antigen in high levels and not normal cells. Not only was the scientific team comforted to find this was in fact the case, it could also report that perhaps 70% of all the tumour samples that it studied were Cripto-1 positive.

PRR is now working with Bioceros to develop Cripto-1 antibodies. PRR announced in August 2010 that it had partnered the Oncomab programme to Bioceros⁴¹, a Dutch biotech company with expertise in antibody development and protein-producing cell lines. PRR will now fund 70% of the development of anti-Cripto antibodies and Bioceros, which will do the work, will fund the other 30%. This deal has the potential to put back on track a project which has pretty much gone nowhere in eight years in spite of the quality preclinical data⁴². Bioceros will first have to humanise the PRR mouse antibodies before moving on to the other preclinical work that would be needed prior to an IND.

Helping to make cervical cancer history

PRR may be creating an orally available version of Gardasil

PRR wants to create an oral version of Gardasil. In November 2009 Prima unveiled a new R&D project that involved a collaboration between the company, Ian Frazer's laboratory and the laboratory of Professor Neil Foster at the University of New South Wales. The goal of this project is development of an oral delivery system for the Gardasil cervical cancer vaccine, to be achieved using supercritical fluid technology.

A product based on supercritical fluids. Neil Foster is an acknowledged authority on supercritical fluids, that is, substances that have been taken above a 'critical point' in terms of temperature and pressure where they can effuse through solids like a gas, and dissolve materials like a liquid. Working over many years Foster and colleagues have demonstrated that pushing a drug above its critical point can help to improve its bioavailability through a transformation in the drug formulation resulting in smaller and more consistent drug particle size. With the Frazer lab, the Foster team now want to see if they can do the same to the Gardasil vaccine as they have to various drugs. This would potentially allow Gardasil to be orally available rather than just via injection as at present. Obviously, the oral Gardasil project is at an early stage of development, but the upside is strong given the advantages of oral over injection delivery and the fact that Merck & Co enjoyed US\$988m in worldwide sales from the existing vaccine in calendar 2009.

⁴⁰ See Xing et. al., *Cripto: a novel target for antibody-based cancer immunotherapy*, *Cancer Res.* 2004 Jun 1;64(11):4018-23.

⁴¹ Utrecht, The Netherlands, privately held, www.bioceros.com.

⁴² When the relevant intellectual property covering these antibodies (see WO/02/077033, priority date 26 March 2001) was moved into Oncomab in mid-2002, the scientists were continuing to look for other, potentially more effective anti-Cripto antibodies, however PRR's main aim was to undertake humanisation of the mouse antibodies that the early work had identified. PRR started talking to various antibody engineering companies around the world before striking a deal in March 2003 with a Princeton, NJ-based firm called Medarex, a leading developer of antibody drugs that had been built on technology to obtain human antibodies. Medarex was acquired by Bristol-Myers Squibb in 2009, and PRR's antibody was effectively been dropped by the merged group as a candidate. Consequently the Oncomab project remains just a mouse antibody to an interesting cancer target.

Appendix V – PRR’s intellectual property

PRR’s intellectual property is currently covered by five published patent applications:

Cancer Vac (PRR 100%)

- 1) **Conjugates of human mucin and a carbohydrate polymer and their use in cancer treatment, WO/95/18145⁴³** (Priority date 24/12/1993; Invented by Ian McKenzie, Vasso Apostolopoulos and Geoff Pietersz)

This patent application covers the original mannan/MUC-1 combination of CVac.

- 2) **Mimicking Peptides in Cancer Therapy, WO/97/11715⁴⁴** (Priority date 27/9/1995; Invented by Mauro Sandrin, Ian McKenzie and Vasso Apostolopoulos).

This patent application covers peptide analogues of MUC-1 for use in the mannan/MUC-1 combination.

- 3) **Mannose Receptor Bearing Cell Line and Antigen Composition, WO/99/16455⁴⁵** (Priority date 29/9/1997; Invented by Ian McKenzie, Vasso Apostolopoulos and Geoff Pietersz).

This patent application the *ex vivo* part of *ex vivo* dendritic cell priming.

- 4) **Mucin-1 Derived Antigens and Their Use in Immunotherapy, WO/01/57068⁴⁶**, (Priority date 1/2/2000; Invented by Ian McKenzie, Vasso Apostolopoulos and Geoff Pietersz).

This patent application covers MUC-1 as a target for cancer therapy.

Oncomab (PRR 100%)

- 5) **Antibodies Against Cancer, WO/02/077033⁴⁷**, (Priority date 26/3/2001; Invented by Ian McKenzie and Pei-Xiang Xing).

This patent application covers mouse antibodies to the cancer antigen Cripto-1.

⁴³ This patent has been granted as US Patents 5,989,552 (November 1999) and 6,177,256 (January 2001) and 6,548,643 (April 2003) and in Europe as EP 0 659 768 (April 2005).

⁴⁴ This has been granted as US Patents 6,344,203 (February 2002) and in Europe as EP 0 859 627 (November 2003).

⁴⁵ This has been granted in Europe as EP 1 027 063 (February 2009).

⁴⁶ This has been granted as US Patent 6,548,643 (April 2003).

⁴⁷ This has been granted as US Patent 7,318,924 (January 2008).

Appendix VI – A Prima Biomed glossary

5-Fluorouracil - A drug used in systemic chemotherapy, particular in cancers of the breast and intestine, which Roche developed in the late 1950s and introduced in 1962. The drug works by inhibiting take-up of DNA and RNA by cells, with rapid-growth cancer cells thereby being starved.

Amino acids - The building blocks of proteins. There are around twenty naturally occurring amino acids.

Antibodies - Also called immunoglobulins, antibodies are substances in the blood that can attach themselves to antigens, thereby neutralising them.

Antigen - The 'bad guy' substance that stimulates the immune system to respond to the perceived threat.

Antigen-presenting cells - White blood cells that instruct the immune cells on what foreign thing (antigen) they should attack. They eat what they identify to be foreign substances in the blood then process (degrade) antigen into small peptides, place the peptides that indicate the characteristics of an antigen on their surface, and present the antigen to T cells so as to produce the appropriate immune system response. The class of cells called antigen presenting cells also includes dendritic cells or dendritic macrophages.

Apheresis - Removal of blood from a patient so that certain cells can be extracted therefrom, after which the blood is returned to the patient.

B cells - Another name for B-Lymphocytes, which are white blood cells that are responsible for the production of antibodies.

CA125 - A tumour marker that is indicative of ovarian cancer.

Cancer vaccine - A vaccine that has been developed to target a cancer molecule to either prevent cancer (prophylactic vaccine) or treat existing cancer (therapeutic vaccine). CVac is a cancer vaccine.

CD4+ cells - White blood cells that assist in the body's immune response by helping B cells create antibodies. CD4+ cells receive the antigen of foreign cells from the MHC Class II molecules on Antigen Presenting Cells.

CD8+ cells - White blood cells that assist in the body's immune response by killing foreign cells, which is why CD8+ cells are also called Cytotoxic T-Lymphocytes or Killer T-cells. CD8+ cells receive the antigen of foreign cells from the MHC Class I molecules on Antigen Presenting Cells.

Cell therapy - The process of introducing new cells into a tissue in order to treat a disease. CVac is a cell therapy in that it introduces an MFP into the body to generate an anti-cancer immune response.

Cisplatin - A platinum-containing chemotherapy drug first approved by the FDA in 1978. In conjunction with Taxol, it is the current standard for ovarian cancer treatment.

Class I, Class II - see Major Histocompatibility Complex.

Clinical hold - An order from the FDA to stop treating patients in a clinical trial.

CMI - Short for Cell Mediated Immunity, where specific defence cells are mounted against a foreign substance, as in Killer T Cells.

CMS - The Centers for Medicare & Medicaid Services, which administer's these programmes for America's federal Department of Health and Human Services. CMS reimbursement helps drive commercial value for US-approved drugs and medical devices.

Cripto-1 - An antigen of cancer cells for which Oncomab has developed a monoclonal antibody.

Cryopreserved – Frozen for long-term storage purposes.

CTL - see Cytotoxic T Lymphocytes.

CVac – The trade name for PRR’s Mannan Fusion Protein product.

Cytokines - Molecules in the human body that regulate inflammation. TNF is a cytokine.

Cytotoxic T Lymphocytes – see T lymphocytes.

DC - Short for dendritic cell.

Dendritic cells, dendritic macrophages – Types of antigen presenting cells.

Effector cells – Cells that bring about an appropriate immune system response. CD4+ and CD8+ cells are effector cells.

EMA – The European Medicines Agency, Europe’s answer to the FDA.

Endpoint – Data which a clinical trial is designed to collect, such as ‘disease free interval’ or ‘survival rate’, on which the product in question will be evaluated by regulators.

Enzyme - A protein that helps speed up biochemical reactions in the body. Often you can tell a substance is an enzyme if its name has the suffix ‘ase’. Telomerase is an enzyme.

Epithelial cells – Cells that line the surface of organs in the body.

Epitope - The shape or marker on the surface of an antigen that triggers a corresponding antibody response.

Ex vivo – Latin for ‘out of the body’.

Ex vivo dendritic cell priming – The priming of dendritic cells outside the body to go after a certain antigen, these dendritic cells being extracted from a sample of the patient’s blood, after it has been removed from his or her body.

FDA – The Food and Drug Administration, the US drug and medical device regulator.

Glycoproteins – Substances that are sugar-protein combinations.

Glycosylation – The act of putting sugar molecules in a glycoprotein, usually by an enzyme.

Growth factor – A protein that stimulates cell division, differentiation and proliferation.

Heat shock proteins – Proteins expressed by cells when they are exposed to elevated temperatures.

Helper T-Cells, Helper T-Lymphocytes – see CD4+ cells.

Her2/neu – The protein targeted by the cancer antibody drug Herceptin which is overexpressed on breast cancer cells.

Human Papilloma Virus (HPV) – A virus which can cause cervical cancer in women. Merck’s Gardasil vaccine generates immunity to a number of strains of HPV. PRR has been funding research into an orally available HPV vaccine.

Humoral immunity – Immunity communicated through B-cells rather than T-cells.

HPV – See Human Papilloma Virus.

Ig – Short for Immunoglobulin.

Immunogen – A substance provoke an immune responses in a subject.

Immunoglobulin - An antibody protein. There are five different types, known as IgG, IgA, IgD, IgM and IgE.

Immunotherapy – A treatment that seeks to make use of the immune system so as to manage a disease condition.

IND – Short for Investigation New Drug, an FDA designation of a drug that has been approved for clinical trials in the US.

In vitro – Latin for ‘in glass’, that is, ‘in the test tube’.

In vivo – Latin for ‘in life’, meaning, in an animal model or in a human.

Killer T cells – see T lymphocytes.

Liposomes - Fatty molecules ideal for antigen delivery because of their ability to get to a cell in the body and deliver their payload.

Lymphokine - A general term for immune system cells that are not antibodies or complement proteins (that is, proteins in blood sera that are activated by antibodies to destroy foreign cells). The role of lymphokines is, broadly speaking, is to direct and regulate an immune response, which is why they’re often called ‘immunomodulating proteins’.

Macrophage – A white blood cell that kills foreign cells by engulfing and digesting them.

Major Histocompatibility Complex – A group of genes on chromosome 6 that codes for a class of proteins located on the surface of human white blood cells. MHC molecules play a role in the body’s immune response to foreign substances. MHC Class I molecules pass antigens to Cytotoxic T Cells while MHC Class II molecules call forth a helper T cell response.

Mannan Fusion Protein (MFP)– A combination of mannan and MUC-1 that Cancer Vac uses to prime dendritic cells.

Mannose – A sugar, C₆H₁₂O₆, found in many cells. Cancer Vac’s Mannan Fusion Protein makes use of the mannose receptor on dendritic cells to induce an immune response to MUC-1.

MHC - see Major Histocompatibility Complex.

Monoclonal antibodies - Antibodies cloned from a particular cell-making antibody that is highly specific for a particular antigen.

Monotherapy – A treatment situation where only one drug is used.

MUC-1 – A mucin that Cancer Vac’s Mannan Fusion Protein targets. MUC-1 is of interest to cancer researchers because a wide variety of tumour cells, including those from breast, colon, prostate, pancreatic and lung cancers, not only overproduce mucin, and in particular MUC-1, but seem to produce a variety that is poorly glycosylated.

Mucin – A ‘mucoprotein’ occurring in secretions of mucous membranes. MUC-1 is a mucin.

Neutrophil - A white blood cell that can ingest and killing bacteria by releasing various substances, such as antibacterial enzymes and oxidizing agents.

Non-small-cell lung cancer – One of two main types of lung cancer, the other being – you guessed it – small-cell lung carcinoma. Non-small cell lung cancer is easier to surgically remove while small cell lung cancer responds better to chemotherapy and radiation.

Oncomab – A PRR subsidiary working on antibodies to Cripto-1.

Orphan Drug – A drug that benefits less than 200,000 potential patients in the US. Orphan drug designation provides tax benefits as well as market exclusivity in both Europe and the US.

Peptide - Two or more amino acids linked by chemical bonds.

PFS – See Progression free interval.

Phase II – A clinical trial in humans to test efficacy in a small sample. Phase IIa trials test primarily for safety while Phase IIb are more focused on efficacy.

Phase III – A clinical trial in humans to test efficacy in a large sample.

Pivotal trial – Another word for a Phase III trial.

Polypeptide - A chain of peptides.

Potency assay – A test used to evaluate the consistency of vaccine product from batch to

batch in a manufacturing process.

Precursor – A cell that will divide and differentiate into a mature version of the cell.

Priming – Action to get immune system cells to recognise an antigen.

Progression free interval – The period of time in which a patient in a clinical trial for a cancer therapy experiences no worsening of their cancer after being administered the treatment. Also called Progression Free Survival.

Protein - A class of fairly common molecules in living things. Antibodies, hormones and enzymes are all proteins.

P-value – A measure of statistical significance. Generally a p-value below 0.05 is considered statistically significant.

Receptor – A molecule in a cell to which a signalling molecule such as a growth factor may attach.

Scientific Advice – Guidance from the EMA about what they require in order to approve a drug or medical device.

Statistical significance - The probability, measured by the 'p-value', that an observed outcome of an experiment or trial is due to chance alone. Generally p-values below 0.05 are taken as markers of statistical significance.

Subcutaneous – Refers to matters 'below the skin'. A subcutaneous injection is one that is given below the skin rather than directly into the bloodstream.

Taxol – A chemotherapy drug first discovered in the mid-1960s from bark of the Pacific yew tree, *Taxus brevifolia*, but not introduced into general use until the early 1990s. Taxol is often used in the treatment of ovarian cancer.

TCR – Short for T-cell receptors.

T-cell receptors – Receptors on the surface of Helper T lymphocytes that recognise the combined MHC Class II and peptide epitope and then pass the word on to create the appropriate B lymphocytes.

Telomerase - An enzyme that has been associated with cellular immortality. The American biotech Geron has developed cancer vaccines that target telomerase.

Th – the common symbol for 'Helper T lymphocytes'.

T Lymphocytes – White blood cells that are responsible for killing cells infected by viruses, in the case of 'Cytotoxic T cells', and inducing B lymphocytes to produce antibodies, in the case of 'Helper T lymphocytes'.

Variable Number of Tandem Repeats – Sequences of amino acids that repeat themselves in the MUC-1 structure.

VNTR – See Variable Number of Tandem Repeats

WBC – Short for white blood cells.

Prima Biomed

COMPANY DESCRIPTION

The Sydney-based Prima Biomed (PRR) is an early-stage biotech company. The company was formed in 2001 in order to take part interests in four early stage biomedical projects emanating from Melbourne’s Austin Research Institute⁴⁸. Since 2004 PRR has focused primarily on developing a cellular therapy called CVac for the treatment of various cancers but particularly ovarian cancer. CVac performed well in a Phase IIa clinical trial in this indication. A Phase IIb trial will complete recruitment around June 2011 while a Phase III will commence shortly.

INVESTMENT STRATEGY

We see a payoff to shareholders in PRR arising from commercial sales of CVac after FDA and EMA approval, expected in 2014 or 2015.

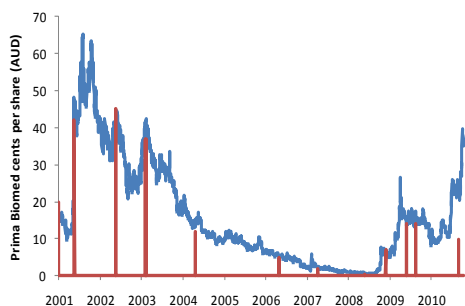
VALUATION

We value PRR on the assumption that it brings the product to market itself. Our 75 cent target price for PRR is at the lowpoint of our base case \$0.77 / optimistic case \$1.02 per share probability-weighted DCF valuation range. We assume that PRR can be re-rated by the market as the quality of the science behind CVac and the fact that a pivotal trial is not far away for this product comes to be more appreciated by the market. We think that the current market capitalisation of Dendreon (Nasdaq: DNDN) of US\$5.6bn is indicative of the potential of PRR. Dendreon gained FDA approval for Provenge, a cell therapy similar to CVac, in April 2010.

RISKS

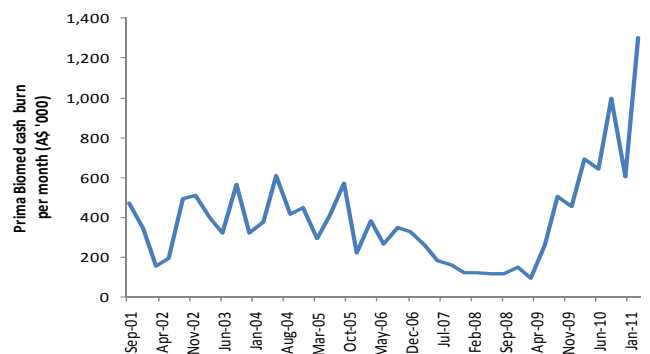
We see the main risk in PRR as being clinical risk – ie that CVac fails to perform well in its Phase IIb trial. Another major risk is burn rate. As at March 2011 PRR had around \$16.1m cash and burned around \$740,000 per month through 2010. It has raised \$59m in equity capital since 2001. The CVAC trial will cost around US\$45m, which will have to be financed by new equity.

Figure 11 - PRR has made 14 major capital raisings worth A\$59m since 2001



SOURCE: PRR

Figure 12 - Prima’s burn rate has been increasing since mid-2009



SOURCE: PRIMA BIOMED

⁴⁸ Merged in 2006 into the Burnet Institute (www.burnet.edu.au).

Recommendation structure

Spec Buy: Expect >30% total return on a 12 month view but carries significantly higher risk than its sector

Buy: Expect >15% total return on a 12 month view

Accumulate: Expect total return between 5% and 15% on a 12 month view

Hold: Expect total return between -5% and 5% on a 12 month view

Reduce: Expect total return between -15% and -5% on a 12 month view

Sell: Expect <-15% total return on a 12 month view

Research Team
Steve Goldberg
Head of Research

T 612 8224 2809
E sgoldberg@sceq.com.au

Daniel Blair

Industrial Analyst

Telco/Media
T 612 8224 2886
E dblair@sceq.com.au

Chris Whitehead

Associate Analyst
Resources
T 61 28224 2838
E cwhitehead@sceq.com.au

David George

Resources Analyst
Diversifieds
T 613 9235 1972
E dgeorge@sceq.com.au

Fleur Grose

Resources Analyst
Iron Ore/Coal/Diversifieds
T 613 9235 1678
E fgrose@sceq.com.au

Johan Hedstrom

Resources Analyst
Energy
T 612 8224 2859
E jhedstrom@sceq.com.au

Justin Hilford

Industrial Analyst
Emerging Growth
T 613 9235 1966
E jhilford@sceq.com.au

Judith Kan

Associate Analyst
Energy
T 612 8224 2844
E jkan@sceq.com.au

TS Lim

Financials Analyst
Banks/Regionals
T 612 8224 2810
E tslim@sceq.com.au

Toby Molineaux

Associate Analyst
Industrial
T 612 8224 2813
E tmolineaux@sceq.com.au

Paresh Patel

Industrial Analyst
Retail/Beverages
T 612 8224 2894
E ppatel@sceq.com.au

Hamish Perks

Industrial Analyst
Emerging Growth
T 612 8224 2804
E hperks@sceq.com.au

Stuart Roberts

Industrial Analyst
Healthcare/Biotech
T 612 8224 2871
E sroberts@sceq.com.au

Emma Sellen

Executive Assistant
T 612 8224 2853
E esellen@sceq.com.au

Jonathan Snape

Industrial Analyst
Emerging Growth
T 613 9235 1601
E jsnape@sceq.com.au

Mathan Somasundaram

Quantitative Analyst
Head of Quant & Data
Services
T 612 8224 2825
E mathan@sceq.com.au

Lafitani Sotiriou

Analyst
Financials/Industrials
T 613 9235 1668
E lsotiriou@sceq.com.au

Janice Tai

Quantitative & System
Analyst
T 612 8224 2833
E jtai@sceq.com.au

Joel Weiss

Associate Analyst
Industrial
T 612 8224 2895
E jweiss@sceq.com.au

Peter Chapman

Resources Analyst
Gold/Uranium
612 8224 2847
E pchapman@sceq.com.au

Trent Allen

Resources Analyst
T 61 28224 2868
E tallen@sceq.com.au

Stuart Howe

Resources Analyst
T 61 39235 1783
E showe@sceq.com.au

Fred Truong

Associate Analyst
Resources
T 61 39235 1629
E ftruong@sceq.com.au



Limited Incorporated ACN 071 935 441

Level 32, Aurora Place
88 Phillip Street, Sydney 2000

Telephone +61 2 8224 2811
Facsimile +61 2 9231 0588

Email general@sceq.com.au
www.sceq.com.au

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Southern Cross Equities earned a fee of 2.0 million options exercisable at 25 cents by May 2015 for preparing our initiation report on PRR in October 2009. Southern Cross Equities Ltd and its associates hold Nil shares in PRR as at the date of this report.