

Company Review

Ord Minnett Research

Tuesday, July 19, 2011

Prima BioMed Limited

Developing the CVac vaccine for ovarian cancer

- Prima Biomed Limited (PRR) is a biotechnology company with a focused on technologies in the fields of cancer immunotherapy and immunology. It is developing a vaccine known as CVac to treat ovarian cancer and has assembled an experienced and well-regarded team to oversee the development process.
- There is a large, unmet market need in ovarian cancer treatment, and CVac is being developed to meet this need. The company has a clear strategy to develop and commercialise CVac over the next three to five years, with opportunities to expand the scope of the treatment to other types of cancer.
- A Phase III clinical trial will commence in 3Q11. It aims to recruit 800 patients and will be a pivotal study of CVac. If the trial is successful regulatory approvals will follow. OML believes that CVac, if successful, can achieve "blockbuster" status (sales of \$1 billion or more per annum), and at current prices offers an excellent opportunity to participate in this highly prospective and locally developed oncology treatment.
- Catalysts** for the stock over the next 18-24 months include: 1) completion of Phase IIb recruitment (expected by 3Q11), 2) German/EU manufacturing approval (Q311), 3) completion of Phase III trial recruitment (expected by 4Q12), and 4) indicative results of the Phase IIb trial (expected by Q312). **Key risks** for CVac include: 1) a lack of efficacy, given the treatment is yet to be tested on a large population, 2) difficulty in scaling the manufacturing procedures, and 3) delays in the clinical trials imposed by regulatory bodies.
- OML initiates coverage with a Buy recommendation and a risk-adjusted valuation of \$0.53 per share. If the data plays out favourably, we believe PRR is materially undervalued and that this value will be unlocked progressively over the coming years.

Key Financials

Year-end June (A\$)	FY10A	FY11E	FY12E	FY13E	FY14E
Revenue (\$m)	0.5	0.8	5.3	18.6	43.6
EBITDA (\$m)	-18.2	-12.5	-23.0	-20.9	-16.9
Net profit after tax (\$m)	-18.2	-11.9	-22.7	-21.5	-22.6
EPS (¢)	-3.6	-1.4	-2.3	-2.0	-2.0
P/E (x)	-7.7	-19.7	-12.3	-14.0	-14.0
EV/EDITDA	-7.4	-15.0	-10.6	-12.8	-18.8
Dividend (¢)	0.0	0.0	0.0	0.0	0.0
Net Yield (%)	0.0	0.0	0.0	0.0	0.0
Franking (%)	na	na	na	na	na
Normalised NPAT (\$m)	-18.2	-13.2	-22.6	-21.5	-22.5
Fully Diluted EPS (¢)	-3.6	-1.6	-2.3	-2.0	-2.0
EPS Growth (%)	308.8	-56.5	43.4	-11.9	-0.1
Normalised P/E (x)	-7.7	-17.7	-12.3	-14.0	-14.0
Normalised ROE (%)	-114.8	-22.4	-46.9	-37.9	-66.0

Source: Iress, Company, Ord Minnett Estimates

Note: all share price data as at 18 July.

Disclosure: Ord Minnett was a Co-Manager in a recent offering of securities by PRR and received fees for providing this service.

Tuesday, July 19, 2011

PRR A\$0.28

Recommendation
Buy

Risk Assessment
High

Biotechnology

Brad Dunn

Analyst

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Prima BioMed Limited

ASX Code	PRR
52 week range	A\$0.42 -A\$0.09
Market Cap	A\$274 m
Shares Outstanding	980m
Av Daily Turnover	A\$2.23m
ASX All Ordinaries	4539.9
ASX200 Industrials	3492.6
NTA FY10 (¢ per share)	3.1
Net Debt FY10 (\$m)	4.9

Relative price performance



Source: Iress

Consensus earnings

	FY11	FY12
NPAT (C)	-	-
NPAT (OM)	-	-
EPS (C)	-	-
EPS (OM)	-	-

Source: Iress

Financial Summary

Note: Full financials are provided in Appendix 4. Forecasts are unrisks. FY17 is the first full year of sales.

Prima Biomed Limited Price: \$0.28

Profit & Loss Statement (A\$m)	FY10A	FY11E	FY12E	FY13E	FY17E
Operating Revenue	0.5	0.8	5.3	18.6	693.4
Operating Costs	18.7	13.3	28.3	39.4	172.1
Share of Associates	0.0	0.0	0.0	0.0	0.0
EBITDA	-18.2	-12.5	-23.0	-20.9	521.3
Depreciation & Amortisation	0.1	0.1	0.9	1.7	13.5
EBIT	-18.2	-12.6	-23.9	-22.5	507.8
Net Interest Expense	0.0	-0.8	-1.4	-1.2	-0.3
Pre-Tax Profit	-18.2	-11.8	-22.5	-21.4	508.1
Tax Expense	0.0	0.0	0.0	0.0	152.4
Reported NPAT	-18.2	-11.8	-22.5	-21.4	355.7
Significant Items (After Tax)	0.0	0.0	0.0	0.0	0.0
Normalised NPAT	-18.2	-13.2	-22.5	-21.3	355.7
EBITDA Margin (%)	nm	nm	nm	nm	nm
Effective tax Rate (%)	0.0%	0.0%	0.0%	0.0%	30.0%
Diluted EPS (cps)	-3.6	-1.4	-2.2	-1.9	30.8
Diluted Normalised EPS (cps)	-3.6	-1.5	-2.2	-1.9	30.8
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Payout Ratio (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	na	na	na	na	na

Cash Flow Statement (A\$m)	FY10A	FY11E	FY12E	FY13E	FY17E
EBITDA	-18.2	-12.5	-23.0	-20.9	521.3
Change in Working Capital	1.3	0.4	1.4	-0.4	-66.8
Net Interest (paid)/received	0.2	0.8	1.4	1.2	0.3
Tax Paid	0.0	0.0	0.0	0.0	-152.4
Other Operating Items	0.0	0.0	0.0	0.0	0.0
Operating Cash Flow	-6.5	-11.4	-20.2	-20.1	302.4
Asset Sale Proceeds	0.0	0.0	0.0	0.0	0.0
Net Acquisitions	-10.0	0.0	0.0	0.0	0.0
Capex	-0.1	-2.0	-2.8	-11.6	-16.4
Other investing items	0.0	0.0	0.0	0.0	0.0
Investing Cash Flow	-10.1	-2.0	-2.8	-11.6	-16.4
Inc/(Dec) in Equity	14.9	60.0	12.0	30.0	0.0
Inc/(Dec) in Borrowings	6.3	0.0	0.0	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0	0.0
Other Financing Items	0.0	0.0	0.0	0.0	9.0
Financing Cash Flow	21.3	60.0	12.0	30.0	0.0
Net Inc/(Dec) in Cash	4.7	46.6	-11.0	-1.8	286.0

Balance Sheet (A\$m)	FY10A	FY11E	FY12E	FY13E	FY17E
Cash	5.6	52.2	41.2	39.5	325.8
Inventories	0.0	0.0	0.0	0.0	0.0
Receivables	0.1	0.1	0.8	2.8	104.5
Other Current Assets	10.9	10.9	10.9	10.9	10.9
PP & E	0.1	2.1	4.1	14.1	36.6
Intangibles	0.5	0.5	0.4	0.4	0.3
Other Non Current Assets	0.9	0.9	0.9	0.9	0.9
Total Assets	18.1	66.6	58.3	68.5	478.9
Short term Debt	0.7	0.7	0.7	0.7	0.7
Other Current Liabilities	1.5	1.9	4.1	5.6	24.5
Long term Debt	0.0	0.0	0.0	0.0	0.0
Other Non Current Liabilities	0.0	0.0	0.0	0.0	0.0
Non current liabilities	0.0	0.0	0.0	0.0	0.0
Total Liabilities	2.2	2.6	4.8	6.4	25.3
Total Equity	15.8	64.0	53.5	62.1	453.7
Total liability & Shareholder equity	18.1	66.7	58.3	68.5	478.9
Net (Debt)/Cash	4.9	51.5	40.5	38.8	325.1

Source: Ord Minnett estimates, Company data.

Recommendation: Buy

Key Statistics	FY10A	FY11E	FY12E	FY13E	FY17E
Expenses Breakdown					
Research and Development					
- Cvac	3.0	3.0	14.0	14.0	0.0
- Other	2.0	2.0	2.0	2.0	0.0
Manufacturing					
- Capex and Maintenance	2.0	2.0	2.0	10.0	3.0
- Production costs	0.0	0.0	0.0	0.0	83.9
General (includes marketing)	0.0	6.0	11.2	12.4	57.4

Addressable Market

Ovarian Cancer ('000s new cases)	56.7	57.8	59.0	63.9
Other Indications ('000s new cases)	138.4	141.2	144.0	155.9

Treatments Administered

Ovarian Cancer (k)	0.1	0.2	6.4
Other Indications (k)	0.0	0.0	1.4

Price per Treatment (US\$)

	75,000	75,000	75,000
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Cvac Sales (\$A)

	5.3	18.6	693.4
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DuPont Analysis	FY10A	FY11E	FY12E	FY13E	FY17E
EBIT Margin	nm	nm	nm	nm	73.2%
x Asset Turnover	0.03	0.01	0.09	0.27	1.45
x Interest Burden	1.00	0.94	0.94	0.95	1.00
x Tax Burden	1.00	1.11	1.00	1.00	0.70
= Return on Assets	nm	nm	nm	nm	74.3%
x Leverage	1.1	1.0	1.1	1.1	1.1
= Return on Equity	nm	nm	nm	nm	78.4%

Per Share Ratios (A\$ cents)	FY10A	FY11E	FY12E	FY13E	FY17E
Normalised EPS	-3.6	-1.5	-2.2	-1.9	30.8
Dividend Per Share	0.0	0.0	0.0	0.0	0.0
Cash Flow Per Share	-1.3	-1.3	-2.0	-1.8	26.2
NTA per share	3.1	7.5	5.2	5.6	39.3

Valuation Ratios (x)	FY10A	FY11E	FY12E	FY13E	FY17E
P/E Multiple	-7.7	-18.1	-12.7	-14.4	0.9
Price To Cash Flow	-21.7	-20.9	-14.2	-15.3	1.1
EBITDA Multiple	-7.4	-14.9	-10.7	-12.9	0.0
EBIT Multiple	-7.4	-14.7	-10.3	-11.9	0.0

Leverage	FY10A	FY11E	FY12E	FY13E	FY17E
Net Debt/Equity	-31.2%	-80.5%	-75.7%	-62.4%	-71.7%
Net Debt/Total Assets	-27.4%	-77.3%	-69.5%	-56.6%	-67.9%
EBIT Interest Cover (x)	nm	15.4	17.6	19.4	-1603.3

Valuation	A\$
WACC (%)	25.0%
Number of shares (m)	1047.2
Cost of Equity	25.0%
D/EV	0%
Risk Free Rate	6.50%
Operational NPV (10 yr Forecast)	\$0.40
Terminal Value	\$0.61
Net Debt / (Cash)	\$0.00
Franking Credits Value	\$0.00
Group NPV (pre-discount)	\$1.06
Group NPV (post-discount)	\$0.53
Current Share Price	\$0.28
Relative to NPV:	47.2% Disc. to NPV

Executive Summary

Prima Biomed Limited (PRR) is developing a vaccine called CVac to treat ovarian cancer. It has assembled an experienced and well-regarded team to oversee the development process.

The company has solid scientific and management credentials, which OML believes will be crucial in delivering the best outcomes for shareholders.

CVac is the premier product in PRR's portfolio, and has shown good promise in early clinical trials. CVac is expected to be released as a maintenance therapy for ovarian cancer patients following first-line treatment with chemotherapy. It uses the patient's own immune system to target and attack cancerous cells only, stabilising or substantially slowing the growth of tumours.

Global incidence of ovarian cancer rates vary by geography, but OML estimates that approximately 65,000 of the 300,000 new cases diagnosed each year occur in developed markets such as North America, Europe, Japan and Australia, where CVac is being targeted.

We believe that a significant gap exists in the market for a product such as CVac, given our understanding that there is no maintenance-style treatment currently available. With the ovarian cancer treatment market estimated to be between \$2.5–3.6bn per annum, there is a strong incentive to provide this type of treatment option for physicians.

Concurrently with the clinical trials, PRR is developing an automated and replicable manufacturing process that will ensure demand can be satisfied quickly and safely. We believe that this facet of the commercialisation process requires as much consideration as the treatment itself to ensure CVac can fully penetrate its target markets.

We initiate coverage on PRR with a Buy recommendation and risk adjusted DCF valuation of \$0.53 per share. As the clinical trials progress and commercial sales begin in some jurisdictions as early as FY12, some of these events will be catalysts for substantial upside revision to this valuation. We believe CVac can achieve "blockbuster" status (sales of \$1 billion or more per annum), and at current prices offers an excellent opportunity to participate in this highly prospective and locally developed oncology treatment.

Catalysts for the stock over the next 18-24 months include: 1) completion of Phase IIb recruitment (expected by 3Q11), 2) German/EU manufacturing approval (Q311), 3) completion of Phase III trial recruitment (expected by 4Q12), and 4) indicative results of the Phase IIb trial (expected by Q312).

Key risks for CVac include: 1) a lack of efficacy, given the treatment is yet to be tested on a large population; 2) difficulty in scaling the manufacturing procedures; and 3) delays in the clinical trials imposed by regulatory bodies.

Figure 1: Expected Key Milestones

	2011				2012				2013				2014				2015				2016			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
NASDAQ listing	■	■																						
Recruitment Completed for Phase IIb		■	■																					
First patient enrolled in Phase III trial			■																					
Manufacturing Approval (AU)				■	■																			
Recruitment Completed for Phase III								■	■															
Indicative Results for Phase IIb								■	■	■														
Interim Data Analysis for Phase III									■	■	■	■	■											
Final Data for Phase III													■	■	■	■	■							
Regulatory Approval																	■	■	■	■	■	■	■	■
First Sales in US and Europe																					■	■	■	■

Source: Ord Minnett estimates

OML notes that these estimates are based on current information and may be subject to substantial revision. If a milestone is missed or delayed, this may have a significant impact on the share price.

SWOT analysis

Strengths

- PRR will retain full ownership of the CVac intellectual property allowing the development path to be fully controlled by PRR.
- Experienced management team with all the skills necessary to progress the development program expeditiously.
- Similarly, the medical team has vast experience in commercialising oncological products, led by Professor Ian Frazer.
- Early testing has shown a high level of tolerability and safety in patients with late stage disease.
- Orphan Drug status gives the drug several years of exclusivity and priority treatment.
- Large investor base which provides significant liquidity as well as a wider audience when seeking capital.

Weaknesses

- Still in the early stages of development, with only a small Phase IIa study completed and a Phase IIb only now entering the recruitment phase.
- The Australian biotechnology market is decidedly less mature than other developed markets, leading to a lack of understanding among some market participants.
- Immunotherapy has a limited track record with only one previous application achieving approval to date (Dendreon's Provenge).

Opportunities

- Develop and receive approval to market CVac, the first dendritic cell-based, autologous, maintenance-style treatment for ovarian cancer.
- Adapt the CVac platform for other indications including breast cancer where the mucin-1 protein is over-expressed.
- Partner with global pharmaceutical companies to provide resources for manufacturing scale-up as well as marketing and distribution networks.
- Continue work on PRR's other technologies which are at a significantly earlier stage of development.
- Listing on an overseas exchange to enhance liquidity, increase its profile in other markets and broaden the avenues available to attract capital.

Threats

- The lack of testing on large patient populations is a threat because it is not yet clear if the benefit to patients is statistically significant relative to current standard of care.
 - Execution of Phase III study, sloppy record keeping or statistical technicalities could cause significant delays or prompt a regulator to request a repeat of the Phase III study.
 - Safety issues during the trials could arise, causing delays and potentially leading regulatory authorities to re-design testing procedures.
 - For a company in cash-burn mode, delays could cause a requirement for further funds in future to complete trials.
 - Competition from new emerging technologies could emerge, however OML is not aware of any similar treatments at an equivalent or more advanced stage than PRR.
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Valuation and recommendation

The valuation approach for a mid-stage biotech requires several adjustments to account for the increased risk and global nature of the product release.

Our valuation assumptions are as follows:

- A WACC of 25% (beta 1.85, ERP of 10% and risk-free rate of 6.5%).
- A conservative longer-term exchange rate assumption of AUD:USD 0.85. See Table 6 for more detailed currency assumptions.
- Product sales price of US\$75,000 equivalent per course.
- Sales begin in Australia in 2014 with wider release from FY16, achieving peak sales in 2020 of \$1.7b. Sales then grow at a more modest 5% pa from FY21 onwards.
- Our DCF-based valuation has a probability weighting attached based on the progress of the project. See Table 8 below.

Table 1: Valuation milestones

Stage of Progress	Discount to Valuation	Possible WACC	Terminal Growth	Equivalent PRR valuation
Clinical Trials Successful, Regulatory Approval, Fully Funded to Commence Sales or Licencing Deal	0%	10-12%	3%	\$5.09+
Clinical Trials Successful, Awaiting Regulatory Approval, Fully Funded to Commence Sales or Licencing Deal	15%	12-15%	3%	\$2.75-\$4.34
Clinical Trials Successful, Awaiting Regulatory Approval, Partially Funded to Commence Sales	33%	15-20%	3%	\$1.18-\$2.30
Phase III trial continuing, yet to seek regulatory approval, likely to require further funding	50%	20-25%	3%	\$0.53-\$0.88
Phase II trial continuing, likely to require further funding	75%	25-35%	3%	na
Phase I or earlier	85%	35-50%	3%	na

Source: Ord Minnett estimates

We have applied a discount of 50% to our unrisks DCF valuation given the company is now embarking on a Phase III trial. We will look to re-assess this discount with the release of indicative Phase IIb results as well as interim and final data from the Phase III trials. If the new data reflects earlier results we would see this as major de-risking event given the rigour with which the studies have been designed.

We have also calculated a valuation based on a range of multiples applied to a discounted estimate of fully diluted earnings per share in FY17 (the first full fiscal year of commercial sales) discounted at 25%. The fully diluted share count includes the exercise of all options and a further capital raise of \$30m at current prices in FY13. This would increase the fully diluted share count from 1.11 billion post the recent placement and SPP by 11% to 1.23 billion shares.

Table 2: Multiples valuation (cents per share)

Multiple	FY17E EPS: 32.7	Discounted FY17E EPS: 8.6	Valuation Discount: 50%
10x	326.9	85.7	42.8
15x	490.3	128.5	64.3
18x	588.4	154.2	77.1
20x	653.8	171.4	85.7
22x	719.2	188.5	94.3
25x	817.2	214.2	107.1

Source: Ord Minnett estimates

Weighted average cost of capital

The other swing factor will be a re-assessment of the WACC, which would most likely come down considerably when PRR becomes earnings positive and can fund projects internally with cheaper capital.

Table 3 below shows the valuation sensitivity to changes in WACC that could occur over time if CVac is successfully commercialised.

Table 3: Unrisked valuation sensitivity

		WACC						
		12.0%	15.0%	20.0%	25.0%	26.0%	27.0%	32.0%
Terminal Growth Rate	1.5%	\$4.46	\$2.94	\$1.65	\$1.01	\$0.93	\$0.85	\$0.56
	2.0%	\$4.65	\$3.04	\$1.69	\$1.03	\$0.94	\$0.86	\$0.57
	3.0%	\$5.09	\$3.24	\$1.76	\$1.06	\$0.97	\$0.88	\$0.58
	3.5%	\$5.34	\$3.36	\$1.80	\$1.08	\$0.98	\$0.90	\$0.59
	4.0%	\$5.63	\$3.48	\$1.84	\$1.10	\$1.00	\$0.91	\$0.59

Source: Ord Minnett estimates

OML believes that, based on the table above, and assuming the market gives CVac a 50% chance of success (and hence applying a 50% discount to an unrisked valuation), the current trading price implies a WACC of 32%, which we believe is too conservative for a company at PRR's stage of progression.

Recommendation

Based on clinical results to date, the large unmet medical need and clear path to commercialisation, we initiate with a Buy recommendation.

Along the path to commercialisation, there will be several catalysts which may bring about a re-rating, and these are summarised in Table 4 below.

Table 4: Expected Key Milestones

	2011				2012				2013				2014				2015				2016				
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	
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Final Data for Phase III																									
Regulatory Approval																									
First Sales in US and Europe																									

Source: Company data, Ord Minnett estimates

OML notes that these estimates are based on current information and may be subject to substantial revision. If a milestone is missed or delayed, this may have a significant impact on the share price.

With funding for the clinical program secured via the recent placement and SPP, we believe the focus must now turn to the recruitment of patients for Phase III and the progression and indicative results of Phase IIb testing.

Board and Management

Ms Lucy Turnbull, AO

Chairman

Ms Turnbull has strong links to the healthcare sector, having previously been Chairman of the New South Wales Government's Ministerial Advisory Committee on Biotechnology from 2001–02, a Director of the Sydney Cancer Foundation from 2002–06 and Director and Chair of the Sydney Children's Hospital Foundation from 1993–2000. She is currently on the Board of the Cancer Institute NSW.

Mr Albert Yue-Ling Wong

Deputy Chairman

Formerly a stockbroker for 21 years, Mr Wong is a corporate adviser and investment banker with over 28 years' experience in the finance industry. He was admitted as a Member of the Australian Stock Exchange in 1988 and was the principal of Intersuisse Limited until 1995. Mr Wong is currently Chairman of RIMCapital Limited and Winmar Resources Limited.

Mr Martin Rogers

Managing Director and Chief Executive Officer

Mr Rogers is the Managing Director and Chief Executive Officer of Prima Biomed. He has a strong science background, which includes degrees in science and chemical engineering and is currently a member of the management committee of the National Breast Cancer Foundation. Mr Rogers also has strong expertise in the corporate sector, with a focus on the incubation and development of new business ideas. He has previously been involved in the origination of a number of new business concepts and the establishment of internal ventures and external partnerships, including finance concept origination in the corporate banking sector.

Dr Richard Hammel

Non-Executive Director

Dr Hammel is a partner with ProPharma International Partners, a pharmaceutical/biotechnology consulting firm providing a range of business, financial and product development services.

Dr Neil Frazer

Non-Executive Director

Dr Frazer has more than 23 years of drug development experience in multiple therapeutic areas, including more than six years of oncology drug development experience.

Matthew Lehman

Chief Operating Officer

Mr Lehman has a strong depth of experience in clinical research, development programs and obtaining drug approval. He has specific expertise in clinical development strategies, operations and outsourcing.

Ian Bangs

Chief Financial Officer

Mr. Bangs has over 25 years' experience working in senior finance positions with companies involved in a range of diversified industries. Mr Bangs has worked as Chief Financial Officer and Company Secretary for a number of public companies listed on the ASX including LandMark White Limited, IFC Capital Limited and 10 years as the CFO of the Regent Hotel in Sydney.

Hind al-Saadi

GM, Prima BioMed Middle East

Dr al-Saadi, a pharmacist by training, has nearly 20 years of international industry experience in marketing, sales, distribution, and regulatory affairs. She has previously worked for Baxter Healthcare in New Zealand, as well as Globalpharma and The Center for Healthcare Planning and Quality in Dubai.

Sharon Gargosky

Senior Vice President, CVac Program

Dr Gargosky has 17 years experience in the biotechnology and pharmaceutical industries, and has worked in senior positions to successfully received FDA approval for orphan drugs. She is responsible for managing the clinical team working on the Cvac immunotherapy cancer vaccine.

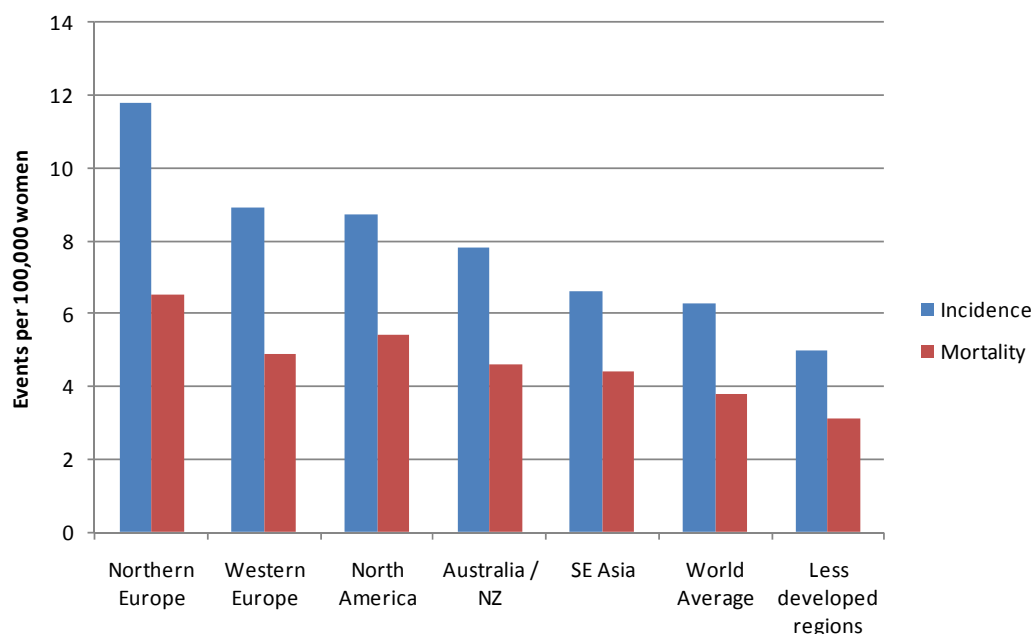
The statistics

Key points

- Ovarian cancer has one of the highest incidences in the developed world.
- Mortality rates are high because it is difficult to detect in its early stages.
- There is an opportunity to develop a new approach to ovarian cancer.

Data from the World Health Organisation in 2008 shows that ovarian cancer is seventh in terms of incidence and in the top ten in terms of mortality worldwide. With the population in developed countries such as the United States, Australia and much of Western Europe aging, it is expected that ovarian cancer will increase in prominence given its predisposition to older people.

Figure 2: Ovarian cancer by region



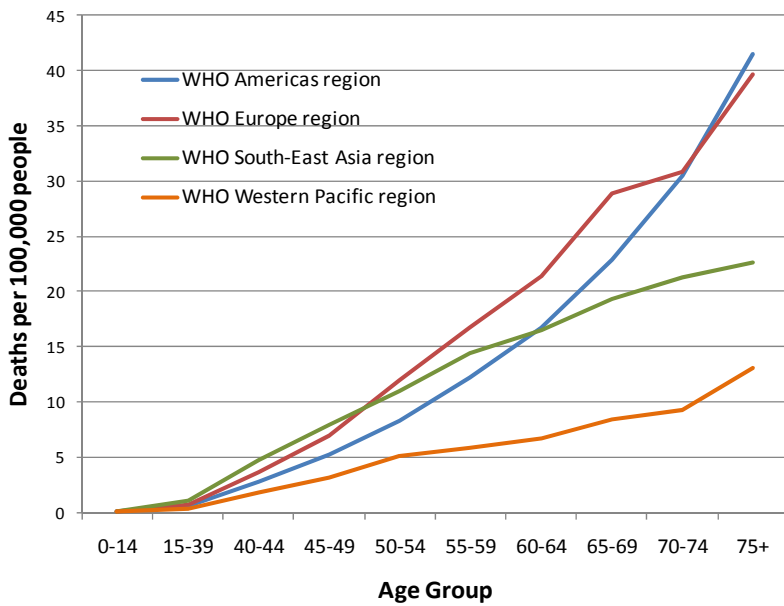
Source: World Health Organisation

Complicating matters is the often late-stage discovery of the disease, hampering efforts to contain the cancer before it metastasises (or spreads to other parts of the body). Therefore, the rate of mortality is high relative to other cancers and presents a significant challenge to physicians and researchers investigating new ways to treat this disease.

Not surprisingly, mortality rates are closely correlated to the age of the patient, however Figure 3 shows a marked difference between certain regions, as defined by the WHO.

Ninety percent of ovarian cancers are epithelial, with the remainder being either germ cell or stromal cell tumours. CVac targets epithelial tumours. Over three quarters of diagnosed cases are for late stage cancer, where the treatment often needs to be more severe, or the cancer has already spread to other parts of the body. This means the opportunity for a maintenance therapy is clear, one that can at least slow down the progression of the disease, maintain it a level, or work toward full remission.

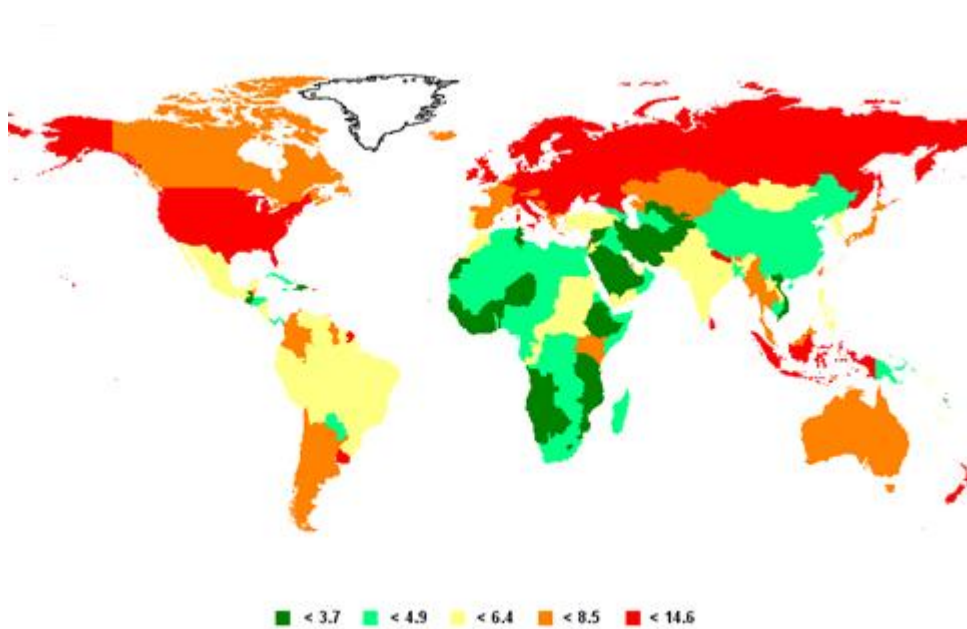
Figure 3: Mortality statistics by age group



Source: World Health Organisation

From a global perspective, ovarian cancer is a developed world problem. OML estimates that up to 25% of the 180,000 new cases of ovarian cancer each year are found in North America, Europe, Japan or Australia.

Figure 4: Age-standardised incidence rate per 100,000 people



Source: World Health Organisation

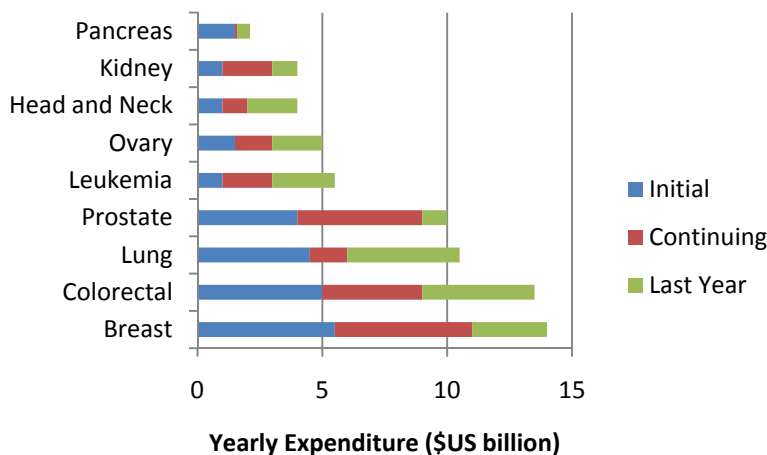
Market potential

Key points

- Large global market of between \$2.5bn and \$3.6bn in the ovarian cancer indication alone.
- Treatment is demonstrably less toxic than chemotherapy.
- Specialised production process means demand likely to outstrip supply in the early stages.

It is estimated that total spending on cancer treatment in 2006 exceeded US\$150bn. Table 5 below shows some of the most costly types of cancer, but still excludes more than half the yearly burden. The chart also compartmentalises the burden based on the phase of the patient's care.

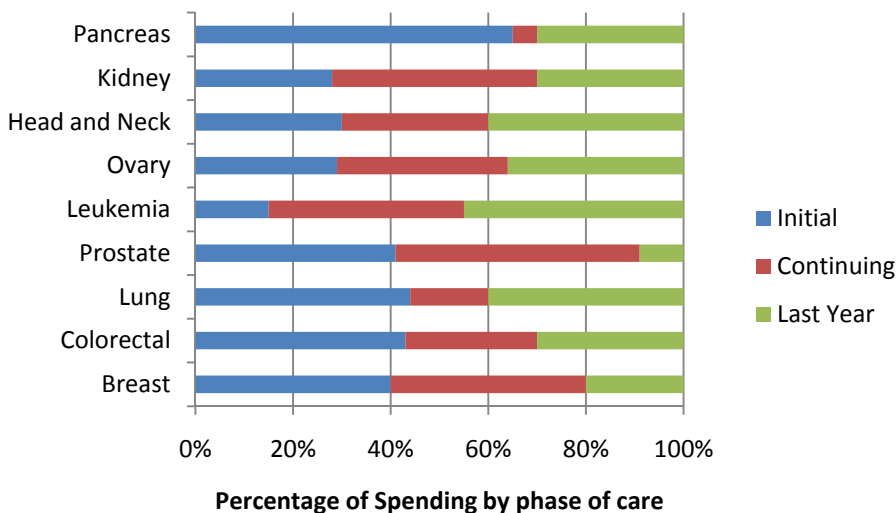
Figure 5: Annual Oncology Expenditure by Phase of Treatment



Source: Academic Papers by Mariotto, Yabroff, Feuer, DeAngelis and Brown, 2008

The data shows a disproportionate amount is spent in a patient's final year of life relative to initial and continuing care. This is often for the purpose of improving the patient's quality of life as the end nears. CVac aims to extend the length of a patient's life while at the same time improving quality of life.

Figure 6: Oncology Expenditure by Phase of Treatment



Source: Academic Papers by Mariotto, Yabroff, Feuer, DeAngelis and Brown, 2008

The direct medical costs of cancer in the United States have increased substantially in the past 20 years. By one set of estimates, expenditures increased from about \$27 billion in 1990 to more than \$90 billion in 2008, representing a CAGR of 17.1%. The high cost of cancer treatment often leads to financial hardship for patients and their families, including those with health insurance.

Median out-of-pocket medical spending was more than \$15,000 in 2003–04 for privately insured adults with cancer, while 10% of those surveyed had out-of-pocket costs exceeding \$18,000. In a 2006 survey of adults in households affected by cancer, almost a quarter of insured respondents reported using most or all of their savings during treatment, and a similar proportion said their insurance plan paid less than expected for a medical bill.

Given the larger population size of continental Europe and estimates of £6–18bn of direct treatment costs in the UK alone, the European burden could conceivably be as large as the US.

This data reveals the extent of the cost on society, with the figures representing the combined imposts of direct treatment costs (surgery, medications etc), as well as the impact on families and the loss of productivity due to incapacity and early death.

While incidence figures are growing by only 3–4% per annum, the costs per patient and overall costs are growing at a faster rate as relatively expensive new therapies are approved. Research in the Journal of the American Medical Association estimates that the average gross cost of cancer treatment is ~US\$8,000, while new therapies are adding US\$35–40k to the overall costs. The benefit of these new treatments is an extension of life expectancy of approximately seven months.

For cancer types with short survival times following diagnosis, such as pancreatic, stomach and lung cancer, the majority of expenditures in 2006 were for patients in the initial and last year of life phases, with only a small percentage for patients in the continuing phase. Other cancer types with longer survival times, such as female breast cancer, melanoma and prostate cancer, have a higher percentage of expenditures for patients in the continuing phase of care. Overall, approximately 33.6% of expenditures are in the initial phase, 36.8% in the continuing phase, and 29.6% in the last year of life.

Ovarian cancer

There are varying projections as to the level of global expenditure on ovarian cancer treatment each year, with estimates varying between \$2.5bn and \$3.6bn per annum. There is currently no maintenance therapy for patients subsequent to this course of treatment, and it is here the company is aiming CVac .

Table 5: Estimated market size by region, ovarian cancer

US\$m	2008	2009	2010	3-year CAGR
US	1,425	1,760	2,035	12.6%
Canada	75	87	104	11.5%
Japan	214	248	292	10.9%
Europe	721	850	1,025	12.4%
Rest of World	104	125	153	13.7%
Total	2,539	3,070	3,609	12.4%

Source: Global Industry Analysts

If these compound annual growth rates are maintained over the next four years, the size of the market could be well in excess of \$5 billion per annum, representing a significant opportunity for CVac to fill the unmet medical need. CVac has the potential to capture a portion of the current market as well as expanding the overall market by providing another treatment option to physicians. **Support for CVac from physicians is crucial to its long term success.**

Potential market share

Market share assumptions are difficult to make at this early stage, but if Dendreon's experience with Provenge is any guide, demand is very likely to outstrip supply in the years immediately following FDA approval. The main limitation in the early stages is having sufficient manufacturing capability to support demand.

The time taken to reach peak sales is usually 3–5 years, while market share of between 10 and 25% could be achievable in ovarian cancer, with a smaller percentage likely for other indications.

Table 6: CVac revenue build, ovarian cancer

	2011F	2012F	2013F	2014F	2015F	2016F	2017F	2018F	2019F	2020F
New incidences per annum	315,000	321,300	327,726	334,281	340,966	347,785	354,741	361,836	369,073	376,454
Available market	56,700	57,834	58,991	60,170	61,374	62,601	63,853	65,130	66,433	67,762
Market share	0.0%	0.1%	0.3%	0.8%	1.5%	2.0%	10.0%	18.0%	20.0%	25.0%
Treatments administered per annum	0	58	177	481	921	1,252	6,385	11,723	13,287	16,940
Assumed price per treatment (US\$)	0	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000	75,000
AUD/USD Forecast	1.00	1.05	1.00	0.95	0.90	0.90	0.85	0.85	0.85	0.85
Forecast Revenue (\$A)	0.0	4.1	13.3	38.0	76.7	104.3	563.4	1034.4	1172.3	1494.7

Source: Ord Minnett estimates

To derive the available market we estimate that 18–20% of new cases (characterised by incidence data below) originate in the developed world countries of Australia, North America, Europe and Japan. We also assume that because of the high relapse rate of ovarian cancer, the potential patient pool increases over time to include those currently not being treated by other means (characterised by prevalence data below).

We make our assumption of the available market by taking the average of the two totals in Tables 7 and 8 to get a starting figure of 56,700, and then assume a steady growth in market share over the first five years of commercial sales, reaching nearly 17,000 treatments in FY20 for ovarian cancer alone.

Table 7: Market potential based on incidence

	Total Incidence	Excluded due to death in year 1	Excluded due to early stage disease	Total Potential market for CVac
Australia / NZ	1,553	373	295	885
USA	25,162	6,039	4,781	14,342
Europe	39,830	9,560	7,568	22,702
Japan	6,588	1,581	1,252	3,755
Total	73,133	17,553	13,896	41,684

Table 8: Market potential based on prevalence

	Total Prevalence	Excluded due to death	Excluded by competing therapy	Total Potential market for CVac
Australia / NZ	4,072	957	1,558	1,557
USA	74,444	16,005	29,220	29,219
Europe	83,290	25,781	28,755	28,754
Japan	21,812	4,261	8,776	8,775
Total	183,618	47,004	68,309	68,305

Source: Company data, Ord Minnett estimates

Pricing

Current treatment options are particularly expensive, ranging from \$40k to \$110k per cycle. Importantly, the expected price point of CVac will be similar to current autologous treatments, and reflect not only the considerable time and cost involved in bringing the treatment to market, but also the benefit to the broader health system by having fewer bed days for patients, which helps to free up resources.

In the United States, Dendreon's Provenge was initially expected to sell for around US\$65,000 per course, however following discussion with and approval from regulators Dendreon is marketing Provenge for US\$93,000 per course.

Our base case assumption is a selling price of US\$75,000 per course, with a relatively low fixed cost base and a variable cost of ~US\$10,000 per course. The key components of the variable cost would be for laboratory time and transport costs. This number is also subject to change based on the eventual manufacturing method adopted. Consequently, we arrive at an operating margin that exceeds 80% by the time peak sales is reached in FY20, with fixed costs only representing 26% of total costs.

Table 9: EBITDA Margin

	FY11E	FY12E	FY13E	FY14E	FY15E	FY18E	FY20E
Revenue	0.8	5.3	18.6	43.6	82.6	1209.0	1822.1
Fixed Costs	13.3	29.7	39.4	52.6	42.6	69.6	72.0
% of total	100.0%	100.0%	100.0%	91.6%	82.2%	33.8%	25.9%
Variable Costs	0.0	0.0	0.0	4.8	9.2	136.3	205.8
% of total	0.0%	0.0%	0.0%	8.4%	17.8%	66.2%	74.1%
EBITDA	-12.5	-23.0	-20.9	-16.9	25.0	966.7	1495.2
EBITDA Margin	-1660.1%	-431.8%	-112.3%	-38.8%	30.3%	80.0%	82.1%

*assumes US\$75k per course

Source: Ord Minnett estimates

Other indications

Ovarian cancer is not the only target that CVac may be effective against. The same antigen that is over-expressed in 85% of ovarian cancer patients is also prevalent in colorectal cancer, some types of breast cancer as well as some types of lung cancer. PRR has not yet determined which, if any, of these indications will be the next target of CVac, and OML believes that it remains a low order priority with the clear focus on ovarian cancer.

However, in the longer term, receiving approval in another indication will greatly add to the value of the treatment as well as its longevity. The decision to pursue ovarian cancer first is very strategic given the large unmet medical need and because of the low survival rate stemming from its difficulty to detect in its early stages.

Regulatory dynamics in key markets

Notwithstanding the fact that there is currently no maintenance treatment for ovarian cancer, the US Medicare system covers the cost of any infusion drug for patients 65 and over. For younger patients with private health care coverage is also often provided. **Support from health insurers in the US is also critical for the longer-term success of CVac.**

In Europe, extremely generous public funding of healthcare provides opportunities for new technologies to penetrate this key market. The Therapeutic Goods Administration (TGA) in Australia has recently allowed some monoclonal antibodies such as Avastin on the Pharmaceutical Benefits Scheme (PBS), despite exceeding the \$40k limit for the PBS. Prima Biomed hopes that if approved for use, CVac will be another candidate for PBS support. In short, PRR is targeting those markets where there is a high likelihood of cost reimbursement, making the product accessible and more likely to be prescribed.

Current and proposed treatment options

Key points

- **Chemotherapy can be effective but has many side effects.**
- **Monoclonal antibodies have had sporadic success.**
- **Immunotherapy is the next generation of treatment.**

Current treatment involves tumour debulking surgery, followed by heavy metal- (platinum) based chemotherapy. Monoclonal antibodies (mAb) are also beginning to emerge as the “third generation” of treatment.

Chemotherapy

Chemotherapy aims to disrupt the proliferation of cancer cells by using medicines which contain heavy metals such as platinum to bind to and kill the cancerous cells. Unfortunately, chemotherapy treatment damages healthy cells as an unintended consequence, leading to severe nausea, vomiting, hair loss and a general weakening of the immune system. Bristol Myers Squibb owns and produces two of the most popular current chemotherapy treatments, Platinol (generic name cisplatin) and Taxol (generic name paclitaxel). Paraplatin (generic name carboplatin) is also a popular treatment.

Monoclonal antibodies

A monoclonal antibody is a laboratory-produced molecule that is carefully engineered to attach to specific defects in cancer cells. Monoclonal antibodies mimic the antibodies the body naturally produces as part of the immune system's response to germs, vaccines and other invaders.

Monoclonal antibodies can work by:

- 1) **making the cancer more visible to the immune system.** One example of this is rituximab (trade name Rituxan), which binds to the cluster of differentiation 20 (CD20). CD20 is widely expressed on B cells, from early pre-B cells to later in differentiation, but it is absent on terminally differentiated plasma cells. CD20 does not shed, modulate or internalise. Although the function of CD20 is unknown, it may play a role in Ca²⁺ influx across plasma membranes, maintaining intracellular Ca²⁺ concentration and allowing activation of B cells.
- 2) **blocking growth signals.** The epithelial growth factor receptor (EGFR) is a family of receptors known as Type I receptor tyrosine kinases. This receptor family is comprised of four structurally similar tyrosine kinase receptors. Several monoclonal antibodies (mAb) of EGFR have been developed and evaluated in patients with ovarian cancer. Of these, cetuximab, a monoclonal antibody that targets EGFR (HER1), has failed to show clinical activity. However, antibodies directed against HER2 have demonstrated clinical efficacy.
- 3) **stopping new blood vessels forming.** Vascular endothelial growth factor (VEGF) is a potent mediator of angiogenesis. As VEGF is overexpressed in most ovarian cancers, the VEGF pathway holds promise as a target for anti-angiogenesis therapy against cancer. Preclinical studies have demonstrated that the inhibition of VEGF activity by a humanised monoclonal antibody, bevacizumab (trade name Avastin), inhibited the growth of ovarian cancer and enhanced the efficacy of cisplatin in the body. Bevacizumab has demonstrated clinical activity against human malignancies including colorectal, lung, ovarian and breast cancers.

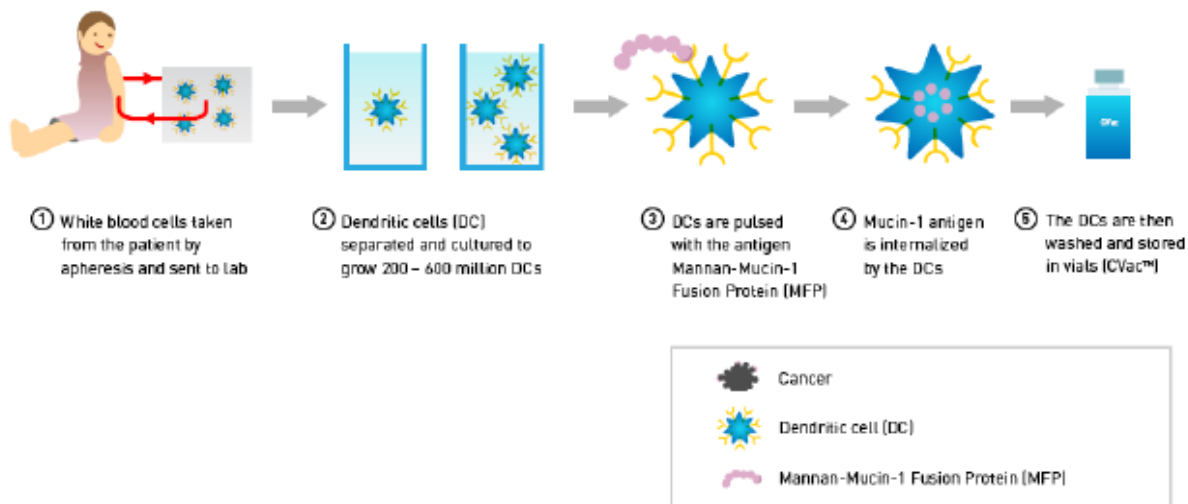
Therapeutic vaccines (of which CVac is an example)

This is described as the “fourth generation” of cancer treatment, which recruits the patient’s own immune system to attack the cancer by enabling dendritic cells to recognise foreign proteins and empower the body’s own lymphocytic (or killer) T-cells to recognise and destroy only the affected cells. Not to be confused with prophylactic vaccines (where a small amount of the virus is administered to allow the immune system to combat subsequent occurrences), therapeutic vaccines are not intended to “cure” patients, but rather provide a mechanism to stave off reinfection, or, in the case of CVac, to control metastases of the cancer.

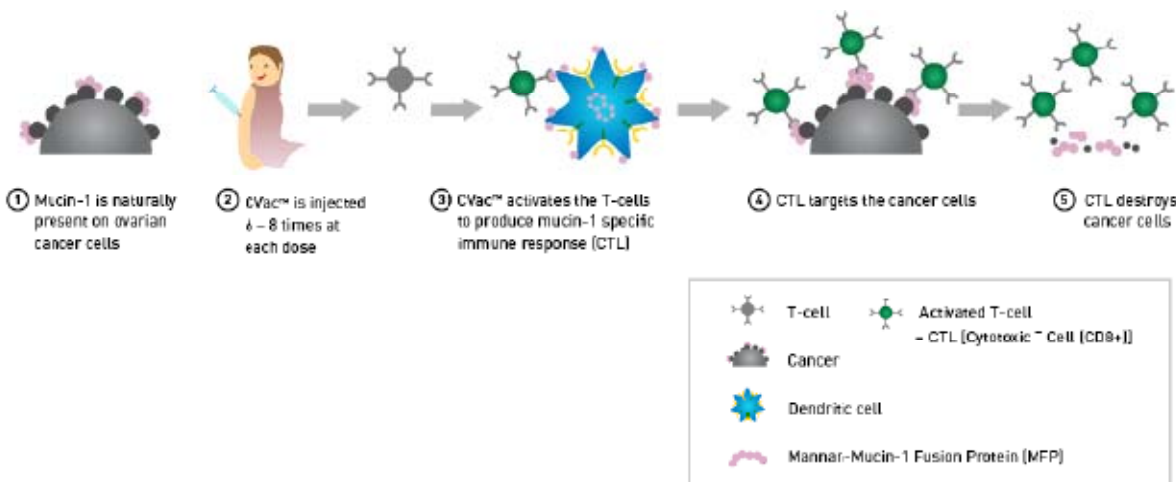
Therapeutic vaccines are relatively new technology and have only had one previous acceptance by the US FDA. The drug Provenge had to overcome several obstacles prior to being approved, however the troubles were not due to a lack of efficacy.

Figure 7: How does CVac work?

Manufacturing of CVac



Mechanism after injection



Source: Company Presentation

The main appeal of an immunotherapy treatment is its use of the patient's own immune system to fight the cancer, resulting in lower toxicity and therefore increasing patient quality of life. PRR has also found on small patient populations that CVac provides a measurable survival advantage when compared to the current standard of treatment.

A targeted and patient-specific approach increases the relevance of the treatment, and with improvements in technology and the use of automation the production process can be streamlined for patients allowing greater availability for a wider patient pool.

CVac results to date

Clinical data collected on CVac to date shows promising results. During the Phase IIa trial 28 patients were recruited (of which 21 were evaluable) with the primary endpoint to see a response in at least 15% of patients, measured by the level of CA125 (which is a protein linked to ovarian cancer) in the patient's system. One-fifth of patients responded to therapy and 47% saw disease stabilisation.

To put this in context, several approved cancer therapies have not had the same level of success at this stage of the approval process. For example, the Roche blockbuster Avastin achieved treatment response rates of 16% at Phase IIa, while anti-estrogen treatment Aromasin only achieved 36% disease stabilisation.

Table 10: Oncology treatments, early stage results

Treatment	Activity	Disease Modification	Stable Disease
Avastin	Monoclonal antibody for colon cancer	16%	-
Aromasin	Anti-estrogen for breast cancer	-	36%
Tarceva	Monoclonal antibody for lung cancer	10-20%	-
Provenge	Therapeutic vaccine for prostate cancer	19%	-
CVac	Therapeutic vaccine for ovarian cancer	21%	47%

Source: Company Presentation

It is still too early for any meaningful data from the current Phase IIb study, however the first cohort has shown that the treatment passes safety requirements and has allowed recruitment to continue up to 60 patients, which OML expects to be completed by the end of June 2011.

Indicative results of the Phase IIb trial are expected by 3Q12.

The path to commercialisation

Key points

- PRR has a clear path to commercialisation of CVac.
- Sales will commence in certain jurisdictions from 2011 onwards.
- Manufacturing approval and potency assays are important intermediate steps.

NASDAQ listing

Prima BioMed plans to list on the NASDAQ exchange to gain access to the North American biotechnology sphere. The US market is familiar with therapeutic vaccines given the success of Dendreon (NAS: DNDN). Given that the US market is likely to be a key driver of CVac sales, it makes sense to give investors there an avenue to invest as well.

Dubai Pilot Facility (expected commencement end of 2011)

In late May 2011, PRR received approval to commence commercialisation plans in Dubai Healthcare City (DHC). The deployment will run as a small pilot program and it is expected that the first patient will receive treatment towards the end of 2011.

PRR will own an apheresis machine at DHC primarily for its own purposes, but will also be co-opted by the hospital for other blood processes for a small fee each year. The apheresis product will be shipped back to Australia for processing at PRR's manufacturing facilities in Melbourne before returning to the UAE.

Ongoing costs in Dubai to run the trial are expected to be around \$500k per annum. PRR expects the process to be reimbursed for UAE residents but are not expecting a large volume of participants.

OML believes the company is targeting 50–100 patients in the first 12 months of operation. Against a backdrop of over 5,000 patients being treated in Dubai and more than 10,000 in the UAE each year, this seems somewhat sub-scale, however PRR is not approaching this strictly from a commercial standpoint given its strong focus remains on approval in the US and European markets.

The study also provides the opportunity for off-label usage on other forms of cancer that over-express the mucin-1 antigen. For example, a certain proportion of colorectal, breast and some lung cancers over-express mucin-1.

Potency assay (framework agreed in June 2011)

A key part of the commercialisation process that is often overlooked is the potency assay. A potency assay has two main outcomes: to ensure that each batch of a therapy or vaccine will have at least a given level of biologic activity such that it stimulates the required result or response, and also seeks to show batch-to-batch consistency of biological activity and result/response.

Measurements of biological activity can be performed in three ways:

- 1) Animal studies in which a defined animal model demonstrates a measurable, physiological change in response to application of the drug,
- 2) Cell-based assays that use a specified cell system, which on addition of the drug, demonstrate a measurable biological response, and
- 3) Enzymatic reactions where the biological activity of the drug can be measured by the accumulation of product following the chemical reaction facilitated by the drug.

Manufacturing approval (expected by end of 2011)

The only factor remaining to be completed before operations in Dubai can commence is manufacturing approval from the Therapeutic Goods Administration (TGA) in Australia. To obtain this requires a full audit of the processes and procedures which in PRR's case is expected to occur in the next couple of months.

PRR's manufacturing base currently sits inside the Peter MacCallum Cancer Institute on the edge of Melbourne's CBD. The facility is shared with Mesoblast Limited (ASX: MSB), which has already received an approval to manufacture.

First Australian sales (possibly in FY12)

Assuming manufacturing approvals and potency assays come back favourably, it is very likely sales in Australia will commence as early as FY12. This is because in Australia CVac is classed as a blood product rather than a biologic.

Given our analysis in Table 7 and 8 above, we estimate the market potential in Australia and New Zealand to be between 885 and 1,557 patients per annum. The figures depend heavily on whether admission will be granted to the Pharmaceutical Benefits Scheme (PBS), which would subsidise a large portion of the costs.

The Australian government has recently frozen new additions to the PBS in certain circumstances in a bid to contain costs. However, this does not apply for treatments where there is currently no option available. OML believes that CVac fits this category and will be available for consideration to be added to the PBS when it is eligible to do so.

Development of manufacturing method (progressively over next two years)

One of the key considerations will be the method of manufacture once commercial sales begin.

Currently the process is almost entirely completed manually. This is not surprising given the relatively early stage of the treatment, however it is interesting to note that Dendreon continues to struggle to automate the production process for Provenge.

It is highly likely that demand will outstrip supply in the years immediately following approval in each jurisdiction. The extent of this mismatch can be reduced by having a robust production process in place that is approved by the regulators and can demonstrably show comparability of batch relative to hand-made batches.

FDA and EMA approval (possibly in 2014)

Global sales are dependent on the Phase III trial which will commence in 3Q11, and after recruitment is finalised by the end of 2012 the study will become event-driven. This means that there will be an interim analysis and if the data is better than expected, approval applications may be fast-tracked. See our detailed discussion in the section headed "Key milestones in the development pipeline" for further details of the clinical trials. Notwithstanding the event-driven nature of the trial, OML conservatively expects FDA and EMA approval in early 2016, following the conclusion of Phase III testing.

Global sales begin (possibly from 2015)

Assuming positive study results and no delays by the regulators, CVac could be on the market in 2015. For further market information refer to the "Market potential" section of this report. OML has taken a conservative approach, however, and estimates that FY17 will be the first full fiscal year of worldwide commercial sales.

Key milestones in the development pipeline

Key points

- The stock will be driven by the achievement of key milestones.
- Commencement of Phase III and interim data points are likely to be very influential.
- Short-term catalysts include Phase IIb recruitment and manufacturing approval.

Table 11: Expected Key Milestones

	2011				2012				2013				2014				2015			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Recruitment Completed for Phase IIb		■																		
First patient enrolled in Phase III trial			■																	
Recruitment Completed for Phase III					■	■	■	■												
Indicative Results for Phase IIb					■	■	■	■	■	■	■	■								
Interim Data Analysis for Phase III									■	■	■	■	■	■	■	■				
Final Data for Phase III													■	■	■	■	■			

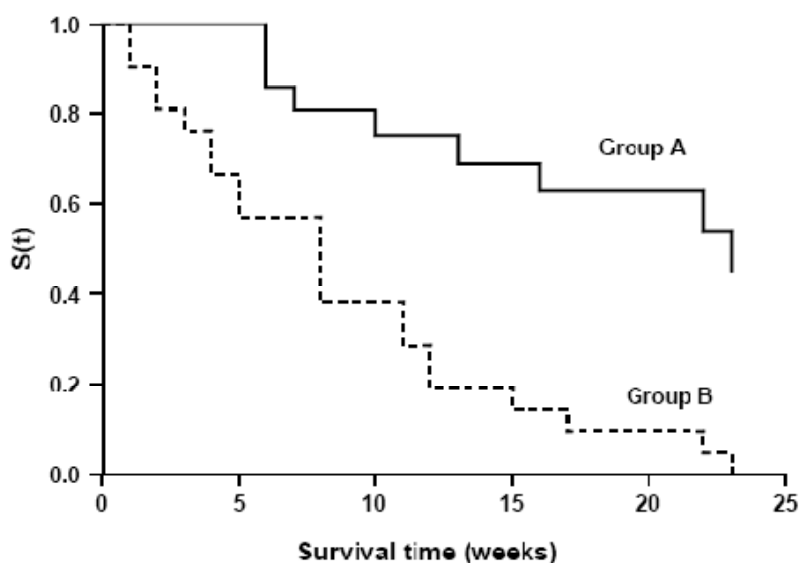
Source: Company data, Ord Minnett estimates

Several milestones are expected to also be share price catalysts. Concurrent Phase IIb and Phase III trials mean that there will not be large gaps between results data, with the longest gap expected to be 12 months between the start of Phase III recruiting and indicative Phase IIb results possibly in 3Q12.

Production and sales may start earlier in Australia because CVac is designated as a blood product, which does not require the rigorous testing procedures required by offshore regulators. Manufacturing authority may be granted later in CY11 and sales could commence as early as FY12.

The Phase III trial will be structured as an event-driven study, meaning that as time passes and participants either respond to treatment or pass away, a data set will be created that PRR hopes will show a tangible survival benefit relative to the control group. Graphically, this can be shown by plotting a set of Kaplan-Meier curves as shown below. The horizontal distance between the curves indicates the survival advantage, which may or may not be statistically significant based on the “power” of the study.

Figure 8: Sample Kaplan-Meier Curves



The development timeline is expected to be helped by the **Orphan Drug Designation**, which was received from the US FDA in the middle of 2010. Being an orphan drug offers several advantages including:

- priority review of data
- greater protection of intellectual property
- marketing and regulatory advantages
- financial advantages such as tax benefits.

See Appendix 3 for further details.

The data catalysts will be keenly sought for any information on efficacy based on the primary endpoints of progression-free survival and overall survival. However, interim data does not carry the same statistical power and should not be misread as a precursor to the final results. It will, however, give PRR the chance to alter the size of the test group to ensure the study is statistically relevant.

Phase IIb – further details

An initial cohort of seven subjects who met the Phase IIb Trial's eligibility criteria completed the first injection of the CVac vaccine in January 2011, in an open label fashion. The group was monitored for a period of (at least) 28 days to assess any treatment-related adverse effects. The group did not suffer any therapy-related adverse effects and received confirmation from the Data Safety Monitoring Board in January 2011 that the Phase IIb Trial was safe to proceed. This was based on a detailed review of patients' blood, serum, vital signs, and any reported study agent effect (or adverse events reported to date).

As a result, patient enrolment into the randomised component of the Phase IIb Trial (a further 54 patients) is now open. This patient cohort will be tracked on either standard of care versus treatment with CVac. The trial will run over five sites in Australia and 15 sites across the US.

Phase III – further details

This trial is set to commence recruitment in 3Q11 and complete the recruitment by 4Q12. The trial will be conducted on 800 patients in a double-blind, placebo controlled environment, randomised 1:1 to CVac vs Standard of Care across multiple sites in Europe (~70% of the cohort), the US (20-25% of the cohort) and Australia (5-10% of the cohort).

The study will assess both progression free survival (PFS) and overall survival (OS) as primary endpoints, while also building on earlier safety data.

Other programs

PRR also has two other clinical programs in much earlier stages of progression, and will remain secondary to the CVac program for the foreseeable future, although work will continue on them in concert with CVac.

Figure 9: Progress of other PRR intellectual property



Source: Company Website

Similar treatments in development

Table 12: Comparable listed companies and key metrics

Company	Code	Mkt Cap (\$m)	Enterprise Value (\$m)	Cash on Hand (\$m)
Dendreon	DNDN	4,600	4,400	200
Geron	GERN	610	425	185
Celldex	CLDX	125	88	60
Cel-Sci	CVM	112	94	26
Agenus	AGEN	92	127	20
Oncothyreon	ONTY	110	80	30
Bavarian Nordic*	DEN: BAVA	1,400	1,045	355
Prima Biomed^	PRR	265	210	55

*shown in Danish kroner; ^shown in AUD.

Source: Bloomberg, IRESS, Company data.

Dendreon (NASDAQ: DNDN) – Dendreon applies its expertise in antigen identification, engineering and cell processing to produce active cellular immunotherapy. Dendreon is developing treatments that use a patient's own cells to stimulate an immune response against cancer. Dendreon is headquartered in Seattle and has a manufacturing facility in New Jersey and is in the process of constructing facilities in Georgia and California.

Geron (NASDAQ: GERN) – Geron is developing next generation biopharmaceuticals for the treatment of cancer and chronic degenerative diseases. The company is advancing anti-cancer therapies through multiple Phase II clinical trials in different cancers by targeting the enzyme telomerase. The company is developing cell therapy products from differentiated human embryonic stem cells for multiple indications, including central nervous system (CNS) disorders, heart failure, diabetes and osteoarthritis, and has initiated a Phase 1 clinical trial in spinal cord injury.

Celldex (NASDAQ: CLDX) – Celldex Therapeutics is the first antibody-based combination immunotherapy company. Celldex has a pipeline of drug candidates in development for the treatment of cancer and other difficult-to-treat diseases based on its antibody-focused Precision Targeted Immunotherapy (PTI) Platform. The PTI Platform is a complementary portfolio of monoclonal antibodies, antibody-targeted vaccines and immuno-modulators used in optimal combinations to create disease-specific pharmaceutical candidates.

CEL-SCI (NASDAQ: CVM) – CEL-SCI is dedicated to improving the treatment of cancer and other diseases by unleashing the power of the immune system. Its flagship product, Multikine, is the first immunotherapeutic agent being developed as a first-line standard of care treatment for cancer. Multikine simulates the activity of a healthy person's immune system, and unleashes and empowers the body's own anti-tumour immune response. Multikine has been cleared in the U.S. and Canada for a groundbreaking global Phase III clinical trial in advanced primary (not yet treated) head and neck cancer patients. This trial is expected to be the largest head and neck cancer clinical study ever conducted.

Agenus (NASDAQ: AGEN) – Agenus' product pipeline includes antigen-based vaccines, however the key product currently in development is the autologous cancer immunotherapy known as the Prophage Series of cancer vaccines.

Oncothyreon (NASDAQ: ONTY) – Oncothyreon is currently developing multiple therapeutic candidates designed to target cancer in specific and effective ways. The pipeline includes both synthetic vaccines and small molecules for a variety of cancer indications.

Bavarian Nordic (DEN: BAVA) – Bavarian Nordic's clinical pipeline targets cancer and infectious diseases, and includes seven development programs. Two programs under preparation for Phase III are PROSTVAC, a therapeutic vaccine for advanced prostate cancer under a collaboration agreement with the National Cancer Institute, and IMVAMUNE, a third-generation smallpox vaccine being developed under a contract with the US government. Bavarian Nordic is listed on NASDAQ OMX Copenhagen.

Unlisted companies

Optimer Pharmaceuticals - OPT-822/821 is a novel cancer immunotherapy composed of Globo-H linked to a protein carrier. The company has applied the OPopS technology to manufacture effectively complex carbohydrate cancer antigens, including Globo-H, a prominent antigen in breast cancer cells, and Sialyl Lewis A, an antigen in breast and small lung cancer cells. In January 2011, Optimer initiated a Phase II/III clinical trial of OPT-822/821. This study, referenced as OPT-822-001, is designed as a multi-centre trial with sites in Taiwan, South Korea, Hong Kong and Singapore. The Phase II/III clinical trial is expected to enrol up to 342 patients.

Menarini – Menarini is developing Abagovomab, a monoclonal antibody that has been designed to mirror the CA-125 tumour antigen, which is highly expressed in epithelial ovarian cancer. Abagovomab does not bind directly to CA-125, but it works as a "surrogate" antigen, enabling the immune system to identify and attack tumour cells displaying the CA-125 protein. It is hoped that the body's immune system may be able to combat any remaining individual tumour cells and thus prevent recurrence of the disease. In a Phase II study on 119 patients with advanced ovarian cancer in which the standard therapies had already been ineffective, treatment with Abagovomab led to a prolongation of survival time (23.4 months compared to 4.9 months) in those patients who responded to the vaccination (almost 70 % of patients).

Key risk factors

The following is not an exhaustive list of potential risks and investors should be aware of the high risk nature of the company.

- **Clinical risk** – This is the most significant risk given that approval hinges on statistically powered data. The lack of data at this stage on CVac brings this risk into sharper focus. That said, data released to this point has shown promise in both safety and efficacy.
- **Trial structuring risk** – This was a key issue encountered by Dendreon during the Provenge trial. The risk here is that statistically significant data may not be considered by the regulators if the trial is mis-specified with regard to endpoints. PRR has the benefit of Dendreon going before it and a set of guidelines released by the FDA in 2009 regarding immunotherapeutic vaccines.
- **Timing risk** – This is in relation to trials that have timing overruns due to inability to recruit suitable patients or operational hiccups regarding manufacturing. These issues can often not be foreseen, however, PRR is using well regarded contract manufacturers.
- **Partnering risk** – This risk refers to “Big Pharma” finding alternative technology to support prior to CVac achieving marketing approval, allowing Big Pharma to drive a harder bargain which could be to the detriment of shareholder value.
- **Capital risk (burn rate)** – With the expected initiation of Phase III trials, burn rates are likely to increase from current levels. The company therefore becomes more susceptible to delays or unexpected occurrences.
- **Manufacturing risk** – This involves the commercialisation of the process as well as the quality of the product being provided. If quality standards drop the product may not work as advertised or cause safety issues.
- **Key person risk** – The science and expertise required is specialised, the loss of which may delay progress in the clinical program or otherwise hamper the commercialisation prospects of the firm’s products.
- **Regulatory risk** – This could involve governments changing reimbursement rules, or changing the procedures required to get new products approved, or other changes in legislation that hamper the development or sale of the company’s products.
- **Accounting risk** – The standards used to account for certain revenue and expense items may change during the life cycle of a particular product, requiring potentially significant accounting revisions.
- **Taxation risk** – The taxation of certain components of research and development expenditure and other expenses are dependent on current taxation rulings, which may change in future.

Appendix 1

Antibody-mediated immunity vs. cellular immunity

Humoral immunity is the aspect of immunity that is mediated by antibodies. In response to markers recognised as “non-self” or “foreign”, B lymphocytes (see below) are stimulated to produce antibodies. The antibodies may bind to the antigen or foreign marker and attempt to clear or neutralise it. However, antibodies cannot kill cells; they need to recruit other elements of the immune system. They may recruit complement leading to complement-dependent cell cytotoxicity (CDCC) or they may act as flags to mark cells for destruction by natural killer cells in antibody-dependent cell cytotoxicity (ADCC).

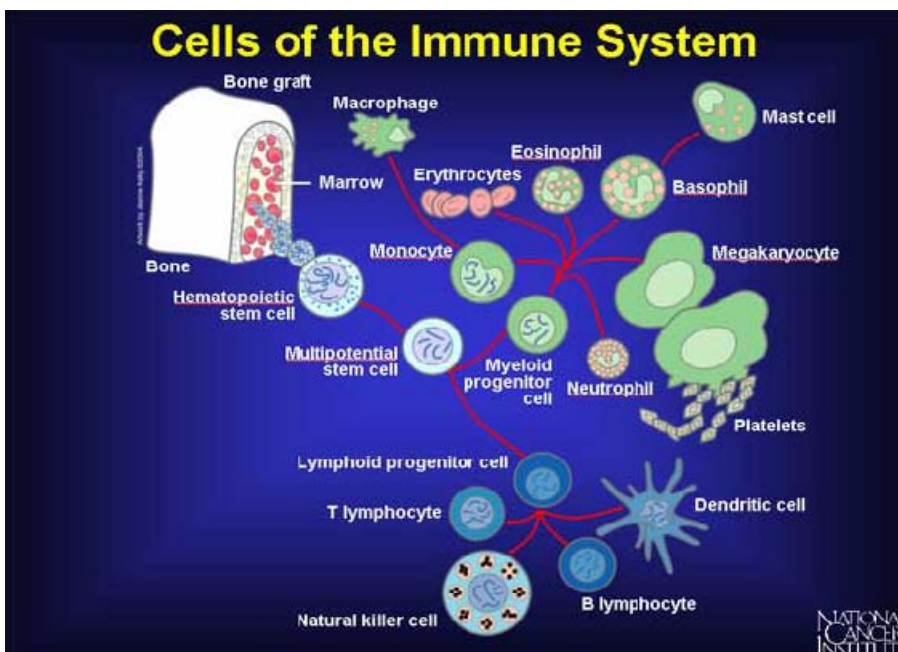
Antibodies are not always successful in recruiting other elements of the immune system, therefore there may be a lack of immune protection despite high levels of antibodies present. Furthermore, antibodies can only recognise surface markers – if the antigen is internal, it escapes detection.

Cellular immunity is the aspect of immunity mediated by cytotoxic T lymphocytes and natural killer cells. T cells do not recognise antigens unless these antigens are bound to a cell surface molecule known as the major histocompatibility complex (MHC).

The role of antigen presenting cells (APCs) such as macrophages and dendritic cells is to digest the proteins of viruses and other pathogens and display the degraded peptides on their surface coupled with MHC in order to enable recognition by T cells. Tumour cells do not consistently exhibit modified proteins or carbohydrates on their surface but in cases where they do display distinct tumour-specific surface antigens, an immunotherapy approach may be feasible.

A tumour antigen may elicit an antibody response or a cellular response. However, antibodies, even if present, may bind to but not be able to kill tumour cells. Cytotoxic T cell-mediated responses, on the other hand, tend to be more effective against tumours.

Figure 5: The human immune system



Source: National Cancer Institute

Immunotherapy

Immunotherapy is a medical term defined as "treatment of disease by inducing, enhancing, or suppressing an immune response".

Immunotherapies designed to elicit or amplify an immune response are classified as activation immunotherapies.

Immunotherapies designed to reduce, suppress or more appropriately direct an existing immune response, as in cases of autoimmunity or allergy, are classified as suppression immunotherapies.

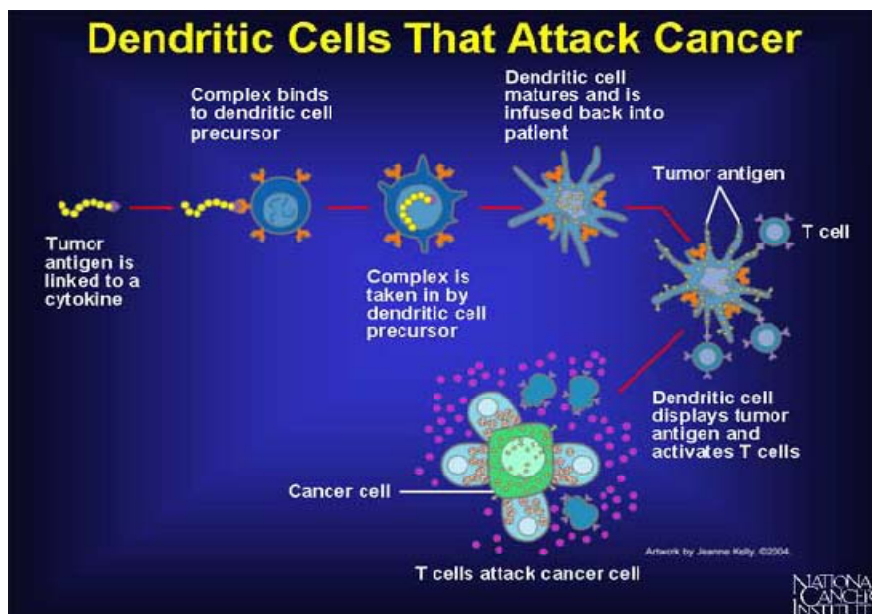
The active agents of immunotherapy are collectively called immunomodulators. They are a diverse array of recombinant, synthetic and natural preparations, often cytokines. Some of these substances, such as granulocyte macrophage colony-stimulating factor (GM-CSF), interferons, imiquimod and cellular membrane fractions from bacteria are already licensed for use in patients. Others including IL-12, various chemokines, synthetic cytosine phosphate-guanosine (CpG), oligodeoxynucleotides and glucans are currently being investigated extensively in clinical and preclinical studies. Immunomodulatory regimens offer an attractive approach as they often have fewer side effects than existing treatments, including less potential for creating resistance in microbial diseases.

Cell-based immunotherapies are proven to be effective for some cancers. Immune effector cells such as lymphocytes, macrophages, dendritic cells, natural killer cells and cytotoxic T lymphocytes work together to defend the body against cancer by targeting abnormal antigens expressed on the surface of the tumour due to mutation.

Dendritic cell based immunotherapy

Dendritic cells can be stimulated to activate a cytotoxic response towards an antigen. Dendritic cells, a type of APC, are harvested from a patient. These cells are then either pulsed with an antigen or transfected with a viral vector. Upon transfusion back into the patient these activated cells present the tumour antigen to effector lymphocytes (CD4+ T cells, CD8+ T cells, and B cells). This initiates a cytotoxic response to occur against cells expressing the specified tumour antigen (against which the adaptive response has now been primed).

Figure 6: Cell-based immunotherapy



Source: National Cancer Institute

T-cell based adoptive immunotherapy

Adoptive cell therapy (ACT) using autologous tumour-infiltrating lymphocytes is an effective treatment for patients with metastatic melanoma, but may also have applications in other indications.

Adoptive cell transfer uses T cell-based cytotoxic responses to attack cancer. T cells that have a natural or genetically engineered reactivity to a patient's cancer are expanded *in vitro*, made more effective using a variety of means and then adoptively transferred back into the patient.

For example, T cells with a naturally occurring reactivity to a patient's cancer can be found in the patient's own tumours. The tumour can be harvested, and these tumour-infiltrating lymphocytes (TIL) can then be expanded, or made more effective *in vitro* using high concentrations of interleukin-2 (IL-2), anti-CD3 and allo-reactive feeders. These T cells can then be transferred back into the patient along with exogenous administration of IL-2 to further boost their activity.

Appendix 2 - Glossary

Adaptive immune system: is composed of highly specialised, systemic cells and processes that eliminate or prevent pathogenic challenges.

Anti-cripto-1 mAb: helps prevent tumour development and inhibit the growth of established tumours.

Antigen-presenting cells: are cells that display foreign antigen complexes with major histocompatibility complex (MHC) on their surfaces. T-cells may recognise these complexes using their T-cell receptors (TCRs). These cells process antigens and present them to T-cells.

Asymptomatic: a patient is a carrier for a disease or infection but experiences no symptoms.

Autologous: In blood transfusion and transplantation, a situation in which the donor and recipient are the same person.

CA-125: cancer antigen 125.

Carboplatin: is a chemotherapy drug used against some forms of cancer (mainly ovarian carcinoma, lung, head and neck cancers).

Chemotherapy: is the treatment of an ailment by chemicals, especially by killing micro-organisms or cancerous cells.

Cisplatin: is a chemotherapy drug. It is used to treat various types of cancers, including sarcomas, some carcinomas (e.g. small cell lung cancer, and ovarian cancer), lymphomas, and germ cell tumours.

CVac: cancer vaccine product that stimulates the patient's own immune system to target and destroy tumours.

Cytotoxic T-cells (CTL): belongs to a sub-group of T lymphocytes (a type of white blood cell) that are capable of inducing the death of infected somatic or tumour cells; they kill cells that are infected with viruses (or other pathogens), or are otherwise damaged or dysfunctional.

Debulking surgery: is the surgical removal of part of a malignant tumour which cannot be completely excised, so as to enhance the effectiveness of radiation or chemotherapy. It is used only in specific malignancies, as generally partial removal of a tumour is not considered a worthwhile intervention.

Dendritic cells (DC): Their main function is to process antigen material and present it on the surface to other cells of the immune system, thus functioning as antigen-presenting cells.

Epithelial ovarian cancer (EOC): is a disease in which malignant (cancerous) cells form in the tissue covering the ovary.

Gene therapy: is the insertion, alteration, or removal of genes within an individual's cells and biological tissues to treat disease. It is a technique for correcting defective genes that are responsible for disease development

Germ cell tumour: is a neoplasm derived from germ cells. Germ cell tumours can be cancerous or non-cancerous tumours. Germ cells normally occur inside the gonads (ovary and testis).

Hazard ratio: in survival analysis it is the effect of an explanatory variable on the hazard or risk of an event. The hazard ratio is designed to be an estimate of relative risk.

HPV: Human Papilloma Virus (HPV) is a common virus that is spread through sexual contact. Some HPV types can cause cervical cancer in women and can also cause other kinds of cancer in both men and women.

Immunotherapy: Treatment of disease by inducing, enhancing, or suppressing an immune response.

Innate immune system: comprises the cells and mechanisms that defend the host from infection by other organisms in a non-specific manner. This means that the cells of the innate system recognise and respond to pathogens in a generic way, but unlike the adaptive immune system, it does not confer long-lasting or protective immunity to the host.

Kaplan- Meyer Curve: estimates the survival function from life-time data. In medical research, it might be used to measure the fraction of patients living for a certain amount of time after treatment.

Major Histocompatibility Complex (MHC): is a large genomic region or gene family found in most vertebrates that encodes MHC molecules. MHC molecules play an important role in the immune system and autoimmunity.

Metastatic disease: is the broad term used to describe any disease which can spread throughout the body; through the blood or lymphatic system.

Monoclonal antibodies (mAb): are monospecific antibodies that are the same because they are made by identical immune cells that are all clones of a unique parent cell.

Mitosis: is the process by which a eukaryotic cell separates the chromosomes in its cell nucleus into two identical sets in two nuclei.

Mucin-1 (MUC1): is a mucin, the protein part of which is encoded by the MUC1 gene in humans. Mucin proteins penetrate the membranes of epithelial cells, on the inner surface of the intestine and other organs. Mucin protects the body from infection by binding to pathogens. Over expression of the mucin protein is often associated with colon and many other cancers.

Natural killer cells (NK cells): are types of cytotoxic lymphocytes that constitute a major component of the innate immune system. NK cells play a major role in the rejection of tumours and cells infected by viruses.

Natural killer T (NKT) cells: are a heterogeneous group of T cells that share properties of both T cells and natural killer (NK) cells. Many of these cells recognise the non-polymorphic CD1d molecule, an antigen-presenting molecule that binds self- and foreign lipids and glycolipids.

Paclitaxel: a mitotic inhibitor used in cancer chemotherapy. Paclitaxel is now used to treat patients with lung, ovarian, breast cancer, head and neck cancer.

Placebo-controlled: A term used to describe a method of research in which an inactive substance (a placebo) is given to one group of participants, while the treatment (usually a drug or vaccine) being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective than the placebo.

Radiation therapy: is the medical use of ionizing radiation as part of cancer treatment to control malignant cells.

Receptor: is a protein molecule, embedded in either the plasma membrane or the cytoplasm of a cell, to which one or more specific kinds of signaling molecules may attach.

Survival analysis: is a branch of statistics which deals with death in biological organisms and failure in mechanical systems.

Appendix 3: The approval process

Phase 0

Phase 0 is a recent designation for exploratory, first-in-human trials conducted in accordance with the United States Food and Drug Administration's (FDA) 2006 Guidance on Exploratory Investigational New Drug (IND) Studies. Phase 0 trials are also known as human micro-dosing studies and are designed to speed up the development of promising drugs or imaging agents by establishing very early on whether the drug or agent behaves in human subjects as was expected from preclinical studies.

OML Comment: *Cripto-1 mAb and oral HPV vaccine at this stage currently.*

Phase I

Phase I trials are the first stage of testing in human subjects. Normally, a small (20-100) group of healthy volunteers will be selected. This phase includes trials designed to assess the safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics of a drug. Phase I trials also normally include dose-ranging, also called dose escalation, studies so that the appropriate dose for therapeutic use can be found. Phase I trials most often include healthy volunteers. However, there are some circumstances when real patients are used, such as patients who have terminal cancer or HIV and lack other treatment options. The reason for conducting the trial is to discover the point at which a compound is too unsafe to administer.

OML Comment: *CVac for other indications currently at this stage, however safety data from ovarian cancer trials can be used here to speed up the progression to later stage trials.*

Phase II

Once the initial safety of the study drug has been confirmed in Phase I trials, Phase II trials are performed on larger groups (20–300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients. When the development process for a new drug fails, this usually occurs during Phase II trials when the drug is discovered not to work as planned, or to have toxic effects. Phase II studies are sometimes divided into Phase IIa and Phase IIb.

OML Comment: *CVac Ovarian Cancer trial at Phase IIb, with patients being enrolled in the randomised part of the study after initial safety data revealed no issues.*

Phase III

Phase III studies are randomised controlled multi-centre trials on large patient groups (300–3,000 or more depending upon the disease/medical condition studied) and are aimed at being the definitive assessment of how effective the drug is, in comparison with current 'gold standard' treatment. Because of their size and comparatively long duration, Phase III trials are the most expensive, time-consuming and difficult trials to design and run, especially in therapies for chronic medical conditions.

It is common practice that certain Phase III trials will continue while the regulatory submission is pending at the appropriate regulatory agency. This allows patients to continue to receive possibly lifesaving drugs until the drug can be obtained by purchase. Other reasons for performing trials at this stage include attempts by the sponsor at "label expansion" (to show the drug works for additional types of patients/diseases beyond the original use for which the drug was approved for marketing), to obtain additional safety data, or to support marketing claims for the drug. Studies in this phase are sometimes categorised as "Phase IIIb studies".

Once a drug has proved satisfactory after Phase III trials, the trial results are usually combined into a large document containing a comprehensive description of the methods and results of human and animal studies, manufacturing procedures, formulation details, and shelf life. This collection of information makes up the "regulatory submission" that is provided for review to the appropriate regulatory authorities in different countries.

OML Comment: *A Phase III trial in Europe will be launched in 2011 targeting 800 patients in a pivotal study with statistically powered endpoints for progression-free survival and overall survival. Regulatory Scientific Advice has already been received from the EMEA.*

Phase IV

Phase IV trials are also known as a Post Marketing Surveillance Trial. Phase IV trials involve the safety surveillance and ongoing technical support of a drug after it receives permission to be sold. Phase IV studies may be required by regulatory authorities or may be undertaken by the sponsoring company for competitive (finding a new market for the drug) or other reasons (for example, the drug may not have been tested for interactions with other drugs, or on certain population groups such as pregnant women, who are unlikely to subject themselves to trials). The safety surveillance is designed to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase I–III clinical trials.

Orphan drug designation

An orphan drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease. The assignment of orphan status to a disease and to any drugs developed to treat it is a matter of public policy in many countries, and has resulted in medical breakthroughs that may not have otherwise been achieved due to the economics of drug research and development.

Orphan drugs generally follow the same regulatory development path as any other pharmaceutical product, in which testing focuses on pharmacokinetics and pharmacodynamics, dosing, stability, safety and efficacy. However, some statistical burdens are lessened in an effort to maintain development momentum. For example, orphan drug regulations generally acknowledge the fact that it may not be possible to test 1,000 patients in a phase III clinical trial, as fewer than that number may be afflicted with the disease in question.

Benefits of Orphan Drug Designation:

- Ten years exclusive rights (trumping patent regulations). CVac has patents which are due to expire in 2018, however the Orphan designation was granted in 2010 and therefore has exclusive rights until at least 2020.
- Priority review of data. This will greatly speed the path to market if the data provides satisfactory results.
- Study sizes can be smaller. Given that the disease only affects a small portion of the population, it may be impractical to require sample sizes of 1,000 or more.
- No registration or regulatory fees.
- Tax grants in various countries relating to research and development expenditure.

Appendix 4

Numbers are unrisks and show projected revenues to “peak” sales in FY20.

Profit & Loss Statement (A\$m)	FY09A	FY10A	FY11E	FY12E	FY13E	FY14E	FY15E	FY16E	FY17E	FY18E	FY19E	FY20E
Operating Revenue	0.0	0.5	0.8	5.3	18.6	43.6	82.6	173.9	693.4	1,209.0	1,393.2	1,822.1
Operating Costs	2.9	18.7	13.3	28.3	39.4	60.5	57.6	91.2	172.1	242.3	268.3	326.9
Share of Associates	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	-2.9	-18.2	-12.5	-23.0	-20.9	-16.9	25.0	82.7	521.3	966.7	1,124.9	1,495.2
Depreciation & Amortisation	0.0	0.1	0.1	0.9	1.7	5.7	11.7	12.5	13.5	14.7	15.9	17.1
EBIT	-2.9	-18.2	-12.6	-23.9	-22.5	-22.6	13.3	70.2	507.8	952.0	1,109.1	1,478.1
Net Interest Expense	0.0	0.0	-0.8	-1.4	-1.2	0.0	0.0	0.0	-0.3	-1.2	-2.5	-4.3
Pre-Tax Profit	-2.9	-18.2	-11.8	-22.5	-21.4	-22.6	13.3	70.2	508.1	953.2	1,111.6	1,482.4
Tax Expense	0.0	0.0	0.0	0.0	0.0	0.0	4.0	21.1	152.4	286.0	333.5	444.7
Reported NPAT	-2.9	-18.2	-11.8	-22.5	-21.4	-22.6	9.3	49.1	355.7	667.3	778.1	1,037.7
Significant Items (After Tax)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Normalised NPAT	-2.9	-18.2	-13.2	-22.5	-21.3	-22.5	9.3	49.2	355.7	667.3	778.2	1037.7
EBITDA Margin (%)	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm	nm
Effective tax Rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	30.0%	30.0%	30.0%	30.0%	30.0%	30.0%
Diluted EPS (cps)	-0.9	-3.6	-1.4	-2.2	-1.9	-2.0	0.8	4.3	30.8	57.8	67.4	89.9
Diluted Normalised EPS (cps)	-0.9	-3.6	-1.5	-2.2	-1.9	-2.0	0.8	4.3	30.8	57.8	67.4	89.9
DPS (cps)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Payout Ratio (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	na	na	na	na	na	na	na	na	na	na	na	na

Cash Flow Statement (A\$m)	FY09A	FY10A	FY11E	FY12E	FY13E	FY14E	FY15E	FY16E	FY17E	FY18E	FY19E	FY20E
EBITDA	-2.9	-18.2	-12.5	-23.0	-20.9	-16.9	25.0	82.7	521.3	966.7	1124.9	1495.2
Change in Working Capital	0.1	1.3	0.4	1.4	-0.4	-0.8	-6.3	-9.0	-66.8	-67.7	-24.1	-56.3
Net Interest (paid)/received	0.0	0.2	0.8	1.4	1.2	0.0	0.0	0.0	0.3	1.2	2.5	4.3
Tax Paid	0.0	0.0	0.0	0.0	0.0	0.0	-4.0	-21.1	-152.4	-286.0	-333.5	-444.7
Other Operating Items	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating Cash Flow	-1.9	-6.5	-11.4	-20.2	-20.1	-17.7	14.7	52.6	302.4	614.2	769.9	998.5
Asset Sale Proceeds	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Acquisitions	0.0	-10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Capex	0.0	-0.1	-2.0	-2.8	-11.6	-20.6	-13.6	-14.9	-16.4	-17.6	-18.8	-20.0
Other investing items	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Investing Cash Flow	0.0	-10.1	-2.0	-2.8	-11.6	-20.6	-13.6	-14.9	-16.4	-17.6	-18.8	-20.0
Inc/(Dec) in Equity	1.6	14.9	60.0	12.0	30.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Inc/(Dec) in Borrowings	0.1	6.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Dividends Paid	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Financing Items	0.0	0.0	0.0	0.0	0.0	0.0	3.0	6.0	9.0	12.0	15.0	18.0
Financing Cash Flow	1.7	21.3	60.0	12.0	30.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Inc/(Dec) in Cash	-0.2	4.7	46.6	-11.0	-1.8	-38.3	1.0	37.7	286.0	596.6	751.1	978.4

Balance Sheet (A\$m)	FY09A	FY10A	FY11E	FY12E	FY13E	FY14E	FY15E	FY16E	FY17E	FY18E	FY19E	FY20E
Cash	0.9	5.6	52.2	41.2	39.5	1.1	2.2	39.9	325.8	922.4	1673.5	2652.0
Inventories	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Receivables	0.4	0.1	0.1	0.8	2.8	6.6	12.4	26.2	104.5	182.2	209.9	274.6
Other Current Assets	0.1	10.9	10.9	10.9	10.9	10.9	10.9	10.9	10.9	10.9	10.9	10.9
PP & E	0.0	0.1	2.1	4.1	14.1	29.1	31.1	33.6	36.6	39.6	42.6	45.6
Intangibles	0.5	0.5	0.5	0.4	0.4	0.3	0.3	0.3	0.3	0.2	0.2	0.2
Other Non Current Assets	0.6	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Total Assets	2.5	18.1	66.6	58.3	68.5	48.9	57.8	111.7	478.9	1156.2	1938.0	2984.1
Short term Debt	0.2	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Other Current Liabilities	0.4	1.5	1.9	4.1	5.6	8.6	8.2	13.0	24.5	34.5	38.2	46.6
Long term Debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Non Current Liabilities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Non current liabilities	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Liabilities	0.7	2.2	2.6	4.8	6.4	9.3	8.9	13.7	25.3	35.3	39.0	47.3
Total Equity	1.8	15.8	64.0	53.5	62.1	39.5	48.8	98.0	453.7	1120.9	1899.1	2936.8
Total liability & Shareholder equity	2.5	18.1	66.7	58.3	68.5	48.9	57.8	111.7	478.9	1156.2	1938.0	2984.1
Net (Debt)/Cash	0.7	4.9	51.5	40.5	38.8	0.4	1.5	39.2	325.1	921.7	1672.8	2651.3

Source: Ord Minnett estimates, Company data.

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Guide to Ord Minnett Recommendations

BUY	The stock's total return (nominal dividend yield plus capital appreciation) is expected to exceed 15% over 12 months.
ACCUMULATE	The stock's total return is expected to be between 5% and 15%. Investors may add to existing holdings, or initiate holdings on share price weakness.
HOLD	The stock is fairly priced, and its total return is expected to be between 0% and 5%.
LIGHTEN	The stock's total return is expected to be less than 0% and possibly down 15%. Investors should consider selling into share price strength.
SELL	The stock's total return is expected to lose 15% or more.
RISK ASSESSMENT	Classified as High, Medium or Low, denotes the relative assessment of an individual stock's risk based on an appraisal of its disclosed financial information, volatility, nature of its operations and other relevant quantitative and qualitative criteria.

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Ord Minnett acted as a broker to the capital raising in June 2011. Ord Minnett acted as underwriter to these issues and received fees for acting in these capacities. Ord Minnett also received a distribution fee for the placement.

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