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In this edition...
A strong clinical trial result from Dendreon's Phase III Provenge trial looks to have put the wind into Prima Biomed's share price. Prima Biomed is a stock to watch in the next two months as it submits an IND with the FDA.

Consolidation is the name of the game in the diagnostics sector as Polartechnics and Fermiscan are seeking to merge. Will the quest for critical mass see other similar plays emerge?

Halycgen Pharmaceuticals is progressing well, yet its strategy continues to evolve. Will its super generic cause a major shift in the itraconazole anti-fungal market?.

The Editors
Companies Covered: ACG, AVH, HGN, FER, PRR, PLT

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - current)	-10%
Cumulative Gain	**86%**
Av Annual Gain (7 yrs)	**17.8%**

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au
David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph: (03) 9671 3222
Email: pachacz@bioshares.com.au

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Bioshares

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Prima Biomed Back in the Spotlight

Shares in Prima Biomed have had an extraordinary run over the past few weeks, increasing by 347% from 1.5 cents on April 8, 2009 to 6.7 cents on Friday. The company is now capitalised $23.6 million. If 169 million, $0.02 December 2011 options, which are now well in the money, are factored in, then on a fully diluted basis, Prima Biomed is capitalised at $35 million. Prima is developing CVac, an immunotherapy (vaccine) to treat ovarian cancer. What has been behind this stellar run for a company that until recently was verging on oblivion?

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

Secondly, and perhaps much more significant for Prima, has been the massive increase in Dendreon's share price, which increased by 132% on April 14, 2009. Like Prima, Dendreon has been developing a cancer immune-therapy, named Provenge, but targeted at prostate cancer. Dendreon said that its treatment increased overall survival times in a just completed 512 patient Phase III study, although by how much was not revealed at the time (but will be at a forthcoming oncology conference).

The company was confident enough to say that Provenge "significantly prolongs survival". It would appear that the result is the validation sought for many years by immunotherapy developers that cancer vaccines not only stabilize disease but increase survival. Previously we have used Dendreon as a proxy for Prima's potential (see Bioshares 210), however in May 2007 the FDA sought more information from Dendreon regarding the clinical evaluation and manufacturing of Provenge. At that time, Prima's financial situation was very weak (with only $1.2 million in cash) and the negative Dendreon news was a setback for Prima. Until board changes commenced in October 2007, with the appointment of Martin Rogers and Ata Gokyildirim in December 2007, Prima Biomed was a company in a parlous condition.

Phase IIb/III Clinical Trial Plan for CVac

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

Cont'd over

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

Based on discussions with the FDA, instead of running a 120 patient trial as was considered at one stage, the company may only need to conduct a randomised 60 patient trial, with 35 in a treatment arm and 25 in a standard of care arm (e.g. second line therapy that includes a platinum based drug and taxol). The trial is likely to require 15 sites in the US and 15 sites in Australia and New Zealand. While the primary endpoints have yet to be made known, they will not include stabilization of CA125 biomarker levels as occurred in the Phase II trial.

The trial is likely to commence as a Phase IIb and roll into a Phase III trial. The company anticipates receiving the IND acceptance by June with enrollments to commence in the September quarter.

For Australia, Prima plans to submit the Phase IIb data to the Therapeutic Goods Administration (TGA) and seek approval for CVac as a Category 3 product, which are applications that do not need to include clinical, preclinical, or bioequivalence data. If successful, this would then enable the **Australian New Zealand Gynaecological Oncology Group** (ANZGOG) to administer CVac off-licence although Prima would be providing CVac on a not-for-profit basis.

Summary

Prima Biomed looks to have found, after several tumultuous years, a stronger footing and a clearer focus, with the commercialisation of CVac its principle goal. The company also holds three other assets which it aims to divest. The CVac product warrants continued clinical investigation and the current treatment regimes for ovarian cancer are unsatisfactory.

Prima Biomed is a stock to watch. However, we recommend that investors wait until the FDA 'approves' the company's IND application and full clinical trial protocol details are made available by the company. When that event occurs, a more timely and detailed assessment of the clinical and funding risks in front of the company can be made.

Bioshares recommendation: **Wait**

Bioshares

Halcygen Pharma's Evolving Strategy for SUBA-Itraconazole

Halcygen Pharmaceutical's strategy with its lead super generic, SUBA-Itraconazole, is evolving. The drug is a generic variation of the antifungal drug itraconazole, with the market leader being Sporanox, sold by **Janssen Pharmaceutical Products** (**Johnson & Johnson**). The market for this drug is worth US$600 million a year. Initially, Halcygen was considering introducing its generic version which has been formulated to deliver the same active ingredient at half the dose. Now the company is considering whether to aim for improved safety claims with its super generic with a view to causing a dramatic shift in the current market dynamics.

The drug candidate was licensed from **Mayne Pharma (Hospira)** which re-engineered the manufacturing of the drug to significantly improve its absorption in the body. Sporanox has a low absorption profile with the excess active drug not absorbed causing gastrointestinal side effects such as nausea (11% of people) and diarrhea (4%). The drug also needs to be taken with a high fat meal to facilitate absorption.

Halcygen and Mayne Pharma have completed eight pharmacokinetic (PK) studies (absorption and duration profiles in the blood stream) showing that its version of the drug can achieve the same PK profile using only half the dose. This has the capacity to significantly reduce side effects with the drug. This is particularly important in patients who are high absorbers.

Black Box Warning for Sporanox

The drug has a black box warning from the FDA on the use of Sporanox due to deaths linked to the drug. The drug is not to be administered to people with chronic heart failure.

Between 1992 - 2001, the FDA believes that Sporanox contributed to or may have been the cause of chronic heart failure in 58 patients with deaths reported in 13 cases, although there were confounding factors. As of March 2001, the FDA was aware of 24 cases of liver failure associated with Sporanox use.
(see www.fda.gov/CDER/drug/advisory/sporanox-lamisil/advisory.htm)

It is a very reasonable assumption that reducing the dosage of itraconazole would likely reduce both minor and serious adverse events associated with this drug. The question for Halcygen now is whether the company needs to conduct a 600 person Phase III trial, which would take around one year and cost less than $10 million, or whether by simply showing similar blood levels to Sporanox that the assumption could be made that a half dose of the active ingredient would imply safety benefits.

Phase II Trial Underway

In March this year Halcygen initiated a 91 patient Phase II trial in patients with onychomycosis (fungal infection) of the toenail. The trial is recruiting patients across four centers in the USA (Florida, Idaho, Oregon and South Carolina) with 13 patients recruited to date.

This trial will compare a half dose of itraconazole (100mg of Halcygen's SUBA-Itraconazole) taken before breakfast against a full dose of Sporanox (200mg of Itraconazole) taken with breakfast. There will also be a placebo group. Patients will be treated for 12 weeks with a 12 week follow-up period.

Cont'd over

Efficacy at 24 weeks will be the primary endpoint, although there may also be some information on the relative safety of drugs. Results are expected towards the end of this year. The trial will cost US$1.2 million to conduct.

Paradigm Shift for Itraconazole Use?

There are some serious safety issues around Sporanox use, albeit in a very small number of patients. A half dose form of Itraconazole that delivers the same amount of active pharmaceutical product into the bloodstream should be very well received by regulators. The potential benefit of this drug is heightened in those patients who are the one in 20 patients who are 'super absorbers' of Sporanox where the risk for serious side effects could be far greater with increased spiking events. A drug such as SUBA-Itraconazole with twice the absorption levels should also deliver more consistent treatment levels of the active drug to the patient. Fore this reason the Phase II trial may deliver some beneficial efficacy results over Sporanox together with a better safety profile.

But does Halcygen's drug have the potential to cause a major change to the itraconazole market? The current annual market for itraconazole is worth US$600 million a year, with US$90 million of that in the USA, $100 million in Europe, US$150 million in Japan and around US$45 million in Korea. In the USA there are only two main versions of itraconazole because of the level of difficulty in manufacturing the drug. Eon Labs and Janssen (Sproanox) have secured almost 50% each of that market.

If there is a paradigm shift on the safety issue of itraconazole use, leading to adoption of a safer half dose form, then Halcygen will be looking for a global deal with its product to try and gain at least a 30% market share. If it will be sold as a half dose form with no specific safety or efficacy claims, them more regional deals may be more likely.

Regulatory Pathway

The outcome of the current Phase II trial and discussions with European regulators with be a pivotal point for the company. If Halcygen will be in a position to file in Europe for approval within 12 months with safety claims then it may force discussions on a global licensing deal. Whether the FDA and will require a Phase III study is unknown at this stage but there may be a greater chance that a Phase III study will not be required in Europe.

If Halcygen signs smaller, regional licensing deals, then it will prevent one global licensing deal being transacted. If Halcygen can achieve the safety claims in Europe, then a paradigm shift in usage of itraconazole for the safer SUBA-Itraconazole form may be possible.

There are several 'ifs' for Halgygen at the moment, with the company sensing that the potential for global use of its drug may be far greater than first expected. However negotiating through the regulatory pathways is the key risk for the company right now.

Potential Royalty Outcome

Halcygen could stand to receive around 25%-30% royalty from sales, with one third of this going to Mayne Pharma (unless Mayne secures a manufacturing role). Gaining only one sixth of the global market represents a potential US$16 million - US$20 million royalty income. For Halcygen which is capitalised at $14 million, there is considerable upside.

Halcygen remains well funded with $9.3 million in cash at the end of last year and with an annual burn rate of $6 million a year.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Atcor Medical Generating Strong and Positive Cash Flows

Atcor Medical delivered a positive cash flow in the first quarter of 2009 of $924,000. The strong cash flow in this quarter is not surprising given the high increase in trade debtors in the first six months of this financial year from $1.9 million to $4.2 million at the end of last year.

Over the last three months the company has generated new contracts valued at $3.2 million, which is consistent with the company looking to exceed sales in this financial year of $10 million (over 55%).

The clinical data regarding the increasing acknowledged benefit of the measurement of central blood pressure (which reflects arterial stiffness) from the use of Atcor's global gold standard for this test (non-invasively) continues with the second article in recent months highlighting the benefit of using the company's Sphygmocor test to predict and in the treatment of pre-eclampsia (pregnancy-induced hypertension).

The latest study shows that the Atcor device can detect changes in blood pressure in women with pre-eclampsia, changes that could not be detected using the standard cuff pressure. The previous article indicated that the Sphygmocor test could predict 70% of all pre-eclampsia cases. Pre-eclampsia is responsible for hundreds of thousands of deaths annually in mother and unborn babies.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Avita Medical - Will ReCell Get a Second Chance?

Avita Medical was formed last year through the merger of Clinical Cell Culture (C3) and Visiomed Group. C3 brought with it the spray-on-skin wounding healing technology (ReCell) and $10 million in cash, and Visiomed Group two asthma drug spacers, one for children (Funhaler) and one for adults (Breath-A-Tech).

The drug spacer products are now a profitable division, generating sales of around $2.5 million a year. The products are sold through distributors. Sales have increased about 80% in the last year although long term this business has moderate growth opportunities. There is the potential to use these devices for the delivery of other pharmaceuticals as well.

Cont'd on page 6

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Polartechnics and Fermiscan Propose Merger

Two Sydney-based diagnostic companies, Fermiscan Holdings (FER: $0.19) and Polartechnics (PLT: $0.13), have announced a scrip-for-scrip plan to merge the two companies. The merger will be effected by Polartechnics making an off-market offer for all of Fermiscan's shares, with Polartechnics offering three ordinary shares for each Fermiscan share. On a pre-merger basis there are 241.9 million Polartechnics ordinary shares outstanding and 143.5 million Fermiscan ordinary shares outstanding. A principal term of the offer is that Polartechnics achieves 90% of acceptances.

The bid has been recommended by the boards of both companies, and it is proposed that the merged entity be renamed **Novus Diagnostics**.

Rationale for the Merger

To build critical mass in women's health diagnostics

Fermiscan and Polartechnics both operate in the field of women's health diagnostics. Polartechnics markets the Truscreen product and is developing the Cerviscreen product.

Truscreen is electro-optical technology used as a real time analysis and screening tool for cervical cancer and pre-cancerous lesions. Another product, Cerviscreen, is a self sampling kit (the Genswab sampler) that can be used for the detection of HPV infection. Polartechnics has partnered with **Genera Biosystems** to access an advanced HPV detection and genotyping technology and **Healthscope** to enable access to pathology laboratory services (**Gribbles**) to process the samples. Cerviscreen is an attractive concept because it may open the way for women who either neglect to conduct regular pap smears or do not like pap smears being taken by a healthcare professional and would take advantage of the opportunity to self sample, even if done in a physicians consulting room.

Fermiscan is developing a non-invasive breast cancer detection technology which makes use of hair samples as the test 'tissue'. Hair samples are sent to synchotron facilities where X-ray diffraction patterns are produced and which are then used as tests for the presence of breast cancer. This detection may have the potential to become adjunct or even alternative to breast cancer mammography screening. Fermiscan has established a commercial user agreement at the Australian Synchrotron at Clayton, Victoria. Fermiscan also acquired the **Sydney Breast Clini**c in 2008, which brings a 10,000 referred patient group within direct reach of the company.

Merger of the two companies would create a company with increased mass and capabilities, with the potential to sell more products to similar sets of customers who require women's health diagnostic and screening technologies.

Marketing benefits

Fermiscan is less developed than Polartechnics from a marketing perspective. Polartechnics has been actively marketing its products and technologies for some time. Polartechnics is currently marketing products in Australia and New Zealand, the United Kingdom, Ireland, China, Korea, Taiwan, India, Greece, Hungary, Turkey, Egypt and UAE. At the same time Fermiscan recently established a commercial relationship with **Hitachi** in Japan, with Japan a missing piece in the Polartechnics list of territories, and Fermiscan has established interest in its screening technology in Italy. The Fermiscan test has yet to be approved, with a European CE mark being sought in 2009.

Corporate – cost savings and board

Management expects the combined entity to immediately generate savings on corporate overheads with the lease on the Fermiscan property running out in mid year and staff can be relocated to the Polartechnics site at Esrkinville. An additional benefit that should accrue to the company is that an improved standard of governance can be expected from an enlarged board, which will include all existing board members. Both boards each comprise three members; on the Polartechnics board are Robert Hunter, Ben Dillon and Neville Hacker, and on the fermiscan board sit Gary Garton, David Young and Ronald Shnier. An opportunity will also exists for the board to be adjusted as the merged entity evolves and matures.

Cash for Polartechnics

A very compelling reason for Polartechnics to merge with Fermiscan is that Fermiscan has superior cash resources. As of December 31, 2008, Fermiscan declared cash at hand of $7.5 million. In contrast, Polartechnics' cash resources amounted to $870,000. Polartechnics net operational cash flows for the half year ending December 31, 2008 were -$4.2 million. In other words, Polartechnics cash position is dire.

Although Fermiscan experienced a large reduction in its cash balance for its financial year ending December 31, 2008 of $13.5 million, it does have 34.1 million 30 cent options which expire on October 9. Should the two companies successfully create a stronger business and stimulate positive investor sentiment, there is the possibility that these options could generate up to $10 million in shareholder contributed funding.

Comment

The proposed merger between Polartechnics and Fermiscan is a positive move for both companies. The objective of developing a critical mass is worthy and appropriate, and a number of corporate overheads, for example where they relate to listing costs, will be reduced as a consequence.

The move is ideally timed to tap into shifts and trends in diagnostics and healthcare where patients and payors are seeking new technologies but improved ways of organizing the collection, flow and dissemination of personal biological information.

If the merger is successful and the merged entity successfully consolidates both businesses, then the opportunity may exist in due course for additional businesses that could also benefit from scale to be absorbed into the firm.

An issue for companies that aim to develop screening technolo-

Cont'd over

gies is the trade-offs that must be made between cost and economic benefit, availability and accessibility, patient acceptability and convenience, and clinical performance and acceptance by public health policymakers. Screening technologies must be scalable if the desire is to address large population sets. The point is that finding the sweet spot that meets the demands from each of these groups is quite challenging and certainly time consuming. A weakness with the Fermiscan screening technology is its reliance on synchrotron facilities, of which there are perhaps twenty around the globe, and which generally are devoted to academic and industrial research. For the Fermiscan screening tool to achieve optimal outcomes additional commercial relationships with other synchrotron facilities must be developed so that the business has more certainty and reliability of supply. It has very good access to the Australian synchrotron facility.

Going forward, the merged entity will need to address the allocation of the CEO role. As it stands the respective incumbent CEOs Ben Dillon and David Young will be taking on executive roles, with the CEO position yet to be determined.

Summary

The proposed merger between Polartechnics and Fermiscan is to be welcomed as it looks to offer reasonable benefits to shareholders of both companies, is based on merging businesses with a similar patient or customer focus, and potentially creates a merged entity with reduced risk profile and a strengthened ability to achieve commercial goals.

Bioshares

Avita – from page 3

The real upside in this company is from escalating the demand for the ReCell product.

The product is sold through distributors. It can be a trial and error process selecting the right distributors and if the distributors are not supported adequately, which has been a problem in the past for this product, product sales can fall away and interest can wane.

The ReCell product has been on the market now for several years with annual sales estimated at still less that $1 million a year, although sales have more than doubled in the last year. The product has been re-released in Australia under a new distributor and is going well. In France the product is generating good interest, with a 2.1 million Euro grant from the French Ministry of Health to investigate the product's use to reduce medical costs with the treatment of burns in a 200 patient study.

France is the leading market for the company for ReCell at the moment. A new distributor with better company support is progressing well with six surgeons signed on to using the product, two of these being strong users. The product is also being used regularly in at least two hospitals in Australia.

Over the next two years the company will seek to get the product approved in the US. The company has been cleared by the FDA to proceed with a revised trial protocol. There is a strong interest in regenerative medicine in the US which is helping drive interest in this technology in that market.

In the US the company plans to sell the product with a combination of a direct sales force (4-5 people) and distributors. The main issue with the company is the funds it has and is prepared to invest into commercialization of the ReCell product. Avita had $5.3 million at the end of March this year. Its burn rate is about $4 million a year. This will be reduced significantly over the next nine months, although there will be an increase in clinical trial costs in the US.

The company will need to show strong signs of progress with the ReCell product over the next 12 months to warrant continued investment in this product line. The company has the benefit of an underlying profitable respiratory products business should the progress on ReCell product prove unsuccessful or too difficult to commercialise.

Bioshares recommendation: **Speculative Hold Class C**

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Bioshares Model Portfolio (24 April 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	$0.35	$0.30	December 2008
QRxPharma	$0.48	$0.25	December 2008
Hexima	$0.39	$0.60	October 2008
Atcor Medical	$0.22	$0.10	October 2008
CathRx	$0.68	$0.70	October 2008
Impedimed	$0.74	$0.70	August 2008
Mesoblast	$0.79	$1.25	August 2008
Cellestis	$2.85	$2.27	April 2008
IDT	$1.58	$1.90	March 2008
Circadian Technologies	$0.80	$1.03	February 2008
Patrys	$0.07	$0.50	December 2007
Bionomics	$0.23	$0.42	December 2007
Cogstate	$0.20	$0.13	November 2007
Sirtex Medical	$3.00	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.34	$0.66	September 2007
Starpharma Holdings	$0.30	$0.37	August 2007
Pharmaxis	$2.13	$3.15	August 2007
Universal Biosensors	$0.80	$1.23	June 2007
Biota Holdings	$0.89	$1.55	March 2007
Probiotec	$1.76	$1.12	February 2007
Peplin Inc	$0.60	$0.83	January 2007
Arana Therapeutics	$1.38	$1.31	October 2006
Chemgenex Pharma.	$0.41	$0.38	June 2006
Cytopia	$0.10	$0.46	June 2005
Acrux	$0.62	$0.83	November 2004
Alchemia	$0.35	$0.67	May 2004

Portfolio Changes – 24 April 2009

IN:

No changes

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C
Sell

Corporate Subscribers: Phylogica (note, accidently omitted from this list from Eds 297 onwards), Pharmaxis, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical