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Bioshares

9 May 2014
Edition 550

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Companies covered: CYP, IIL, IMC, LCT, PVA, RHS, UCM

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - Current)	26.6%
Cumulative Gain	**351%**
Av. annual gain (13 yrs)	**17.3%**

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Specialised Therapeutics Australia Takes on pSivida's Iluvien Eye Drug

pSivida's (PVA: $3.50) licensee Alimera Sciences has signed a distribution deal with Specialised Therapeutics Australia (STA) to sell Iluvien in Australia and New Zealand. pSivida will be entitled to a 20% royalty stream as well as 33% of any other payments that Alimera receives. STA will be responsible for managing regulatory approvals in these countries.

What makes this deal important is not just that Alimera is expanding its distribution markets, but also that STA is a very dynamic local pharmaceutical company that sees considerable value in this product. STA was founded by Carlo Montagner, who held a senior position with Abraxis Bioscience, which was sold to Celgene for US$3.2 billion in October 2010 .

Alimera resubmitted its New Drug Application to the FDA in March this year, with additional safety data from commercial use of the product in Europe, where the product is approved for the treatment of chronic diabetic macular edema, in patients who are insufficiently responsive to available therapies. Sales in the December quarter for Iluvien were only US$935,000. However, growth is starting to occur with US$2.1 million of sales in the March quarter. The product is currently being sold into Germany and the UK, where it sells for ~£5,500.

Another endorsement of the company came in March when the specialist life science investment group RA Capital approached the company to invest US$7 million into pSivida. Of interest to RA Capital is the further application of pSivida's Tethadur biodegradable silicon technology that allows delivery of large molecules such as antibodies and peptides into the eye for controlled long term release.

The advantages of the Iluvien product over blockbuster eye drugs such as Eylea and Lucentis is that it provides controlled drug release over three years, compared to Eylea which is injected once every two months and Lucentis which is injected monthly. One of the risks with Iluvien is the incidence of increased intra-ocular pressure.

In the US, pSivida has initiated a 120 patient Phase III study with its Medidur product for the treatment of posterior uveitis. It is also planning a second Phase III trial, with both trials to enroll a total of 300 patients. Medidur is technically equivalent to Iluvien, containing the same corticosteriod with the same delivery vehicle.

pSivida is capitalised at $104 million. The company has an estimated US$17 million in cash. Should Iluvien gain FDA approval, pSivida will be entitled to a US$25 million milestone payment.

Bioshares recommendation: **Speculative Buy Class A**
pSivida has been added to the Bioshares Model Portfolio.

5 Stock Wrap

Company	Uscom	**Code**	UCM	**CMP**	$0.29	**Cap'n ($M)**	$21.9	**Cash ($M) 31/3**	$0.4	**SI**	**0.2**

- Uscom markets a non-invasive cardia monitor, the USCOM 1a, which measures blood flow across the heart valves using Doppler waves
- UCM acquired NZ company Pulsecor in June, to obtain its Cardioscope BP+ central blood pressure measurement device
- Cardioscope BP+ competes with products from Atcor Medical, Healthstats International, I.E.M Gmbh, Tensiomed and BP Labs
- Cardioscope BP+ is a suprasystolic oscillometer; Atcor Medical's Sphygmocor is a radial artery applanation tonometer
- Central blood pressure measurement is emerging as the gold standard for the preferred measurement of blood pressure
- Announced results of study in the *Am. Journ. of Hypert.* which compared BP+ favourably with Atcor Medical's Sphymgmocor, in children
- A Cambridge University study rated the BP+ as the highest rated BP+ device
- Has appointed MedCaT as its distributor of the BP+ for the Netherlands, SMT for Germany, Avalon Medical for Norway and Sweden
- Uscom's 5 year US$7 million sales arrangement for the USCOM 1a is not expected to start until 2015

Comment: UCM's cash has been boosted by a $0.372 M tax refund but working capital requirements look to be an immediate challenge

Bioshares recommendation: **Take Profits** | Timing -

Company	Cynata Therapeutics	**Code**	CYP	**CMP**	$0.355	**Cap'n ($M)**	$16.0	**Cash ($M) 31/3**	$5.7	**SI**	**3.5**

- Cynata's Cymerus technology uses induced pluripotent stem cells and mesenchymoangioblast stem cells to create a range of cell types
- Cymerus can deliver both therapies and a manufacturing method. Recently partnered with Waisman Biomanufacturing
- The technology's advantage is an 'unlimited' ability to expand specific (e.g mesenchynal) stem cells from a single donor
- The technology could be of benefit to many smaller companies seeking a scalable manufacturing platform
- Cynata is initiating a Phase I trial in Graft-versus-host disease (a template indication for mesenchymal cell therapies)
- The goal of the trial is to evaluate efficacy as well as validate the manufacturing platform
- Mesenchymcal cell therapy trials are growing (~200), implying a growth in demand for robust manufacturing approaches
- A risk for the field of cell therapies is that products and processes will be challenged by competitors on a 'freedom to operate' basis

Comment: Cynata is a high risk, long term play. However, its manufacturing platform is a potential source of significant value, if validated

Bioshares recommendation: **Speculative Buy Class B** | Timing -

Company	Immuron	**Code**	IMC	**CMP**	$0.005	**Cap'n ($M)**	$9.7	**Cash ($M) 31/12**	$0.4	**SI**	**0.2**

- Immuron listed in 1999 under its then name Anadis. The company has brought Travelan, a traveller's diarrhea product to market
- The company develops products by immunising dairy cows and then harvesting polyclonal antibodies that result, from colustrum milk
- The company recently completed a $9.6 M rights issue, which was underwritten by Patersons Securities
- The funds will be used to commence a long awaited trial of IMC-124E in Non-alchoholic Steatohepatitis (NASH), and pay off $1.5M in debt
- The company's $1.5 M debt to Paladin has now been paid back
- A key milestone ahead for Immuron will be the filing, and then acceptance of an IND for IMC-124E
- NASH is a major global therapeutic opportunity, with no approved treatments and a market fed by trends in obesity and diabetes
- With almost 2 billion shares on issue, a timely consideration for the company will be to effect a share consolidation

Comment: IND clearance by the FDA will a transformational event for Immuron and form the basis for a re-rating of the stock

Bioshares recommendation: **Speculative Hold Class B** | Timing - Wait for IND clearance

Company	Reproductive Health Sciences	**Code**	RHS	**CMP**	$0.220	**Cap'n ($M)**	$10.4	**Cash ($M) 31/3****	$0.3	**SI**	**1.8**

- Reproductive Health Sciences listed on the ASX on April 22, 2014, using AO Energy as a backdoor vehicle. ****Raised $3 million (post 31/3)**
- RHS has developed a pre-implantation genetic screening (PGS) step for the IVF (in vitro fertilization) process i.e. assisted reproduction
- The technology permits the counting of chromosomes inside single cells - the wrong number can lead to mis-carriage or birth defects
- The purpose of the technology is to contribute to decreasing the 70%-80% failure rate for IVF cycles
- A driver for IVF is the increase in the median age of mothers, coupled to fertility declining as age increases
- While PGS is used in an estimated 2% of IVFcycles, growth rates for IVF cycles globally is expected to grow at 10% p.a.
- RHS has partnered with Kappa Biosystems to manufacture and market testing kits, for sale into the global IFV market
- Company is completing validation studies of its microarray formatted kit, the results of which will be published in a peer reviewed journal
- An appeal of the business is limited competition and ease of access for marketing via journals and conferences to the customer base

Comment: Although RHS is an uncomplicated business from a product and opportunity pov, achieving product apdoption will take time

Bioshares recommendation: **Speculative Hold Class B** | Timing - Wait for publication of validation studies

Company	Living Cell Technologies	**Code**	LCT	**CMP**	$0.089	**Cap'n ($M)**	$31.8	**Cash ($M) 31/3**	$4.76	**SI**	**NA**

- Living Cell Technologies is developing porcine islet cells (DIABECELL) to treat Type 1 diabetes
- The cells are encapsulated to prevent immune rejection and are transplanted into the abdomen to boost insulin production
- Program has been funded since 2011 as a 50:50 joint venture (Diatranz Otsuka Limited (DOL) with Otsuka Pharmaceutical Factory
- Announced restructure in April, which saw 55 staff transferred to DOL
- Also transferred were pre-clinical, clinical development, manufacturing, pig husbandry, QA and admin functions
- LCT continues with oversight of Phase I trials of NTCELL for Parkinson's diseases and other pre-clinical projects
- LCT retains its 50% interest in the joint venture, including a 50% share of future profits
- Service fee income relating to the JV is now expected to decline, imposing funding requirements for the NTCELL as it moves forward
- The basis by which LCT will access the JV for its product requirements is not clear

Comment: The transfer of unique animal assets and facilities into the DOL joint venture without compensation is an investment negative

Bioshares recommendation: **Sell / Coverage Ceased** | Timing -

Notes: PE - Price/Equity ratio SI - Survival Index (refer to Bioshares 549 for explanation)

Innate Immunotherapeutics On Track To Commence Phase IIb Trial in MS

Innate Immunotherapeutics (IIL: $0.18) is on track to start its Phase IIb trial in Australia with its lead drug candidate, MIS416, for the treatment of secondary progressive multiple sclerosis.

That trial is due to begin towards the end of June with 90 patients to be enrolled. MIS146 is a biologically derived immune system modulator. MS is caused by the immune system attack on the myelin sheath protecting the nerve fibres.

Innate is continuing to provide treatment to a number of patients (17 at last record) in New Zealand under a compassionate use program. What is appealing about this technology is that there is good evidence of a significant improvement in the symptoms of most patients who are receiving therapy under a compassionate use program who have secondary progressive MS.

Drivers for this stock going forward will be updates on the progress of patients receiving therapy under the compassionate use program, the start of the Phase IIb study, and the rate of recruitment into the study, which is expected to be rapid. The company expects to have the trial 50% recruited within three months after starting the trial.

This trial will be the first time that the therapy is will be compared against a placebo, with 60 patients to be treated with MIS416 and 30 to receive placebo. It is expected that the trial will take six months to fully enroll, and patients will be on treatment for 12 months. Objective data comparing the effect of the drug and a placebo will be the key information the potential partners will be seeking at the end of the Phase IIb trial.

At the end of March, Innate had $7.9 million in cash. The company is fully funded to get to the end of the Phase IIb study. Innate is capitalized at $29 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Bioshares Model Portfolio (9 May 2014)

Company	Price (current)	Price added to portfolio	Date added
pSivida	$3.800	$0.089	May 14
Invion	$0.061	$0.089	February 14
Impedimed	$0.195	$0.245	December 13
Analytica	$0.033	$0.025	December 13
Imugene	$0.010	$0.022	November 13
Oncosil Medical	$0.100	$0.155	September 13
IDT Australia	$0.270	$0.260	August 13
Viralytics	$0.270	$0.300	August 13
Tissue Therapies	$0.300	$0.255	March 2013
Somnomed	$1.46	$0.94	January 2011
Cogstate	$0.300	$0.13	November 2007
Universal Biosensors	$0.36	$1.23	June 2007

Portfolio Changes – 9 May 2014

IN:

pSivida has been added to the Model Portfolio

Recommendations: PVA - **Speculative Buy Class A**

OUT:

No changes

Recommendations:

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. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

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: Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Antisense Therapeutics, Benitec BioPharma, Admedus, Calzada, Invion, Circadian Technologies, Imugene, Analytica

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