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Bioshares

6 June 2014
Edition 554

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

Companies covered: CGS, RHT, Orthocell IPO Profile

	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 - May '14)	26.6%
Year 14 (May '14 -)	-1.3%
Cumulative Gain	**344%**
Av. Annual gain (14 yrs)	**16.0%**

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Orthocell IPO Profile

Perth-based regenerative medicine company Orthocell is seeking to raise up to $8 million through an IPO, with the company offering 20 million shares at 40 cents. The minimum subscription the company is seeking is $6 million. The indicative capitalisation of the company on completion of the IPO is $33 million.

The joint lead managers of the offer are KTM Capital and Azure Capital, with Shaw Capital acting as co-manager. The offer is not underwritten.

The company was founded in Perth in 2006 and employs 15 people. The company's board comprises of Dr Stuart Washer (Executive Chair), CEO Paul Anderson, Qi Xiao Zhou, Professor Lars Lidgren and Matthew Callahan. The company was founded by Paul Anderson and CSO Professor Ming Hao Zeng.

Products: Ortho-ATI, Ortho-ACI and CelGro

Orthocell has developed and brought to market in Australia, Ortho-ATI (autologous tendocyte injection) and Ortho-ACI (autologous chondrocyte injection).

Ortho-ATI is intended for the repair of tendons and ligaments. Orthocell will seek regulatory approval for Ortho-ATI in either Japan or Europe followed by the USA.

Ortho-ACI is intended for regeneration of damaged cartilage. More than 250 patients in Australia have paid to be treated with Ortho-ACI. Orthocell does not plan to commercialise Ortho-ACI outside of Australia. However, Ortho-ACI has been licensed to a Chinese company, Grandhope Biotech Co Ltd, which has the rights to commercialise the product in China. Orthocell is entitled to a 3.5% royalty on net sales.

The company is also developing CelGro, a scaffold derived from porcine collagen, which has the potential to be used for the surgical repair of tendon tears and detachments and the reconstruction of damaged or missing tissue such as ear drums, or repair of hernias, vaginal walls and pelvic floor defects. Orthocell believes its collagen scaffold offers the necessary mechanical strength as well as being more conducive to host tissue integration than competing biological products.

Orthocell intends to sell CelGro direct in Australia and find a partner for distribution into international markets.

Clinical Trials

Orthocell has completed two small trials with Ortho-ATI in 12 patients with tennis elbow and 17 patients with gluteal tendinopathy. Some initial results from these open label studies suggests that the product is clinically useful. A larger 90 patient randomized, blinded study conducted at Erasmus University in Rotterdam, The Netherlands, is expected to deliver full results in 2014 Q3. A table setting out Orthocell's clinical programs can be found on the page 4.

Cont'd on page 3

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Current Speakers & Panellists

Paul Anderson – CEO Orthocell
Bob Atwill – CEO Cytomatrix
David Blake – Editor, Bioshares
Matt Callahan – Director, Orthocell
Rick Carreon – CEO Impedimed
Bob Crane – CFO GI Dynamics
Jackie Fairley – CEO Starpharma
David Fisher – Exective Director, GI Therapies
Neil Frazer – CEO Oncosil Medical
Peter French – CEO Benitec Biopharma
Mark Heffernan – CEO Nexvet
Michael Johnson – CEO Rhinomed
Michael Kavanagh – CEO Nanasonics
Philippa Lewis – CEO Simavita
Ross Mangelsdorf – Director, Analytica
John Martin – Executive Chairman, Regeneus
Malcolm McColl – CEO Viralytics
Ross McDonald – CEO Cynata Therapeutics
Amos Melzer – CEO Immuron
Matthijs Smith – Analyst, Cannacord Genuity
Alan Taylor – Executive Chairman, Clarity Pharmaceuticals
Brad Walsh – CEO Minomic International
Simon Wilkinson – CEO Innate Immunotherapeutics

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Orthocell intends to strengthen the clinical evidence backing Ortho-ATI by conducting trials specifically addressing patients with tennis elbow, and patella (knee), gluteal and rotator cuff tendinopathies which are resistant to other treatments. These trials will be essential to the company's goal of expanding the market for Ortho-ATI.

These trials may not be initiated as planned if the full amount from the company's IPO is not secured. The designs of the trials has not been made available; however, they should all be (where relevant) blinded, randomized, placebo-controlled trials to ensure that the results are sufficiently robust and can be used in support the marketing of Ortho-ATI.

The company commenced, in February, a 15 patient open label trial of its CelGro Collagen Bioscaffold in patients requiring repair of a perforated ear drum.

Intellectual Property

Orthocell has five families of patents which provide protection for its products, although the company makes use of trade secrets to further protect its products. Its patents are titled 'Tenocyte Culturing Method', 'Tenocyte Containing Bioscaffolds', 'A Collagen Scaffold for Cell Growth and a Method for Producing the Same', 'Method of Tissue Repair' and 'Method for Producing A Collagen Membrane and Uses Thereof'.

The company's earliest patent, 'Tenocyte Culturing Method', has been granted in the Australia, New Zealand, Singapore and the USA. This patent expires in 2027.

This patent claims the use of insulin, betamethasone, antibiotics and media to culture tenocytes, which are sourced from tendon tissue.

Strengths

One of the strengths of the Orthocell investment proposition is that not only has Orthcell begun the clinical evaluation its autologous cell therapy products but it has also seen these same products taken up on a commercial basis. The record of 250 Ortho-ACI procedures completed on a commercial basis supplies evidence that Orthocell is a commercially focused and capable organization.

Autologous therapies such as Ortho-ATI and Ortho-ACI offer the benefit common to all autologous therapies: that of greater safety compared to allogeneic therapies, which carry the risk of immune rejection (although it is argued that some allogeneic products are made from cells which are immune privileged.)

Weaknesses

One of the features of cell therapy products is that they are tied to specific licensed manufacturing facilities. For autologous cell therapies, harvested tissue or material which contains cells of interest for expansion, must be processed at such an approved facility before the expanded cells can be returned to the point of care for injection into the region of the patient requiring treatment.

Such an arrangement can become a challenge to manage in the context of logistics and handling on a global basis, in terms of processing capacity, and in terms of regulatory oversight (by multiple agencies) of facilities. How these challenges will be addressed by the company and how company will address the COGS of product processed from a single Australian site is an issue for investors to consider.

(It should be noted that these challenges to do apply to Orthocell's CelGro, a processed surgical tissue product, which can be exported globally on a finished product basis, assuming all regulatory and manufacturing approvals are in place.)

Another challenge for Orthocell is that its manufacturing processes for CelGro have not been scaled up.

Opportunities

The market opportunities for Ortho-ATI are considerable, e.g. 1-3% of the US population suffer from tennis elbow and 250,000 rotator cuff operations occur annually in the USA. The Ortho-ATI could be applied both pre- and post- surgery of the rotator cuff.

Threats

Orthocell does not have a uniquely competitive position covering the treatment of tendons and cartilage. Other regenerative medicine companies may yet bring to market (if not already in some markets) products that offer superior results, or are more attractive in terms of processing steps and duration (e.g. are processed more quickly than the 4-5 weeks taken for Orthocell's products), or harvesting and implantation steps or in terms of the total cost of a treatment.

Regulatory Status in Australia – An Outstanding Risk

Ortho-ATI and Ortho-ACI were formerly regulated through the Therapeutic Goods Administration's cGMP license regulations. Following changes to the regulatory regime covering biological products, Ortho-ATI and Ortho-ACI must now be listed on the Australian Register of Therapeutic Goods. Such listings have required Orthocell to submit design dossiers to the TGA for Ortho-ATI and Ortho-ACI, as Class III biological devices.

The company has yet to receive TGA approval for Ortho-ATI and Ortho-ACI for listing on the ARGT, leaving these approvals as an outstanding risk for investors.

Once the TGA approval has been received and the data from the Rotterdam Achilles Tendon randomised trial is available, Orthocell intends to submit a reimbursement application to the Commonwealth Department of Health and Aging.

Key Dates

Opening Date: June 5, 2014
Closing Date: 27 June, 2014
Expected Trading of Shares: 16 July, 2014

A copy of the prospectus can be downloaded from http://www.orthocell.com.au

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Orthocell Clinical Trials

Ortho ATI (Autologous tenocytes injection)

Completed

Limb/Tissue /Joint	Name or Code	Phase	Num Pts	Design	Dose	Assessment Points (Post-treatment)	Commence	End/ or Report	Outcomes
Tennis Elbow (Lateral epcondilitis)	ACTRN12607000402448	Phase I/II	Planned (30); Actual (12)	Open label, single arm	2 ml of 3x 10^6 cell/ml	*1,3,6,12 months*	2007	2008	VAS pain score improved by 86% at 12 months;Grip strength improved by 133% at 12 months*
Gluteal Tendon	ACTRN12612000383864	Phase I/II	Planned (20); Actual (17)	Open label, single arm	2 x 10^6 cells	*3,6,12, 24 months*	May-12	2013	At 12 months, 67% of patients reported being satisfied or highly satisfied with treatment**

** 24 month data was published in Amer Journ Sports Med Oct 2013; Data at 3 years is being prepared for publication*

** Data is being prepared for publication*

Results Pending

Limb/Tissue /Joint	Name or Code	Phase	Num Pts	Design	Dose	Assessment Points (Post-treatment)	Commence	End/ or Report	Endpoints
Chronic Achilles Tendon	EudraCT 2010-021869-73 [also NCT01343836 ??]	Phase II/III	90	Double-blind, placebo		*24 weeks*	Jan-11	Q3 2014	VISA - A Score; pt satisfaction; return to sports; ultrasonograchic evaluation

Planned

Limb/Tissue /Joint	Name or Code	Phase	Num Pts	Design	Dose	Assessment Points (Post-treatment)	Commence	End/ or Report	Endpoints
Resistant Tennis Elbow (Lateral epcondilitis)	The designs for these trials have not yet been published						Q3 2014		To show that Ortho-ATI is a safe and effective procedure that reduces pain and improves function
Resistant Patella (Knee) Tendinopathy							Q4 2014		To show that Ortho-ATI is a safe and effective procedure that reduces pain and improves function
Resistant Gluteal Tendinopathy							Q4 2014		To show that Ortho-ATI is a safe and effective procedure that reduces pain and improves function
Resistant Rotator Cuff Tendinopathy							Q2 2015		To show that Ortho-ATI is a safe and effective procedure that reduces pain and improves function **prior to**

Celgro Collagen Bioscaffold

Underway

Limb/Tissue /Joint	Name or Code	Phase	Num Pts	Design	Dose	Assessment Points (Post-treatment)	Commence	End/ or Report	Endpoints
Repair of Symptomatic Ear Drum Perforations	ACTRN12614000532606	Phase I/II	15	Open Label		Weekly for one months then at 3, 6, 12 months	Feb-14		Safety/efficacy; audiology assessment that measures frequency threshold, pure tone average and air-bone Gap

A Disappointing Year for Cogstate

Cogstate (CGS: $0.245) has announced a disappointing expected result for FY2014. Sales are expected to be down slightly on last year, to $11.4-$12.0 million, but the expected full year loss is expected to be between $4.5 - $5.0 million before tax.

The company recorded a $2.7 million loss in the first half of this financial year. What is disappointing is that the difficult trading conditions have continued into the second half of the financial year following an optimistic forecast in February. The inconsistent contract flow from the provision of clinical trial services and products continues to result in lumpy revenue for the company, which this year will result in a large loss for the company.

Also disappointing for the company was the decision by its marketing partner Merck to stop promoting the Cognigram cognitive testing product to general practitioners in Canada. Cogstate will now sell the product directly into the Canadian market, assuming full revenue from the tests from July 2015.

Cogstate has also announced that it will be selling its Axon Sports training business and has implemented cost reductions across its overall business. The sports business generated revenue of $0.7 million in FY2013 and a net loss of $1.2 million.

New Revenue Stream – Precision Recruitment

Cogstate is forecasting a stronger year ahead from its clinical trials business. The company has $4.2 million of contracted revenue that is expected to be realised in FY2015, and expects to sign sales contracts worth between $6 - $8 million in the next two months. The company is also expecting a new revenue stream to support sales moving forward from what it calls Precision Recruitment.

In the next financial year, the company is forecasting revenue of between $3 - $6 million from the Precision Recruitment service. This new product, which is expected to generate higher margins, is being offered to pharmaceutical companies conducting clinical trials to identify which patients are likely to be suffering from Alzheimer's disease or some type of cognitive impairment.

This enrichment of the patient population being recruited into clinical trials has the potential to increase the statistical powering of clinical studies. It comes from evidence that in major Phase III clinical studies in Alzheimer's disease, around 25% of patients tested for a new Alzheimer's disease drug candidate did not have the disease. By having a greater surety that patients being enrolled into clinical programs actually have the target disease that is being attempted to be treated should reduce costs and help improve trial outcomes.

The Alzheimer's disease trial market is a prime target market for this patient enrichment strategy. One of the reasons is that there has been a move in this area to seek to test drug candidates in patients with earlier stage disease, where the disease should be easier to treat, and where treating later stage patients with Alzheimer's disease has been littered with trial failures. In some of the Phase III trial failures however, some success has been seen when treating those patients who were diagnosed to be at an earlier stage of disease.

Cogstate has shown that its test can detect subtle changes in cognition in patients that it says are asymptomatic. While Cogstate's test has not been approved by the FDA as a validated test for a primary endpoint in Phase III Alzheimer's disease trials, it may be useful in improving the likelihood that the patients actually have the disease before they are enrolled into these studies through this patient enrichment process.

Cogstate is now offering the full service in clinical trials that measure cognitive changes from screening of patients, to recruitment, site training, testing and reporting.

Summary

For Cogstate, the focus now is on getting its core clinical trial business back to profitability and keeping it there. Cogstate is well funded, having raised $8 million in November last year at 37 cents a share.

It continues to build its leadership position in the early detection of Alzheimer's disease using its computer-based test. However it has yet to successfully leverage that technology into a more widely used product, either in dementia screening or in concussion management.

The Precision Recruitment product for patient enrichment into cognition measurement studies will seek to do that and will be a metric to monitor with the company, along with quarterly cash flow and revenue figures.

Cogstate is capitalised at $24 million.

Bioshares recommendation: **Hold**

Bioshares

Bioshares Model Portfolio (6 June 2014)

Company	Price (current)	Price added to portfolio	Date added
pSivida	$4.000	$4.000	May 14
Invion	$0.062	$0.089	February 14
Impedimed	$0.180	$0.245	December 13
Analytica	$0.051	$0.025	December 13
Imugene	$0.011	$0.022	November 13
Oncosil Medical	$0.105	$0.155	September 13
IDT Australia	$0.230	$0.260	August 13
Viralytics	$0.290	$0.300	August 13
Tissue Therapies	$0.330	$0.255	March 2013
Somnomed	$1.50	$0.94	January 2011
Cogstate	$0.245	$0.13	November 2007

Portfolio Changes – 6 June 2014

IN:

No changes

OUT:

No changes

Recommendations:

Resonance Health Assesses Stent Company

Resonance Health (RHT: $0.05) has announced it has signed a non-binding agreement to assess the acquisition of a covered metal stent technology with the potential acquisition of VeuKlar Cardiovascular Ltd. Resonance Health has developed and is selling the Ferriscan product for the non-invasive measurement of iron levels in the liver.

VeuKlar Cardiovascular is developing a covered metal coronary stent. Standard metallic stents can not be imaged using MRI because of the image distortion as a result of the material and radio interference. Stents are implanted with the assistance of contrast media and X-ray, however there is the risk of kidney damage as a result of the injected contrast media used.

The material that VeuKlar Cardiovascular uses allows MRI to be used without distortion, achieving three to four times improved contrast in the image according to the company. This improved imaging also has the potential to look at restenosis and thrombosis.

The core technology from VeuKlar Cardiovascular has the potential to be used in not just coronary stents but also in catheters, heart valves and other stents.

Resonance Health is generating sales of around $2 million a year from its Ferriscan product, with those sales increasing at around 20% a year. The Ferriscan technology works by taking an MRI of a patient's liver, and then applying a proprietary algorithm to calculate the iron levels. The image can be taken remotely with the analysis conducted by the company at its Perth office.

In December last year, the company gained FDA approval for its next test, HepaFat-Scan, to non-invasively measure fatty liver levels, also with MRI technology. The company received TGA approval to market the device in Australia last month. Fatty liver disease affects around 25% of the western population. The initial market for this test will be for use in clinical trials.

Resonance Health announced it has raised $0.5 million in a placement in April with up to $4.6 million (before costs) to be raised through a non-renounceable rights issue, which closes on June 13. The company had $0.8 million in cash at the end of March and is approaching a breakeven point, with cash out flow in the nine months to March of only $266,000.

The proposed acquisition of Resonance Health is a surprising one, given the known high costs involved in bringing coronary stents to market. A decision on the acquisition is expected in July. More information could be provided by the company to the market on the expected funding costs for the proposed acquisition, and how those costs will be managed by Resonance Health.

Resonance Health is capitalised at $19 million

Bioshares recommendation: **Hold**

Bioshares

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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