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Bioshares

14 February 2014
Edition 539

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

Companies covered: **ALT, AVH, IMU, RNO**

	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)	66.6%
Cumulative Gain	493%
Av. annual gain (13 yrs)	20.4%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)

\$400 (Inc. GST)

Edition Number 539 (14 February 2014)

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Rhinomed – Adoption Of The Turbine Underway

Rhinomed (RNO: \$0.047) is commercialising the Turbine, which is a device inserted into the nose to improve airflow. Rhinomed is following a direct to the consumer approach (similar to Analytica, discussed on page 3), where its products will be sold via the Internet, bypassing the cumbersome multinational distributors that stand at the gateway to the marketing of many or most medical products.

The Turbine works by dilating the nostrils, allowing nearly 40% more air through the nose according to the company.

New Director Appointments

This week the company announced the appointment of two directors, Brent Scrimshaw and Dr Eric Knight. Scrimshaw, an Australian who has returned to Australia, will be a valuable addition to the company, having formerly been Chief Executive for Nike in Western Europe. He worked for Nike for 19 years. The benefit of having someone such as Scrimshaw working with the company is that he may be well placed to work with elite athletes around the world to evaluate and then adopt the product.

His appointment is relevant because the first application of the Turbine is for use in sport. Rhinomed was one of the sponsors of the recent 2014 Tour Down Under cycling event. Cycling is the first sports application for the product, as well as for use by triathletes (in cycling and running). CEO of Rhinomed, Michael Johnson, was pleasantly surprised that not only the product received excellent promotion at the event, but did also the three European teams (all riders) used the Turbine during the event.

The Turbine is sold through cycle shops and also directly through the Internet. The product was released late last year and generated \$8,000 of sales in the first three weeks. The marketing approach the company is using is to get the elite bike riders to adopt the product, who are effectively key opinion leaders. For the top 400 professional riders, Rhinomed will be offering free supply agreements for the product. The return for Rhinomed is that the company will be able to reference the elite riders who, are not getting paid to, but have elected to use the product. Also seeing elite athletes at events such as the Tour de France will deliver valuable global awareness of the product. In cycling the main market is for the serious weekend rider.

Rhinomed recently organised a very effective paid marketing campaign through Facebook. For a cost of \$15,000, the company received 200,000 clicks from people interested in the product. How that translates into sales will be seen over the next two months.

Sleep Assist Application

One of the next applications of the product will be for use during sleep. The product will go up against the very successful BreatheRight nasal strips from GlaxoSmithKline that are placed over the nose. This product went off patent in July last year which will reduce the dominance of this product in the market.

Cont'd over

– *Rhinomed cont'd*

Although the Turbine can be used in sleep, Rhinomed will release a dedicated sleep product in Q3 2014. This product will be a once only use (the Turbine can be used several times), it will be softer, have different pressure points on the nostril, and will be sold through pharmacies.

There is also the possibility the Turbine sleep product could be used in conjunction with CPAP devices to improve performance of the CPAP machines with better airflow through the nose.

An added appeal of the Turbine is that it has first been branded as a tool used by elite athletes.

Other Applications

Other applications include for use in yoga, for use by cyclists after racing to improve sleep, and during recovery times in football (the device is not appropriate for use in contact sports). Fragrances can be added to the device to allow appetite suppression or use in drug delivery.

This week the company announced it would be exploring delivery of the migraine drug Sumatriptan with its Turbine device. The company will conduct bioavailability studies in Australia. The benefit of nasal delivery with the Turbine device is that very quick delivery might be achieved with a constant delivery over a specified time.

IP

Rhinomed has a granted global patent over its technology out to 2018 with 18 patent families or variations around the technology.

Financials

Rhinomed is capitalised at \$16 million. The company had \$1.0 million in funds at the end of last year. It is spending between \$120,000-\$180,000 a month. Rhinomed is seeking to move to a breakeven position as soon as possible. The last capital raisings were conducted at 2 cents and 4 cents a share.

Summary

Rhinomed has in its possession a nasal device which has potential for use in multiple settings. The Turbine offers advantages over incumbent products on the market. The direct to consumer selling approach is an attractive feature of this stock. The company has made excellent headway in building product awareness at a low cost and in a short amount of time with early adoption evident. The stock will be one to watch in 2014.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Can Avita Medical Be Turned Around?

Avita Medical (AVH: \$0.12) markets the 'spray on' ReCell skin regeneration product. The product is approved in Australia, Canada, China and Europe and is being evaluated in the USA. It also manages a second business selling respiratory products, including a medication spacer and the Funhaler, a small volume spacer designed for use with children, in Australia.

ReCell is an autologous cell harvesting, processing and application system for treating small burns and scars and as a cosmetic procedure.

Change of Management

Avita made changes to its board and management late in 2013, which saw long-standing Chairman Dalton Gooding step down in favour of Ian Macpherson and CEO William Dolphin step down in favour of CFO Tim Rooney. The changes were made on an interim basis until June 2014.

Shareholders, with life science investor Bioscience Managers a voice leading a call for change, would have been disappointed by the slow progress made by the company on a number of fronts, including a rapid run down in its cash resources over 2013. Avita Medical retained cash of \$6.8 million at December 31, 2013, down \$7.7 million from the same time a year ago.

In the last five years the company recorded sales of \$2.4 million (FY2009), \$2.7 million (FY2010), \$3.1 million (FY2011), \$3.3 million (FY2012) and \$2.8 million (FY2013). In the last five years the company has posted of losses of \$5.1 million (FY2009),

\$5.9 million (FY2010), \$1.8 million (FY2011), \$7.7 million (FY2012) and \$8 million (FY2013).

In short, the company had failed to build sales with spending significantly outpacing revenue.

Change of Strategy

Avita Medical is seeking to change its business strategy on a number of fronts.

Its US registration strategy for ReCell has been based on a burns treatment study that has been funded by the US Army. The trial, which began in June 2010, has been very slow to complete, with 88 of 106 patients enrolled to date. This is a non-inferiority study which is randomized to compare ReCell to split-thickness meshed skin grafts for the treatment of second degree burns on the same subjects.

Avita will seek to develop Recell as an adjunct treatment for mixed depth thermal burns requiring grafts and has targeted 2013 Q3 to lodge an IDE submission for ReCell with that specification with the FDA.

Slightly sooner, in 2013 Q2, Avita will make a submission for the use of ReCell with large acute or traumatic burns using compassionate use data. To date, five burns patients have been treated with ReCell on compassionate use grounds, even garnering national newspaper coverage in USA Today.

Cont'd over

Analytica Update

The newly appointed CEO of Analytica (ALT: \$ 0.025) Geoff Daly gave a presentation this week to update investors on commercialization progress by the company. Daly was formerly the COO at Analytica and has been with the company for eight years. The product the company is commercialising is a medical device which helps women to perform pelvic floor exercises which in turn can improve their management of urinary incontinence.

About one in three women are affected by some level of urinary incontinence following child birth. The issue can generally be resolved using exercises without any devices according to the company. Analytica's 'PeriCoach' device assists in managing and improving the pelvic muscles. It works in two ways.

The sealed device is fitted with sensors. Similar to Dorsavi's bio-feedback physiotherapy product for managing soft tissue injuries around the back and joints, the PeriCoach, which is inserted, helps train the user in conducting the correct pelvic floor exercises, ensuring the correct muscles are being strengthened.

The system is linked to a smart phone which provides the user with a visual cues for exercise and for the real-time monitoring of the exercise regime. The system also provides reminders and a web portal where exercise history is recorded. This information can be shared with the person's doctor, who can determine which patients are using the device, which patients are improving, and which patients may have a more serious condition that requires other treatments. There is no cost to the doctors with this system, which patients buy direct or subscribe for a 12 month period.

Analytica is due to start production of the device in Sydney in May this year. The company received TGA approval in November last year. Domestic sales are scheduled to begin around June this year, and an international launch is planned at the ICS meeting in Brazil in October.

The device will cost around \$300 (or \$30 a month), which includes

– *Avita Medical cont'd*

The company will also shift its marketing focus away from key opinion leaders and focus on selling ReCell as a product that delivers economic benefits across the wound or burns treatment process. This for example, means understanding how it fits in with wound debridement (cleaning) and donor site morbidity. Success for wound or burns care for a product such as ReCell is not only a function of time to healing and the quality of healing but the degree of pain and infection that occurs at the donor site.

Improvements to ReCell

Avita has been working to improve ReCell in two ways. It has developed a temperature ambient enzyme, which means that the enzyme used to 'break up' harvested skin cells does not need to be accessed from cold storage, which should add a level of convenience to how the product is used. Shipments of ReCell with the improved enzyme began in December.

The area of damaged skin tissue that can be treated by a ReCell kit is currently 320 cm². A desirable capacity for treating burns

access to the web portal. One of the attractions of this company is that, as with Rhinomed, Analytica has a direct to consumer model, where the product can be purchased online.

The market size is potentially very large for Analytica. According to the company, in Australia alone, if the company only sold to 1% of the market, it would translate to annual sales of around \$10 million a year. At 15% market penetration, annual sales would reach an estimated \$148 million. Globally, these adoption rates would potentially correspond to annual sales of \$388 million and \$5.8 billion. By comparison, the incontinence pad market in the US alone is worth \$5 billion a year. This marks out Analytica as a very appealing investment opportunity.

Analytica is seeking to gain US approval this year under the 510(k) approval pathway. The company filed patents over the technology in 2011 and believes it has a first mover advantage in this market, as an integrated smart phone exercise device delivering data to physicians and physiotherapists.

The company believes there is already good awareness of the product in some areas with strong orders expected as soon as product is available. The company is currently finalizing product design, mainly around product aesthetics.

Clinical trials

Analytica has completed a 12 person trial with the device. The next trial will involve between 50-60 women, ahead of a larger third trial.

Analytica is capitalized at \$17 million. The company had \$1.4 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

would be 10,000 cm². Avita Medical has been working to lift the area it could treat from a single kit to 2,000 cm² by using more buffer in its solution, and by processing one sample into more samples and into more 'spray-on' syringes.

Summary

Avita's shift in focus to articulating the value adding benefits of Recell are a welcome move as is its decision to find a faster route to approval in the US for burns applications. Looking ahead, Avita could be a turn around story if it gains FDA approvals for burns and vitiligo this year, addresses its funding base through out-licensing and releases its high capacity burns kit in the third quarter. We remain sceptical of the company's plans to pursue opportunities in the chronic wounds space.

Avita Medical is capitalised at \$39 million.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

Bioshares Model Portfolio (14 February 2013)

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	\$0.900	\$0.620	December 13
Impedimed	\$0.220	\$0.245	December 13
Analytica	\$0.025	\$0.025	December 13
Imugene	\$0.016	\$0.022	November 13
Oncosil Medical	\$0.125	\$0.155	September 13
IDT Australia	\$0.360	\$0.260	August 13
Viralytics	\$0.310	\$0.300	August 13
Tissue Therapies	\$0.355	\$0.255	March 2013
Somnomed	\$1.66	\$0.94	January 2011
Cogstate	\$0.380	\$0.13	November 2007
Universal Biosensors	\$0.43	\$1.23	June 2007

Portfolio Changes – 14 February 2014**IN:**

No changes

Recommendations:

OUT:

No changes

Recommendations:

Imugene's Competitors

In *Bioshares 526* we discussed Imugene (IMU: \$0.016) and its novel immunotherapy, the Her-VAXX cancer vaccine for treating Her2 positive cancers. An earlier version of the vaccine has completed a Phase I study in Austria and the company is planning to commence a Phase II study in patients with gastric cancer in 2015.

We also tabled a list of other Her2+ therapies in development, including a number of immunotherapies. The most advanced immunotherapy in development is Galena Biopharmaceutical's T-cell vaccine, NeuVaxx, which is in a 700 patient Phase III trial and a 300 patient Phase II trial. In the Phase II trial NeuVaxx is being tested in combination with Herceptin. The Phase III trial, which commenced in 2011, will study 3, 5 and 10 year survival rates.

The University of Washington in conjunction with the US National Cancer Institute (NCI) is assessing a T-cell peptide vaccine in a Phase II trial.

Programs at the Phase I level include two autologous dendritic cell vaccines; Dendreon's DN24-02 and the NIH/NCI's AdHER2/neu DC vaccine

There are two B cell vaccine programs, including Duke University's AVX-901 vaccine, and an unlabelled vaccine from Ohio State University vaccine. Imugene's Her-Vaxx is also a B-cell vaccine.

The B cell vaccine methodology involves stimulating B cells to manufacture antibodies which bind to cancer cells. However, a vehicle, such as a modified or inert virus, is needed to deliver antigens, typically peptides unique to cancerous cell, into the body so that the immune system can react to the foreign material and construct the antibodies.

The effectiveness of peptide vaccines is dependent not only on which peptide antigens are chosen, but the way they are arranged or linked to each other, or to other chemical intermediates or particles such as a virosome.

Antigen Express' AE37 Vaccine

Missing from the table in *Bioshares 526* was Antigen Express's AE37 vaccine. (Antigen Express is a wholly owned subsidiary of Genex Biotechnology, which has a primary focus on drug delivery systems.)

Antigen Express recently announced it had completed its 300 patient Phase II study of AE37 but will announce full results at this year's American Society of Clinical Oncology meeting in May/June. Interim data released in 2012 showed the vaccine lowered the rate of relapse for patients who had been previously treated for Her2+ positive breast cancer.

The results will be of interest because it is the largest randomised trial of a breast cancer vaccine completed to date. The results will also reveal if the vaccine's design focus on T-helper cells delivers a robust response.

The AE37 vaccine comprises of two peptides, 'AE36' and 'Ii Key'. Together, they boost the immune system's T-helper cells ability to recognise Her2+ cancer cells.

Summary

Imugene is well placed in the field of Her2 cancer vaccines, and looks to be the most advanced of the programs in the B-cell category. Developments with T-cell vaccines, such as Antigen Express AE37 vaccine, will be worth monitoring because they may deliver important insights about the effectiveness of various peptides, or even a lack of clinical success may improve the relative attractiveness of the B-cell approach.

Imugene is capitalised at \$14 million and retained cash of \$2.5 million December 31, 2013.

Bioshares recommendation: **Speculative Buy Class B**

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

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