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Bioshares

20 September 2013
Edition 521

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

In this edition...

A bevy of biotech companies were under the spotlight in Perth this week, offering depressed mining investors a mixed bag of investment propositions, ranging from Consegna's Turbine nasal insert, to Calzada's Novosorb wound and burns product to Oncosil Medical's Oncosil, which is being developed as treatment for pancreatic cancer.

Regeneus made headlines by being the first proper IPO to take place since Osprey Medical listed in 2012.

While Ellex Medical Lasers has been traded since 2001, when it made a backdoor listing through Gemstone Corporation of Australia, the company has been frequently been challenged to sustain growth in sales and to be consistently profitable.

Companies covered: CGP, CZD, ELX, OSL, RGS

	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)	61.0%
Cumulative Gain	**473%**
Av. annual gain (13 yrs)	**20.0%**

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Perth Biotech Briefing

A number of companies presented at the AusBiotech 'Brokers meet Biotech' lunch in Perth this week, which was attended by approximately 130 investors and Bioshares. Below is a summary of some of the presentations made.

Consegna Set for Commercial Launch of the 'Turbine'

Consegna (CGP: $0.035) changed its management in February this year and is now changing its name to Rhinomed to better reflect the company's business focus. Consegna is commercialising a plastic nasal insert that improves airflow by dilating the nose. It will go head-to-head with GlaxoSmithKline's BreatheRight, which is a nasal strip that achieves a similar effect but is placed on the outside of the nose.

Consegna believes that its strip is much more effective than its competitor's and it has the advantage that it is largely not visible once it is in place. In clinical trials Consegna's insert, called the Turbine, increased airflow by 38%.

Consegna will officially launch the product in November this year. The first target market is in sports, specifically elite cyclists. The product will sell for $24.95 for a packet of three, and will be sold on-line, as well as through affiliates such as cycle shops.

Consegna says it has improved the design of earlier models, which had the problem of not staying in place over long periods, and also that they were too durable and thereby not needing replacement. The company has commenced manufacturing the product through a third party, ChinaMed.

There is an established market for these types of products. GSK acquired the BreatheRight business in 2007 for US$566 million, when the product was generating $170 million of annual sales. In July this year, the product came off patent and generic products are expected to enter the market.

Consegna is starting in the sports/cycling market, and will then move into the sleep treatment application next year, and then potentially into using the device to deliver drugs. Consegna CEO Michael Johnson said the nose is a highly vascularised part of the body and thereby suitable for drug delivery into the body.

After launching in Australia, the company will look to sell the product into the US, where the company says there are 40 million cyclists who cycle three times a week or more. The company is in discussions with distributors for regions outside of Australia.

Consegna is capitalised at $12 million, with an estimated $1.6 million in cash, which the company says is sufficient to achieve its goals. Anyone interested in trialing the device can pre-order at www.theturbine.com.

Bioshares recommendation: **Speculative Hold Class C**

Cont'd over

Calzada's NovoSorb to Reach the US in 2014

Calzada (CZD: $0.081) is commercialising two technologies. The first is a biodegradable polymer for use in wound treatment and the second is an old metabolic asset, AOD9604, which was trialed as a treatment for obesity and failed. Chairman David Franklyn said that longer term the two assets do not belong together.

Calzada intends to sell the wound treatment product, NovoSorb, in the US in the first quarter of next year, with the company having this week filed a regulatory application under the 510k pathway. The first application is for use in topical negative pressure (TNP) wound therapy. It will go up against the market leader Granufoam. The market for these products is around $400 million a year.

Granufoam is sold by KCI but these products have their faults with foam particles remaining in the wound after treatment. In a clinical trial conducted by Calzada this year in 18 patients, it was shown that NovoSorb achieved less fragmentation in the dressing than existing products, and was easier to remove with less bleeding.

KCI is the market leader with its Granufoam product with another three or four emerging products from other companies. Of particular interest is that last year David McQuillan was appointed to the Calzada board. McQuillan was formerly Senior Vice President of research at KCI. Franklyn said the company is speaking with a number of potential distributors for the NovoSorb product in the TNP application, including KCI. The company expects to sign a partner on in the next six months for the US market.

Franklyn said that the NovoSorb product has a number of other advantages. This includes the synthetic nature of the product, which means there are no logistic or storage issues. This was in reference to the wound healing product Integra, that NovoSorb will compete with in the wound healing market, including burn wounds.

The Integra product costs around $3,000 for an A4 sheet and treatment of one patient with large scale wounds can cost $250,000 with the Integra product. Franklyn said that the NovoSorb product will transform the way patients are treated in the future and that NovoSorb is significantly better than current treatments.

The NovoSorb treatment was successfully used in a full thickness wound trial, where the full depth of the skin needed to be replaced. At day five, using the NovoSorb product, vascularisation into the product had started to occur, achieving full vascularisation at day 15 and allowing for a skin graft at day 21 to complete the wound therapy.

Advantages of NovoSorb

The advantage of the NovoSorb product in major wounds is that the wound can be immediately sealed and that less skin graft from other areas of the body is required. Final results from this 10 patient trial are expected by year's end and the company anticipates filing the product for approval in the US (for the treatment of chronic wounds) in Q1 2014.

Calzada will soon commence a multi-centre trial this year in patients with burn wounds, which is expected to cost around $2 million. Calzada is capitalised at $33 million with approximately $6 million cash at hand, including an expected government R&D tax rebate.

Bioshares recommendation: **Speculative Buy Class B**

Oncosil Medical – Ready for Pivotal Trial

Oncosil Medical (OSL: $0.145) raised $10 million recently to bring its pancreatic cancer treatment, Oncosil, to market. Those funds will allow the company to complete a pivotal trial in more than 100 patients. The prognosis for people diagnosed with pancreatic cancer is very poor. Median survival is less than six months with chemotherapy only having an effect on one in six patients. Of the 280,000 patients diagnosed each year globally with this disease, around 265,000 will die in that year according to CEO Neil Frazer.

The potential market for this therapy, which involves the local delivery of P-32 radioactive particles attached to porous and biodegradable silicon, is estimated at around $500 million a year for the US, Europe, Australia and Japan.

Oncosil expects to start the pivotal trial in Q1 2014. What attracted Frazer to the technology was that in a Phase I/II trial, stable disease was achieved in 14 from 17 patients, which was a phenomenal event said Frazer. In that study, the median survival period was almost doubled from 5.7 months that is seen with the standard of care treatment to over 10 months with the Oncosil therapy.

PMA, not 510k Path

In the US, the company will follow the PMA approval path, not the 510k, which will allow the company to sell Oncosil with claims. The pivotal trial will be conducted in 20 centres, including six in Australia. Patients in the trial will have their tumours imaged every two months with a CT scan. The control arm in the trial is standard of care, and with this technology, it can not be blinded, so the company will be able to monitor progress.

On the question of how Oncosil Medical will sell Oncosil, Frazer said the company was keeping its options open. The product could be sold with only a small sales force – some specialist pancreatic cancer treatment centres such as Johns Hopkins treat 30 patients a week.

Oncosil Medical is capitalised at $44 million (excluding the $2.5 million being raised under the SPP in process). It has around $11.2 million in cash, excluding proceeds from the SPP.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Can Ellex Medical Lasers Grow Sales and Profits?

Ellex Medical Lasers (ELX: $0.29) will inject funds into the development of several new business opportunities with $3.3 million in funds raised through placements to institutional investors. The last time the company took on equity funding was through a $1.6 million rights issue completed early in 2009. The placement was made at 26 cents per share.

Ellex launched its first ophthalmic laser in 1998 (when it was still part of Quentron Electronics). The company has built a 13% share of the global ophthalmic laser market, and is second after Lumenis with a 19% share.

The company's current product line-up includes:
- **superq**, **ultraq** - photodisruptors for treating secondary cataracts
- **ultraqreflex** - photodisruptor for vitreolysis
- **solitaire**, **integre** - photocoagulator for DME and diabetic retinopathy
- **tango**, **solo** - selective laser trabeculoplasty for glaucoma
- **2RT** - retinal rejuvenation therapy for diabetic macular edema (DME) and age related macular degeneration (AMD)
- **eyecubed** - diagnostic ocular ultrasound

Financial Results

Ellex recorded a 9.9% drop in revenues to $42.8 million for FY2013. The company posted a loss for FY2013 of $0.8 million. Non-recurring sales of retinal cameras in FY2012 contributed a $3.5 million one time effect on the FY2013 results, as did the depreciation of the Yen against the AUD, which reduced revenues by $1.2 million.

Recent Developments

Glaucoma (trabeculoplasty) - USA

Ellex was finally permitted to contest the US glaucoma market in July this year following the expiration of a patent held by Lumenis, which blocked competition. Two other companies, Quantel and Lightmed, will also compete in this market. Ellex estimates the US market to be worth US$13-$14 million.

Ellex has a 42% market share outside of the US. It expects to build a similar position in the US. However, to gain that market share, the overall market will need to grow with Ellex needing to drive sales through education and marketing activities

The glaucoma market is amenable to laser treatment because drug therapy in the form of eye drops (for a range of different class of drugs, including beta-blockers) is subject to compliance issues. Trabeculoplasty is a technique in which a laser is used to unclog drainage canals in the eye.

However, one challenge for the market generally is that ophthalmologists must invest $60-$70,000 in the laser device.

Ellex expects this 'fresh' opportunity in the US will be a strong contributor to growth in FY2014 and in later years.

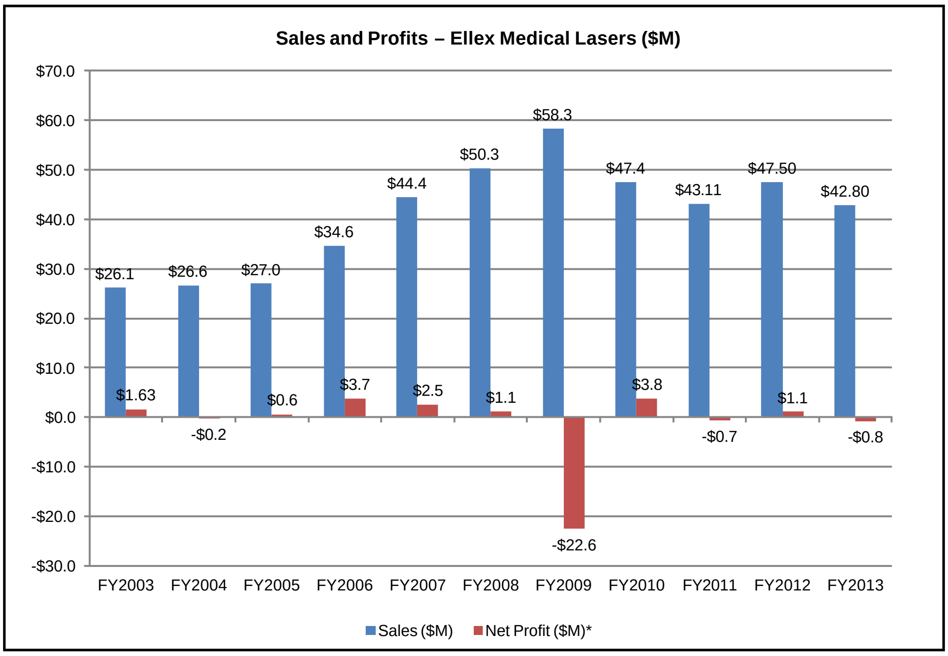
2RT for DME and early AMD

Ellex has developed a proprietary laser, the 2RT, for treating DME and *early* AMD. The system has received its CE Mark in 2012 and its 510(k) clearance recently in July, for DME.

The company believes it can be the first to market for the AMD market opportunity, for which there are an estimated 112 million early AMD patients who have not had access to an approved laser treatment. The logic behind the targeting of early AMD is that the laser treatment can potentially delay the use of drugs such as Lucentis and Elyea.

The company is supporting a randomised trial in 300 high risk, bilateral patients with early AMD. The purpose of the trial is to generate data to aid sales of the product in European countries.

Ellex's marketing strategy for 2RT in the US will be to first target early adopters who take on the system for DME treatments and leverage this user base into trials it will need to conduct for the AMD approval process.



Laser Vitreolysis for Vitreous Detachment

Another market opportunity identified by Ellex is the application of lasers to treat collagen fibre clumps which float over the retina.

The treatment is difficult to achieve with a conventional laser and has been previously undertaken by experts. Ellex has developed a specific laser, the Ultraq Reflex, for the treatment.

The market is attractive because 25% of people over the age of 60 experience the spots or strings which characterise the condition. An even greater attraction is that reimbursement codes exist in most jurisdictions.

Cont'd over

Bioshares Model Portfolio (20 September 2013)

Company	Price (current)	Price added to portfolio	Date added
Oncosil Medical	$0.145	$0.155	September 13
Calzada	$0.081	$0.073	September 13
Invion	$0.070	$0.060	August 13
IDT Australia	$0.370	$0.260	August 13
Viralytics	$0.380	$0.300	August 13
Circadian Technologies	$0.280	$0.270	March 2013
Tissue Therapies	$0.290	$0.255	March 2013
Benitec Biopharma	$0.370	$0.40	November 2012
Somnomed	$1.16	$0.94	January 2011
Cogstate	$0.495	$0.13	November 2007
Universal Biosensors	$0.76	$1.23	June 2007

Portfolio Changes – 20 September 2013

IN:
No changes.

OUT:
No changes.

– Ellex cont'd

The Business Model

Ellex Medical Lasers is a supplier of capital equipment items, which typically means substantial cash outlays must be made by ophthalmology practices (which also mean a single unit may be accessed by more than one ophthalmologist). Lasers are a durable product with a long functional life, making for a long time delay until a replacement product sale can be achieved.

Currently, medical lasers sold by Ellex have not been designed to generate income on a per use basis, imitating the consumables income model adopted by many other equipment suppliers. However, that may change in the future as new products are brought to market and where Ellex is able to hold some market power to force through a change in the structure of payment arrangements.

Capital equipment suppliers can benefit from building scale through mergers so that an industry with fewer suppliers can increase its power to restructure payment arrangements with customers. Some M&A has taken place in the ophthalmic lasers industry recently but the potential for more to take place exists.

Summary

Ellex Medical Lasers has struggled to generate growth in recent years and profitability has been patchy.

Ellex Medical is capitalised at $28 million, post placement.

Bioshares recommendation: **Hold**

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Regeneus Lists

Stem cell therapy company Regeneus (RGS:$0.27) listed on September 19, with its shares finishing on the day up 2 cents (up 8%) from its offer price of 25 cents. The company raised $10.5 million, slightly more than its minimum target of $10 million. The company's net cash position post-IPO will be slightly more than $9.3 million. The company has 183 million shares on issue and is capitalised at $49.6 million.

The top four shareholders are Vesey Investments (representing the CEO Prof. Graham Vesey) with 7.2%, Thomas Mechtershiemer, 6.5%, Marc Wilkins, 5.1% and Ben Herbert, 4.7%. Wilkins and Herbert (a director of Regeneus) were co-founders of Proteome Systems, the Sydney-based proteomics instrumentation business which listed in 2004 and re-badged as Tyrian Diagnostics in 2008. Executive Chairman, John Martin with a 3.7% interest, was a deputy CEO of Proteome Systems. Vesey was a co-founder of BTF, a microbiology testing company sold to bioMerieux in 2007.

A concern with Regeneus is that its business is not scaleable, or at least without the addition of very substantial capital. The absence of the full results of its OSCARS study of its HiQCell product is another concern, as is the fact that the study did not generate a statistically significant result for the treatment arm. A patent challenge by Norwood Immunology is another concern.

A review of the Regeneus offer can be found in *Bioshares* 517.

Bioshares recommendation: **Sell**

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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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