ISSN 1443-850X

In this edition...
Politicians of all shapes and sizes would be crawling over any company that increases its head count by 30% in a year. Better for investors is that employment growth is a sign of future growth in a business and Cogstate, which is now feeding 82 mouths compared to 62 a year ago has growth written all over it. Growth in Alzheimer's Disease drug trials are a part but not all of the growth story. Nanosonics CEO Ron Weinberger is a horse whisperer of sorts for GE Healthcare, having reworked an agreement which will see GE cover the cost of half-a-dozen Nanosonics sales staff. IPO hopeful Regeneus is seeking $10 million to continue the commercialisation of its stem cell products HiQCell (for humans) and Cryoshot (for animals).
Companies covered: NAN, CGS, Regeneus IPO

	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)	45.9%
Cumulative Gain	**419%**
Av. annual gain (12 yrs)	**16.6%**

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

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 - Editor
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz - Research Principal
Ph:(03) 9348 9317
Email: pachacz@bioshares.com.au

Individual Subscriptions (48 issues/year)
$400 (Inc.GST)
Edition Number 517 (23 August 2013)

Bioshares

23 August 2013
Edition 517

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

Cogstate Results – Investing to Expand Markets and Applications

In the last 12 months Cogstate (CGS: $0.42) has added 20 staff to take total staff numbers to 82, based mainly in Melbourne and on the east cost of the US. It has built a sustainable and profitable business from selling its product and services for measuring changes in cognition in pharmaceutical clinical trials. This business is now supporting the expansion of the product into other applications, those being in sports and in dementia screening.

Total revenue for FY2013 was $12.6 million, up 4% on the previous year. The company recorded a net loss of $1.9 million, however its cash resources, taking into account the increase in debtors ($1 million), fell by only $230,000 for the year. The company finished the year with $3.4 million in cash.

Over the year, the company has expanded its range of services offered as part of its clinical trials business, adding five staff. It has added two staff to its Axon Sports business, four have been added to the Cognigram program with Merck in Canada, five to support program development, ensuring its products are available on all electronic devices such as tablets and i-phones, three have been added to support Cogstate's work in research (including involvement in long term aging studies such as ABIL) and three have been added into administration, including two in-house lawyers.

Payments to employees in FY2013 increased by $2.9 million to $8.7 million. Cogstate is investing for growth, something which did not occur in FY2013. Its revenue from clinical trials can still be swayed by major contracts. In FY2013, one major pharmaceutical contract was not awarded because the trial did not proceed, and a second major trial has been delayed to the current financial year.

At the end of June, Cogstate had $8.6 million in revenue contracted (this is based on a AUD/USD of 95 cents so will likely be higher) with $5.5 million expected to realised in this financial year. The heightened interest in the Alzheimer's disease area positions Cogstate well. In a company briefing this week, CEO Brad O'Connor said the level of interest in Alzheimer's disease was unprecedented, with the Cogstate test being considered for use as a primary and secondary endpoint. O'Connor said he was confident the Cogstate test will be used as a primary endpoint in a pediatric oncology study, with regulators expected to require more cognition measurement in children's studies.

Axon Sports

Cogstate's fully owned subsidiary Axon Sports has two core product streams. The first is using the Cogstate technology to assess cognitive impairment post concussion. The second is distinctly separate, involving a sports training technology, that allows athletes to train their brains for improved results in sports. The first sports training product is for use in better reading baseball pitches, and the second is in predicting gridiron plays.

Cont'd on page 3

Nanosonics Briefing Summary

Nanosonics held an investor briefing this week, providing more information on its markets and the amended GE Healthcare agreement. CEO Ron Weinberger said the company was moving into an 'adolescence' phase, with the second full year of sales of the Trophon unit in North America behind it. With the US market well on its way through the company's exclusive partner GE Healthcare, Weinberger spent some time discussing the approach in Europe, which looks to be the next major target for the company.

Stage I – North America.....Revamped GE Agreement

Weinberger provided some further information on the revamped GE agreement. While the original agreement is still in place, the arrangement has been strengthened. GE will now fund between eight to 14 dedicated sales staff to sell the Trophon system in North America. This will include existing Nanosonics sales staff, of which there are currently six, which will likely see Nanosonics' sales and marketing costs fall in the US. Working off a cost per sales staff of $300,000 each, this represents an annual investment by GE of up to $4.2 million.

Also, GE Ventures will fund an additional marketing effort. These payments will be made to Nanosonics, under a joint committee that includes GE Healthcare, GE Ventures and Nanosonics. The payments will be milestone based and will be made in advance.

Stage II – Europe

In this financial year, unit sales in Europe are expected to be in the hundreds, not thousands, according to Weinberger, which should generate sales in the order of $2 - $5 million this year, largely agreeing with estimates from house broker Canaccord Genuity.

Weinberger said that the company had to press the reset button in Europe with previous distributors that were not generating a lot of sales. The company is now focusing on France, Germany and the UK, having recently placed country managers into those regions.

In the UK, the company's non-exclusive distributor is Toshiba Medical Systems. Weinberger said that Nanosonics has a very pleasing and productive relationship with Toshiba. This week the company announced that King's Mill hospital has installed six Trophon systems with up to six more units to be potentially be sold. The company said that this site is one of the most highly regarded ultrasound departments in the UK.

Nanosonics has had to develop a validation kit to be used for each Trophon unit sold in the UK, which now forms part of the Nanosonics product offering. Nanosonics is also working with Welsh and Scottish healthcare authorities in an effort to have high-level disinfection become standardized across those countries.

In France, Weinberger said it is a complicated market, with the company having to tender to sell into the public hospital system, a process that is managed by a group purchasing intermediary.

Cross contamination of intracavity probes has become a very public health concern in France, following a report in the French major newspapers. The Greens party in France is now seeking to have a bill enacted in the European Union to change regulations for high level disinfection of intracavity probes. The move is being driven by a French politician championing for improved women's rights and healthcare practices. The bill is expected to be submitted next month.

The Ministry of Health in France is also seeking to legislate these changes to healthcare practices in the French Parliament.

In Germany, the company has made early sales according to Weinberger.

Stage III – Asia and Latin America

In what will likely be the third assault on changing global healthcare practices and positioning the Trophon system as the standard of care of ultrasound probe high-level disinfection, Nanosonics is also working on Asia and Latin America, with regulatory approval applications recently submitted for countries in those regions.

Regulatory filings have been submitted in Japan, Mexico and South Korea. Approval in Mexico is anticipated by year's end; South Korean approval is expected in the next six to nine months; and in Japan, regulatory approval will take about 12 months.

Market Size

On the question of market size, the forecast has previously been for a market worth 40,000 Trophon systems in the US and the same for the rest of the world. Nanosonics has re-assessed this estimate using its own market research, GE's recent data, and a third party's market data, supporting the original market estimate.

Deficiencies in Existing Processes

Nanosonics has been working with physicians to investigate the efficiency of the Trophon system in removing pathogens against the existing chemical process (CIDEX OPA). It found that the chemical process left microbacterial flora on probes, including golden staph, whereas the Trophon system left no traces of pathogens.

Consumable/Trophon proportion sales

On the question of consumables sales, the company indicated that the goal initially was to keep this low, as a proportion of overall sales. Consumable, accessories and service contract revenue makes up around 20% of overall sales.

The reason the company is aiming to keep this figure proportionally low (not low in terms of sales value) is that the focus at this stage is to be selling as many Trophon units as possible to set up the ongoing consumables and other similar sales.

When the company starts to mature, consumable sales should exceed Trophon unit sales in *Bioshares* view. Consumables, accessories and service contracts are still expected to be maintained at around 20% for the next year.

Cont'd over

– Cogstate cont'd

The sports training products achieved some credible revenue, with $400,000 (from January 2013). It is being used in three high performance labs and has been used by six elite sports teams in the US so far. Cogstate expects to see growth in FY2014 in the sports training products. To date it has been concentrating on elite sports people. However, it will soon release consumer products for I-pads and other tablets.

The Cogstate cognition test in sports generated around $200,000 in sales.

Cognigram

Only minor revenue was recorded for the Cognigram product, with $4000 of sales. The test is still being rolled in Canada. To date around 450 doctors have signed up to use the test. Cogstate's partner Merck will start to move the test into specialist centres soon that can conduct the test on site. Public reimbursement in Canada is a longer-term process.

The next challenge will be to have doctors regularly prescribe the test. The test is conducted at 150 Bayshore sites across Canada. O'Connor agreed to a question that suggested the first year for this test would be a loss, the second year a breakeven result, and that the company would start making a profit in the third year. The investment in this product is more than geographic specific, according to O'Connor, relating to the use of the test in other future markets. Expansion into other markets will presumably occur once the model has been proven in Canada.

O'Connor said that Merck has shown to be an excellent partner. Merck has conducted its own market research which supports the demand for such a product. O'Connor said that the test is being well received and is a potential game changer for the company. The global market for such a test has been estimated at $500 million a year.

Summary

Cogstate's aim at the start of FY2013 was to run the business at close to cash flow neutral as it was setting up new businesses and product applications. This year will see the company benefit from a lower Australian dollar against the US dollar, which alone should deliver an additional $3 million in revenue if US dollar sales are flat. The positive currency movements, the potential acceleration of sales in the sports training products, and the high level of activity in the Alzheimer's disease area are three drivers for this stock.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

– Nanosonics cont'd

Profitability and Sales/Profit Targets

Weinberger would like to see the company move to breakeven in the next financial year. Weinberger's performance bonus is on achieving 'sales of $50 million in 2015 with a 12% profit' ($6 million).

On the question of why the stock has moved so much in recent weeks, Weinberger said that the company was very well received in a US roadshow, which has seen four US funds invest. Weinberger believes there is further institutional interest in the US.

The stock is appealing to not just healthcare funds, but also small-mid cap industrial funds according to Weinberger. The company has been received so well in the US not just for the product, but also for the business model.

Nanosonics is capitalised at $247 million. It held cash of $24.1 million at the end of June.

Bioshares recommendation: **Take Profits**

Bioshares

Bioshares Model Portfolio (23 August 2013)

Company	Price (current)	Price added to portfolio	Date added
Invion	$0.068	$0.060	August 13
IDT Australia	$0.340	$0.260	August 13
Viralytics	$0.315	$0.300	August 13
Circadian Technologies	$0.270	$0.270	March 2013
Tissue Therapies	$0.310	$0.255	March 2013
Benitec Biopharma	$0.285	$0.40	November 2012
Somnomed	$1.19	$0.94	January 2011
Cogstate	$0.420	$0.13	November 2007
Universal Biosensors	$0.70	$1.23	June 2007

Portfolio Changes – 23 August 2013

IN:

No changes.

OUT:

Nanosonics is approaching our upgraded valuation of 96 cents a share. It has had a very strong run, having been added to the portfolio at 49 cents. Although it is shaping up to be an outstanding company, we will recognise some profits and remove it from the portfolio at 91.5 cents.

IPO Profile – Regeneus

Sydney-based stem cell company Regeneus is seeking to raise $10 million through an IPO. Regeneus has developed therapies by accessing stem cells contained in adipose (fat) tissue. Adipose tissue is rich in mesenchymal stem cells which are an adult stem cell which grow into to cartilage, bone and muscle. The company claims that adipose tissue contains 500-1000 times (per gram) the quantities of mesenchymal stem cells than is found in bone marrow.

The company has developed two products, an autologous human cell therapy named HiQCell and a veterinary product Cryoshot. HyQCell is intended for the treatment of musculoskeletal conditions such as osteoarthritis. It was first made available on a commercial basis through the Sydney Sports Medicine group in October 2011. To date, more than 300 people have been treated at these and other clinics.

HyQCell is a suspension of non-adipocyte cells that are fractionated from adipose tissue, harvested using liposuction, then separated using enzymes such as collagenase with a centrifuge. The suspension is a mixture of cells, containing white blood cells and T-reg cells, among others.

Cryoshot is an off-the-shelf (allogeneic) adipose tissue derived product intended for the treatment of musculoskeletal conditions in animals such as horses and dogs.

Revenues in FY2011 were $0.8 million, $1.2 million in FY2012 and $0.9 million in the six months ending December 31, 2012.

Regeneus was founded in August 2007 and employs 32 people (FTEs).

From FY2012 onwards, Regeneus has raised $7.5 million.

The Capital Raising

Regeneus is seeking $10 million through the issue of 40 million shares at 25 cents. Assuming the minimum funds are raised, there will be 181 million shares on issue, giving an indicative valuation of $45.5 million.

Regeneus believes the funds raised will support the company for two years. The company's net cash position after the raise will be $9.3 million.

The company has allocated $1.7 million towards clinical trials of Cryoshot necessary for approvals in the USA and Australia, $1.4 million for market development trials of HiQCell, $0.9 million for pre-clinical and safety trials of the human version of Cryoshot.

It also plans to spend $1.2 million on expanding the availability of HiQCell in Australia (and in some international markets) and $1 million for the rollout of canine Cryoshot and equine Cryoshot in Australia.

In addition, $0.27 million will be spent on toxicology studies for topical secretions products (i.e. an acne product).

Board and Management

The Executive Chairman of Regeneus is John Martin. The CEO of the company is Prof. Graham Vesey. Other directors are Assoc. Prof. Ben Herbert, Dr Roger Aston and Barry Sechos. On completion of the offer, the board and its related parties will own 16.6% of Regeneus.

Business Model

Regeneus generates income by charging license fees to the centres which undertake the HiQCell treatment as well as charging a separate cell processing fee. The company recently introduced an option for patients to have cells stored cryogenically for later use.

The company is making use of the TGA's 'Excluded Goods' order to sell HiQCell. The regulatory provision permits medical practitioners or supervised persons to manufacture autologous cell and tissue products, collected by a medical practitioner for a single treatment for a single indication. Regeneus believes that it can eventually roll out HiQCell in the UK and Singapore, which have similar provisions.

The off-the-shelf Cryoshot animal health product is cryogenically preserved and sold directly to vets. The product has pre-registration status from the Australian Pesticides and Veterinary Medicines Authority, which enables the product to be used on a test basis (at 70 vet clinics), with full approval a goal of the company. This product has yet to be produced on a large scale, which is another challenge for the company.

Data Obtained to Date

HiQCell has been evaluated in a 40 patient randomised trial (the OSCARS Study). The complete results will be published in FY2014. The company reported in its prospectus a 55% reduction in pain scores at 12 months for the treatment group (pains cores were the primary endpoint). There was no statistically significant difference between the treatment group and the placebo group.

The company has also established a patient registry for HiQCell, which collects data from patients who have been treated with the product. At June 2013, 103 patients had been followed up for six months or longer

Human Therapeutic Product Development Challenges

A major challenge for Regeneus in the area of human therapeutic product development is that the field of adipose-derived stem cell therapies is subject to competition on a number of levels. The clinicaltrials.gov website records about 80 trials of adipose tissue derived cell therapies, including osteoarthritis trials.

Similar autologous adipose tissue derived cell therapies are being evaluated in other parts of the world with two trials underway in China and Panama specifically for the treatment of osteoarthritis (see table next page).

US-based Cytori Therapeutics (CYTX; Market Cap US$162 million) is currently running three trials of its adipose tissue derived cell therapy, which is processed by its Celution system. Two trials

Cont'd over

are with heart attack/heart failure patients and another is with sclerosis subjects.

The two osteoarthritis trials also point to a current weakness with the HiQCell product, which is a lack of information about dose response. By way of contrast, the Chinese study in 120 patients is a randomised trial evaluating three different doses administered at different points in time.

Dose effects (or characteristics) matter not only in regards to efficacy, but to safety, and also to the costs of therapeutic product development.

A drug regulator such as the US FDA would in all likelihood seek information from a sponsor of a cell therapy product information about dose effects so that is could understand the safety profile of the product to its satisfaction.

And although autologous products are in theory much safer than donor-based products, the FDA is an organisation which typically demands detailed safety data.

Another issue for Regeneus' autologous therapy is that of scalability. Individualised (autologous) therapies are more likely to be successfully commercialised where very small patient groups exist. They are much less amenable to being scaled-up to address large market disease or conditions. It should be noted that Regeneus has plans to develop a human allogeneic cell therapy product which could be applied to large market opportunities. However, the safety thresholds are much higher and the manufacturing requirements also introduce new and extensive capital demands.

Patents

Regeneus' patent portfolio comprises of nine families, with the one patent granted in New Zealand, and the Australian applications for three families yet to be published. Several of Regeneus' patent applications have been identified through the international search step of the examination process as lacking novelty or inventive steps. While the outcome of these patent applications is not known, the fact that the issues of a lack of novelty or inventiveness has occurred on more than one occasion may signal weakness with Regeneus' IP position.

Opposition

Regeneus' Australian patent application numbered AU2009201915 has been accepted by IP Australia but has been challenged by Norwood Immunology. Most recently, April 2013, Norwood Immunology filed an opposition to amendments submitted by Regeneus. These amendments had been accepted by IP Australia. The patent opposition creates uncertainty for investors in respect of whether Regeneus' '1915 patent application is valid, and uncertainty in respect of the time it will take to resolve the dispute.

Summary

The Regeneus offering contains a number of issues for investors to consider. While the company has demonstrated that it can build a modest business supplying an autologous therapy (for humans) in Australia under the TGA's Excluded Goods order, the challenge to build a much more sizeable business is likely to be much, much harder. At this stage, it appears that outside of Australia, its market opportunities are limited to the UK and Singapore and it is potentially subject to competition from other companies operating unencumbered in other jurisdictions.

It is disappointing the full clinical trial results for Regeneus' OSCARS trial of HiQCell have not been available for inclusion in the prospectus, given that the trial commenced in 2010 and in all likelihood completed in 2011.

Offer Closes: 30 August, 2013

A copy of the prospectus can be downloaded from http://regeneus.com.au/investor-centre/business-overview

Bioshares

Selected Adipose-derived Cell Therapy Trials

Sponsor	Condition	Treatment	Design	Phase	Num. Pts	Dose	Freq.	Start	Compl.	Primary EP	Location
Underway											
Translational Biosciences	Osteoarthritis (knee)	Autologous adipose tissue stromal vascular fraction (SVF)	Unblinded/ not-randomised	Phase I/ Phase II	20	2 x 15 ml injections; 1 x 10^7 to 5 x 10^7	Once	Jun-13	Jul-14	Adverse events	Stem Cell Institute, Panama
Cellular Biomedicine Group	Osteoarthritis (knee)	Autologous adipose mesenchymal progenitor cells	Open label, single arm, dose escalating, placebo-controlled	Phase I	120	3 ml injections; 1 x 10^6 to 1 x 10^7 to 1 x 10^8	0,1,3 months	Mar-13	Mar-14	WOMAC score	Renji Hospital, Shanghai
Completed											
Regeneus	Osteoarthritis (knee)	Autologous adipose derived stem cells (in a cell suspension)	Randomised, double-blind, placebo-controlled		40	One 5 ml injection; 5 x 10^7	Once	Feb-12	Mid-2012	Change in ICOAP pain scale at 4, 12 & 24 weeks	Royal North Shore Hospital

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Tissue Therapies, Viralytics, Phosphagenics, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Calzada, Bioniche, Atcor Medical, Invion, Circadian Technologies

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **$400**

For multiple email distributions within the same business cost centre, our pricing structure is as follows:	$630	2-3 email addresses
	$855	4-5 email addresses
	$1090	6-10 email addresses

To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
Fax: +61 3 9329 3350

I enclose a cheque for **$** made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card **$** MasterCard ☐ Visa ☐

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Signature _____ Expiry date _____

Subscriber details

Name _____

Organisation _____

Ph ( ) _____

Emails _____

_____

_____