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Bioshares

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Edition 541

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

Companies covered: BLT, NAN, SOM, TIS, Global Kinetics Corporation

	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)	60.4%
Cumulative Gain	**472%**
Av. annual gain (13 yrs)	**19.9%**

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Somnomed – Building the Complete Oral Appliance Therapy Company

Somnomed (SOM: $1.64) increased revenue in the first half of this financial year by 39% to $12.5 million. Profit before tax for the half was $370,000, down slightly from $412,000 in the previous corresponding period. Unit sales of the company's devices used for the treatment of sleep disorders were 19% higher from the previous corresponding period.

For the full year, the company is forecasting unit sales of around 43,000, up 20% over the 35,841 sold in the previous financial year. However guidance on sales for the full year is in the order of $25 million, which is conservative given the unit sales forecast, which would correspond by our estimates for $27 million in sales for the full year. This lower and more conservative sales guidance for the year perhaps explains some weakness in the stock this week.

Executive Chairman and CEO Peter Neustadt said this week in an investor update that Somnomed has become the best custom oral appliance company in the world. Its strategy going forward is to develop all major markets in Europe and access Asian markets over the next five years, and to continue with the company's medical initiative in the US. The Somnomed devices compete with Resmed's and Respironics' CPAP devices which Neustadt believes his products are more durable and cost effective.

In the US, Somnomed continues to invest in marketing its devices through sleep specialists. This top-down approach will continue with Somnomed to continue re-investing its profits into growing the business. The medical initiative is expected to translate into additional sales in FY2015, with signs that this investment is working among sleep physicians. Spending on the US medical initiative is expected to be around $2 million this financial year.

The last three quarters has seen an acceleration in the company's business, particularly in the December quarter, where sales were up 22% over the September quarter. The company's European strategy, which has involved the acquisition of four distributors, has paid off, with Europe sales now largely matching those from the US.

Of interest is that margins are higher in Europe, with the company able to command a higher price. In two countries at least, Holland and Sweden, devices such as the Somnodent products are prescribed as a first line therapy before CPAP. Dentists in Europe charge considerably less than what is charged in the US, at around 400 Euros.

New Products

Last year Somnomed released its own Herbst product, which is a lower cost oral device costing between $300-$400. This device is only available in the US and has already allowed the company gain some large volume competitor accounts.

Cont'd over

New products to be launched by Somnomed are a new MAS (mandibular advancement splint, which is what the Somnodent device is technically known as), a 'Herbst Advance' product, the Dentitrac compliance recording product, and 'SomTabs', a consumable to clean the oral appliances that the company sells, which will add a regular consumable to the company's product line. With over 150,000 devices sold, the addition of ongoing consumable sales is a sensible and worthwhile strategy, even if initial sales will be modest.

Competing with CPAP

The company is pitching its COAT (Continuous Open Airway Therapy) products as a better alternative to CPAP (Continuous Positive Airway Pressure). Somnomed is seeing signs of frustration in the market place with the cost of CPAP therapy. The company is conducting a pilot study with one of the very large managed care organisation in the US, Kaiser Permanente. Kaiser Permanente has 8.9 million members and has a focus on delivering better health outcomes for its members.

Results from this study should be available by the end of this year, with the study due to start in the next few weeks. If it could be shown that COAT is a more beneficial outcome for patients with mild-moderate sleep apnea in this study, changing Kaiser's treatment of sleep disorders, then this would translate to a pivotal moment for Somnomed. However, it will likely require more than the one study. Kaiser has around 2,000 of its members assigned a CPAP each month.

Somnomed is in discussions with additional payers in the US healthcare market. At the moment about 60% of people in the US under private health cover are reimbursed most of their costs, and Medicare reimburses about half of the dental costs (around $1100).

Somnomed also expects to start a compliance trial with truck drivers, which will use the soon to be released Somnomed-DentiTrac system.

Somnomed is capitalised at $73 million.

Bioshares recommendation: **Buy**

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Nanosonics Update

Nanosonics (NAN: $0.80) increased its sales in the first half of this financial year by 119% to $9.7 million. The company's net loss fell by 42% to $3.5 million, and the company retained cash of $21.7 million.

The US still dominates the company's business, with 1,286 centres now using the company's Trophon EPR ultrasound probe disinfection system, up a staggering 31% from October last year only. This represents just under 20% of the potential hospital base for Nanosonics' product.

By comparison in Australia, there are at least 452 sites using the Trophon system, which is a good indicator of the potential reach of the technology for the rest of the world, according to CEO Michael Kavanagh. There are also 17 sites in New Zealand using the Trophon system.

In the US, another three to four of the top 50 hospitals have adopted Trophon use recently, which now totals 76% of the top 50 hospitals in the US using the product. Growth is also expected from not just new centres coming on board, but also from expansion of use within current hospitals. Sales are still dependent of the budget cycles of hospitals and clinics, with the Trophon system being a capital item expense.

Europe is an emerging market for the company although Kavanagh said that market is gaining traction. The company sells direct into the UK, Germany and France. Nanosonics has been adding sales staff in each of these countries. In France, the company is waiting on the results of tenders for which it has submitted proposals. If successful, sales are expected to be strong.

In Germany, clinical studies are close to completion with the foundations for that market in the process of being built. In the UK, review of disinfection processes for ultrasound probes is nearing completion in Wales and Scotland, with outcomes expected in the second half of this calendar year. This may see changes in guidelines favourable to Nanosonics.

Other Markets

The Trophon system has recently been approved for use in South Korea. The regulatory dossier submitted to the Japanese regulator is progressing faster than anticipated. Other future markets the company will look at entering are India, China and the Middle East.

Margins

Gross margins fell in this first half compared to the previous corresponding period from 67.4% to 61.8%. This was due to a relative increase in Trophon unit sales compared to consumables. At the moment consumables make up around 20% of total sales and are expected to grow to 36%-40% of total sales in the future.

Summary

The company has secured the Australian market, is well on the way to securing the US market, and is now building the foundations in Europe for Trophon adoption. However heathcare policies will affect adoption rates. In Germany and France awareness of the issue of cross-contamination from ultrasound probe use is building, with the company winning a healthcare award in Germany (M&K award) for its Trophon product. And potential changes to guidelines this year in the UK may accelerate adoption in that market.

Nanosonics is capitalised at $210 million.

Bioshares recommendation: **Hold**

Bioshares

Private Company Report

Global Kinetics' PKG System Now in 50 Clinics

Global Kinetics is a privately-held public company based in Melbourne which was founded in 2007. The company's technology originates from the Florey Institute of Neuroscience and Mental Health. As with our recent report on Minomic International, we provide the following report for readers of Bioshares who are interested in and capable of, investing in private companies, and in advance of any future possible IPO of the company.

Global Kinetics Corporation has developed a device, the PKG (Parkinson's Kinetigraph), which enables neurologists to objectively assess the symptoms of Parkinson's Disease. The PKG system is now available in 50 sites from a worldwide total potential pool of 1,500 movement disorder clinics. GKC is aiming to increase the PKGs presence to 60 sites by June, 2014 and 120 by June 2015.

The PKG is a wrist worn data logger, built around an accelerometer, which is worn by a patient for ten days. The device is handed back to the clinic and movement data is then collected and processed and a report is generated for the treating physician, usually a neurologist.

What is Parkinson's Disease and How is it Treated?

Parkinson's disease is characterized by a movement disorder and is associated with the loss of neurons in a part of the brain called the substantia nigra. Parkinson's disease can manifest itself as dyskinesia, where a person is in a hyperkinetic state (excessive uncontrolled movement) or bradykinesia, in which a person is in a hypokinetic state (a slowness in the execution of movement).

The gold standard for drug treatment of motor disorder symptoms, but especially bradykinesia, has been to administer doperminergic drugs e.g. Levadopa, as a dopamine replacement therapy. Problems with this therapy include the tendency for patients to become dyskinetic for a period of time following administration and that as the disease progress, the half-life of Levadopa decreases and the dosage required to be effective has to be increased. This means that the management of dopamine replacement therapy becomes increasingly difficult.

How is it Assessed?

Currently, the most common approach to the assessment of Parkinson's symptoms is dependent on the subjective assessments of doctors, the patients themselves and also their carers or other family members. These assessments might involve diary keeping or extend to observational studies conducted in a hospital over several days.

What subjective assessments do not capture is what a patient is doing when they are going about daily living and not thinking about their movements. The PKG allows neurologists to see what a patient's movements are in relation to therapies she or he is taking, to study the correlation between medications and symptom response as well as to know if the patient is complying with their drug prescriptions.

Business Model

GKC generates revenue from its PKG systems in two ways. Clinics can purchase a block of reports (e.g. 50 or 100) which must be used in a specific time period, but not buy any equipment, with reports charged at $225 each. This sales structure delivers 95% of revenue.

The alternative is that clinics purchase hardware from GKC for about $9,000 and then pay on an individual report basis. The hardware package includes a charge cradle, 10 wrist worn devices, 25 wrist straps, and one year's worth of 3G connectivity.

Competition

Competition for the PKG comes in the form of Great Lakes Technologies' Kinesia system. This system requires a Parkinson's patient to stand in front of a computer and make movements with their hands to obtain a bradykinesia score. They then must stand in front of a video camera to be filmed to obtain a dyskinesia score. This must be done several times in a day.

In contrast, Global Kinetics Corporation's PKG system is a wristwatch style data logger which a patient wears for ten days, after which it is sent back to their neurologist. The greatest contrasting feature is that the device can be worn while patients go about their daily activities. Patients can also use the device to log when they have taken their medications.

Other technologies exist, including smart phone apps which address one or more aspects of Parkinson's disease, such as tremor or freezing of gait. However, according GKC CEO Andrew Maxwell the 'key issue is what is happening with bradykinesia because that is what they treat with therapeutic agents'.

The Market Opportunity

The market opportunity for supplying medical products and diagnostic products or a symptom measurement tool such as the GKC PKG is very large, based on the 6 million people worldwide who suffer from Parkinson's diseases. An estimated 60,000 people suffer from Parkinson's disease in Australia.

Of the 6 million, GKC estimates that 3.1 million patients are located in the territories where the following criteria are met: key opinion leader engagement; regulatory approval obtained; the potential for early revenues; and have a path to recurrent funding (reimbursement).

The PKG system is most relevant to Parkinson's patients are at Stage 2 of the disease's classification spectrum, which is where patients have moved past three doses of levadopa a day and are showing early signs of bradykinesia and dyskinesia. This represents 1.6 million patients.

However, the more relevant metric is the opportunity for the annual number of tests. Stage 2 Parkinson's patients on average visit their medical specialist two to three times a year. GKC has identified and focused on 1,500 movement disorder clinics in its target markets. These clinics see 1.13 million patients a year, which translates to an annual 3.4 million testing opportunity. Each clinic sees an average of 750 patients, with each clinic representing 2,250 tests per annum (on average).

– Cont'd over

GKC's estimates that, in the long term, the 1,500 centres are worth about $350 million as a total addressable market, assuming 2-3 tests per patient and with reports selling for between $100 and $150. Each report currently is priced at $225 but the likelihood over the longer term is for pricing to fall as volume buying increases.

How Scalable is the Business?

GKC estimates that to achieve $15 million of turnover a year it would need to have an installed base of 300 clinics, based on an average price per report of $190, and five reports per week per clinic. So far the company has built its installed base of 50 sites over 18 months using a sales force of two. The addition of 5-6 sales staff would take it towards a 300 clinics target over a three-to-four year period.

Regulatory Status

The PKG is approved in Europe (CE Marked) and in Australia by the TGA, which means the company can sell in most of the European countries, in Australia and in many parts of Asia.

This year the company plans to submit the PKG for approval by the FDA, using the 510(k) pathway. For the approval pathway, a predicate device or devices must be referred to. In the case of the PKG, the company will refer to various predicate devices. It intends to use a device developed by Axon Instruments founder and now Monash University Chancellor, Alan Finkel, as the predicate device for measuring movement in Parkinson's disease. It intends to refer to other devices that measure movement using accelerometry and other devices that remind patients to take medication.

Patents and IP

GKC has licensed a number of patents which claim to differentiate normal movement from Parkinsonian movement as well as the measurement of impulse control disorders. Other patents cover metrics for determining where a patient might sit on the Parkinson's stages of disease progression.

However, none of those patents have been granted. The earliest patent date is from 2008, which means that if granted, the primary patent would expire in 2028.

Experience in Sweden

GKC's experience in the Nordic markets has been very positive. In Sweden, for example, all seven major movement disorder clinics now use the PKG system. This is because GKC met Swedish clinicians 'who felt that what we were trying to achieve with the PKG aligned very closely with their philosophy about how to manage Parkinson's disease,' said GKC CEO Andrew Maxwell.

Unlike Australia and the UK where national reimbursement schemes exist to pay for medical services and products, in Sweden, regional governments have a much greater say over health spending. Hospitals in Sweden can also buy products and services using their own budgets, i.e. purchasing decisions are not entirely dependent on a national or regional authority.

What the experience in Sweden has done 'is to give us some scale in talking about our product in other European markets. It has also led to some large pharmaceutical companies who rely on those key opinion leaders to provide feedback about new products, to become comfortable with us to start working with us to expand the use of the product in those markets and other markets,' according to Maxwell.

Industry partners are expected to become a source of revenue in the future were the PKG could be used as an objective measure of outcomes of the use of their agents or used as a tool to more accurately administer new treatments.

Future Investments and Spending

GKC's future spending is largely marketing focused, with investments to in be hiring more sales staff and for the development of market access plans in new territories. Smaller sums will be allocated to the release of a next generation data logger. The company also intends to make investments in backend operations so that it has the infrastructure to support larger volumes of reports, as well as billings and payments systems.

GKC sees a need to support some of the clinical work being undertaken by key opinion leaders as well as their presence at conferences and user meetings. Some spending on clinical trials managed directly by GKC is also envisaged.

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Bioshares Model Portfolio (21 February)

Company	Price (current)	Price added to portfolio	Date added
Invion	$0.077	$0.089	February 14
QRxPharma	$0.930	$0.620	December 13
Impedimed	$0.235	$0.245	December 13
Analytica	$0.025	$0.025	December 13
Imugene	$0.016	$0.022	November 13
Oncosil Medical	$0.130	$0.155	September 13
IDT Australia	$0.330	$0.260	August 13
Viralytics	$0.315	$0.300	August 13
Tissue Therapies	$0.300	$0.255	March 2013
Somnomed	$1.64	$0.94	January 2011
Cogstate	$0.350	$0.13	November 2007
Universal Biosensors	$0.37	$1.23	June 2007

Portfolio Changes – 28 February 2014

IN:
No changes

Recommendations:

OUT:

No changes

Recommendations:

Another Transformational Capital Raising – This Time for Benitec

Since Benitec Biopharma (BLT:$2.09) announced a $31.5 million capital raising on Monday its share price has increased 31% from its closing price a week ago of $1.59.

The capital raising is in two parts, with the first tranche of $15.8 million now completed and the balance subject to shareholder approval.

The share were issued at a $1.07, which represented a 5.3% discount to the 15 day VWAP.

A number of institutional life science investors have entered the BLT register through the raising, including RA Capital Management, Perceptive Advisors, Special Situations Funds and Sabby Management.

The capitalisation of the company based on the full completion of the raising is $249 million.

Benitec is now in a position to properly exploit its gene silencing technology and particularly to forge ahead with its Hepatitis C trial.

For investors, however, the stock at its current level is represents an opportunity to 'Take Profits'.

Bioshares recommendation: **Take Profits**

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Clarification - Cogstate - Bioshares 540
In its 4D, Cogstate reported that it had $7 million of contracted future revenue at 31 December, of which $3 million will be recognised in the second half of FY14. In its business update lodged on 18 February, Cogstate noted that, following the award of a number of studies in December and January, the amount of contracted and awarded (Cogstate has won the bid and are in the process of contracting) future revenue had ballooned from $7 million to US$18.06 million of which US$5.2 million will be recognised in the second half of the financial year, and the balance in periods thereafter.

(Yet) Another Delay for Tissue Therapies

As part of its CE Mark review by the European Medicines Agency (EMA) of Tissue Therapies (TIS: $0.30) wound healing product VitroGro, the company has been requested to supply data from its contract manufacturers. The effect of this is to 'stop the clock' on the mandated review period of 210 days, pushing back final approval to 2014 H2.

Whilst frustrating for the company and investors, it is important to properly satisfy the demands for information by regulators especially where manufacturing is concerned.

The risk does exist that the EMA could impose new conditions on manufacturing of VitroGro. However, if that were the case, it would raise issues with the EMA's internal processes and promote doubts about the integrity of its review processes, given that it has had the product under review for some time.

At this stage, we assume the EMA's enquiries are of an administrative nature rather than being concerns of a more fundamental nature.

Tissue Therapies has originally anticipated EMA approval for Vitro Gro in mid-2012. However, a product classification wrangle slowed the approval process down. That problem was resolved but the EMA chose to initiate a 210 day manufacturing audit in August 2013, to commence 6 September 2013.

Tissue Therapies retained cash of $10.3 million as at December 31, 2013.

Tissue Therapies is capitalised at $79 million.

Bioshares recommendation: **Speculative Buy Class A**

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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

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