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Bioshares

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

Somnomed to Launch New Products in FY14 and Complete Trials to Support Compliance Claims

Oral appliance sleep therapy (OAT) company Somnomed (SOM: $1.20) has been meeting with the investment community to discuss its full year results for FY2013.

One of the company's achievements in FY2013 was an expansion in direct geographic coverage in Europe, which has occurred through the acquisition of a 65% stake in Orthosom in France and MAS Nordic in Sweden. Just after the end of the fiscal year, the company announced the acquisition of Orthosleep 19 in Germany, a service lab and licensee of Somnomed.

These acquisitions contributed to an improvement in Somnomed's gross margin, as distributor margins were returned to Somnomed. Somnomed's revenues are received via four channels, which when combined, delivered an overall gross margin of 66% for FY2013.

Margin from device sales, which account for 95% of sales, was 69%. Seminars and billing services both operate on a break even basis and the diagnostic product, MATRx, operates at a loss.

New Products

Somnomed also introduced new products in FY2013 and expanded the availability of the relatively new all-plastic, slimmer Somnodent G2 to all markets. The company introduced a mid-priced product, the Somnomed Herbst, to cater for the market segment in the USA which draws from Medicare insured patients. Currently Somnomed's products are priced in the premium range, with combined device and fitting costs charged by dentists in the US ranging from $3,000-$4,000 per patient. This cost bracket is not covered by Medicare.

New US Management

Somnomed also added to its additional management capabilities during the year, particularly to address shortcomings in its US operations. These positions included: a President of North American operations, Kien Nguyen; a VP of Managed Care, Stacey Gilbert; a VP of Marketing & Sales, Andrew Tosdevin; and a Chief Medical Officer, Dr Jagdeep Bijwadia. The restructuring of lab and dental operations in the US has already begun to deliver positive results.

Growth in Accounts Receivables

Despite cash at hand growing by $700,000 to $4.2 million, accounts receivables grew in the year as a consequence of increased dealings with insurance companies. Days debtors in the US are between 60-70 and in Europe, 80-90, but for dentists in both regions days debtors are less than 60. The longer payment terms are not a sign of greater payment risk, but rather a reflection of the payment cycles typical for insurance companies. In contrast and by way of example, dentists, as small operators, often settle their accounts using credit cards.

Cont'd over

	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)	60.5%
Cumulative Gain	**472%**

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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: 0403 850 425
Email: pachacz@bioshares.com.au

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Balance Sheet

The company believes it has a strong balance sheet and has sufficient cash to expand the business without going to the market to raise capital. Executive Chairman Peter Neustadt said 'we are very cautious on investing money where we don't know what the outcome is...(but)...we are not against raising money to go faster if something comes up.' At the moment the company has a medical sales staff of only four in the US. If the US market looks like it is set to take off for Somnomed, then the company is prepared to move to a full sales team of 20-30 staff, but only when the company is confident that such an investment will pay off.

Results by Region

Somnomed generated 31% of unit sales out of Europe, 12% from Asia-Pacific and 57% from North America. The European share of sales is expected to grow in the medium term. However, North America is expected to dominate over the longer term with a 55%-60% share because the US is the biggest sleep medicine market.

US Operations

One of the immediate changes that has taken place since new senior staff were appointed in the US, especially that of the CMO, is that Somnomed has been able to meet with more senior and influential medical personnel in insurance organisations.

Among the positions filled in the US management makeover was that of Operations Manager, which was filled by Felix Silva, who has initiated training programs for staff and is working to improve turnaround times for support services.

Somnomed has also been implementing a new ERP (enterprise resource planning) system to better coordinate sales and marketing.

Relations with Insurers and Managed Healthcare Groups

Some of Somnomed's most important challenges come from working with insurers and managed care organisations in the USA.

Managed health care organisations (HMOs) are now wanting to work with Somnomed to work out rates for them to pay dentists for the fitting and supply of Oral Appliance Therapy (OAT) devices. Somnomed is the only oral appliance therapy company conducting discussions of this nature. The driver is the huge variance which exists in charges by dentists for oral appliance therapy. If agreements can be reached, then this will open up more sleep apnea patients to Somnomed.

Insurers and managed care organisations are also seeking information about the compliance benefits of OAT. This makes BRAEBON Medical Corporation's Dentitrac compliance recorder an important technology for Somnoned. Somnomed became an exclusive worldwide distributor of the technology late in 2012. Compliance measurement is important for payors who want to make sure that patients are using their OAT products properly. Patient self-reporting has been the main method of measuring compliance to date. The Dentitrac system, which makes measurements at one minute intervals, creates data sets that can be collected every few weeks and can be assessed for compliance.

Somnomed Results Summary and Expectations

Revenues

FY2013 – $18.5 million (up 21%)
FY2012 – $15.3 million

FY2014 Expectation > $22 million

Unit Sales

FY2013 – 35,841 (up 16%)
FY2012 – 30,878

FY2014 Expectation >43,000

Profit

FY2013 – $0.71million (up 1%)
FY2012 – $0.70 million

Compliance is especially important in the transportation sector, covering trucking, train, bus, taxi and airline operations and Somnomed expects to derive more business from the transportation sector in the future.

Somnomed will be conducting some studies of its own to provide stronger or better evidence of OAT compliance, which on a patient self reported basis is around 90%.

One of the issues with compliance is a discrepancy between definition of successful compliance. The standard used by CPAP sellers (e.g. Resmed and Respironics), is based on CPAP users achieving a minimum of four hours sleep (of a particular quality) a night, but over 21 days per month. In contrast, Somnomed's devices deliver 6 ¼ - 6 ½ hours a night of sleep over 30 days. Somnomed's claim is that it does not have a compliance issue yet the inconsistent standards muddy the arguments that compare OAT with CPAP.

A HMO that Somnomed has had a relationship with for three years, Kaiser Permanente, is also keen to conduct a trial of Somnomed's OAT device. This trial will start and finish this year.

Somnomed and Kaiser are also working on a new sales model that may increase the take-up of OAT devices. This model involves bringing dentists into Kaiser facilities in order to make the process of patient testing and the fitting of devices more user friendly.

(To give some context for the OAT uptake issue for Somnomed, Kaiser supports 200,000 CPAP prescriptions over nine regions but only covers 1,500 Somnomed units across four to five Kaiser regions.)

This pilot has implications for growth generally because if it works it could be the model potentially adopted by other HMOs.

Push Backs and Barriers

One of the other barriers that Somnomed must address is that physicians have yet to develop relationships of trust with the dentists in sleep dentistry networks. The lack of knowing where to send patients increases uncertainty.

Cont'd over

Bioshares Model Portfolio (27 September 2013)

Company	Price (current)	Price added to portfolio	Date added
Oncosil Medical	$0.130	$0.155	September 13
Calzada	$0.078	$0.073	September 13
Invion	$0.065	$0.060	August 13
IDT Australia	$0.380	$0.260	August 13
Viralytics	$0.390	$0.300	August 13
Circadian Technologies	$0.280	$0.270	March 2013
Tissue Therapies	$0.320	$0.255	March 2013
Benitec Biopharma	$0.390	$0.40	November 2012
Somnomed	$1.20	$0.94	January 2011
Cogstate	$0.460	$0.13	November 2007
Universal Biosensors	$0.76	$1.23	June 2007

Portfolio Changes – 27 September 2013

IN:
No changes.

OUT:
No changes.

– Somnomed cont'd

Somnomed sees that one its jobs is to build bridges between physicians and dentists, including its 2,500 strong dental network.

Outlook for FY2014

Somnomed expects unit sales to exceed 43,000 units for FY2014 and to post revenues of greater than $22 million. This increase excludes any major success from the company's medical marketing initiative to sleep physicians in the US.

The company will release a second mid-range price segment product, the Herbst Plus, in October. This will be priced in the $370-$380 range, compared to $350 for the Herbst.

Somnomed also will release a new upper-price segment OAT device. The prototyping of this product is finished and it is now undergoing clinical testing. This new product will be presented at trade events in Europe in November or December and FDA approval is expected by May 2014.

The company intends to integrate the markets of Korea and Italy into its global operations and expects to launch its products in Finland and Russia this financial year. Partners will be used in Russia both for sales and service. Wealthy private customers will be targeted in Russia. Finland is the biggest CPAP market of the Nordic countries, representing a major opportunity for Somnomed.

In Europe, Somnomed has rapid acceptance where it gets reimbursed, although the exception is Germany where gaining reimbursement from that country's public insurers, which cover 90% of the population, is painful and slow.

Somnomed has now seen a significant trend towards greater acceptance of OAT begin to take shape in markets that offer reimbursement and operate fairly. For example, in the Netherlands four years ago the ratio of OAT to CPAP was 7% to 93%. Now OAT has 35% share and is on its way to 50%. Somnomed expects the market share to be 50-50 in fully reimbursed, open and level-playing field countries. The company is beginning to see this shift take place in Norway.

Summary

There are two growth propositions to note with Somnomed. The first is that growth in Europe is stronger in Europe in the short to medium term. This is aided by a clearer reimbursement status in a number of territories. In contrast, growth in the US is a much longer term proposition, with sustained efforts required to link sleep physicians to dental networks, to rigorously communicate the medical and compliance benefits of OAT to insurers and HMOs and additionally to improve the access of sleep apnea patients to Somnomed's products. Anticipated growth of 20% should, however, be recognised in the share price of Somnomed over the year ahead.

Bioshares recommendation: **Buy**

Bioshares

Ophthotech's US$630 Million Technology Value Validates Circadian's Combination Eye Therapy Program

This week US company Ophthotech Corporation listed on the Nasdaq, raising US$167 million. The company listed at US$22 a share and closed the week up 32% at US$29 a share. The company has a market capitalisation of US$880 million, which equates to a technology value just over $650 million (US$225 million in cash). The relevance of this to Australian investors is that Ophthotech is commercialising a combination eye therapy technology, using approved eye drug Lucentis with its eye drug candidate Fovista. This is a very similar approach to that being taken by Australian listed biotech Circadian Technologies (CIR: $0.28).

Ophthotech has completed Phase II studies, being significantly more advanced that Circadian, which is still around 12 months from starting a Phase I eye therapy trial. In a Phase IIb trial involving 449 patients, Ophthotech showed that when combining its drug candidate Fovista with Genentech's eye drug Lucentis, patients' eyesight improved by a mean of 10.6 letters, compared to only a 6.5 letter improvement when Lucentis was used alone.

Ophthotech has since started a Phase III trial with Fovista in combination with Lucentis.

Fovista targets what is called the 'platelet derived growth factor'. It works effectively, judging by Phase II studies, with Lucentis, which stops the growth of new blood vessel formation, blocking the VEGF-A proteins. Fovista causes what are called pericytes to be stripped from newly formed blood vessels, which then makes those blood vessels more susceptible to Lucentis.

Circadian's is approach is to block the VEGF-C and VEGF-D proteins involved in new blood vessel formation, which is relevant to the abnormal blood vessel growth that causes wet age related macular degeneration (AMD). Using Circadian's VGX-300, in combination with Lucentis, will block the VEGF-A, VEGF-B and VEGF-C pathways, giving potentially a more complete shut down approach to unwanted blood vessel formation in the eye. It may also mean that patients may not need to return to their Ophthalmologist as frequently – every four weeks currently – to be injected with the drug into the eye, with a combination approach potentially delivering a longer lasting therapy.

Circadian is currently in the process of having its drug candidate VGX-300 manufactured. VGX-300 is a soluble receptor molecule of VEGFR-3, which works by soaking up the VEGF-C and VEGF-D proteins. It is manufactured in a similar process to antibody drugs. Circadian is seeking to start preclinical toxicology studies in the first half of next year, with Phase I/II studies in patients (not volunteers) expected to commence in late 2014 at the earliest.

Robert Klupacs, CEO of Circadian, believes that VGX-300 may be more effective than Fovista, with VGX-300 showing single agent activity in preclinical mouse models of wet AMD similar to the very successful eye drug Eylea, where Fovista did not.

In the first year of sales, Eylea generated sales of US$838 million. However more than 50% of patients do not experience an improvement in vision by taking the VEGF-A type drugs such as Lucentis and Eylea. This has left a gap in the market for potential combination therapies, to improve and potentially extend therapy. Shutting down all VEGF pathways using a combination approach using VVG-300 with Eylea or Lucentis is looking to be a valid commercial approach.

Funding

Circadian has a number of funding options to commercialise VGX-300 for ophthalmic applications. The asset is housed in a Circadian subsidiary called Opthea. One option is to list the company on the ASX as a separate entity, similar to what Circadian has done previously (with Optiscan Imaging, Axon Instruments, Metabolic Pharmaceuticals and Antisense Therapeutics), raising funds for Opthea from the US venture capital markets, or funding the program as it is currently, through Circadian. The company is not sufficiently advanced to seek a US listing.

Klupacs said the company is seeing major interest from the US because of Ophthotech's success.

Phase I Lymphedema trial

Circadian is currently conducting a Phase I safety study with its VGX-100 oncology drug candidate in 40 patients. Once results are available, which is expected in early November, the company expects to start a Phase II trial in women with breast cancer related lymphedema. VGX-100 also shuts down the VEGF-C pathway, which has been shown by others using a different (more toxic) VEFG-C inhibitor to produce beneficial results in breast cancer related lymphedema. Results from this trial should be quick, taking no more than nine months. Circadian is seeking to start that trial this year.

Circadian is also receiving demand to from oncologists to start a Phase II study in glioblastoma in combination with Avastin. This trial could start in 1H 2014, and would also be a fast readout, taking no more than nine months.

Circadian is capitalised at $13 million with an estimated $12 million in cash and a further $2.3 million in other financial assets (including listed companies ANP and OIL). It is a stock that has been ignored by the market, but one which has numerous drivers in the coming 12 months.

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

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