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Bioshares

11 July 2014
Edition 559

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

Companies covered: LBT, SOM, SVA

	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 - May '14)	26.6%
Year 14 (May '14 -)	1.6%
Cumulative Gain	374%
Av. Annual gain (14 yrs)	16.2%

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Somnomed Builds Leading Position in Europe

The distributor model is largely a trial and error process and is more often an unsuccessful approach, with companies relying on third parties to sell their products alongside an array of other company products. This week, Somnomed (SOM: \$1.62) announced it had taken over its Italian distributor operations, now giving Somnomed direct sales and marketing operations in all 16 countries it operates in within Europe.

Somnomed is focusing firstly on securing operations in Western Europe, which it breaks down to Southern Europe, Central Europe and Northern Europe (Scandinavia). The company has used the approach of initially operating through distributors, and then moving to a direct sales and marketing approach, either acquiring its distributor or establishing its own operations. With its own sales and marketing teams in place, Somnomed often operates through a partnership arrangement, whereby the partner provides logistic and after sales service support to the dental networks.

Scandinavia Market Coverage Completed May 2014

In December 2012, Somnomed announced it would acquire its Swedish distributor, which had been Somnomed's distributor since 2008. One of the reasons for acquiring this distributor would be not only to gain more control of sales into that market, but to also expand and support entry in other parts of Scandinavia. In 2013 Somnomed expanded operations into Denmark and a sales manager for Norway was installed in April 2013.

In May this year, Somnomed announced it had started operations in the last remaining market in Scandinavia, Finland, by entering into a partnership with an orthodontic laboratory in Helsinki to provide logistic and after sales support, and installing a local sales manager.

In Sweden, the use of oral appliances (termed continuous open airway therapy or COAT) to treat sleep apnea is prescribed as a first line therapy, before CPAP machines. In Sweden, COAT products have 55% of the market, and CPAP makes up the remaining 45%.

Southern Europe Operations Secured July 2014

At the start of this financial year, Somnomed commenced operations in Spain and Portugal. The company has entered into a partnership arrangement with a Spanish orthodontic group to provide logistic and after sales support as well as installing a local sales and marketing manager.

As mentioned above, then company has taken over Italian operations, with its distributor becoming a partner that will provide logistic and after sales service. This will allow

Cont'd over

Summit Publication Schedule

The next edition of Bioshares (560), with coverage of the 10th Bioshares Biotech Summit, will be emailed to subscribers on Wednesday July 23, 2014.

Somnomed to control the sales and marketing of its products in that region.

A regional manager controls the operations of Southern Europe, which includes France, Italy, Spain and Portugal. In December 2012, Somnomed acquired 65% of the Orthosom orthodontic group in France to give the company a local operation.

Enters UK/Ireland May 2014

In May this year Somnomed announced it would start selling its products into the UK and Ireland through a partnership arrangement. The company has formed an agreement with JJ Thompson which has a client base of over 1,000 dentists. JJ Thompson will similarly offer logistic and after sales service support.

The UK market is dominated by CPAP machines, and Somnomed will need to form its own trained network of dentists to fit the Somnomed devices. With no reimbursement in the UK, it will make it a more difficult market to penetrate, although the company believes the interest in COAT is increasing.

The remaining region for Somnomed to secure in Europe is the Baltic countries that make up Eastern Europe.

New Product Launches for US market

This month Somnomed expects to start selling two new products into the US market. These are the Somnomed Herbst Advance (a variation on the Somnodent Herbst product) and the Somnodent Fusion product. Both products have received FDA product clearance.

The US market has returned to a growth phase, with unit sales up 22.8% in the March quarter over the previous corresponding period. Introduction of the low cost Somnomed Herbst product has contributed to increased volume in US sales as has the smaller and more comfortable G2 device.

Strong Q4 Result Anticipated

Somnomed is due to release its fourth quarter results on 23 July. For the last four years, fourth quarter results have shown strong growth over the preceding quarter, increasing by 16.6% last year, and by 7.7%, 15.4% and by 13.5% respectively in the three prior years.

There were good signs of growth in March, with the March quarter unit sales up 28% over the previous corresponding period. The lower Australian dollar also made a positive contribution with sales up 50%. The positive movements in the foreign exchange rate will also help accentuate results in the June quarter.

To date over 175,000 Somnomed devices have been sold. We expect sales for FY2014 to be in the range \$26-\$27 million.

Summary

Somnomed is following the tried and tested approach in Europe that Cochlear and Resmed have used of installing distributors firstly, and then moving to a direct sales approach either by acquiring its distributor, or setting and a partnership arrangement with existing orthodontic groups to provide logistic and after sales service.

Europe now contributes to 40% of the company's sales and remains the fastest growing market for the company. Converse to most other medical products, higher pricing is achieved in Europe than in the US. And in countries such as Sweden and Holland, adoption rates are comparable to CPAP, at 55% and 35% respectively. Europe is becoming an increasingly important market for Somnomed, one which Somnomed has secured its dominant position this year.

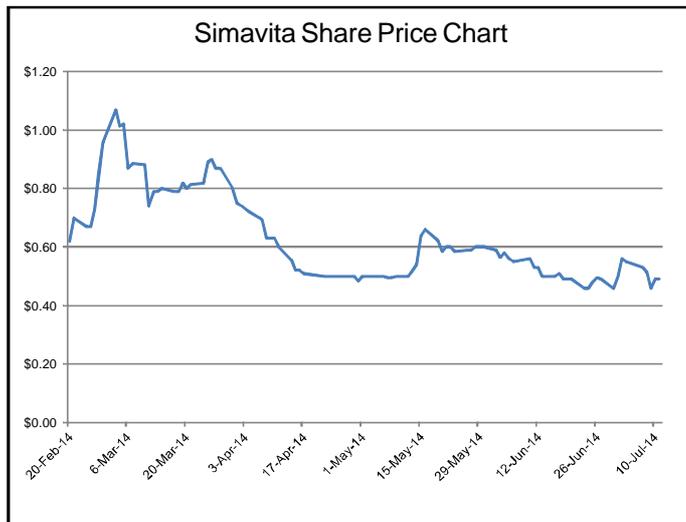
Somnomed is capitalised at \$73 million. The company had \$3 million in cash at the end of March.

Bioshares recommendation: **Buy**

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Somnomed Unit Sales & Revenue				Growth Over Preceding Quarter			
		Rev (\$M)	Unit Sales	Weak 1st Qtr	Strong 2nd Qtr	Weak 3rd Qtr	Strong 4th Qtr
FY2014	Q3	\$6.5	11,010	-7.0%	19.7%	-1.2%	16.6%
	Q2	\$6.9	11,146				
	Q1	\$5.6	9,309				
FY2013	Q4	\$5.5	10,009	-3.3%	8.7%	-4.1%	7.7%
	Q3	\$4.3	8,582				
	Q2	\$4.9	8,950				
FY2012	Q1	\$4.2	8,232	-8.1%	14.5%	2.5%	15.4%
	Q4	\$4.5	8,515				
	Q3	\$3.8	7,903				
FY2011	Q2	\$3.6	7,711	-4.9%	17.8%	2.4%	13.5%
	Q1	\$3.2	6,732				
	Q4	\$3.3	7,323				
FY2010	Q3	\$3.0	6,346				
	Q2	\$3.1	6,196				
	Q1	\$2.8	5,260				
FY2010	Q4	\$3.2	5,531				

Simavita Revives Capital Base with \$6 Million Placement



Simavita (SVA: \$0.49) sells the Smart Incontinence Management (SIM) product (or system), which aids in the assessment and management of urinary incontinence. Its primary market focus is directed at aged care facilities. The system connects a sensor-enabled incontinence pad to a transceiver and data acquisition device. Data from a 72 hour observation period is then uploaded for analysis by nursing staff, who are able to profile or map a incontinence behaviour in conjunction with fluid and food intake events. The system allows residents' toileting to be managed more efficiently.

Simavita is a company of Australian origin but is listed through a Canadian parent vehicle, the former Gtec International Resources, on the Toronto Stock Exchange, with 1:1 Chess Depository Interests being traded on the ASX.

Simavita recently completed the first part of a capital raising, securing \$3 million through a placement. A second tranche, dependent on shareholder approval, is expected to bring in close to \$3 million.

Simavita has also initiated an SPP, which could see it raise up to \$1 million.

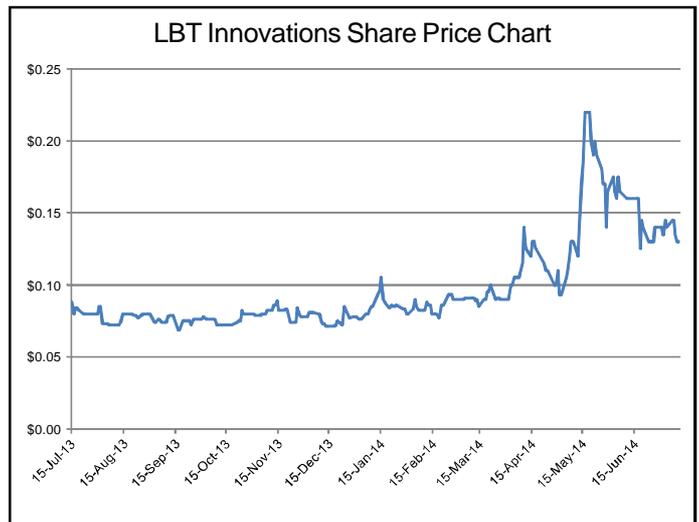
The funds obtained from the capital raising will be used to support the roll-out of its incontinence management system in the US and Europe, advance the development of its cloud-compatible SIM Generation 5 product and its SIM Community Care product, and to acquire and develop IP.

The company reported a net loss of \$9.6 million for the nine months ending March 31, 2014, on revenues of \$254,000. At the close of the March quarter, the company retained cash of \$5.8 million.

US Sales Commence

Simavita announced that its North American partner, Medline Industries, has commenced sales of its Wi-Fi enabled SIM Generation 4 product, following the launch of the system at the National

LBT Innovations Boosts Cash Reserves Ahead of Distribution Deal



LBT Innovations (LBT: \$0.13) recently initiated a \$3 million capital raising, firstly receiving \$0.4 million from a placement to professional sophisticated investors, with a further \$1.1 million to follow once shareholder approval has been obtained. The company has also implemented a Share Purchase Plan to raise up to \$1.5 million at 13.5 cents per share.

The capital raisings come at a time when the company has passed a key milestone for the development of its Automated Plate Assessment System (APAS), which it is managing through a 50:50 joint venture (Clever Culture Systems) with German lab equipment supplier Hettich AG. This milestone resulted in the receipt of a \$1 million milestone payment, bringing to \$5 million the total received to date from upfront payments (\$2 million) and milestone payments (now \$3 million) from the joint venture partner. The payment relates to the development of software for the APAS and preparation of modules for the clinical testing of the system across three sites in Australia and the USA. The next and final milestone payment (of \$1 million) is related to clinical trial progress.

510k Application

The trial data will be used to support a 510k application with the US FDA, in which the system will be required to show equivalence to microbiologists. Several thousand samples will be read by APAS and also by human operators. Regulatory approval is being targeted for 2015.

LBT has outlined in general terms how the joint venture company will distribute income received from a global distributor of APAS. Recurring payments for APAS instruments will flow through to Hettich but recurring payments for APAS software, upgrades and support will flow through to LBT Innovations. Both parties will stand to receive dividends i.e. a 50% share of commercialization profits.

Study Results Published

LBT Innovations also recently presented the results of a study of the APAS device in which 526 urine samples were analysed. The

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Bioshares Model Portfolio (11 July 2014)

Company	Price (current)	Price added to portfolio	Date added
LBT Innovations	\$0.130	\$0.130	July 14
pSivida	\$4.680	\$3.800	May 14
Invision	\$0.067	\$0.089	February 14
Impedimed	\$0.220	\$0.245	December 13
Analytica	\$0.037	\$0.025	December 13
Imugene	\$0.015	\$0.022	November 13
Oncosil Medical	\$0.097	\$0.155	September 13
IDT Australia	\$0.220	\$0.260	August 13
Viralytics	\$0.275	\$0.300	August 13
Tissue Therapies	\$0.280	\$0.255	March 2013
Somnomed	\$1.62	\$0.94	January 2011
Cogstate	\$0.260	\$0.13	November 2007

Portfolio Changes – 11 July 2014**IN:**

LBT Innovations has been added to the Model Portfolio.

Recommendations:

LBT - Speculative Buy Class A

OUT:

No changes

– Simavita cont'd

Association Directors of Nursing Administration in Long Term Care in California in June.

In North America, Simavita will be selling hardware (pods) and consumables (sensors, which are placed with incontinence pads), in addition to a selling software licences to users on a per building basis. Simavita estimates that annual revenue per site could range from \$15,000 to \$75,000. On the assumption of accessing 10% of the US nursing home market implies an annual revenue estimate to Simavita of \$71 million. The driver for adopting the changes is that Simavita believes it can generate close to \$1,600 in savings per bed per annum.

Summary

Simavita has addressed a key weakness with this capital raising. A next objective for the company is to secure a beachhead in North America. Positive feedback from a number of early adopter sites will be helpful in generating product awareness across the USA. Furthermore, feedback that can improve the implementation of the SIM Generation 4 system would also be useful.

Simavita is capitalised at \$35 million (assuming the shares issued for the second tranche of funds are approved.)

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

– LBT Innovations cont'd

study reported that APAS screened routine urine samples with a sensitivity of 97% and a specificity of 95%.

Key Events to Monitor

Events for investors to monitor for the APAS program over the next 12 months include the enlistment of a global distributor, the filing of regulatory submissions with the FDA (in the US) and for CE Marking (in Europe), and evidence that the manufacturing process of the APAS and its associated incubator has moved from a test phase to validated-for-sale phase.

WoundVue Program

LBT is planning to invest \$2 million over the next 12-18 months into its WoundVue program, to demonstrate proof-of-concept. This product originates from the company's experience in image assessment, as acquired and developed for the APAS program. The need for accurate and objective measurement of chronic wounds in the wound care treatment market is high, with immediate relevance being for therapies in development.

The appeal of LBT Innovations is that it is a customer and need driven innovator, rather than a scientific discovery company looking for 'commercial opportunities' for its inventions.

LBT Innovations is capitalised at \$14 million (assuming the shares issued for the second tranche of funds are approved.)

Bioshares recommendation: **Speculative Buy Class A**

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

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