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Bioshares

22 January 2016

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

Companies covered: CGS, IMU, OSL,
SOM

	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 - May '15)	23.0%
Year 15 (May '15 - current)	23.6%
Cumulative Gain	585%
Av. Annual gain (14 yrs)	18.1%

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Cash Flow Reports – December Qtr, 2015

Somnomed – Quality Growth Continues

Somnomed (SOM: \$2.62) achieved a booming result for the December quarter. It sold 16,151 of its Somnodent devices, which are used in the treatment of sleep apnea (28,997 in the half). This was 25% more than the number of devices sold in the September quarter, which is generally a lower selling period, and 1,634 devices more than it sold in the previous highest quarter in the June quarter last year. Compared to the 2014 December quarter, unit sales increased by 19% in this quarter.

What should also be taken into account is that 400 devices narrowly missed the end of year delivery due to a production delay.

For the quarter, Somnomed achieved revenue of \$21.3 million with a positive operating cash flow of \$0.74 million.

Europe continues to perform well for the company, with unit sales increasing by 23.4% over the previous corresponding period (pcp) and that followed an 18.3% increase in the September quarter. Europe now makes up 37% of overall unit sales for Somnomed.

In the US, direct sales, which make up the majority, increased by 22.1% with sales to licensees falling 2.5% in North America in this quarter. Licensee sales deliver a lower margin for Somnomed. Licensee sales fell by 83% in the September quarter to around 200 devices, with direct sales accounting for around 8,600 units for this quarter.

Licensee sales have fallen because on Somnomed's increasing direct sales presence. In November Somnomed announced it had acquired sleep apnea company Strong Dental in Canada for C\$0.7 million, with Canada being the last market that had a strong licensee operation. This will give Somnomed a direct presence in Canada as well as a service hub which is required to sell direct into Canada. It will also allow the company to growth sales more aggressively in that country.

Analysis

The key metric for investors to follow is US product sales as this represents the most direct upside for the company and has been a market that the company has needed to address in recent years.

Cont'd over

Save the Dates

The 12th Bioshares Biotech Summit
July 29-30, 2016
The Heritage Hotel
Queenstown - New Zealand

Mandibular Advancement Splints (MAS) make up only around 7% of the sleep apnea market with CPAP used in 93% of the market. There remains a very large addressable market, both as an alternative to for CPAP users, and for those patients not willing to adopt CPAP treatment.

The US is also a very competitive market, with prices lower than in Europe. Somnomed has maintained its leading competitive position through product development, ensuring it operates in all aspects of the market, from budget devices, to popular Herbst devices as well as its core proprietary products including the Somnodent Flex and G2. Products released in late 2014 contributed to 36% of unit sales in the US in the December half period, confirmation that the company has a good understanding of the market needs and segments.

Although Europe is also an important market, Somnomed's country-by-country strategy of acquiring distributors to gain more direct sales access has proven to be a precisely successful approach.

Forecasts

Somnomed indicated that global direct sales were increasing at around 25% a year (if production delays are excluded) and it expects this rate of growth to continue into the third quarter.

The company has forecast unit sales in excess of 62,000 for this financial year, sales of \$42 million and an EBIT of \$3 million. A move into profit growth for this company this year and next can be expected to expand investor interest in this stock.

Note that the March and September are generally weaker quarters for the company (see table). However the company also appears to have a stronger year each alternative year, so a strong performance can be expected over calendar year 2016. Other companies such as Sirtex Medical also follow this trend.

Somnomed is capitalised at \$137 million with cash of \$7.4 million at 31 December, 2015.

Bioshares recommendation: **Buy**

Bioshares

Somnomed Unit Sales & Revenue				Growth over preceding quarter					
		Revenues (\$M)	Unit Sales	Weak 1st qtr	Strong 2nd qtr	Weak 3rd qtr	Strong 4th qtr	Calendar year unit sales	Growth
FY2016	Q2	11.66	16,151	-11.5%	25.7%			55,577	16%
	Q1	9.64	12,846						
FY2015	Q4	10.07	14,517	-6.5%	21.2%	-11.1%	20.3%	47,758	22.3%
	Q3	7.62	12,063						
	Q2	8.1 (est.)	13,575						
FY2014	Q1	6.7 (est.)	11,200	-7.0%	19.7%	-1.2%	8.7%	39,046	16.2%
	Q4	6.8	11,973						
	Q3	6.5	11,010						
	Q2	6.89	11,146						
FY2013	Q1	5.61	9,309	-3.3%	8.7%	-4.1%	16.6%	33,600	19.5%
	Q4	5.5	10,009						
	Q3	4.33	8,582						
	Q2	4.85	8,950						
FY2012	Q1	4.15	8,232	-8.1%	14.5%	2.5%	7.7%	28,112	10.4%
	Q4	4.5	8,515						
	Q3	3.8	7,903						
	Q2	3.6	7,711						
FY2011	Q1	3.2	6,732	4.0%	17.8%	2.4%	15.4%	25,468	
	Q4	3.3	7,323						
	Q3	3	6,346						
	Q2	3.1	6,196						
FY2010	Q1	2.8	5,260				3.8%		
	Q4	2.63	5,058						
	Q3	2.36	4,082						
Av.									18.6%

Cogstate Delivers A Second Consecutive Strong Quarterly Performance

Cogstate (CGS: \$0.575) has delivered its second positive quarter performance, generating a net operating cash flow of \$1.01 million, and by our estimates the second consecutive profitable quarter of around \$1.0 million in EBIT per quarter, excluding pass through costs. Cash receipts from customers totaled \$7.36 million for the quarter (including pass-through costs - see below), up 57% on the previous corresponding period (pcp).

Cogstate conducts cognitive testing for pharmaceuticals in clinical trials. Its contracts can run for up to three to five years for larger Phase III studies, and one to two years for smaller trials.

In the first two quarters of the current financial year, Cogstate has signed contracts worth US\$8.4 million and US\$8.2 million respectively for the September and December quarters, representing Australian dollar values of \$23.1 million in total at the time of signing.

Cogstate receives some benefits of a falling dollar, with 98% of its sales in US dollars and 78% of costs in US dollars according to Cogstate CEO Brad O'Connor. With revenue increasing more than costs now, this will continue to provide an additional advantage, as well as some FX gains from invoiced amounts that increase between the time of invoice and payment if the local currency continues its fall.

Last month the company provided an update to the market indicating that it had a backlog of work totaling \$45 million. Already secured, the company expects to recognize at least \$23 million of sales for this financial year, and has already locked in sales of \$13 million for FY2017. Having a building backlog of work should deliver more consistency and predictability in the company's performance in coming years, as well as easing the path for the company in maintaining a strong profitability for its shareholders.

Our estimate for full year sales is around \$30 million which should translate to a profit before tax of around \$4 million. If the company can achieve sales of \$40 million in FY2017, then it should translate to a profit before tax of around \$10 million according to Bioshares estimates.

Half year profit estimates

Cogstate will be reporting its half-year results on February 17. Working off the company's cash flow statements, we expect the company will achieve a profit before tax of around \$1.5 million. This profit estimate would have been \$0.5 million higher (circa \$2.0 million) if \$0.5 million of pass-through costs that company had incurred last quarter could have been passed-on last quarter but will be invoiced this quarter.

(Notes regarding Pass-through costs: Cogstate needs to pay for services such as translations of documents for which it passes on directly to its customers. These pass-through costs are not included in the company's clinical trial revenue.)

In the company's December cash flow report, Cogstate had a \$1.74 million increase in payables. Only \$0.4 million of this related to

trade creditors for clinical trial costs, with \$0.5 million as indicated for pass through costs and the balance for employee provisions and accrued income (where the company receives upfront payments from its customers but it is not yet recorded as revenue). The company recorded a \$0.48 million increase in receivables over the quarter.

Recommendation

Applying a forward price-earnings ratio of 23 times (an average for pharmaceutical contract research organisations) for Cogstate for its estimated earnings this year delivers a valuation of \$0.58 for the company, which is inline with where the company is trading. However the company has a very good potential to generate strong shareholder value over the next 12 - 18 months being in a high growth phase of its business and may suit investors with this investment timeframe at this price level.

Cogstate is capitalised at \$63 million. It held cash of \$5.1 million at 31 December.

Bioshares recommendation: Speculative Buy Class A

Bioshares

Stock Updates

Oncosil Medical – Share Price Chart



Oncosil Medical Appoints Chris Roberts To The Board

Oncosil Medical (OSL: \$0.26) has appointed former Cochlear CEO Dr Chris Roberts to the board. This is an impressive draft for Oncosil Medical, enabling the company to lift its profile amongst a wider range of investors as well as further equip the board with the substantial management experience that Roberts gained at not only at Cochlear, where he was CEO for 11 years, but also at Resmed, where he served as Executive Vice-President from 1992 to 2004, and a period spent as Chairman of Sirtex Medical (from 2000 to 2002).

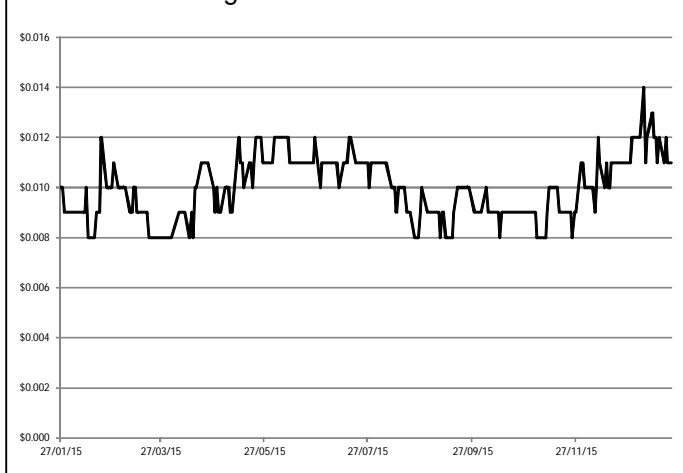
We suggest that the appointment of Roberts is a unmistakably clear signal of the intention of the board to build a sizeable medical device company, in a patient and thorough manner. The move also improves credibility at the board level which can help with its task of accessing funding where required as it moves Oncosil, its brachytherapy device for treating pancreatic cancer, from the clinical development phase through to the marketing phase. It is also our view that the board may be strengthened with additional appointments in the near future.

The company is waiting to receive its CE Mark for Oncosil, an approval which had been expected to occur in late 2015. Also ahead is the outcome of the company's Investigational Device Exemption submission to the FDA. FDA guidance on the company's US trial requirements will influence on the company's future funding needs, potentially increasing the cost of a US clinical development program. At this stage, the details of the submission remain unknown.

Oncosil Medical is capitalised at \$95 million and retained cash of \$5.1 million at September 30, 2015, but also received a \$1.5 million tax refund in November.

Bioshares recommendation: Speculative Hold Class B [Pending receipt of CE Mark and announcement of December 31 cash position]

Imugene – Share Price Chart



Imugene Adopts a Portfolio Model to Become a B Cell Vaccines Play

Imugene (IMU: \$0.011) has formed a discovery partnership with the Medical University of Vienna to develop a pipeline of B cell vaccines. B cells are antibody producing cells and are therefore a component of the body's adaptive immune response and immune memory.

In this case, the partnership will look for mimotopes (small peptides) which can mimic antibody targets (called epitopes) on tumour cells. The targets are a combination of validated and new oncology targets. The goal is to find a mimotope (a mimic of the epitope on the tumour cell) which can stimulate B cells to manufacture antibodies that bind to the native epitopes on the tumour cell and initiate the tumour cell's destruction.

B cell peptide vaccines offer the potential advantages of creating high affinity and highly specific polyclonal antibodies, compared

Cont'd over

Bioshares Model Portfolio (22 January 2015)

Company	Price (current)	Price added to portfolio	Recommendation	Cap'n (\$M)	Date added
Reproductive Health Science	\$0.125	\$0.150	Spec Buy B	\$7	December 2015
Rhinomed	\$0.031	\$0.032	Spec Buy B	\$19	December 2015
AirXpanders	\$1.240	\$0.745	Spec Buy A	\$258	September 2015
Osprey Medical	\$0.260	\$0.695	Spec Buy B	\$40	September 2015
Analytica	\$0.005	\$0.008	Spec Buy C	\$6	August 2015
Atcor Medical	\$0.200	\$0.20	Spec Buy A	\$40	June 2015
Clinuvel Pharmaceuticals	\$2.80	\$4.15	Spec Buy A	\$125	December 2014
Innate Immunotherapeutics	\$0.180	\$0.190	Spec Buy A	\$35	November 2014
Opthea	\$0.420	\$0.160	Spec Buy A	\$63	November 2014
Actinogen	\$0.054	\$0.050	Spec Buy A	\$33	September 2014
pSivida	\$5.230	\$3.800	Spec Buy A	\$154	May 2014
Impedimed	\$1.120	\$0.245	Spec Hold A	\$329	December 2013
IDT Australia	\$0.340	\$0.260	Spec Buy B	\$73	August 2013
Viralytics	\$0.710	\$0.300	Spec Buy B	\$164	August 2013
Somnomed	\$2.62	\$0.94	Buy	\$137	January 2011
Cogstate	\$0.575	\$0.13	Spec Buy A	\$63	November 2007

Portfolio Changes – 22 January 2016**IN:**

No changes

OUT:

No changes

– Imugene cont'd

to monoclonal antibodies, as well as delivering an immune memory benefit.

The program is aiming to discover four mimotope candidates in the first half of 2016, obtain pre-clinical study results in the second half and complete IND enabling studies in the first half of 2017.

The company's lead drug candidate is expected to re-enter the clinic this year, a Phase Ib/II trial in Her2+ gastric cancer patients. This program has been delayed because of design changes made to the vaccine, with the design now at a third generation (now called HER-Vaxx 3G).

The vaccine now is based on a single peptide (previously three), includes an adjuvant and is delivered using an easier to manufacture carrier system (CRM197, a non-toxic mutant of diphtheria toxin^{1,2}). The construct delivers a 10 fold increase *in vivo*, compared to the second generation construct. The second generation construct had yielded a 2 fold betterment in antibody response when compared to its three separate peptide components.

The company is targeting a US FDA IND submission this quarter and to have its first patient enrolled in 2016 Q2. The Phase Ib trial will enroll 15 patients and run for 12 months, followed by the Phase II trial which will enroll 68 patients and run for 24 months, with end points covering progression free survival, overall survival and immune response.

The plan to lift the number of Imugene's drug candidates is a sensible move, which makes sense given that company is continuing to operate in the same technology space of B cell peptide vaccines.

With former Genentech staffer Leslie Chong taking the reigns as Chief Operating Officer, investors should be more confident that the company will be able to properly execute its clinical program for HER-Vaxx 3G

Imugene is capitalised at \$19 million and holds cash of approximately \$4 million.

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: Cogstate, Bionomics, Impedimed, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Benitec BioPharma, Invion, Imugene, Analytica, Circadian Technologies, Reproductive Health Science, Regeneus, Innate Immunotherapeutics, Anatara Life Sciences, ResApp, Pharmaxis, Starpharma, Antisense Therapeutics, Atcor Medical

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