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Bioshares

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Edition 562

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

Somnomed To Double Manufacturing Capacity

Somnomed (SOM: \$1.70) has delivered an impressive full year result for FY2014. Unit sales increased by 21% to 43,438 for the year, and with the help of a lower Australian dollar, sales increased by 40% to at least \$25.8 million (pending audit of accounts).

Somnomed is at a pivotal point, where sales are expected to accelerate, with significant more flow-through from sales to the bottom line is forecast. The company has announced a capital raising of \$7.05 million to help fund manufacturing expansion and to meet increased working capital requirements. Somnomed will also invest in digital manufacturing processes to reduce costs and improve turnaround times.

Strong Forecasts For The Year Ahead

After the mid year results released in February, Somnomed's management made forecasts of 43,000 units and sales of \$25 million for the full year. These forecasts were very accurate, suggesting the company has a good understanding of its business. For the year ahead, the company is forecasting unit sales of 55,000 of its oral devices used to treat sleep disorders, and revenue of at least \$32.5 million at current exchange rates. This represents an increase of around 26% in both measures.

EBITDA for the year just passed is expected to be around \$1 million, and this is forecast to grow to between \$2-\$4 million for this year. Aside from increased sales, one of the reasons for a greater flow-through to the bottom line is because last year the company invested in entering new regions as well as on its medical initiative in the US (marketing to sleep physicians). This cost around \$2.3 million last financial year. In the first half of this year, that investment should cost the company around \$0.8 million, and should be cost neutral in the second half.

Manufacturing Upgrades

Somnomed announced that it raised \$5.55 million before costs from a private placement at \$1.50 a share. This money was all raised from existing shareholders with directors contributing \$405,000 in this placement. A further \$1.5 million will be raised through a share purchase plan at the same price. The capital raising was around 300% over subscribed according to the company.

Some of those funds, around \$1 million, will be used to double the manufacturing capacity at the facility in the Philippines. The company has a spare 500 square meter area that will be used for that purpose. The manufacturing facility currently employs around 120 staff. Funds will also be used to recruit and train additional staff. Somnomed currently has around 250 employees and that number is expected to increase to around 350 in the next 12 months.

The current manufacturing facility has a capacity of 48,000 Somnodent units. This will be increased to a capacity of 96,000 units. As indicated, the company believes that at least

Cont'd over

Companies covered: CUV, SOM,
Fitgenes, Cash Analysis

	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 -)	5.6%
Cumulative Gain	376%
Av. Annual gain (14 yrs)	16.5%

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55,000 units can be sold in the current year, with the company seeking to potentially exceed this level.

As the company prepares for higher volumes, it will introduce manufacturing efficiencies into the business. One of those upgrades will be the digital imaging of the dental cast that is taken in preparing the Somnomed devices.

At the moment, the casts are sent to one of Somnomed's 13 hubs around the world, which includes Sydney, Texas, France, Germany and Japan, and then sent on to the Philippines. Through digital imaging, the cast will be imaged at the hub, then printed in the Philippines factory to reconstruct the model.

This process will reduce freight costs, as well as reducing turnaround time by two days, which is not insignificant according to Executive Chairman Dr Peter Neustadt.

Regional Progress

Dr Neustadt said that all three regions around the world are showing good trends. In Australia, growth has been increasing, with the company having added people to its medical initiative here (educating sleep physicians).

The clinical data that has been emerging about the effectiveness of Somnomed's oral appliance therapy has been a very important marketing tool. In Australia, Korea and Japan, Somnomed is beefing up its sales forces to cater for higher demand from physicians. The company expects to see accelerated growth in these countries.

In Europe, it has been an extraordinary year according to Dr Neustadt, where the established markets in Sweden, Holland and Germany have experienced high growth.

The emerging markets for Somnomed include France, Belgium and Norway, and these markets should experience high growth in the future. And there are also the new markets for Somnomed (that will contribute to future growth), which include UK/Ireland, Spain and Portugal.

In North America, all sectors showed good growth for the company. In North America the company's products are marketed through four different channels. These are:

- *Direct sales to dentists*
- *Sales to managed care organisations*
- *Marketing to sleep physicians (the 'medical initiative'), and*
- *Licencees*

Direct Sales to Dentists

Direct sales to dentists is progressing well, with the company continuing to pick up new accounts.

Medical Sales

Dr Neustadt said there is now evidence that the medical initiative in the US is starting to translate into product sales growth. Florida has been a test case for the company, where it has been running a committed education program to sleep physicians.

This includes educational events where Somnomed's Chief Medical Officer presents to sleep physicians on the clinical research data that has been generated with the company's oral appliance products for the treatment of sleep apnea. This education program is starting to see an increase in referral rates from the sleep physicians.

Managed Care Organisations

There has been good growth through the managed care organisations. Kaiser Permanente, which covers 9 million people around California through 19 sub-centres, is a large focus for the company but not the only managed care organisation the company is working with. Somnomed has three account managers that focus on the work with Kaiser. There has been an increase in authorisations from Kaiser which Dr Neustadt expects to continue to build.

While some centers within Kaiser are using the Somnomed devices, each centre can set its own policy. In Northern California, Kaiser is using Somnomed treatment for mild sleep apnea. However they like to see a 'boil and bite test' or a Matrix test to make sure the therapy is suitable. Somnomed dentists have now been credentialed to operate within the Kaiser system. There are ongoing trials within Kaiser, which is assessing the whole oral appliance process.

Success with Kaiser will be very meaningful for Somnomed. Dr Neustadt said that Kaiser is seen as a trend setter and is very tough with respect to payments and processes. Kaiser is "an enormously credible account and an entrance ticket to talk to other insurers."

Managed care sales currently make up about 15% of North American sales. The guidance provided for FY2015 sales is not dependent on a strong uptake by Kaiser according to Dr Neustadt.

Licencees

In Canada, Somnomed has six licencees who manufacture some of the Somnomed devices under license. The licencees have shown good growth. The company uses licencees in what it calls non-core areas.

Somnomed Herbst

The Herbst product has shown good growth. This is a lower cost product that receives US Medicare reimbursement. It is made up from two mouth guards that are connected with metal components. It is a popular device made by lab technicians.

In September, Somnomed will release its Herbst Advance product, which will have a better and faster titration system. The Herbst products from Somnomed include the company's proprietary Flex material which provides a more comfortable fitting.

Summary

Somnomed is capitalised at \$84 million, taking the capital raising into consideration. It has an estimated \$10 million in cash. The company is trading on a forward Price/Sales ratio (market capitalisation/FY2015 sales) of 2.6 times.

Bioshares recommendation: **Buy**

Private Company Profile – Fitgenes

Fitgenes is a healthcare company which integrates individual genetic and non-genetic information with nutrition and exercise to build health and wellness programs for clients or patients, helping them achieve their health and wellness goals.

An essential feature of the business is that the programs are delivered and managed by trained healthcare practitioners, for example, integrative medicine specialists, exercise physiologists, physiotherapists, dietitians, nutritionists, naturopaths, chiropractors, osteopaths, traditional Chinese medicine practitioners and potentially even dentists.

Fitgenes is not a gene testing business. Its preference is to outsource the gene profiling and pathology capabilities to other providers, although it generates some revenues from these services.

The core value adding element of Fitgenes is its cloud-based PracWarePro software. This software integrates personal genetic and non-genetic data with management tools.

The company does not undertake whole genome analysis, choosing instead to analyse smaller numbers of genes that are validated with, or fall into categories associated with, inflammation, cellular defence and detoxification, heart health and cholesterol regulation, fat metabolism and Vitamin D metabolism.

The Fitgenes' General Health panel looks at 38 genes, the Advanced Health Panel looks at 54 genes and the Women's Health Panel looks at 81 genes.

Non-genetic data is taken from pathology reports encompassing cholesterol, triglycerides, HDL, LDL, blood lipid ratios, homocysteine, Vitamin D, glucose, insulin, ferritin and CRP readings (for a basic report).

Other non-genetic data also includes medical history information.

History & Board

Fitgenes was founded in September 2009, originating from genomics research conducted by Dr Paul Beaver (Chief Science Officer), who co-founded the company with Leigh Beaver. Beaver was motivated to explore the links between genetic and epigenetic information, nutrition and lifestyle following the deaths of his parents.

The company's board comprises of Dr Carrie Hillyard (Chair), Robert Mair (CEO) and Conrad Crisafulli and Dr John Hurrell as Non-Executive Directors.

Today the company operates on a virtual basis, employing two people full-time but involving 24 people across board and operational activities.

The Fitgenes Business Model

Fitgenes is deploying a parallel channel strategy to roll out its service offerings. The company currently works with 350 clinics in Australia, New Zealand, Hong Kong, Singapore and in the US.

From the independent clinics, Fitgenes receives four income streams. The first is from training clinical staff on nutrigenomics, the second from software licenses (of Pracware), the third from diagnostic services and fourth from pathology services.

A single user 12 month license to Pracware costs \$1200.

In parallel, Fitgenes has commenced setting up its own clinics. There are two benefits to this strategy. The first is that the company can capture significantly more revenue from the sales of personalised health management programs, including the sales of nutritional supplements. This revenue uplift could be as much 10-15 times the revenue from the basic product offering.

On another level, the launching of Fitgenes' own clinics serves to develop and communicate the Fitgenes brand. The presence of these clinics provides endorsement of the Fitgenes brand, which should benefit independent clinics offering the Fitgenes personalised healthcare offering and increase revenues through that channel.

Scalability

An additional but not insignificant feature of the Fitgenes business model is that is very scalable. Pracware is a cloud-based software offering, which means access is less complicated by a practitioner's existing IT systems. Healthcare professionals wanting to licence Fitgenes Pracware do require physical consultation space but in many cases this is space they already have available. The final requirement is that healthcare professionals must complete training and qualify as Fitgenes Certified Practitioners.

One emerging opportunity for Fitgenes offering is in Australian pharmacies, which are subject to competitive pressures from the discount warehouses on the one hand, and pressure from the supermarket operators on the other. Pharmacies have a strong product focus and could be easily attracted to installing a Fitgenes practice on their premises if it meant that sales (of supplements) could be increased.

Points of Difference

Fitgenes differentiates itself from other health and wellness service businesses or product offerings, from ad hoc medical interventions and from gene profiling businesses.

In contrast to gene profiling or gene testing businesses, such as **23andMe**, **DeCodeme** and **Navigenics**, Fitgenes offers guidance on what a client or patient can do in terms of diet and exercise once certain genetic information is available. However, perhaps more importantly, it links this guidance to following up with assistance to achieve a desired change. This is done by harnessing what are in effect coaching or mentoring methods and principles.

In contrast to health and wellness service businesses, for example, Fitgenes is building a genomics-informed, personalised offering of services and products.

Cont'd over

– *Fitgenes cont'd*

In contrast to ad hoc medical interventions Fitgenes is building a business which is grounded on the client experience. The concept of the client experience is one better understood in the hospitality industry and is an expression of business values and actions that place the customer and the customer's experience at the forefront of the business relationship. It is a concept that is largely unknown in the world of orthodox medicine.

In contrast to clinics and medical centres which offer ad hoc (or one off) responses to a 'patient', Fitgenes not only delivers structured programs (which might include a number of visits over several months) but aims to do so with a high level of consistent customer service.

The company takes some inspiration for this approach from partners in Singapore that have decades of experience in managing and operating wellness spas.

Summary

Fitgenes is pioneering a new service offering in the health and wellness space, and it is quite possibly the first company in the world to integrate genomics with standard pathology test data to provide customised health plans for clients.

The health and wellness industry, which includes the domain of allied health, is very fragmented, being populated by many small independent operators. One of the interesting growth prospects for Fitgenes is that is a business that can facilitate aggregation amongst many of these small independent operators. Why it will be able to do that is because it is being built as a brand-driven business, which overcomes the limits to growth problems of owner-operated, practitioner-run businesses that develop reputations which are difficult to monetize.

Fitgenes has of today had its replacement prospectus approved by ASIC. Bioshares will prepare an IPO Profile of Fitgenes in the near future. The company is making a backdoor listing through ATW Holdings. Fitgenes has become a Private Company Corporate Subscriber to Bioshares, which entitles the company to copyright access to analysis and commentary from Bioshares.

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Clinuvel Pharmaceuticals Receives Takeover Proposal

Clinuvel Pharmaceuticals (CUV: \$2.15) has received an unsolicited acquisition proposal from US biotech **Retrophin**, which has acquired a 4.88% stake in the business. The bid values Clinuvel at \$95 million (\$2.17 a share), which is a 39% premium to the one month volume weighted average price of the company before Retrophin made its bid.

Clinuvel is in a critical phase of the commercialisation of its lead product Scenesse, which is being developed for the prevention of disorders of sunlight intolerance. Clinuvel has filed its drug candidate for approval with European regulators and a decision is expected by the end of October this year.

Retrophin is small biotech company by US measures. It has a market of US\$257 million. It had generated no sales revenue to the end of last year, and in the first quarter of this calendar year generated sales of US\$28,000.

Retrophin has a stated aim of building its company through acquisition as well as internal R&D. The two products the company has on the market were accessed through the acquisition of **Manchester Pharmaceuticals** in March this year. That company was acquired for US\$62.5 million. The products are sold by a third party distributor.

In May this year, Retrophin acquired US rights for a third product, Thiola, for the treatment of a rare genetic disorder, called cystinuria. Retrophin has a focus in rare diseases and life threatening diseases for which there are few treatment options.

Retrophin has estimated revenue of US\$30-35 million for 2014 and US\$60-70 million in 2015 before the Clinuvel acquisition.

In January the company raised US\$36.8 million through public markets. At the start of July, Retrophin raised US\$91 million, half through a secured term loan facility and half through a convertible note facility. In the first quarter the company paid US\$29.5 million as upfront payment for Manchester Pharmaceuticals, with the balance of US\$33 million paid in July.

The proposal allows Clinuvel to select payment either in scrip or in cash. The acquisition proceeding is based on further due diligence and on Clinuvel board agreement for the transaction. The Clinuvel board is reviewing the proposal.

Analysis

The proposed transaction comes at an awkward time because Clinuvel is potentially three months away from gaining approval for Scenesse in Europe. However on the flip side there is the risk that approval for Scenesse may be denied or delayed with further work needing to be done.

For Clinuvel, the proposal is commercial validation of the company's efforts, the first commercial validation received to date, with respect to a financial transaction for the technology, either by way of partnering or acquisition.

The Scenesse product has proven to be a very difficult product to

commercialise. This is because many of the potential conditions are obscure, they are not life threatening, they can be prevented by avoiding direct sunlight (EPP), or are cosmetic indications (vitiligo), and the question of clinical relevance needs to be ascertained (i.e. does the benefit outweigh the treatment and treatment cost).

However a significant aspect of the treatment is the benefit Scenesse can provide younger sufferers of EPP, for many of whom the condition is incredibly debilitating from a social perspective.

The most difficult issue the company has had to deal with however is the potential for abuse of this therapy. Scenesse works by increasing the melanin density of the skin, and could be sought after by people looking for a pharmaceutical-grade product which stimulates tanning.

For Clinuvel CEO Philippe Wolgen, one important issue that arises from the timing of this transaction is how this potential change in ownership of the business could affect the outcome of the regulatory decision in Europe. Clinuvel has worked closely with the European regulator to provide assurances that the product will not be abused once commercially available. Those undertakings will likely need to be reinforced by the new owner of this technology should the transaction proceed.

Retrophin may not be the ideal acquirer of this company, as it does not have a commercial distribution presence in Europe, and as of the end of last year, the company had no commercial infrastructure whatsoever. The products acquired through Manchester Pharmaceuticals are sold by a third party. Retrophin also does not have a commercial track record of running a pharmaceutical sales business.

A reason for considering the transaction however is that Retrophin has and should continue to have better access to funding to commercialise Scenesse. This would be particularly important should the product encounter any further regulatory delays or obstacles.

The proposal for Clinuvel may be opportunistic and could be argued as being pitched at the low end. Clinuvel has raised around \$120 million from inception and \$92 million under its current CEO.

A cash bid for the company at the proposed price or slightly higher may be worthy of consideration given the outstanding risk and potential returns, particularly for long standing shareholders looking to exit the stock.

Bioshares recommendation: **Speculative Hold Class B**

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4.7B Reporting Companies – Cash Balances June 30, 2014

Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Nett Op. Cash Fl. (\$M)	Cash End 30/06/14 (\$M)	Survival Index		
1	LBT	LBT Innovations	\$0.0	\$0.6	\$1.8	A	Not App
2	BXN	Bioxyne	\$2.4	\$0.6	\$1.0	A	Not App
3	LCT	Living Cell Technologies	\$9.4	-\$0.1	\$4.6	A	Not App
4	RHT	Resonance Health	\$2.2	-\$0.2	\$2.1	A	9.5 To not proceed with VueKlar acquisition
5	NAN	Nanosonics	\$23.0	-\$2.6	\$21.2	A	8.2
6	SIE	Scigen	\$11.9	-\$0.3	\$3.7	CY	7.2
7	ACL	Alchemia	\$10.0	-\$1.7	\$11.1	A	6.7
8	VLA	Viralytics	\$0.0	-\$5.5	\$24.3	A	4.4
9	DVL	Dorsavi	\$0.7	-\$3.2	\$13.9	A	4.3 510k received for viMove, plus first US sale
10	NEU	Neuren Pharmaceuticals	\$1.9	-\$2.5	\$21.0	CY	4.1
11	ADO	Anteo Diagnostics	\$2.7	-\$1.9	\$7.1	A	3.8
12	SOM	Somnomed	\$24.7	-\$0.8	\$2.9	A	3.7
13	BLT	Benitec	\$0.0	-\$9.4	\$31.4	A	3.3
14	CUV	Clinuvel Pharmaceuticals	\$1.9	-\$4.8	\$14.6	A	3.0 Received takeover offer
15	VHL	Virax Holdings	\$0.0	-\$1.3	\$3.8	A	3.0
16	ACW	Actinogen	\$0.0	-\$0.4	\$1.1	A	3.0
17	CYP	Cynata	\$0.0	-\$1.9	\$5.1	A	2.7
18	PBT	Prana Biotechnology	\$0.0	-\$12.5	\$34.2	A	2.7
19	HCT	Holista Colltech	\$6.1	-\$0.5	\$1.3	A	2.7
20	SPL	Starpharma	\$5.1	-\$9.8	\$24.0	A	2.4 Vivagel condom received TGA certification
21	MSB	Mesoblast	\$9.3	-\$81.9	\$196.4	A	2.4
22	RHS	Reproductive Health Science	\$0.0	-\$0.6	\$2.6	CY	2.3
23	OBJ	OBJ	\$0.2	-\$1.8	\$4.1	A	2.3
24	BNE	Bone Medical	\$0.0	-\$1.3	\$2.5	A	1.9
25	GID	GI Dynamics	\$1.8	-\$19.6	\$76.1	CY	1.9
26	AHZ	Admedus	\$7.8	-\$10.6	\$19.6	A	1.8 Increased holding in Admedus Vaccines to 66.3%
27	OSP	Osprey Medical	\$0.0	-\$4.7	\$17.1	CY	1.8
28	IIL	Innate Immunotherapeutics	\$0.0	-\$1.7	\$6.2	CY	1.8
29	AVX	Avexa	\$0.0	-\$1.9	\$3.4	A	1.8
30	PRR	Prima Biomed	\$0.0	-\$13.5	\$23.2	A	1.7 Appointed new CEO
31	PAB	Patrys	\$0.6	-\$5.1	\$8.6	A	1.7
32	MLA	Medical Australia	\$11.5	-\$1.1	\$1.8	A	1.6
33	IPD	Impedimed	\$3.6	-\$6.8	\$10.8	A	1.6
34	PAA	Pharmaust	\$1.8	-\$1.5	\$2.3	A	1.5
35	UBI	Universal Biosensors	\$5.3	-\$5.6	\$15.9	CY	1.4
36	BRC	Brain Resource Corp	\$1.1	-\$1.4	\$2.0	A	1.4 Announced commitments to raise \$7M
37	SUD	SUDA	\$9.4	-\$2.9	\$4.0	A	1.4
38	UCM	USCOM	\$0.8	-\$1.2	\$1.6	A	1.3
39	PYC	Phylogica	\$0.7	-\$3.2	\$4.0	A	1.3
40	PXS	Pharmaxis	\$5.4	-\$28.1	\$34.2	A	1.2 Breach of funding agreement notice received
41	OSL	Oncosil Medical	\$0.0	-\$6.0	\$7.0	A	1.2
42	CDY	Cellmid	\$1.5	-\$2.4	\$2.5	A	1.1
43	TIS	Tissue Therapies	\$0.0	-\$7.1	\$7.1	A	1.0
44	ISN	Isonoa	\$0.0	-\$8.8	\$8.2	A	0.9 Said that "Aironoa has never been submitted to the FDA for clearance"
45	IVX	Invinon	\$0.2	-\$4.4	\$4.0	A	0.9
46	QRX	QRxPharma	\$0.0	-\$12.2	\$10.5	A	0.9 Delegated \$3.4 M to cover entitlement obligations
47	SVA	Simavita	\$0.0	-\$8.0	\$6.9	A	0.9
48	IMU	Imugene	\$0.0	-\$1.5	\$1.2	A	0.8
49	BNO	Bionomics	\$3.2	-\$12.7	\$10.5	A	0.8 To receive upfront pmts of US\$20M for BNC375 deal
50	GBI	Genera Biosystems	\$0.1	-\$0.8	\$0.6	A	0.7 Proposed merger replaced by strategic commercial alliance
51	ALT	Analytica	\$0.0	-\$3.1	\$1.9	A	0.6 Has a \$400K line of credit
52	RNO	Rhinomed	\$0.2	-\$2.4	\$1.5	A	0.6
53	BIT	Biotron	\$0.0	-\$3.0	\$1.8	A	0.6
54	AVH	Avita Medical	\$2.9	-\$6.9	\$3.6	A	0.5 Expects to receive R&D Tax refund of \$1.4 M
55	ANP	Antisense Therap.	\$0.0	-\$3.2	\$1.3	A	0.4 Access to \$1M funding facility (re R&D tax refund)
56	RVA	Reva Medical	\$0.0	-\$11.5	\$9.5	CY	0.4
57	RGS	Regeneus	\$1.7	-\$6.2	\$2.5	A	0.4
58	UNS	Unilife	\$25.2	-\$35.0	\$11.5	A	0.3 Access to US\$12.5M under ATM facility
59	BCT	Bluechiip	\$0.0	-\$2.2	\$0.6	A	0.3 Announced sales to local organisations
60	GTG	Genetic Technologies	\$4.8	-\$10.3	\$2.8	A	0.3
61	MGZ	Medigard	\$0.0	-\$0.2	\$0.0	A	0.1
62	AGX	Agenix	\$0.0	-\$0.9	\$0.0	A	0.0

Legend:

Not App. : The SI calculation for these companies is not calculated due to the companies reporting positive operational cash flows, or in some cases marginally negative operational cash flows.

A: The SI calculation for these companies is based on the average of the four quarters of NOCF.

CY: The SI calculation for these companies is calculated on the average of the last two quarters of NOCF, annualised.

Bioshares Model Portfolio (1 August 2014)				Portfolio Changes – 1 August 2014
Company	Price (current)	Price added to portfolio	Date added	
LBT Innovations	\$0.125	\$0.130	July 14	IN: No changes OUT: No changes
pSivida	\$4.800	\$3.800	May 14	
Invion	\$0.065	\$0.089	February 14	
Impedimed	\$0.295	\$0.245	December 13	
Analytica	\$0.035	\$0.025	December 13	
Imugene	\$0.014	\$0.022	November 13	
Oncosil Medical	\$0.125	\$0.155	September 13	
IDT Australia	\$0.280	\$0.260	August 13	
Viralytics	\$0.270	\$0.300	August 13	
Tissue Therapies	\$0.295	\$0.255	March 2013	
Somnomed	\$1.70	\$0.94	January 2011	
Cogstate	\$0.240	\$0.13	November 2007	

4.7B Reporting Companies – Cash Balances June 30, 2014 (Cont'd) Sorted by Survival Index

Commentary

The current analysis of cash balances of 4.7B reporting companies shows that 19 of 62 companies reporting under the rule have less than one year's cash at hand to support activities.

Eight companies have less than six months of cash at hand, based on net operational cash outflows over the last twelve months. At the top of this list is Antisense Therapeutics, however, it has access to a \$1 million financing facility which is tied to a future R&D tax refund. Results from its trial of ATL1103 in acromegaly, expected in August, will be a make or break event for Antisense Therapeutics.

Reva Medical, which has \$9.5 million in cash, is proceeding with the development of its third generation bioresorbable scaffold but is clearly facing a funding challenge to progress the development of that product.

Regeneus, which listed in September last year, raising \$10.5 million, will in all likelihood need to access more capital to support both existing and new programs. While Medigard and Agenix perpetuate their struggle to survive, Genetic Technologies' financial position has become particularly concerning in recent months.

Small cap life science companies that are not required to comply with the 4.7B Rule include: Acrux, Advanced Medical Design and Manufact., Immuron, Cogstate, Circadian Technologies, Clovercorp, Compumedics, Cryosite, Cyclopharm, Ellex Medical Lasers, IDT, ITL Corp, Calzada, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Phosphagenics and Atcor Medical.

pSivida, a re-domiciled company, does not comply with the 4B Rule.

Each quarter, the majority of ASX listed biotech companies are required to report their cash positions. In turn, a key analytical measure we present each quarter is the 'Survival Index' (SI). The index measures how many years those cash reserves will last, based on a company's recent spending patterns. It is limited because it does not account for companies that may increase spending in the next period of activity.

The index is derived for this quarter by dividing net operational cash flows (NOCF) for the last twelve months ending June 30, 2014, into each company's cash assets as recorded at June 30, 2014. For companies that report on December 31 full year basis, the index is based on the last two quarters of NOCF, annualised, into each company's cash assets as recorded at June 30, 2014. The NOCF is net of receipts and outgoings incurred in support of operational activities.

As a rule of thumb, companies that present with an SI of less than one are likely to be raising funds to support their activities, or are in the process of doing so. A healthy SI is either two or more. Companies with SIs of less than 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

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

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