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Bioshares

11 April 2014
Edition 547

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

Universal Biosensors: Signs Of A 'Hockey Stick' Growth Curve Emerge With Service Fees

Universal Biosensors (UBI: \$0.385) is commercialising a number of products, but its core asset is the recurring revenue it receives from Lifescan for every glucose strip that company sells that has been designed by UBI. That revenue, called service fees, has been steadily increasing by around \$100,000 a quarter for the last year. This week, the company announced that its service fee increased by \$240,000 in the March quarter over the December quarter to \$1.2 million. It appears that UBI's service fee revenue has just hit the inflection point of a high growth story, also described as a hockey stick curve.

If that growth can be sustained at that rate as a minimum, then the annual service fee for UBI should be tracking at around \$8 million a year by the end of this year (\$2 million a quarter).

Looking at the investment metrics, UBI is capitalised at \$57 million. The company had \$19.4 million cash at the end of March. It has a further \$1.8 million to receive from its partner Lifescan for inventory. It should receive an R&D tax rebate of around \$6 million later this year. The company has a \$16 million loan outstanding. The net result is that UBI has a technology market value, less cash and after its outstanding loan, of only \$46 million.

If the company were to stop all other operations and pay out its entire service fee, it would equate to a dividend yield of 10.5%, which would be tax free in so far as the company can make use of \$65 million in tax losses. If service fees hit \$2 million a quarter by the end of the year, then it will equate to a dividend yield of 17.4% and this should continue to grow.

As it stands, UBI is investing in the development of four other diagnostic products. The first is expected to be released in the third quarter of this year by its partner Siemens. The company believes the commercial potential from this next product, a PT/INR test to measure correct warfarin levels, is as large as the blood glucose product for the company.

Three other products, two with Siemens, are expected to be released in 2015. The overall product development expenditure we expect to be around \$10 million for these four new products, taking into account the R&D tax rebate and milestone payments from Siemens.

In the March quarter, UBI had an operational cash outflow of \$3.4 million. The company, as stated above, is capitalised at \$57 million.

Bioshares recommendation: Speculative Buy Class A

Bioshares

Easter Publication Schedule

The next edition of Bioshares (548), dated April 25, will be emailed to subscribers on April 28, 2014. (Note, Bioshares is published 48 times a year.)

Companies covered: ADO, RHT, SOM,
UBI

	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)	47.8%
Cumulative Gain	427%
Av. annual gain (13 yrs)	19.0%

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Somnomed – Strong Sales Growth Continues

Somnomed (SOM: \$1.51) has recorded very strong growth in sales for the March quarter 2014. Unit volumes were up 28.3% over the previous corresponding period (pcp) to 11,010. With some currency benefits, sales fared even better, up 50% over the pcp to \$6.5 million.

There has been a strong seasonal pattern to Somnomed's unit sales (see table). Compared with the December quarter, sales volumes were down slightly from the 11,146 sold that generated \$6.9 million of revenue. However this is due to the historically high December quarters for the company. Presumably this occurs because the September quarter is always low due to the holiday period in the northern hemisphere (July/August) with the bag log completed in the December quarter. Over the last four years, September quarter sales were -4.9% (FY2011), -8.1% (FY2012), -3.3% (FY2013) and -7.0% (FY2014) compared to the preceding (June) quarter.

As a result of the very high December quarters, the March quarter looks softer. This has occurred in FY2011 (+2.4% growth over the December quarter), FY2012 (+2.5%), FY2013 (-4.1%), and now FY2014 (-1.2%).

However, from the March quarter to the June quarter has traditionally seen very strong period-on-period growth. In FY2010, FY2011, FY2012 and FY2013, unit volumes increased by 13.5%, 15.4%, 7.8% and 16.6% respectively. If this trend continues, then investors can expect a very strong June quarter coming up given the strong overall growth the company is generating.

Strong Growth in all Regions

The March quarter recorded strong unit growth in all of its regions, including Europe, Asia Pacific (up 17.3%) and in the US (up 22.8%), with 28.3% growth overall as indicated. The company's gross margin was steady at 67%.

Somnomed is capitalised at \$68 million and holds \$3 million in cash.

Bioshares recommendation: **Buy**

Bioshares

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%	
	Q2	\$6.9	11,146				
	Q1	\$5.6	9,309				
FY2013	Q4	\$5.5	10,009	-3.3%	8.7%	-4.1%	16.6%
	Q3	\$4.3	8,582				
	Q2	\$4.9	8,950				
FY2012	Q1	\$4.2	8,232	-8.1%	14.5%	2.5%	7.7%
	Q4	\$4.5	8,515				
	Q3	\$3.8	7,903				
FY2011	Q2	\$3.6	7,711	-4.9%	17.8%	2.4%	15.4%
	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				13.5%

Resonance Health To Move Next Products Forward With \$5.1 M Raising

Resonance Health (RHT: \$0.054) markets Ferriscan, an algorithm-based technology which uses magnetic resonance imaging to measure iron concentrations in the liver. It is a safer alternative to liver biopsies.

Resonance Health is using its stronger share price to raise up to \$5.1 million through a placement and a 1:4 non-renounceable rights issue. The issue price under both plans is \$0.05, which was a 20% discount to its closing price of \$0.063 on Monday April 7, 2014, which was a figure also very close to the average price for the previous 20 days. The company last raised funds in FY2007 (\$3 million) and before that in FY2006 (\$2.3 million).

In January, the Resonance Health share price peaked at \$0.10. The share price began to move in November 2013, after it had announced the signing of a contract with UK MRI service provider, Alliance Medical.

The company's share price received another boost in December 2013 when the FDA approved its HepaFat-Scan medical device, under the 510(k) process. The approval came ahead of an expected first quarter 2014 approval.

The HepaFat-Scan diagnostic market opportunity is much greater than the liver iron overload market, which is confined to the inherited blood disorders market e.g. thalassaemia, sickle cell anaemia and myelodysplastic syndromes as well as the primary iron overload, hereditary haemochromatosis. The HepaFat-Scan product is directed at the (non-alcoholic) fatty liver disease market, for which it estimated that one-third of the US population has the condition. Fatty liver disease is pre-condition to chronic liver inflammation which can lead to fibrosis and cirrhosis and ultimately to liver cancer.

Resonance Health has validated the HepaFat-Scan product against liver biopsy and demonstrated equivalence. The company claims HepaFat-Scan has demonstrated higher levels of sensitivity and specificity than any other published method. Other methods include liver biopsy, CT scans, ultrasound as well as other but less rigorous MRI approaches.

A lead-in market opportunity for the product is for use in the clinical trials of therapies intended for the treatment of fatty liver disease. Almost 250 trials for fatty liver disease are registered on clinicaltrials.gov.

A recent setback for the company's Ferriscan product was rejection by the American Medical Association for a new CPT1 code for the test because it was claimed that the existing codes were adequate.

In reality, this means the company must continue to work with new and existing insurers who cover the test under existing codes. The work load would be the same with a new code, since every insurer would still require substantial efforts to enlist for the purposes of coverage. One of the potential advantages of a unique CPT1 code, if it had been obtained, would have been that it could have created a barrier to entry for rivals if the wording for the code had been written to specify features unique to Ferriscan. However, that was not to be, with the American College of Radiology expressing concerns about the CPT1 application for Ferriscan as being too vendor specific.

The move by Resonance Health to bring in \$5.1 million in new capital is a sensible move, which will give it resources to tackle opportunities in the fatty liver disease market, especially on the clinical trials side of that market, as well as in the liver fibrosis market, another large and global market opportunity.

The company can point to its experience with Ferriscan, which was approved as a companion diagnostic with the drug Exjade (deferasirox), marketed by Novartis. Exjade is an oral iron chelator which approved for treatment of chronically elevated levels of iron in the blood caused by repeated blood transfusions and for patients who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassaemia.

Resonance Health is capitalised at \$19 million.

Bioshares recommendation: Speculative Buy Class B

Bioshares

Anteo Diagnostics – Is It Time To Sell?

The share price of Anteo Diagnostics (ADO: \$0.21) has had a strong run this year, peaking at 28 cents on March 17, 2014, which placed it 66% higher from its close at December 31, 2013. It is currently 268% higher from where its share price was 12 months ago. The company is currently capitalised at \$175 million.

Anteo Diagnostics' origins date back to the founding of Polymerat Pty Ltd in 1999 as a spin out of the University of Queensland. Brisbane-based VC firm, CM Capital, was an early investor in the company. The company changed its name to Biolayer Pty Ltd in 2004, and then back-door listed through the shell of SSH Medical in November 2005. The name change to Anteo Diagnostics took place in late 2008.

Anteo Diagnostics is commercialising a chemistry technology which it has branded, Mix&Go. This chemical reagent improves the surface binding properties of proteins. The technology is relevant to the immunoassay incorporated in *in vitro* and point-of-care diagnostics as well as in the research tools market. The technology has application possibilities in non-biological areas, however, such an area is not at this stage a core focus of the company.

Sales which totaled \$0.7 million from FY2009 through to the half year ending December 31, 2013, have been elusive.

The company's current CEO, Dr Geoff Cummins, was appointed in January 2009. Cummins recently exercised 13 million (8-11-2014) 7

Cont'd over

Bioshares Model Portfolio (11 April 2014)				Portfolio Changes – 11 April 2014
Company	Price (current)	Price added to portfolio	Date added	
Invion	\$0.072	\$0.089	February 14	IN: No changes
QRxPharma	\$0.800	\$0.620	December 13	Recommendations:
Impedimed	\$0.215	\$0.245	December 13	
Analytica	\$0.029	\$0.025	December 13	OUT: No changes
Imugene	\$0.010	\$0.022	November 13	
Oncosil Medical	\$0.110	\$0.155	September 13	Recommendations:
IDT Australia	\$0.280	\$0.260	August 13	
Viralytics	\$0.305	\$0.300	August 13	No changes
Tissue Therapies	\$0.295	\$0.255	March 2013	
Somnomed	\$1.51	\$0.94	January 2011	Recommendations:
Cogstate	\$0.345	\$0.13	November 2007	
Universal Biosensors	\$0.39	\$1.23	June 2007	

– Anteo Diagnostics cont'd

cent options. To cover the cost of \$910,000 needed to for the exercise of the options, Cummins sold 4 million ADO shares at 25.8 cents each, for a total sum of \$1.031 million. The transactions were confined to the superannuation fund of which Cummins is a member. This transaction is positive in the sense that Cummins used the proceeds of the sale of shares to acquire shares of the company he leads.

Anteo Diagnostics bears comparison with Bluechiip. Both companies have a technology that could be used within many different industry settings and by many companies. Yet it appears that even targeting one setting (Anteo – *in vitro* diagnostics, Bluechiip – biological samples storage) is a long and arduous process. The challenge of introducing an improvement into existing industrial systems requires a great deal of patience and commitment because of the amount of trust needed to secure the adoption of a new product or more specifically a new 'component' product. Typi-

cally, small companies underestimate the business development resources required to build and maintain relationships with their potential customers.

In our last review of Anteo Diagnostics (*Bioshares 528*), we placed a **Speculative Hold Class B** recommendation on the stock, when the share price was 7.8 cents and the company was capitalised at \$60 million. Noting that the company now has a lofty capitalisation of \$175 million, but more so the ongoing challenges the company has had in building sales, we place a **Sell** on the stock.

Bioshares recommendation: **Sell**

Bioshares

Anteo Diagnostics Financial Performance: FY2009 -

	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014 H1
Sales (\$M)	\$0.226	\$0.084	\$0.012	\$0.146	\$0.220	\$0.00
Other Revenue (\$M)	\$0.576	\$0.531	\$1.033	\$1.366	\$1.623	\$1.85
R&D Spend (\$M)	-\$1.769	-\$1.753	-\$1.969	-\$2.345	-\$2.269	-\$1.38
Loss (\$M)	-\$1.949	-\$2.255	-\$2.222	-\$2.380	-\$2.179	-\$0.62
Accumulated Losses (\$M)						-\$30.14
NOCF (\$M)						-\$0.13
Cash End 31/12/13 (\$M)						\$7.47
Survival Index						29
Survival Index (adjusted for \$1.2 M Tax Refund)						2.8
Capitalisation (\$M) 11-04-2014						\$175

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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