ISSN 1443-850X

Bioshares

16 May 2014
Edition 551

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

Companies covered: LBT, UBI, VLA

	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%
Cumulative Gain	**351%**
Av. annual gain (13 yrs)	**17.3%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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

Individual Subscriptions (48 issues/year)
$400 (Inc.GST)
Edition Number 551 (16 May 2014)

LBT Innovations Targets Second Product Launch for 2015

LBT Innovations (LBT: $0.22) has seen its share price climb strongly in recent weeks, up 136% in the last two weeks. The company has successfully brought its first instrument into the global pathology market with its partner bioMerieux. Its second instrument is now on in development in a joint venture with Swiss group Hettich AG with market launch expected by the end of next year.

Product 1 – PREVI Isola

LBT has a core focus on delivering automation improvements to the pathology industry. Its first product is called the PREVI Isola and provides robotic streaking of agar plates to test for the presence of microorganisms.

To date, LBT has received $10 million in milestone payments from bioMerieux and receives a minimum annual royalty from each of the plastic applicators used in the machines. The company receives a double digit royalty from each of the applicators used by pathology groups. The minimum royalty is US$600,000 a year, and royalties will continue out to 2028. The company has already received $2.4 million in royalty payments.

This assumes that the minimum royalty payable is not exceeded, which so far it hasn't. However the use of applicators is growing at 35% and that minimum level is expected to be exceeded in 2015 by the company. BioMerieux has a 37% share of the global microbiology laboratory market. According to the company, if the PREVI Isola achieves only a 10% penetration of its current customer based, then it would equate to an estimated annual royalty to LBT of around $3 million a year. The next three year minimum royalties will be renegotiated by LBT with bioMerieux later this year.

Product 2 APAS

The company's second product is called APAS, which stands for Automated Plate Assessment System. Once microorganisms have been cultured on an agar plate, the APAS system will objectively grade the plates as either having a negative result, a positive culture result, or requiring immediate review by a pathologist. What the pathology industry is in need of is an instrument that removes all of the negative result agar plates from the testing process according to LBT CEO Lusia Guthrie.

Last year LBT formed a joint venture (called Clever Culture Systems) with Hettich to commercialise the APAS instrument. LBT has received $4 million in payments already and expects to receive a further $2 million before the end of this year. It's expected that regulatory approvals in major markets will be achieved next year with the official launch in the second half of 2015.

In order to gain FDA approval, the company will have to conduct a clinical trial. This will be conducted at two sites in Australia and possibly two in the US. That trial will have to

– Cont'd over

– LBT cont'd

show that the APAS system is as effective as a trained microbiologist in distinguishing between negative plates and positive plates or others of interest.

One of the key milestones for the company over the coming months is to sign on a global distributor for the APAS instrument via the joint venture. The joint venture will receive any upfront and milestone payments from the partner.

Once operational, LBT will receive an ongoing fee for use of the software in the APAS instruments. Hettich will manufacture the APAS and the incubator used with the instrument. And profits from the JV will be equally distributed between LBT and Hettich.

Product 3 Wound imaging application

LBT is looking to invest $2 million to develop its third product, a wound imaging instrument. Using similar intelligent imaging technology from the APAS system, this product would help monitor and make better decisions for the treatment of chronic wounds.

Summary

LBT is currently capitalised at $22 million and had $1.0 million in funds at the end of March. The company expects to receive a $2.7 million tax rebate for this financial year.

The company is developing a track record with innovative products to help automate the pathology industry. The launch of the company's second product, APAS, in 2015 and growing royalty streams from the PREVI Isola should place the company in a solid commercial position. Key milestones this year will be securing a distribution partner by the joint venture for the APAS product and outcomes from clinical trials with this instrument.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

Viralytics Gets Upgraded at ASCO

Viralytics (VLA:$0.285) has had its presentation at presentation at next month's ASCO cancer conference in the US upgraded to a Poster Highlights Session, which means the company's Phase II trial results with its oncolytic virotherapy program (Cavatak) will be discussed in a panel session.

Cancer immunotherapy programs are generating a lot of interest in the US drug development sector, which is one of the reasons that Viralytics was able to raise $27 million, primarily from US biotech funds. Institutional investors now make up 45% of the company's register.

In this Phase II study in patients with unresectable Stage IIIC to IV melanoma, 35% of the evaluable patients achieved an immune-related progression-free survival at six months. Survival data so far indicates 62% of patients were alive after one year, with full survival data expected in early 2015. This compares equally to Amgen's oncolytic virotherapy which achieved 58% overall survival in a Phase II study.

The next steps for Viralytics is to complete an intravenous study with Cavatak in a range of solid tumours (first results in early 2015) and to commence a randomized Phase II study in patients with advanced melanoma in the second half of this year.

Viralytics is capitalised at $52 million. The company had $26.6 million cash at the end of March

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Universal Biosensors: Now We Know

Universal Biosensors (UBI: $0.135) disclosed information on Monday May 12 concerning its quarterly service fees for each Verio strip sold by Life scan, for use in the Verio range of blood glucose meters, and details of the option Lifescan has to buy out these quarterly service fees.

UBI's share price fell 39% on Monday May 12, to $0.215, with a slide continuing to Friday where it finished at $0.135 cents.

The company disclosed that the quarterly service fees for the first 0.5 billion strips sold was US1.25 cents, and for every strip above 0.5 billion, the fee is US0.75 cents.

The company also disclosed that Lifescan, may, it its option, once cumulative quarterly service fees have reached US$45 million, give notice to buy out the quarterly service fees. The buyout option, at the most general level, has been known for some time and declared by the company (and which was noted in *Bioshares* 492). What was new was the cumulative service fee threshold of U$45 million and the buyout multiples attached to the option, which ranged from 3X if Lifescan gave notice in 2012 to 2X if the notice was given from 2018 beyond.

UBI has received, since 2010 Q1 to 2014 Q1, a cumulative $7.5 million in quarterly service fees, with the highest reached to date being for 2014 Q1 of $1.2 million. On an annualised basis that equates to an estimated 360 million strips, and if a 20% quarterly growth rate is applied, an estimate for CY2014 strip sales is 485 million, in volume terms.

At a quarterly 20% growth rate (and a USD/AUD exchange rate of 93 cents), cumulative quarterly service fees would be an estimated $12.7 million by the year's end.

Assuming an annual growth rate of 90% into CY2015, with 920 million strips sold, the reduction in the per strip fee to U$0.0075 would see a an estimated income for the CY2015 from strip fees of US$6.9 million. This figure is illustrative because the sales of Verio strips could grow at rates at *less* than 90% a year.

What is not appearing in the quarterly strip fee receipts are the signs that the Verio strips together with Verio blood glucose meters are becoming a significant component of Lifescan's product line-up. Part of this slow growth story relates to pricing pressures in the US, as well as a recall in 2013 for Verio meters.

Complicating the above is the debt financing arrangement which UBI entered into in December 2013 with Athyrium Opportunities Fund, for up to US$25 million in funding. A first tranche of US$15 million was drawn down in December 2013.

Two following tranches, each of US$5 million cannot be drawn down until for the first tranche, quarterly service fees and coagulation revenues reach US$1.8 million and for the second tranche, quarterly service fees and coagulation revenues reach US$2.5 million.

Interest on the debt is fixed at 10.5% per annum payable quarterly in arrears over a five year term ending December 19, 2018. The

Cont'd over

ASX Listed Life Science Companies Registering >$50 M Loss in Capitalisation from December 31, 2013 to May 16, 2014

Company	Code	Cap ($M) - June 30, 2013	Cap ($M) - Dec 31, 2013	Cap ($M) - Mar 31, 2014	Cap ($M) - May 16, 2014	Share Price 16/5/14	Change Cap from Mar 31 to 16/5	Change Cap from Dec 31 to 16/5	%age Change Cap from Dec 31 to 16/5	Change Cap from June 30, 2013 to 16/5
Acrux	ACR	$584	**$426**	$286	**$165**	$0.990	-$122	**-$261**	**-61.3%**	-$420
Admedus	AHZ	$51	**$195**	$176	**$132**	$0.099	-$44	**-$62**	**-32.0%**	$82
Bionomics	BNO	$140	**$311**	$221	**$177**	$0.425	-$44	**-$134**	**-43.0%**	$38
Mesoblast	MSB	$1,668	**$1,879**	$1,751	**$1,506**	$4.690	-$244	**-$373**	**-19.8%**	-$162
Neuren Pharmaceuticals	NEU	$84	**$172**	$136	**$110**	$0.071	-$26	**-$62**	**-36.0%**	$26
Prana Biotechnology	PBT	$93	**$321**	$447	**$83**	$0.170	-$364	**-$238**	**-74.1%**	-$10
QRxPharma	QRX	$152	**$122**	$126	**$16**	$0.099	-$110	**-$106**	**-86.7%**	-$136
Reva Medical	RVA	$186	**$160**	$50	**$52**	$0.155	$2	**-$108**	**-67.5%**	-$134
Starpharma Holdings	SPL	$231	**$246**	$218	**$188**	$0.660	-$30	**-$58**	**-23.7%**	-$43
Universal Biosensors	UBI	$117	**$81**	$60	**$24**	$0.135	-$36	**-$57**	**-70.7%**	-$93
Unilife Corporation	UNS	$304	**$485**	$458	**$311**	$0.505	-$147	**-$174**	**-35.9%**	$7
Group Total		$3,611	**$4,398**	$3,928	**$2,765**		-$1,163	**-$1,633**	**-37.1%**	-$846
Bioshares Index Capitalisation Total *		**$7,257**	**$9,238**	**$9,480**	**$8,105**				**-12.3%**	

**Excludes Acuvax and de-listed companies Heartware, Bioniche and Biodiem*

Bioshares Model Portfolio (16 May 2014)

Company	Price (current)	Price added to portfolio	Date added
pSivida	$4.000	$0.089	May 14
Invion	$0.067	$0.089	February 14
Impedimed	$0.200	$0.245	December 13
Analytica	$0.040	$0.025	December 13
Imugene	$0.010	$0.022	November 13
Oncosil Medical	$0.120	$0.155	September 13
IDT Australia	$0.270	$0.260	August 13
Viralytics	$0.285	$0.300	August 13
Tissue Therapies	$0.315	$0.255	March 2013
Somnomed	$1.50	$0.94	January 2011
Cogstate	$0.280	$0.13	November 2007

Portfolio Changes – 16 May 2014

IN:
No changes

OUT:

UBI has been removed from the Model Portfolio.

Recommendations: UBI **- Sell**

credit agreement is secured by substantially all of UBI's assets.

UBI is progressing a product development deal with Siemens, to bring to market three point-of-care devices for blood coagulation testing. The launch of the first product was expected in 2013, but that has now been rescheduled to 2014 Q3. The launch of two other products for Siemans and UBI's own home care coagulation product is expected before the end of 2015.

UBI stands to receive four additional milestone payments from its development deal with Siemens. If the Siemens program remains on schedule, then it is likely that UBI can access the additional funds from Athyrium and remain solvent.

So Why the Sell Down?

An explanation for the sell down in UBI is that new materially relevant information has come to hand, which changes the valuation framework for UBI considerably. One the one hand, the new information essentially puts a cap on the value of the Verio strip asset. At the top end of our estimate is if strip sales reach two billion in 2018, then the quarterly service fees could be bought out for some where in the order of US$30 million.

At the same time, if growth in strip fees is not strong enough for annual strip numbers to exceed 1 billion, coupled to a lower per strip fee, it is much more difficult to characterise the quarterly strip fees as in anyway a sizeable income stream and it is paradoxically less likely that the strip fee buyout option will be exercised by Lifescan. (The annual fees for 1 billion strips is US$7.5 million.)

Investors have grounds to be disappointed with the board of UBI for choosing to impart such materially relevant information so late in the piece.

In hindsight, this recently imparted information goes some of the way to explaining the long term drift in the UBI share price, which peaked at a high of $2.20 in January 2010.

Bioshares recommendation: **Sell**

Collapses in Value

The table on the previous page shows that Universal Biosystems is one of nine ASX listed companies that have experienced a greater than $50 million decline in capitalisation from December 31, 2013 to May 16, 2014. UBI has lost $57 million in value over this period.

Collectively these nine companies have had $1.6 billion of market value wiped out since December 31, 2013, with $1.3 billion occuring since March 31, 2013.Acrux has lost $261 million from its capitalisation since December, suffering the effects of dubious scientific articles proposing that testosterone therapy increases the risk of cardiac related events. Admedus has seen its capitalisation ease back by $63 million, no doubt as investors have taken a breather following its recent capital raising.

Negative clinical trial results have played a role in winding back Bionomics' capitalisation by $134 million (or -43%) and Prana Biotechnology's cap by $238 million (or -74%). Reva Medical's struggle to fund its third generation bioresorble scaffold saw its capitalisation decline by $108 million (-68%).

US domiciled Unilife has still not been able to deliver the revenues that would justify its capitalisation, which currently stands at $311 million, but is 36% under its December 31 figure. Starpharma has struggled to maintain traction with investors. Its capitalisation decreased by $58 million from December 31. Neuren Pharmaceuticals has been sold down, more than likely because investors have seen fit to take some money off the table.

QRxPharma's capitalisation (down $106 million or -87%) was savaged by investors following a 14-0 vote against its combination pain drug Moxduo by an FDA Advisory Committee meeting.

Finally, Mesoblast has had $373 million shaved from its capitalisation (-20%). While a pullback in global biotech markets explains some of this weakness, with the company's expanding product line-up and expansion plans placing more stress on its ability to meet expectations, lies another explanation.

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

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **$400**

For multiple email distributions within the same business cost centre, our pricing structure is as follows:

$630	2-3 email addresses
$855	4-5 email addresses
$1090	6-10 email addresses

To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
Fax: +61 3 9329 3350

I enclose a cheque for **$** made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card **$** MasterCard ☐ Visa ☐

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Signature ____________________ Expiry date ____________

Subscriber details

Name ____________________

Organisation ____________________

Ph ( ) ____________________

Emails ____________________