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Bioshares

28 March 2014
Edition 545

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

Companies covered: CGS, DVL, LBT, QRX

	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)	55.9%
Cumulative Gain	**456%**
Av. annual gain (13 yrs)	**19.6%**

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LBT Innovations' APAS: What Are The Benefits?

LBT Innovations (LBT: $0.09) develops products for use in the microbiology departments of hospital and pathology labs. The company's first product, an automated agar plate streaking system (Microstreak), was launched in late 2008. This product is marketed as the PREVI Isola by bioMerieux. LBT receives royalties on sales of the applicator. The company reported that applicator sales in the last quarter of 2013 were 133% higher than for the same period a year ago.

The company's second product, the Automated Plate Assessment System (APAS), an image capture system, is being developed in a joint venture with Hettich AG, a German manufacturer of centrifuges. The program is currently moving through the prototype stage of development, with the company aiming next to enlist distribution partners.

The APAS is designed to automate a step in the microbiology lab where technicians must visually inspect an agar plate after the incubation period to determine if bacterial colony formation is significant, thereby requiring further analysis, or is not significant. Approximately 70% of plates yield a 'not significant' result. Furthermore, the plate reading step accounts for 29% of the time use in a microbiology lab. Thus the automation of the plate reading step offers the chance for cost savings in the microbiology lab.

Advantages of LBT's APAS over human operators include speed (~four times faster), ability to be trained from the experiences of multiple human operators, is not subject to fatigue, detects colonies beyond the capabilities of the human eye, creates images which can be stored for future analysis and delivers automatic annotation and documentation for the plate assessment task.

Comparison of APAS and Human Plate Assessment

Attribute/Feature	APAS	Technician (Human)
Speed/Rate	14 seconds	1 per minute (at best)
Learning Memory	Can be derived (trained) from multiple human operators	Confined to single operator's experience
Reader Fatigue	None	Yes
Lighting	Highly consistent	Variable
Traceability [Images Archived]	Yes	None
Level of colony detection	Exceeds capabilities of the human eye	Limits of the human eye
Handling Efficiencies	Yes - potential with multiple plate instruments	As per current variable lab practice
Documentation	Automated	Manual (and subject to operator variability)
Annotation	Automated	Manual (and subject to operator variability)

Cont'd on page 4

Dorsavi Update

In December last year, Dorsavi (DVL: $0.56) raised $18 million to fund the commercial rollout of its electronic body movement sensor technology. The company's products have been launched in Australia and the UK, with a US launch expected shortly. In the first six months of this financial year the company generated sales of $0.4 million.

In coming months, the company expects to increase its sales force to around 20. Australia currently has four sales staff and this will be increased to 10. In the UK, the team will increase to four in May and grow to around seven. In the US, the company is due to appoint three people to sell and market the company's products. With the calibre of the staff to be appointed in the US, the company is likely to sell using the expansive existing networks of those sales staff.

ViPerform – Sports

Dorsavi is due to shortly launch its ViPerform product in the US. This product is used by sporting groups to prevent injuries in players, and to help players return from injury sooner and once appropriate recovery was been achieved. It does not require FDA approval.

The product uses sensors that are strapped onto the body and allows relative body movements to be tracked, with alarms generated when movement exceeds set limits. It also allows measurement and speed of body movement to assess recovery progress and injury levels.

The ViPerform product is used by elite sports people first, including AFL teams such as the Hawthorn Football Club, and soccer team Manchester United. These are the Key Opinion Leaders and the expectation is that use will filter down to the local sports club level.

However, solving individual problems for sporting clubs also gives the company new products, such as the ViMove Running product, feeding R&D ideas and solutions for the company. This product development came out of a pilot program run in conjunction with the Olympic Park Sports Medicine Centre in Melbourne.

This new product was launched this week, and allows users to measure limb movement during running, something which could only be accurately measured previously in an expensive sports laboratory. This will be the first time that Dorsavi will target the consumer market directly, as well as selling this product to physiotherapy and sports medicine clinics. The product will presumably be pitched at the serious runner who wants to find out how to improve their running performance.

ViSafe – Workplace Use

This week the company announced an alliance with the insurance group Allianz. The company sees partnerships with insurance groups who will recommend the use of the ViSafe product to prevent workplace injuries as a key strategy for this market. Sales in this market are project based, with a baseline assessment costing between $20,000-$50,000, and tailored solutions costing up to $350,000.

ViMove – For Physiotherapists

However the major market for the company is for use by physiotherapists. Australia was the first market entered by Dorsavi and is what it calls a 'test market'. There are around 24,000 physiotherapists in Australia. The model is that physiotherapists license use of the ViMove device for between $5,000 - $7,000 for the year. It is expected that physiotherapists will ideally purchase at least two devices, one which will be used in their clinic, and the second can be used by the patient at home for short periods.

For the company to move to profitability, it will need an installed base of around 1,000 devices, which will generate around $6 million in annual revenue. Once installed, it will give the company high quality, repeat earnings.

There are around 50,000 physiotherapists in the UK, 128,000 in Germany and 284,000 in the US.

The CEO of Dorsavi, Andrew Ronchi, said the physiotherapy industry has been devoid of (technological) advancement for the last 20 years. Around 15 abstracts have been submitted to conferences and each has been accepted said Ronchi, confirming the interest in this technology.

Another potential growth area for the company is the consumer market for wearable sensors. This market includes the Jawbone product sold by Apple that measures heartbeat, body movement, including during sleep and is a nascent but potentially very high growth market which is generating considerable interest.

Summary

Dorsavi is capitalised at $68 million. The company had $16.6 million in cash at the end of last year. Milestones in the year ahead include FDA approval of the ViMove product for the physiotherapy market, sales into the US elite sports market, and more partnerships with major insurers.

Investors who entered the stock through Dorsavi's IPO are in a position to **Take Profits**, with the stock up 40% on its offer price. Other investors will want to monitor quarterly income receipts and and any trends in net operational cash flows to a cash neutral position over the next four to five quarters.

Bioshares recommendation: **Take Profits**

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QRxPharma: FDA Panel Date April 22, PDUFA Date May 25

QRxPharma (QRX: $0.785) has announced that the FDA has set a date for an Advisory Committee to review its revised New Drug Application for its combination opioid drug MoxDuo IR.

The PDUFA date, as previously set by the FDA in December 2013, is one month later on May 25, 2014. A PDUFA date is at the end of the minimum period (either 10 months or 6 months if a priority review) following an NDA submission after which the FDA makes its decision.

In *Bioshares* view, the advisory committee meeting is likely to play an important role in guiding the FDA's final decision for MoxDuo IR. If panel members find that on balance the benefits of MoxDuo IR substantially outweigh the risks then the drug candidate should have a much greater chance of gaining final FDA approval.

MoxDuo IR has been not approved by the FDA on two previous occasions. The first Complete Response Letter (CRL) in response to its NDA came in June 2012. The FDA sought more information from the company in relation to the safety and effectiveness of MoxDuo IR (See *Bioshares* 461). [A CRL is the FDA's peculiar terminology to describe the status of neither being approved or rejected.]

The second CRL occurred because QRxPharma missed the deadline to resubmit all of the data required for its revised NDA. QRxPharma has now submitted the quality control data relevant to Study 022, in which concerns with oxygen saturation levels were raised, although this problem was observed with patients *not* taking MoxDuo IR.

Capital History - QRxPharma

Quarter	Type of Raising	Funds Raised ($M)
Q4 2013	Placement	$7.50
	SPP	$4.10
Q3 2011	Placement	$25.00
	Rights Issue	$1.51
Q4 2010	Placement	$14.00
	SPP	$5.80
Q4 2009	Rights Issue	$13.60
	Sub-total	**$71.5**
Q2 2007	IPO	$50.0
	Total	**$121.5**

Despite concerns being raised by various members of the US Congress to prescription pain drugs, the demand for safer pain drugs remains high. This is a demand MoxDuo IR has been designed to meet.

QRxPharma is capitalised at $129 million and held cash of $17 million at December 31, 2013.

Bioshares recommendation: **Speculative Buy Class B**

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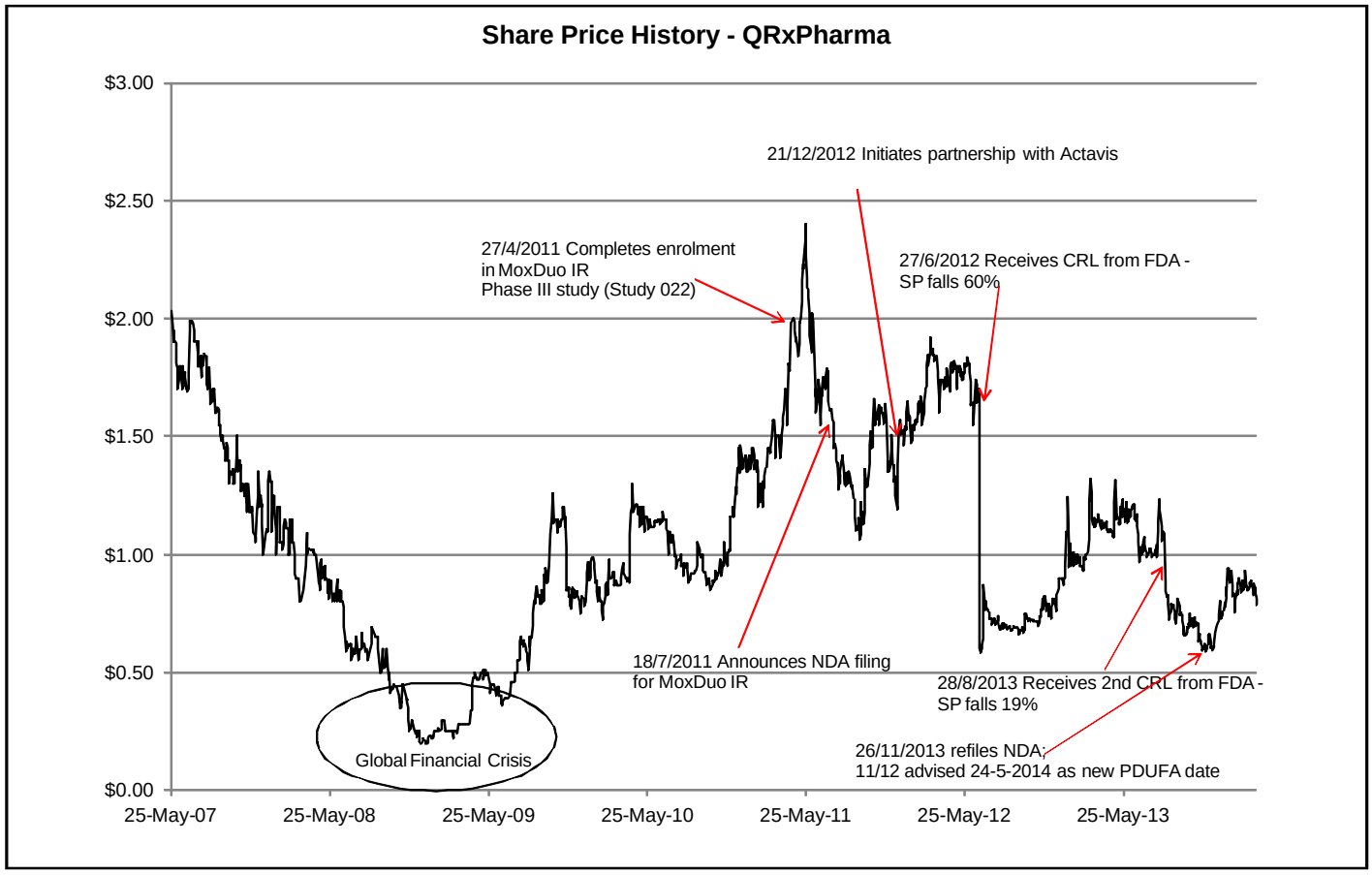

Bioshares Model Portfolio (28 March 2014)

Company	Price (current)	Price added to portfolio	Date added
Invion	$0.074	$0.089	February 14
QRxPharma	$0.785	$0.620	December 13
Impedimed	$0.240	$0.245	December 13
Analytica	$0.025	$0.025	December 13
Imugene	$0.014	$0.022	November 13
Oncosil Medical	$0.130	$0.155	September 13
IDT Australia	$0.300	$0.260	August 13
Viralytics	$0.325	$0.300	August 13
Tissue Therapies	$0.350	$0.255	March 2013
Somnomed	$1.58	$0.94	January 2011
Cogstate	$0.320	$0.13	November 2007
Universal Biosensors	$0.37	$1.23	June 2007

Portfolio Changes – 28 March 2014

IN:
No changes

Recommendations:

OUT:

No changes

Recommendations:

Cogstate Test to be Used in Phase III Alzheimer's Study

Cogstate (CGS: $0.32) this week announced that is computerised cognitive test would be used in a 'landmark' Phase III Alzheimer's study involving 1,000 people.

The trial is an academic study being coordinated by the National Institute on Aging and the University of California in San Diego. The study will look at treating people early on who are at risk but have not shown any symptoms of disease.

People who have high levels of beta amyloid in the brain will be enrolled into the study and treated with Eli Lilly's drug candidate solanezumab, a monoclonal antibody that binds to beta amyloid proteins. Although this drug candidate failed to deliver in a Phase III study, there were signs of efficacy when patients were treated at early stages of disease.

In this study, patients will regularly have their brains imaged using a PET scan to look at changes in beta amyloid.

The primary endpoint in the trial will be pencil and paper cognition tests, with the Cogstate tests used as secondary endpoints and delivered using an iPad. Study participants will be followed for four years.

The ADOSCOG test was not included in this study because it is not considered sufficiently sensitive to detect early and subtle changes in cognition. The primary 'pencil & paper' test to be used will be what is called the ADCS-PACC composite measure.

Although it is not a large commercial contract for Cogstate, the upside for the company is the recognition in being included in such a major study, and that Cogstate's tests could be used as an objective commercial screening tool when an effective Alzheimer's drug, potentially solanezumab, reaches the market.

This is not the first time that the Cogstate tests have been used in a Phase III Alzheimer's disease study. In May last year Cogstate announced that its tests would be used in a Phase II/III study in 210 adults with a genetic mutation that is known to cause Alzheimer's disease. In that study, study participants are being treated

– LBT Innovations cont'd

Looking Ahead

LBT is working on additional products, with CEO Lusia Guthrie stating that investors should soon be able to 'see that there is a pipeline'. The company has flagged that not all new opportunities will be in the area of laboratory automation. The company has taken a very analytical approach to identifying gaps in the workflow of the microbiology lab, and then making products to fill the gaps.

Summary

LBT Innovations is a quiet achiever in the world of microbiology lab automation. The company is both governed and managed prudently. The stock suits patient, long term investors looking for returns from high technology companies experienced in creating and bringing to market productivity tools for the modern economy.

LBT Innovations is capitalised at $9 million and retained cash of $2.1 million at December 31, 2013. Up until the end of 2013, LBT had received $3 million from $7.5 million provided by Hettich AG under the terms of the joint venture agreement.

Bioshares recommendation: **Speculative Buy Class B**

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– Cogstate cont'd

before symptoms appear with Eli Lilly's solanezumab drug candidate or Roche's gantenerumab drug candidate.

Despite last year being a difficult period for the company's clinical trials business, there has been a solid turnaround in early 2014 with respect to the level of new contracts signed. One of the growth areas for the company is in using its tests to measure changes in cognition in children in clinical trials. The appeal of the test to children is that it uses playing cards that are more visually stimulating and achieves good compliance in even very sick children.

Cogstate is capitalised at $32 million. The company had $8.9 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

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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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