ISSN 1443-850X

Bioshares

26 September 2014
Edition 570

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

Companies covered: BNO, DVL, IIL, IVX

	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 - current)	19.0%
Cumulative Gain	**436%**
Av. Annual gain (14 yrs)	**17.5%**

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 570 (26 September 2014)

Invion Shows Escalating Dosing Approach Holds Up

Invion (INV: $0.078) has achieved some positive interim data around the safety of its drug candidate INV102. INV102, which is also known as nadalol, is a commercially available beta-blocker that is contraindicated for the treatment of asthma. However, Invion believes that if the dose is slowly titrated up, then it may prove to be an effective adjunct treatment in asthma and other airway diseases.

In preclinical studies, INV102 has been shown to restore damaged epithelial cells in the airways. All commercially available asthma treatments do not heal the underlying damage in patients with asthma. If this treatment can be shown to be safe and effective, then INV102 could become an important treatment addition to patients with asthma and other patients with damaged airways, such as those with Chronic Obstructive Pulmonary Disease (COPD) and people living with cystic fibrosis.

Because nadalol is currently prescribed for the treatment of migraine and high blood pressure but is contraindicated for use in people with asthma and COPD, this early safety data is very encouraging because it supports the company's theory that slowly increasing the dose of the drug prevents the broncho-constriction seen in patients taking beta blockers for the treatment of cardiovascular conditions.

NIH Funded Trial

The current asthma trial is being funded by US Government agencies NIAID and NIH and is being conducted at the Bayer College of Medicine, Washington University and Duke University in the US. The trial data is still blinded, with around half of the patients receiving placebo. But overall, the data has shown that 19 of the 21 patients have tolerated being titrated with INV102 to the highest dose without severe side effects. Invion CEO Greg Collier said that the two patients who dropped out of the study did so, but not because they could not be titrated. In this trial, no negative effect on blood pressure, pulse or lung function has been observed.

Invion's Chief Medical Officer Dr Mitchell Glass said that this data supports that INV102 should not be contraindicated for patients with asthma and COPD (when taken in a titrated process). Dr Glass stated that if these patients had started at a full dose, then a subset of patients would have needed to use other medications.

The current Phase II asthma study is due to continue to enroll patients this year with a target of 60 patients, and results are expected in the first half of 2015 according to the company. Dr Glass said that "Nadalol is unique against all beta blockers."

The strategy for the company is to move forward with commercialising an oral version of INV102 for use in smoking cessation, preventing the smokers' cough that results when patients try to stop smoking and is a factor in failed attempts to quit. In smoking cessation, patients would be treated with INV102 for three months before giving up smoking, reaching the highest dose of INV102.

Cont'd on page 3

Dorsavi – Commercialisation on Track

Dorsavi (DVL: $0.42) has increased its staff count to 35 people from around 15 last year after its successful IPO in December 2013. The company raised $18 million to expand the commercialisation of the company's motion sensor technology used in the work place, sports recovery and by physiotherapists for the wider population.

Dorsavi's key expertise is in lower back pain, where it has developed product algorithms to train patients to recover from lower back injuries. Its devices are attached to the back and the sensors provide feedback either to a physiotherapist via computer or directly to the patient through a mobile monitor.

Clinical Trial Outcome

In a 112 patient randomised study, the company showed that when patients with lower back injuries were trained with its device, there was a sustained reduction in lower back pain of 54% at 52 weeks, compared to only a 1% drop in the control arm, when the device was worn only for the first eight weeks.

Early Adopters

In the sports sector, which is driving the innovation of new applications for Dorsavi, the company's products are being used by elite sports teams such as Manchester United Football Club (one of three English Premier teams using the product), Sao Paulo Football Club (first South American football team), and locally, seven AFL teams including the Hawthorn and Richmond football clubs.

In the sports area, the company has developed expertise around hamstring recovery and recovery from knee injuries. The company has close to 15,000 datasets from patients across a range of activities and injuries. It has commercial modules available in the areas of lower back, hamstring, knee control, core control, rowing and running. The company is about to release a product around hip control. And it is working on modules for cycling, golf and neck movement.

Within two years it expects to have a running product on the market on the market in conjunction with a third party that will incorporate its technology into running gear.

Business Model

Dorsavi licenses its system to physiotherapists or sporting groups for an annual fee of around $7,500. It currently has an installed base of 100 systems, with 60 of those being used in Australia.

1000 Installed Systems Goal

The medium-term aim for the company is to achieve 1,000 installed systems within the next two to three years which would see the company reach a breakeven position. This would be split with around 200 installed systems in Australia, 200 in Europe and 600 in the US.

The focus at the moment for the company is to sell into the Australian physiotherapy market and also the US sports market. Australia is a test market, with the physiotherapy market being the largest market for the Dorsavi's technology in all countries.

US Sports Opportunities

The focus for the US sports market is in the four major sports of basketball, gridiron, baseball and soccer. The company is currently focusing on the elite teams in the US such as the NFL. One NFL team is likely to start using the technology now to track some of its older players during the season. However when used be elite teams, it is generally incorporated into training at the start of the season.

Once the company has build brand presence in the US, it will focus more on the next level down of the college teams. In Division I alone, there are 250 mens football teams and 330 womens soccer teams. The larger US sports clubs can be expected to use between three-four of the Dorsavi systems, plus there are also consumables that are sold to the customers, although the consumables income is expected to be modest.

FDA Clearance

In July this year the product was cleared by the FDA and in the same month the company made the first sale to a pain physician at a US sports therapy clinic. In April the company hired John Kowalczyk to head up the US operations for the company. Kowalczyk was at Medtronic for 19 years selling medical devices, including to pain physicians, and has good links into that network. More sales to pain physicians in the US are expected.

New Emphasis on US Market

When Dorsavi listed, the aim was to place more focus on building the Australian market than the US market. However the level of interest that has been received from the US means the company will now focus more on the US, with respect to where the new staff additions will be made. Dorsavi has six staff in the US and six in Europe.

OH&S Application – ViSafe

The third application of the technology is in the work place, improving Occupational Health and Safety practices. This application delivers more immediate revenue for the company through contract work.

In July the company made a small acquisition in this area, buying Australian Workplace Compliance for $120,000. AWC conducts OH&S compliance work. The reason for the acquisition is that it will help the company sell its ViSafe product into the work place. The acquisition came with three staff, and Dorsavi now has five staff working in this area.

Physiotherapy – Key Longer Term Market Application

The main long term market for Dorsavi is for use within physiotherapy clinics. While sales to the workplace deliver earlier revenues, and sales to the elite sports clubs help build branding, sales to the physiotherapy market provides the largest commercial opportunity.

Cont'd over

Market Dimensions

In Australia there are around 12,000 physiotherapists in private practice in around 4,000 centers. In total, there 24,000 physiotherapists registered in Australia. In the US there are 284,000 physiotherapists. The company is selling direct to physiotherapists, but is also marketing the product to pain physicians who refer patients to the physiotherapists, and to the patients themselves, who will seek out the clinics that offer the ViMove product. Dorsavi lists the physiotherapy clinics on its website that offers its product. At the moment there are clinics in the UK (6), NSW (11), Victoria (21), Queensland (4), South Australia (5) and Tasmania (3).

Country	Physios (N°)
Australia	24,000
USA	284,000
UK	50,000
Germany	128,000

Source: Dorsavi

A Longer Term Challenge

It is a longer-term sell to the physiotherapy network, which has the biggest barrier to entry. Physiotherapists would generally not be considered early adopters, but building awareness across patients and from pain physicians will help product take-up.

Also important, but a smaller market than the physiotherapy space is the US college teams, and other uses of the product include a running module that will be incorporated into running gear, such as socks or runners.

Summary

Dorsavi is capitalised at $51 million with $14 million in cash at June 30. Commercialisation of the company's technology is on track with the company in a good position following its $18 million capital raising on listing last year.

Revenue growth over the next 12 months, in absolute terms, can be expected to be modest, as the company continues to build its profile through sales to elite sporting groups, and continues to increase its presence in the physiotherapy market.

Dorsavi's business model represents what is effectively an annuity stream for the business. It needs around 1,000 installed systems to become profitable, with around 100 installed systems so far. This will be a key measure to monitor, as will be the inroads the company makes into the US market with sales to elite sporting groups, college sporting teams, pain physicians and into physiotherapy clinics.

Bioshares recommendation: **Speculative Hold Class A**

Bioshares

– Invion cont'd

This Phase II study is looking to enroll 136 patients and complete enrolment this year. Enrolment into this study has accelerated considerably said Collier. Sputum sample results in a subset of patients (this is not a primary endpoint) will be released in the next quarter and final results are expected in Q1 2015.

The current asthma trial is also with an oral version of INV102. However, all other commercial applications of INV102 will be with an inhaled version of the drug. With an inhaled version, because the drug will be delivered directly to the target site, the dose will be 1/100th of the dose in the oral trial.

The oral version with be used for the treatment of three diseases where there is upper airway damage to the epithelium. These are in severe asthma, cystic fibrosis and chronic bronchitis. Because there will be no systemic absorption of the drug with an inhaled version of the drug, and with a low dose, it is expected to have a benign safety profile.

Invion is collaborating with 3M Drug Delivery Systems to deliver INV102 in a pressurised metered dose system. That collaboration has just completed Stage 1 feasibility studies.

INV103 Interim Results in Lupus

Invion is conducting a Phase II trial with its drug candidate INV103 for the treatment of lupus. This program was originally being developed by Cbio which was merged to become Invion. INV103 is a modified natural human protein. This trial was to recruit 32 patients, trialing four intravenous doses, twice weekly for a month – 10mg, 30mg, 100mg and 300mg – with eight patients in each dose (including two patients receiving a placebo).

Results from the first two doses have shown the drug to be safe but with no effect on serum biomarkers. The patients recruited had only mild lupus with serum biomarkers near the normal range.

Invion will now move to higher doses of INV103 (100mg) as well as dosing patients with more severe lupus (at 30mg). Collier is seeking to have these cohorts of patients treated by year's end with data available in early January.

Invion is capitalised at $42 million. The company had just under $4.0 million in cash at the end of June.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (26 Sept 2014)

Company	Price (current)	Price added to portfolio	Date added
Actinogen	$0.041	$0.050	September 14
Benitec Biopharma	$1.025	$1.025	September 14
LBT Innovations	$0.135	$0.130	July 14
pSivida	$4.850	$3.800	May 14
Invion	$0.078	$0.089	February 14
Impedimed	$0.430	$0.245	December 13
Analytica	$0.039	$0.025	December 13
Imugene	$0.014	$0.022	November 13
Oncosil Medical	$0.120	$0.155	September 13
IDT Australia	$0.220	$0.260	August 13
Viralytics	$0.285	$0.300	August 13
Tissue Therapies	$0.350	$0.255	March 2013
Somnomed	$2.08	$0.94	January 2011
Cogstate	$0.290	$0.13	November 2007

Portfolio Changes – 26 September 2014

IN:
No changes

OUT:
No changes

Innate Immunotherapeutics to Start Dosing in Phase II MS Study

Innate Immunotherapeutics (IIL: $0.20) is running three months behind schedule with its Phase II study with its lead drug candidate for the treatment of later stage *secondary progressive* multiple sclerosis (MS), a form of the disease for which there are currently no commercially available therapies. There are nine drugs approved for the early stage of the disease, *relapsing remitting* multiple sclerosis.

The first patient was expected to be treated by the end of June and that is now likely to be by the end of September. The trial will enroll 90 patients. The first site, in Perth, has been initiated, with that site recruiting and screening patients.

The second site is in Melbourne, and with ethics approval to proceed, that site will shortly start to advertise for patients. Melbourne and Perth will be the two key sites, with up 70 patients to be enrolled there. Two other sites, in Brisbane and Adelaide, are expected start recruiting next month.

Why the Delay?

One of the delays in initiating sites is the neurologists who will be coordinating the patients, are not used to prescribing medications that need to be injected through an intravenous infusion. This means the trial needs to be conducted at Phase I/II clinical trial sites, which are located in Perth, Melbourne, Brisbane and Adelaide, but not in Sydney and Hobart. The latter was expected to be a major recruitment location for this trial.

This Phase II trial was expected to take six months to recruit, so as to be finished recruiting by the end of the year. The CEO of Innate, Simon Wilkinson, would like to accelerate the recruitment process, to recruit all 90 patients in closer to four months. However, the company will get a good idea of the recruitment rate over the next six to eight weeks.

An estimated 23,000 people in Australia have multiple sclerosis.

Entry Criteria

The entry criteria into the trial is not overly restrictive. Patients need to be between the ages of 18-65, not have a severe stage of the disease which confines them to a wheelchair, and have not been experiencing relapses in the disease i.e. in the secondary progressive stage of disease, amongst other criteria. Patients can also have been on the older type of MS therapies, as long as there is a four week washout period prior to starting the trial.

Trial Design

In this Phase II trial, 60 patients will receive Innate's drug candidate, MIS416, and 30 will receive a placebo. Patients will be treated once a week for 12 months. Those in the placebo arm, together with those in the active arm, will be offered continued treatment with MIS416 after completion of the study, under a compassionate use program.

Currently 17 patients are receiving treatment under such a program in New Zealand. While Innate has data on the effectiveness of this treatment in a single arm study – showing more than a 30% improvement in symptoms in 80% of patients treated – there is no data in a blinded, placebo controlled study, which is what the company needs to spike the interest of a larger pharmaceutical partner.

Innate is capitalised at $33 million. The company had $6.1 million in cash at the end of June.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

Bionomics Adds Medicinal Chemistry Assets

Bionomics (BNO: $0.58) has acquired the business assets of Prestwick Chemical, a business which has been co-located with Bionomics' Neurofit services business in Strasbourg, France.

Prestwick Chemical has been a provider of medicinal chemistry services and screening libraries, with Bionomics being a customer of Prestwick Chemical since 2009. Bionomics will pay €270,000 for the assets.

The advantage to Bionomics from this acquisition is that the company can build an integrated CNS and drug design services business with which to attract more customers but importantly support its own internal drug discovery and development programs.

The capture of human capabilities is often understated in the modest terms of such transactions.

Bionomics is capitalised at $242 million.

Bioshares recommendation: **Speculative Hold Class A**

Correction: Cogstate – Bioshares 568 (Page 1)

In *Bioshares* 568 , we wrote that "Cogstate has invested in product development over the last 12 months to bring this new product to the market. It expects to generate between $3-$6 million in revenue from this product this financial year."

This should have read:

Cogstate has invested in product development over the last 12 months to bring this new product to the market. It expects to sign between $3-$6 million in sales contracts from this product this financial year.

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, Benitec BioPharma, Admedus, Calzada, Invion, 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 _____

_____

_____