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	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)	58.3%
Cumulative Gain	**464%**
Av. annual gain (13 yrs)	**19.8%**

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Bioshares

22 November 2013
Edition 530

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

IPO Profiles: Dorsavi and Innate Immunotherapeutics

An IPO season is well and truly upon us in the biotech sector in Australia. Following on from the more than 40 biotech IPOs that have taken place in the US this year, at least three companies plan to list on the ASX in coming months. They will follow stem cell company Regeneus, which listed at 25 cents in September and this week finished at 49.5 cents.

Two quality biotechs are expected to list next month. These are medical device group Dorsavi and multiple sclerosis drug developer from New Zealand, Innate Immunotherapeutics. Simavita is due to complete a compliance listing in Australia. Simavita is merging with a subsidiary of Genetic Technologies called Gtech (largely a shell company) in Canada. After raising $15 million from mostly Australian investors, Gtech, which is listed in Canada, also intends to list on the ASX.

Dorsavi – A Sensor Technology for Preventing and Repairing Injuries at Work and from Sport

IPO Summary
Company: Dorsavi
IPO price: 40 cents a share
Funds to be raised: $18 million
Underwritten: Yes
Lead Manager: Canaccord Genuity
Offer opens: 13 November 2013
Offer closes: 29 November 2013
Expected listing date: 11 December 2013
Market cap on listing: $48.5 million

Melbourne-based Dorsavi plans to list on the ASX next month raising $18 million. It is a very straightforward offer for investors. Dorsavi is commercialising a wireless sensor movement monitoring system to prevent and to repair injuries in the work place, in sport and from other causes. The primary market for the company is for use in physiotherapy clinics.

The technology comprises of sensors that are attached to the injured area on the body or the particular area of interest. The movement of muscles and joints can then be visualised on a screen and assessed in real time by the patient and the physiotherapist. The system also comes with alarm system that can be worn at home or at work on the belt to warn the patient if incorrect movements of the body are occurring.

The company believes that its technology is 'the first wireless and wearable system that enables many aspects of detailed human movement and position to be captured, quantified and assessed outside of a biomechanics lab.'

Cont'd over

Three Main Applications

1. Elite Sports

There are three main markets that Dorsavi will focus on. The first is in elite sports to help players recover from injury, to assess those players who are more susceptible to injury, to prevent injury, for player screening and for strength and conditioning of players.

This application is likely to build the profile of the technology. Its customer base is very impressive and includes five AFL clubs (Richmond, Western Bulldogs, Fremantle, Essendon and Brisbane Lions), NSW Cricket and the Manchester United Football Club in the UK.

2. In the Work Place

The second application for the technology is in the work place, to assist with preventing injuries. The company's customers include Coles, Woolworths, Toll, Toyota, Amcor and BHP. This is more project driven work and allows the company to achieve some early cash flow.

3. Physiotherapy Clinics

The core application is in the physiotherapy market. In this market, physiotherapists license the systems on an annual basis, and then charge their patients for use of the product to assist recovery from injury. Currently the product is used by 35 practises (in Australia) and three in the UK.

Funds to Ramp-up Sales

In FY2013, Dorsavi generated sales from products of $0.4 million with a $1.65 million loss. Sales in FY2012 were $244,000.

The funds raised through the IPO will go towards boosting the company's sales teams in Australia, the UK and the other parts of Europe, and then later the US market.

Regulatory Approval

Dorsavi has gained regulatory approval for its technology in Australia and Europe. In the US, the company has filed for approval through the 510(k) pathway. The company expects to start selling into the US in early 2014.

Clinical Trial Data

Dorsavi has conducted a 103 patient trial with its technology. It has shown that lower back pain was reduced by 46% after 12 months and patient mobility improved by 77%. This was with only 8-12 weeks of treatment.

Patients in the placebo arm in this trial showed only marginal improvement (8%) with their symptoms returning back to their pre-existing levels after treatment ended.

Major Investors, Board and Management Team

Venture Capital Group Starfish Technology Fund II is a major shareholder, owning 73% of the company prior to IPO. The chairman of Dorsavi is Olympic gold medallist Herb Elliot, who is also deputy chairman at Fortescu Metals Group. Michael Panaccio from Starfish Ventures is also a director, as is Gregory Tweedy, who was formerly a Director and CEO of WorkSafe. Ashraf Attia, who is Managing Director for the Asia Pacific arm of heart assist device company Thoratec Corporation, is on the board. Andrew Ronchi is the company's CEO and is also a director. Ronchi has a physiotherapy background and with his brother, Daniel Ronchi, founded the company.

The company has a very impressive and appropriate board with experience in finance, sport, medical technologies, OH&S and physiotherapy.

Patents

Dorsavi has six families of patents covering its technology either granted or pending. Looking at the US, the company has one patent granted (protection out to 2026) and five patents pending. In Australia the company has one patent granted, and in Europe all of its patents are pending.

Risks

Dorsavi believes there are no competing technologies or products that have been developed that provide the functional benefit its technology offers.

The core risk for Dorsavi is execution risk, that the company will be able to sign on physiotherapy clinics (and other users) to pay the annual license fee to use the technology (around $7,000 a year).

With Starfish Ventures owning a very large stake of the company, it will have a dominant shareholder position influencing future decisions such as an acquisition of the business. Starfish will be subscribing for $1.5 million under a convertible note with the IPO that will convert to shares at the issue price.

Before participating in this IPO, investors are required to read the prospectus, which can be accessed at http://www.dorsavioffer.com/prospectus.html

Bioshares

Innate Immunotherapuetics – Addressing Unmet Need in Secondary Progressive MS

IPO Summary
Company: Innate Therapeutics
IPO price: 20 cents a share
Funds to be raised: $10 - $12 million
Underwritten: No
Lead Managers: Morgans Corporate and Patersons Securities
Offer opens: 26 November 2013
Offer closes: 11 December 2013
Expected listing date: 20 December 2013
Market cap on listing* (based on $12 million raise): $42.9 million
*Includes loyalty shares, conversion offer, but excludes options
Options (NZ$0.20 - NZ$1.00 ex price): 21.2 million

Innate Immunotherapeutics (Innate) is developing a therapeutic for the treatment of a particular form of multiple sclerosis, called secondary progressive MS. The company is in the fortunate position that it already has patients taking the drug candidate in New Zealand where in most cases, the patients symptoms have not only stopped progressing, but also improved.

What Innate needs to do now is raise money to complete clinical trials that show that the drug can achieve a statistically significant improvement in symptoms above a placebo (or control) with no control arms part of previous trials. If it can show this, then the aim is to conduct a licensing deal with one of the five major pharmaceutical companies in the MS space. The open market for Innate and its future partner is estimated at US$3 billion a year by Innate, with no drugs currently approved for the treatment of secondary progressive MS.

MS is caused by the patient's immune system attacking the protective myelin sheath that surrounds the nerve fibres. Physically, it results in myelin damage or sclerosis, which gives the disease its name. This distorts/interrupts nerve impulses between the brain and the spinal chord.

About 85% of people first diagnosed with MS have what is called relapsing-remitting MS (rrMS). It is well treated for 15 years with nine drugs currently approved. These nine drugs generate over US$11 billion in revenue a year.

After 15 years, about two thirds of people with rrMS move on to the untreatable form or secondary progressive MS. Currently around 60% of people with MS have the relapsing-remitting form and 30% have the secondary progressive form.

Results to Date

Innate has been treating patients with secondary progressive MS using its drug candidate, called, MIS416, in three groups. The first was in a Phase IB trial in 16 patients, the second was in 15 patients in a Phase IIa trial, and the third in 23 patients under a compassionate use program, some of whom (14) are the patients treated in the clinical study.

All use to date has shown no drug related toxicities with MIS416. Of the 17 patients who have been on treatment for six months or more, '14 have reported improvements to a number of their MS related signs and symptoms'. This is an impressive and very encouraging outcome. One patient has now been successfully treated for five years with MIS416.

Next: Phase IIb Study

Of the money raised as part of the IPO, $6 million will be used to conduct a Phase IIb study. That trial will recruit 90 patients and will include a placebo arm (with two thirds receiving active drug). Innate has formed an Australian entity, with its CEO to be based in Sydney and the trial to be conducted at up to nine sites across Australia. Innate should qualify for the Australian R&D tax rebate.

The trial is due to start recruiting patients in the Q2 2014. It is expected that it will take six months to recruit, with a speedy recruitment expected by the company given the well motivated patient population, according to the prospectus. It is expected that all patients will be dosed by the end of 2015, with each patient to be in the trial for 12 months. Results are expected in early 2016.

Innate has been approached by around 30 patients in New Zealand to offer the drug candidate under its compassionate use program. It's expected that whilst results will not be available from the Phase IIb trial in Australia until completion, data will emerge from the extended NZ compassionate use program whilst the Phase IIb trial is underway. Innate expects at least 15 patients to enter the compassionate use program in early 2014.

Method of Action

MIS416 is a microparticle that combines two immunomodulators. These are the 'nucleotide-binding oligomerization domain-binding protein 2, and toll-like receptor 9'. The drug is manufactured using biological fermentation, where bacteria is grown and biochemically modified to include the two immunomodulators. The company currently makes the drug candidate at its leased facility in Auckland. It should not be an expensive compound to manufacture, for future commercial use.

Competition

There are currently nine drugs on the market to treat rrMS. These drugs generate over US$11 billion in sales. However, there are no drugs approved to treat secondary progressive MS. The key players in the MS field are Biogen Idec, Novartis, Merck Serono, Pfizer, Teva and GlaxoSmithKline.

Currently Biogen Idec (with Tysabri) and Novartis (with Siponimod) are conducting Phase III trials with their rrMS drugs for the treatment of secondary progressive MS.

Innate's drug candidate is delivered by a weekly intravenous infusion. Tysabri has a less onerous delivery schedule, with an IV infusion only every week, although Tysabri has a black box warning against the fatal PML infection. Siponimod is a daily oral drug candidate, but it is from the same drug class as Gilenya, also from

Cont'd over

Novartis for the treatment of rrMS, and has the PML safety issue as with Tysabri. At this stage, Innate's drug has a very clean safety profile.

Patents and licenses payable

The company has a core Use patent around the use of MIS416 for the treatment of multiple sclerosis. This patent is granted in the US, Australia and New Zealand and gives patent protection out to 2029.

Innate has licensed it's technologies from various parties and will pay 6% of any revenue it receives to various parties. These entitlements expire between 2020-2022, which will leave at least seven years of patent life when the license fees will not apply.

Board and Management

Innate has a solid board and CEO. Simon Wilkinson is the CEO and has been with the company since 2004. He has 20 years experience in finance, as well as earlier in his working life serving as an officer in the Royal New Zealand Navy.

The chairman is Michael Quinn, a venture capitalist who founded Innovation Capital. Other board members include Christopher Collins, who owns 18% of the company. Aside from being a successful businessman, helping acquire manage and create 17 profitable companies, Collins recently became the Congressman for the 27th Congressional District in New York. The next largest shareholder is the founding scientist through Probe International with a 6% stake.

Corporate Structure

Innate has a somewhat complicated corporate structure, which reflects its 13 year corporate history, its acquisition of Probe Pharmaceutical Corporation in 2001 and no doubt the difficulty in achieving funding of this program without venture capital funding.

There are three convertible note type facilities with $4.7 million to be repaid. It is expected that the majority of these liabilities will be converted to shares with $0.5 million to be repaid from proceeds of the IPO raising. There are currently about 1,700 shareholders, and these shareholders will be eligible for additional shares under a loyalty program (one free share for every three shares held prior to listing) upon Phase IIb trial success (if the program moves into a Phase III setting).

However, the offer price in the IPO looks attractive, with a market capitalisation, assuming $12 million is raised, of $42.9 million. This assumes full conversion of loans and convertible notes, and loyalty program success. This capitalisation does not take into account the 21.2 million options after listing, that will be exercisable at between NZ 20 cents to NZ$1.00.

Listed in the prospectus, the company has secured $5 million of the minimum $10 million to be raised, with investment fund Australian Ethical Smaller Companies Trust committing to $3 million in the IPO.

Risks

Innate has a granted Use patent covering its technology, which is not as strong as a Composition of Matter patent. It's patents outside of the US, Australia and New Zealand have yet to be granted.

Innate current has around 1,700 shareholders. Some of these will have been shareholders for a long period and may take the opportunity to sell down post listing.

Regulatory endpoints for treating secondary progressive MS have not been established with secondary progressive MS with no drugs currently approved. Innate will need to negotiate with the FDA and other regulators the most appropriate efficacy endpoints to select for its pivotal studies.

Innate currently has no IND in place which allows it to test the drug in the USA. Of the funds being raised, $350,000 will go towards preparing its IND submission. This could take longer than expected.

As with all biotechs, there is a risk that a superior technology reaches the market that will outperform the Innate drug candidate. These include the existing rrMS drug candidates which are in late stage testing. There is also the risk from emerging regenerative medicines in development. However in a complicated disease such as MS, a variety of approaches and options for patients will likely be of benefit.

There is the risk that the onerous weekly IV administration of MIS416 reduces appeal of the drug compared to other drugs in development, including Tysabri which requires IV delivery once a month and Siponimod which is taken orally once a day. However it may be likely that patients will require less frequent dosage of MIS416 once patients' symptoms have stabilized.

Before participating in this IPO, investors are required to read the prospectus, which can be accessed at http://www.innateimmunotherapeutics.com/investor-centre/ipo-prospectus

Bioshares

Five Stock Wrap

Company	Acrux	**Code**	ACR	**CMP**	$2.43	**Cap'n ($M)**	$404.6	**Cash ($M) 30/6**	$22.8	**PE**	**58.6**

- Acrux has three partnered transdermal drugs on market - Axiron (testosterone), Ellavie/Evamist (estradiol) and Recuvyra (fentanyl - vet.)
- Company is expecting a milestone payment of US$25 M from Eli Lily for Axiron exceeding annual (CY) sales of US$100 M
- Share price has weakened because of easing in growth (to 11%) in testosterone drug market in the US
- Axiron has built a 14% market share, as a premium priced product, in the US
- Eli Lilly is conducting studies of Axiron in groups of sub-optimal responders to other testerone gels, and in sexual well being settings
- Rest of world markets remain undeveloped relative to the US and represent an important source for future sales growth
- Lilly and Acrux initated a law suit against Watson, which has made a Para IV filing in respect of a generic version of Axiron
- Para IV filings are standard a tactic used by generic drug companies to gain a lead over rivals once patents expire
- ACR has remarked that the major threat to Axiron will be when generic gels emerge in 2017
- Contrarian investor Allan Gray recently increased its stake from 6.75% to 7.84%

Comment: ACR expects to declare a dividend in 2014 Q1; dividend is tax free; we estimate an 8 cent dividend will be paid
A degree of market over-reaction to actions by generic drug companies has re-positioned ACR shares at attractive buying levels

Bioshares recommendation: **Buy** | Timing -

Company	Avita Medical	**Code**	AVH	**CMP**	$0.110	**Cap'n ($M)**	$35.8	**Cash ($M) 30/9**	$8.7	**SI**	**1.2**

- Avita Medical markets ReCell, an autologous, 'spray on' skin cell product, for treating small burns, wounds and for reconstruction
- Product is approved for use in EU, China and Australia, but not the USA; sales have been in the low millions (2013-$2.8M, 2012 -$3.4M)
- ReCell is limited by the level of skill required by surgeons to master the key steps in separating special skin cells from harvested skin
- US Army AFIRM institute is funding a 100+ patient trial of ReCell in treating burns; trial has been slow to recruit
- US burns trial commenced in June 2010; was scheduled for completion in July 2013
- Bioscience Managers (Phillip Capital) invested $3M in AVH in a $10 M funding round in 2012 (holds 7.69% stake); Aust. Ethical - 20.6%
- Bioscience Managers has been frustrated by AVH's management, noting 'a complete lack of urgency to improve the company's situation'
- At 2013 AGM, chairman Dalton Gooding announced he was stepping down from the board
- Company's cash balance at Dec 31, 2012 was $14.4 M, at Sept 30, 2103, was $8.7 M

Comment: The likelihood of further board and executive changes at AVH is high
Decision to move into treating diabetic ulcers is a concern given that harvesting skin from unhealthy subjects may be counter productive

Bioshares recommendation: **Sell** | Timing -

Company	Impedimed	**Code**	IPD	**CMP**	$0.270	**Cap'n ($M)**	$48.9	**Cash ($M) 30/9**	$5.6	**SI**	**0.8**

- IPD is commercialising bioimpedance spectroscopy technology (BIS), with multiple medical and non medical applications
- IPDs lead product is the L-Dex system, which aids in the early detection and assessment of lymphodema
- Lead opportunity is with breast cancer patients, post surgery; but also relevant to other cancer patients e.g prostate and melanoma
- Ex-Medtronic exec, Richard Carreon replaced Greg Brown as CEO in July 2012
- IPD recently announced the receipt of a CPT Category 1 code from the AMA, for BIS lymphodema assessment of extracellular fluid
- Benefit of CPT 1 as opposed to existing CPT 3 code is its acceptability to US Medicare, which covers ~50% of breast cancer population
- CPT 1 code to be active from Jan 2015, one year ahead of previous expectation
- In June, changed label claim with FDA - removed 'diagnosis' and 'prediction' wording - which enabled CPT 1 breakthrough
- New management has made significant inroads in reducing costs and cash burn (now at $1.1 M a qtr)
- IPD will commence a 5 year trial of L-Dex and submit annual data to insurers over time to build in additional years of claimable benefit
- Trial will commence in 2014, with first full year of data to be submitted to private payors in 2017

Comment: The bringing forward of a Cat 1 code is a huge boost for IPD and is evidence of the capabilities of new management

Bioshares recommendation: **Speculative Buy Class B** | Timing -

Company	Osprey Medical	**Code**	OSP	**CMP**	$0.740	**Cap'n ($M)**	$91.1	**Cash ($M) 30/9**	$10.2	**SI**	**1.3**

- OSP has developed products (CINCOR and AVERT) which reduce the amount of dye used in coronary therapeutic or diag. procedures
- Medical objective is to reduce contrast induced nephrophathy (CIN), especially with patients with chronic kidney disease
- The AVERT system minimises amount of injected dye by approx. 40%; the AVERT system received FDA 510k clearance in August
- Priority has shifted to AVERT over CINCOR, and to achieving the label claim the 'reduction of Contrast Induced Nephropathy (CIN)'
- Osprey will advise of the status of the 600 pt CINCOR, 'PRESERV' trial 'at the appropriate time
- Will now commence a 700 pt trial of the AVERT system, which is expected to have final data by December 2015
- A very positive feature of both trials is use of a simple protein level marker (serum creatinine) as an endpoint for CIN
- CIN is defined as serum creatinine = 25% (above the normal value) or an absolute increase of = 0.5 mg/dL
- Company will commence a limited launch of the AVERT system in Texas in 2013 Q4
- OSP completed $14 M placement in November to support new strategy

Comment: Although the revised product strategy may see a better product brought to market, clinical trial execution is an ongoing risk

Bioshares recommendation: **Speculative Hold Class B** | Timing -

Cont'd over

Bioshares Model Portfolio (22 November 2013)

Company	Price (current)	Price added to portfolio	Date added
Imugene	$0.020	$0.022	November 13
Oncosil Medical	$0.115	$0.155	September 13
Calzada	$0.076	$0.073	September 13
Invion	$0.105	$0.060	August 13
IDT Australia	$0.465	$0.260	August 13
Viralytics	$0.345	$0.300	August 13
Circadian Technologies	$0.245	$0.270	March 2013
Tissue Therapies	$0.220	$0.255	March 2013
Benitec Biopharma	$0.510	$0.40	November 2012
Somnomed	$1.30	$0.94	January 2011
Cogstate	$0.390	$0.13	November 2007
Universal Biosensors	$0.52	$1.23	June 2007

Portfolio Changes – 22 November 2013

IN:
No changes.

OUT:
No changes.

Five Stock Wrap (Cont'd)

Company	Progen Pharmaceuticals	**Code**	PGL	**CMP**	$0.230	**Cap'n ($M)**	$12.7	**Cash ($M) 30/6**	$1.45	**SI**	**0.6**

- Progen Pharmaceuticals has been developing a class of anti-angiogenic and metallo-protinease inhibitors, to treat cancer
- First generation compound PI-88 was partnered with Taiwanese group, Medigen Biotech in 2010
- Medigen expects to complete recruitment of a 500 pt Phase III trial of PI-88, in the adjuvant liver cancer setting, by end CY2013
- Medigen expects to begin marketing PI-88 in Taiwan and China by the end of 2014, 'at the earliest'
- Next generation compound PG545 was partnered with Medigen Dec 2012, specifically for liver cancer and non-oncology indications
- In the first Phase Ia trial of PG545, unexpected injection site reactions were observed; trial was put on hold
- Progen expects to initiate a Phase I trial PG545 [IV administration] in 25 pts with advanced cancers; goal is to evaluate dose limiting tox
- PGL's Pharmasynth subsidary recorded revenues of $2.8 M for 2013, up 40% from the previous year
- Pharmasynth revenues may weaken if Prima Biomed reduces its requirements for drug material for its Cvac immunotherapy trials

Comment: PGL has struggled to succeed with its anti-cancer technology; with cash position a more near term issue with this stock

Bioshares recommendation: **Sell** | Timing -

Notes: PE - Price/Equity ratio SI - Survival Index (refer to Bioshares 527 for explanation)

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: Starpharma Holdings, Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Tissue Therapies, Viralytics, Phylogica, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Calzada, Atcor Medical, Invion, Circadian Technologies

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