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Bioshares

13 September 2013
Edition 520

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

Biotech Bull Market Special Edition Bioshares Top 10 Picks

Biotech has been experiencing a bull run this year, with the Nasdaq Biotech Index continuing to hit new highs, including its latest close of 2,165 points. Biotech listings on the Nasdaq have exploded this year, with 29 completed so far this year compared to 13 in 2012. Another six IPOs are expected to be priced in September.

With sentiment strong towards biotech stocks, what should a biotech investor be looking at? The answer is the focus of this edition, in which Top 10 picks have been made, but spread across three drug developers (Benitec, Viralytics and Invion), three device companies (Oncosil Medical, Calzada and Universal Biosystems), three deep value plays (Somnomed, IDT Australia and LBT Innovations) and for good measure a blue-sky play with revenues, Cogstate.

Nasdaq Biotech Index



	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)	59.5%
Cumulative Gain	468%
Av. annual gain (12 yrs)	16.6%

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Summary - Top 10 Picks

Company	Code	Cap (\$M)	CMP	Headline Comments
Benitec	BLT	\$32	\$0.38	A High Risk-High Value Play
Cogstate	CGS	\$35	\$0.45	Dementia Screening a Blue Sky Opportunity
Calzada	CZD	\$30	\$0.073	Exploiting a Speed-to-Market Strategy
IDT Australia	IDT	\$28	\$0.37	Under New Management
Invion	IVX	\$40	\$0.088	The Experienced Chemgenex Team Returns
LBT Innovations	LBT	\$8	\$0.079	Automation in the Path Lab
Oncosil Medical	OSL	\$26	\$0.155	Looking to Emulate Sirtex Medical
Somnomed	SOM	\$47	\$1.085	A Small Cap with a Big Future
Universal Biosensors	UBI	\$136	\$0.78	Siemens Deal to Deliver More Upside
Viralytics	VLA	\$30	\$0.34	Interim Phase II Results Look Good

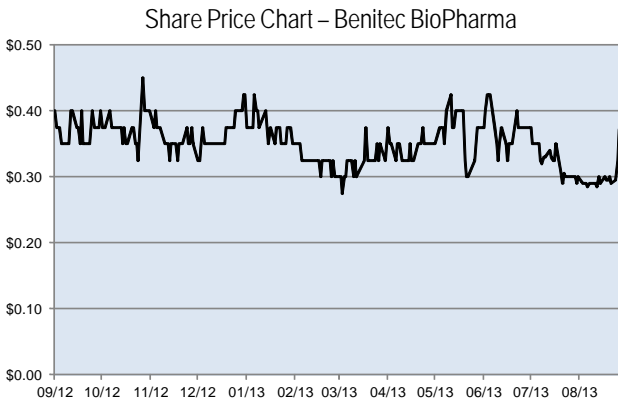
Three Hot Drug Plays

Benitec BioPharma – A High Risk–High Value Play

Benitec is a unique biotech company. It is using a technology called ddRNAi to reprogram cells in the body. The technology risk is extremely high. But the potential return, if it can crack it, is even greater. The company is seeking FDA approval to start a Phase I/II clinical trial in patients with Hepatitis C who have failed all other treatments. If it gets the nod from the FDA, that is significant value creation point number one.

The second value creation point is dosing of patients showing no safety issues. That is expected to start this year. And the third major value inflexion point in the next few months, and the most important, is efficacy results from the clinical study. Success in this trial will also validate the same approach in Hepatitis B.

Bioshares recommendation: **Speculative Buy Class A**

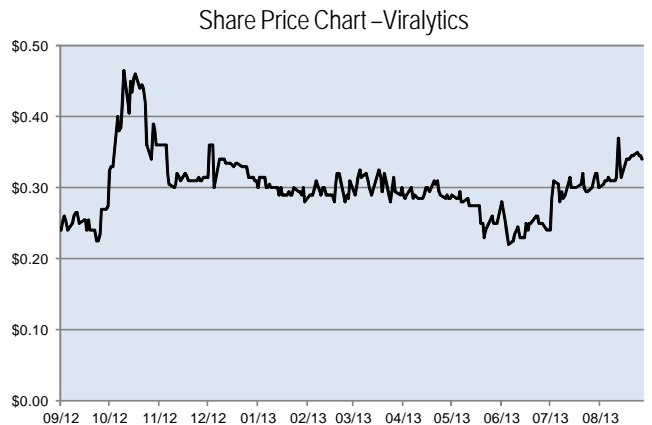


Viralytics – Interim Results Look Good

Viralytics is taking a very interesting approach to treating cancer, using viruses to kill cancer cells. It's not a unique approach, with Amegn, which acquired by Biovex in a billion dollar deal, ahead of Viralytics. Viralytics is conducting a 63 patient Phase II trial with full results expected in mid 2014. Interim results for the company have been very good, comparing favourably with earlier Biovex data.

Viralytics is an attractive proposition given its market cap of \$30 million. The company will likely need to raise cash in coming months. Key milestones are results from the Phase II study, and then a potential licensing deal. The other option for Viralytics is to start a pivotal clinical study without a partner.

Bioshares recommendation: **Speculative Buy Class B**



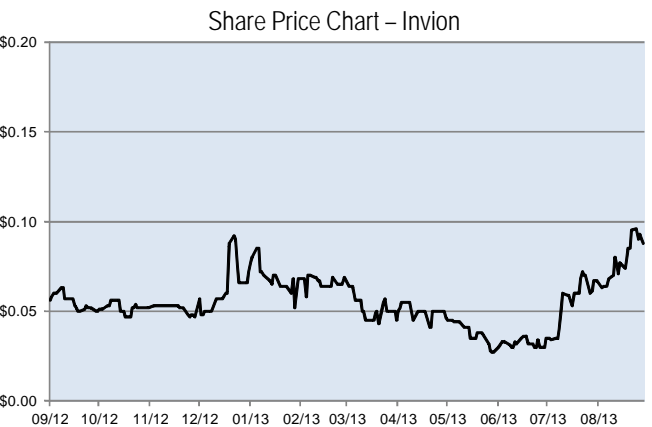
Invion – The Experienced Chemgenex Team Returns

Greg Collier, the former CEO of Chemgenex Pharmaceuticals, has returned to the Australian biotech sector with his next drug development play, called Invion.

Invion has two drug candidates in three Phase II trials. The first is being used to treat smoker's cough in smoking cessation. The second is in asthma. And the third is in patients with lupus. And interim readout in all three trials is expected in over the next six months, and the company has sufficient cash to reach that milestone.

The company has a very experienced team, with James Campbell (also previously at Chemgenex) as an executive director, and Mitchell Glass as CMO, based in the US. Mitchell Glass has put 50 drugs through clinic assessment and has been involved with bringing five new drugs to market.

Bioshares recommendation: **Speculative Buy Class A**



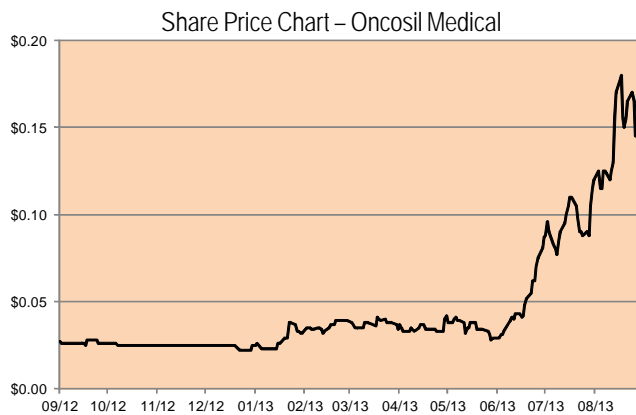
Three Dynamic Device Stocks

Oncosil Medical – In the Tracks of Sirtex

Oncosil Medical is developing a radiation brachytherapy for the treatment of pancreatic cancer. The technology was shelved at pSivida due to lack of funding until it was licensed relatively recently by Oncosil. The company now has the financial capacity to execute on a pivotal study in up to 300 patients, having successfully raised \$10 million this week.

Milestones ahead include confirmation of the regulatory path for the European market, and the start of the pivotal trial in early 2014. The market for this therapy is estimated at over \$400 million a year. Median survival for this disease is only four to five months. Early clinical studies indicates this therapy extends survival out to 10 months together with a considerable reduction in pain for patients.

Bioshares recommendation: **Speculative Buy Class B**

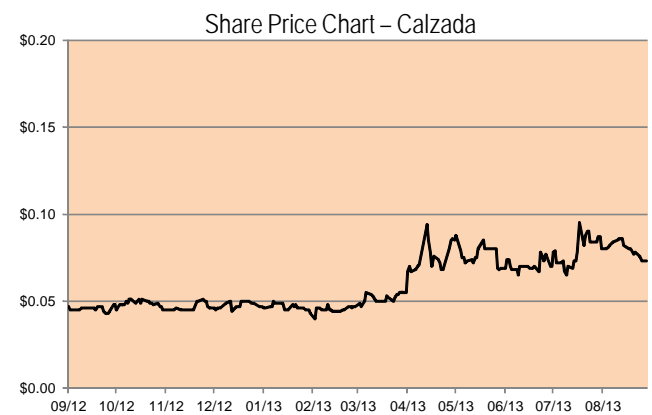


Calzada – A Speed-to-Market Strategy

Calzada's core technology is a biodegradable polymer (polyurethane) that is being commercialised for wound healing applications. The speed-to-market strategy is for use in vacuum pressure dressings. The market for such products is estimated at \$400 million a year. Calzada has shown its product is superior to existing products in an 18 patient trial. The company intends to file the product for approval in the US next year.

The second use is for full thickness wounds, where the full layer of the skin needs to be replaced. A 10 patient trial delivered excellent results according to the company. Full results are due in October. This year the company will also start a trial in patients with 3rd degree burns. The technology is being driven by Adelaide burns surgeon Dr John Greenwood.

Bioshares recommendation: **Speculative Buy Class B**



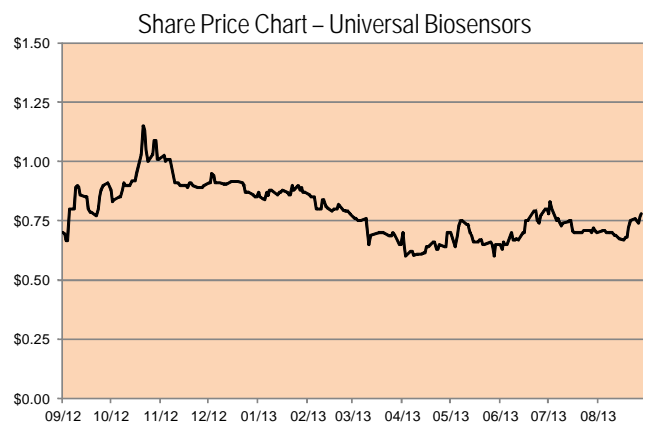
Universal Biosensors – Siemens Deal to Deliver More Upside

Universal Biosensors has developed its first product with Lifescan (Johnson & Johnson), which is a new electronic glucose monitoring device and strips. Lifescan is now selling the strip globally. UBI receives around US1 cent for each strip Lifescan sells and based on the last quarter of sales, is tracking at \$3 million a year in 'service fees', which is effectively a royalty.

Lifescan sells around 4.5 billion electronic glucose strips a year, which would equate to US\$45 million in annual royalties to UBI if it fully converted to the UBI designed strips. However Lifescan has a service fee obligation buyout clause which is undisclosed.

UBI is also due to release its next product, a PT/INR test used to set correct warfarin dosage. This product is due to be released by UBI's partner Siemens this year. UBI expects to share in more of the upside with this product.

Bioshares recommendation: **Speculative Buy Class A**



Three Deep Value Plays

IDT Australia – Under New Management

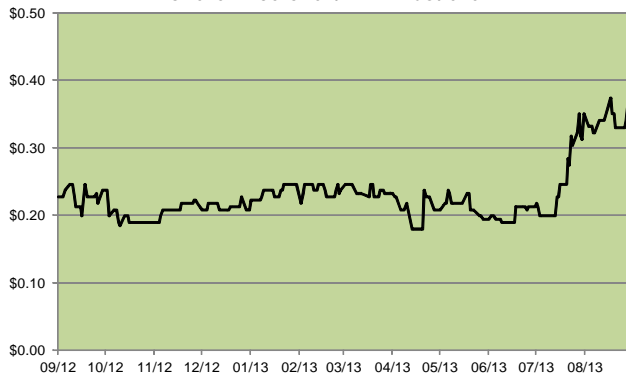
Specialised drug manufacturer and clinical trials services operator, IDT Australia, has installed new management in an effort to return the business to profitability.

The company’s new plans to grow revenues include simply working harder at sales and marketing efforts, to develop a CRO site management in conjunction with its Japanese shareholder, Irom, and thirdly, to develop and submit generic drug packages to the FDA for compounds for which it holds Drug Master manufacturing files (nine in the USA and five in Japan).

IDT’s revenues also benefit from growth in the number of start-up biotechs requiring drug formulation and optimisation services and for the manufacture of product for clinical trials.

Bioshares recommendation: **Speculative Buy Class B**

Share Price Chart – IDT Australia



LBT Innovations – Automation in the Path Lab

LBT Innovations is a quiet achiever which recently locked in a development deal with Swiss-German scientific instruments group Hettich AG for its Automated Plate Assessment System. APAS uses optical pattern recognition technology to assess cultured sample plates processed in pathology labs.

The driver for LBT Innovations products is that microbiology labs have only relatively recently begun to see automation introduced, partly to address workforce demographic issues.

bioMeriueux’s (LBT’s partner for its agar plate streaking technology) recent FDA approval of its Vitek system represents another step forward for automation, and is one with clear complementary benefits for LBT’s labour saving and efficiency generating systems.

Bioshares recommendation: **Speculative Buy Class B**

Share Price Chart – LBT Innovations



Somnomed – A Small Cap with a Big Future

Somnomed, capitalised at \$47 million, manufactures and markets oral appliances for treating sleep apnea and snoring.

An attractive feature of investing in Somnomed is visibility on quarterly unit sales and margins. Regardless of exchange rate fluctuations, trends in volume sales can be analysed and used to assess the stock. Volume sales also take on greater significance with this business which redirects earnings into growing the business. The company posted revenues of \$18.5 million in FY2013, up 21% from \$15.3 million in the previous year. It delivered a net profit result of \$0.6 million for FY2013 and \$0.5 million for FY2012.

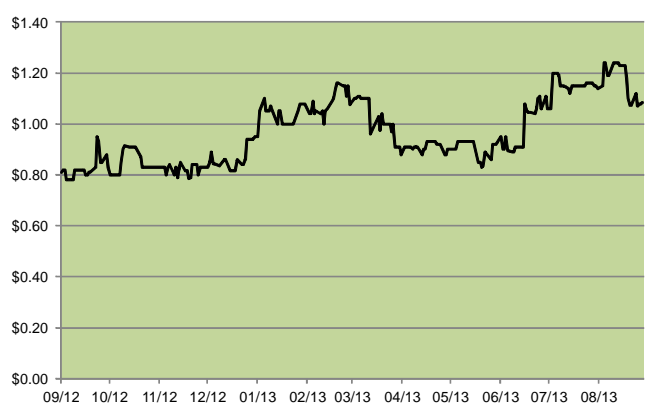
In FY2013, Somnomed sold 35,841 sleep apnea units, a figure 16% higher than the previous year. The direct gross margin on Somnomed’s Somnodent products was 69% for FY2013.

Somnomed recorded strong growth in Europe for FY2013, growing unit sales by 32%. The company has been steadily acquiring distributors across Europe to obtain direct access to customers. However, a major growth opportunity in Germany won’t be captured until it gains reimbursement from insurers which cover 90% of the German population.

In the US, Somnomed has spent time re-configuring its organisational structure and management, including the appointment of a CMO. This investment is expected to pay off with a return to stronger growth in that market, especially as Somnomed’s oral appliance therapy begins to fight more head-to-head with CPAP products marketed by Philips Respironics and Resmed.

Bioshares recommendation: **Buy**

Share Price Chart – Somnomed



Bioshares Model Portfolio (13 September 2013)

Company	Price (current)	Price added to portfolio	Date added
Oncosil Medical	\$0.155	\$0.155	September 13
Calzada	\$0.073	\$0.073	September 13
Invion	\$0.088	\$0.060	August 13
IDT Australia	\$0.370	\$0.260	August 13
Viralitics	\$0.340	\$0.300	August 13
Circadian Technologies	\$0.260	\$0.270	March 2013
Tissue Therapies	\$0.305	\$0.255	March 2013
Benitec Biopharma	\$0.380	\$0.40	November 2012
Somnomed	\$1.09	\$0.94	January 2011
Cogstate	\$0.450	\$0.13	November 2007
Universal Biosensors	\$0.78	\$1.23	June 2007

Portfolio Changes – 13 September 2013

IN:
Oncosil Medical and Calzada have been added.

OUT:
No changes.

Cogstate – Dementia Screening a Blue Sky Opportunity

Cogstate is a business with several growth opportunities in the making. These prospects stand outside of the company’s core clinical trials business, in which the company supplies its cognition test to pharmaceutical companies conducting clinical trials of drugs intended for the treatment of CNS conditions especially Alzheimer’s disease.

The first growth opportunity is being tackled by its Axon Sports subsidiary, which offers sports training and concussion management. While the concussion management product has been available for a number of years, the training product, for baseball pitchers and gridiron play prediction, is more recent. Cogstate intends to grow the sports product from the elite player market into a wider mass market.

A second larger, growth opportunity is in dementia screening, an area that Cogstate aimed to exploit more than a decade ago, but failed because it could not find the right business model and related internet-based technologies were too immature.

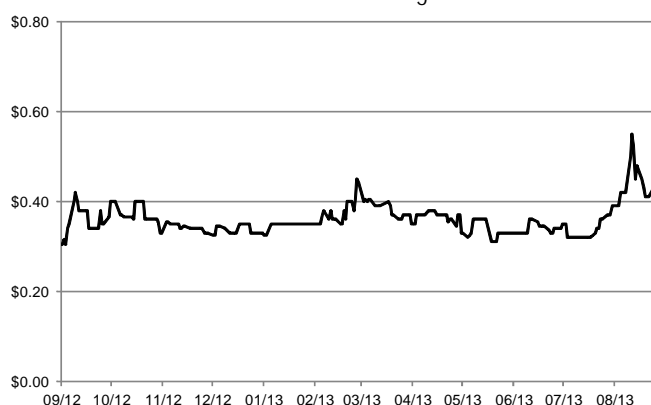
Cogstate has partnered with Merck Canada and Canadian health services firm Bayshore Home Health, the operator of 150 clinics across Canada, to offer Cognigram for dementia screening. The model involves family care physicians referring patients to the clinics for screening, similar to the reference process made for blood tests, with a return visit made to the doctor to discuss results.

The three-way partnership favours Cogstate and Merck because Bayshore is looking to use Cognigram testing to increase site utilisation and to leverage dementia screening data into the management of its overall business. The long term blue sky opportunity for dementia screening will come from the sales of Cognigram in other larger markets, once it is proven to work in Canada.

The market more and more suits Cogstate’s cognition test, following guidance provided by the FDA to ease the hurdles for developing drugs to treat Alzheimer’s disease, simplifying endpoints and encouraging a focus on earlier intervention.

Bioshares recommendation: Speculative Buy Class A

Share Price Chart – Cogstate



NOTICE

The 4th Australian Microcap Investment Conference

The 4th Australian Microcap Investment Conference is being held in Melbourne at the Sofitel on Collins on Tuesday the **22nd** and Wednesday the **23rd** of **October**.
Biotech companies presenting include Bluechiip, Biotron and Invion.

Bioshares subscribers can receive a \$300 discount off the \$695 registration fee using the discount code BIOSHARES2013.

www.microcapconferences.com

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: Pharmaxis, 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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