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The 10th Bioshares Biotech Summit

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for more information

Companies covered: **ALT, TLZ, Nexvet,
Spinifex Ph., Minomic, Immune Sys. Th.**

	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)	34.2%
Cumulative Gain	378%
Av. annual gain (13 yrs)	17.9%

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Bioshares

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

International Investors Extend Interest Into Private Australian Biotechs

Two private biotech companies, Nexvet and Spinifex Pharmaceuticals, recently secured significant investments to enable them to progress development of their respective drug programs. These capital raisings come on the back of Viralytics raising \$27 million and Benitec Biopharma raising \$31 million raising. What is common to all four raisings, apart from the similarity in scale of the raisings, is an influx of a number of North American investors onto the registers of these companies.

Nexvet – US\$31.5 Million

Nexvet is pioneering the development of well known biologics currently used to treat humans as treatments for pain and inflammation in companion animals. It has developed a technology, PETisation, to both cheaply and uniquely translate monoclonal antibodies between different animal species.

Nexvet has raised US\$31.5 (A\$33.6) million to add to its previous seed and pre-seed capital raised of A\$4 million. It is worth noting that four North American investors – Farallon Capital Management, Adage Capital Management, Foresite Capital and Boxer Capital – took part in the raise.

Spinifex Pharmaceuticals – US\$45 Million

Spinifex Pharmaceuticals is developing EMA401 as a novel first-in-class drug to treat chronic pain such as neuropathic pain or osteoarthritic pain, without any CNS side effects. A Phase II trial completed in 2013 showed that EMA401 delivered a greater reduction in pain from baseline over 28 days than patients randomised to placebo.

Spinifex raised US\$45 (A\$47.8) million in a Series C round, with Canaan Partners and pharmaceutical company Novo A/S investing for a first time. The company completed a Series B round in August 2011, raising US\$19 (A\$18.25) million from two tranches.

It first received seed funding of A\$0.45 million in June 2005 followed by A\$2.8 million in March 2006. In total, Spinifex has now raised ~A\$69 million in capital.

The inventor of Spinifex's Pharmaceuticals angiotensin-2 antagonist technology is Professor Maree Smith from the University of Queensland, who is also the inventor of QRxPharma's Moxduo technology, which combines two different opioids, morphine and oxycodone. The attraction of the angiotensin-2 approach is that it does not target opioid receptors which means that the side effects associated with opioid drugs e.g. nausea, dizziness and vomiting, are unlikely to occur.

Capital Raisings Underway

Two private company capital raisings underway at present include Minomic International, which has been seeking \$5 million (see *Bioshares* 538), and Immune System Thera-

– Cont'd over

Selected Private Company Capital Raisings - 2014

Completed

	Date Announced	Funds Raised		Funding Series Status	Purpose	New Investors	Existing Investors
		USD	AUD				
Spinifex Pharmaceuticals	11/04/2014	\$45.0	\$47.8	Series C	To advance development of EMA401	Canaan Partners, Novo A/S	GBS Venture Partners, Brandon Capital Partners, Uniseed, Uniquist
Nexvet	16/04/2014	\$31.5	\$33.6	Series B	To advance clinical programs in monoclonal antibodies in companion animal health	Farallon Capital Mgt, Adage Capital Partners, Foresite Capital, Boxer Capital (subs. Tavistock Life Sciences)	Bioscience Managers, Trans-Tasman Commercialisation Fund
Total		\$76.5	\$81.4				

Underway

	Date Initiated	Funds Sought (AUD)	Funds Rec'd To Date (AUD)	Pre-IPO round	Purpose
Minomic International	Jun-13	\$5.0	\$3.9	No	Development of MiStat ELISA test including clinical testing and regulatory approval
Immune System Therapeutics	Mar-14	\$5.0		Yes [Seeking \$15M at IPO]	To initiate Phase IIb study of IST-1097, a monoclonal antibody targeting the kappa myeloma antigen, relevant to multiple myeloma
Total		\$10.0	\$3.9		

peutics (IST), which is seeking \$5 million, prior to initiating an IPO in 2014 Q3 order to raise \$15 million.

Minomic, which is developing the MiStat prostate cancer diagnostic has so far secured \$3.9 million of the \$5 million it has been seeking.

IST is developing IST-1097 for the treatment of multiple myeloma. This is a monoclonal antibody drug which targets the kappa myeloma antigen, which is highly expressed on the surface of blood cancer and autoimmune cells.

The company has completed a Phase IIa study in 19 patients. IST now plans to conduct a Phase IIb trial in up to 120 patients with refractory or relapsed disease. This open label trial would combine IST-1097 with Celgene's Revlimid and dexamethasone, the current standard of care for multiple myeloma. The objective is to commence the trial in 2014 Q3.

Bioshares

Telezon Signs Third Commercial Order with Serum Institute

Telezon (TLZ - SIM VSE: \$0.03) is a medical device company that is commercialising a polymer needle and cannula technology. The company is currently listed on the SIM VSE exchange. Last month the company announced its third commercial order of the company's polymer cannula to the Serum Institute of India.

Based around the company's polymer core moulding technology, the company has been able to fabricate polymer needles and cannula (used to extract pharmaceuticals from vials) that exceed the length of what other manufacturers, such as B.Braun, have been able to achieve.

The appeal of using polymer needles is the ease in which these needles can be disposed of compared to metal products and the impact on the potential reduction of needle stick injuries. The first product the company is selling is the polymer cannula (SoloFlow non-injection needle) used to transfer pharmaceuticals from a vial to syringe.

Third order with Serum Institute validates interest

The latest order to the Serum Institute of India is for the supply of 950,000 of its SoloFlow needles which will be used in influenza vaccination kits. The main organisations driving vaccine programs in developing countries are UNICEF and PAHO. The Serum Institute is the number two supplier of vaccines to PAHO.

This is the third commercial order from the Serum Institute for Telezon. Previous orders were for 500,000 (worth \$20,000) and 30,000 SoloFlow cannula.

These repeat orders serve as validation for the Telezon products from the Serum Institute. The latest order was followed by an agreement with US medical device group Wolfe Tory Medical (a Teleflex company) to stock the Telezon product. Wolfe Tory Medical supplies components in vaccination kits to groups including the Serum Institute. Telezon CEO Michelle Carr believes the interest from the Serum Institute has been behind the decision by Wolfe Tory Medical to stock its product.

Manufacturing

Telezon manufactures its needles in Germany through a contract manufacturer. Its current manufacturing capacity is around 5 million polymer cannula a year. Potential sales are currently restricted by its manufacturing capacity. The next step for the company is a four-fold increase in capacity with full automation, which will require an investment of around \$1.3 million.

Polymer injectable needle

One of the other products the company is commercializing is an injectable polymer needle, called the PolyDermic needle (or polymer hypodermic needle). The company's proprietary moulding technology has allowed the company to make strong and flexible needles up to 32mm in length, compared to 19mm polymer needles from competitors.

However competitors only make the cannula needles and not injectables. Carr said that flexibility and tip strength are the two core properties with polymer needles, with the company believing

it has superior products to any competitors.

The polymer cannula that the company is selling to the Serum Institute is the more straightforward product to commercialise because they are not injected into people. However, the PolyDermic product will need to go through a clinical trial process. This will take around three years to bring to market.

The appeal of the PolyDermic needle is ease of disposal, similar to the cannula product, and the less resistance in penetrating the skin. This is because with polymer needles, the opening can be placed on the side of the needle, where with metal needles the opening is at the tip, which catches on the skin as it passes through. Another potential advantage is that a polymer needle appears less threatening to patients than metal needles.

Summary

Telezon has received strong validation for its technology with its third order from the Serum Institute. While the value is not significant, estimated at less than \$50,000, it shows there is interest from one of the world's major vaccine suppliers.

A key challenge for the company now is to fund the expansion of its business, both from a contract manufacturing perspective and for additional product development including the PolyDermic needle.

Telezon has around 700 shareholders. The company has raised \$3.5 million since 2004. Investors looking to invest through the SIM VSE market can do so through broking groups Morgans, Taylor Collison and Paterson Securities.

Telezon is capitalised at \$1.5 million and had \$294,986 in cash at 31 December 2013.

The issue of most pressing concern to Telezon is its low cash balance, with the objective of attracting supportive investors of quality a high priority task.

Bioshares recommendation: **Speculative Hold Class C**

Bioshares

Analytica Seeks \$3 Million for Pericoach Product

Analytica (ALT: 3.0 cents) has announced plans to raise \$3 million to enable it to launch its PeriCoach product. The PeriCoach is a personal training device used for the management of pelvic floor exercises. The device is used to treat urinary incontinence which occurs as a result of trauma to pelvic muscles sustained during childbirth.

Analytica has completed a private placement for \$1.8 million, and the remainder will be raised through a rights issue that is underwritten by Patersons Securities.

The company expects to start manufacturing its devices in late May or early June and will begin a controlled market release at that time. The company says there is already strong preliminary demand from over 200 physiotherapists and medical specialists, largely from the Continence Foundation of Australia (CFA) conference late last year. CEO Geoff Daly, who was formerly at Resmed, said there is overwhelming support and enthusiasm for this product from clinicians. One physiotherapist who specialises in this area commented that the device will change the way these physiotherapists run their practices.

The company does not expect any manufacturing delays, with scale up of production possible after the initial controlled release. The company is currently in the process of preparing submissions for European regulatory approval, and expects to file for US approval in the second half of this year. Analytica has already appointed a US reimbursement consultant for the US as well as a US marketing manager. Market launch in Europe and the US is scheduled for 2H 2014.

The device will be sold both through the Internet and through physiotherapists and specialists who will stock the device. The pricing of the device is expected to be around \$300 plus a smaller ongoing fee after the first 12 months for continued access (if required) to data.

Market and Product Features

The PeriCoach has a number of appealing characteristics from an investment perspective. The potential market for this product is very large, with in Australia alone, around three million women having some form of urinary incontinence. Regular and proper pelvic floor exercises can be effective at treating urinary incontinence in many cases, with the PeriCoach a tool that assists with the exercises, providing encouragement and reminders to the user, as well as records for the user and the medical practitioner.

The price is also an appealing aspect, where the company is not reliant on reimbursement to generate sales because of the affordable pricing. As the patient pays for the device, there is also no additional cost to the healthcare practitioner, and it allows the physiotherapists or specialist to monitor treatment.

Another attractive product characteristic is that the device can be sold through the Internet, bypassing traditional distribution channels.

Analytica will continue marketing its device at major industry conferences, including a urinary gynaecology conference in Washington in July, and the next CFA conference in Australia in the second half of this year.

Following the capital raising, Analytica will be capitalised at \$25 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares Model Portfolio (24 April 2014)

Company	Price (current)	Price added to portfolio	Date added
Invion	\$0.067	\$0.089	February 14
Impedimed	\$0.210	\$0.245	December 13
Analytica	\$0.030	\$0.025	December 13
Imugene	\$0.012	\$0.022	November 13
Oncosil Medical	\$0.100	\$0.155	September 13
IDT Australia	\$0.250	\$0.260	August 13
Viralytics	\$0.290	\$0.300	August 13
Tissue Therapies	\$0.300	\$0.255	March 2013
Somnomed	\$1.52	\$0.94	January 2011
Cogstate	\$0.315	\$0.13	November 2007
Universal Biosensors	\$0.38	\$1.23	June 2007

Portfolio Changes – 25 April 2014**IN:**

No changes

Recommendations:

OUT:

QRxPharma has been removed from the Model Portfolio, following an FDA Advisory Committee 14-0 vote against Moxduo this week.

Recommendations: QRX Pharma - **Sell**

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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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