ISSN 1443-850X

Bioshares

6 March 2015
Edition 590

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

Companies covered: ACR, ALT, NAN, PNV, VLA

	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)	8.6%
Cumulative Gain	**389%**
Av. Annual gain (14 yrs)	**16.7%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)
$440 (Inc.GST)
Edition Number 590 (6 March 2015)

Extract from Bioshares –

Polynovo – Improved Corporate Direction

Polynovo's (PNV: $0.078) new CEO, Paul Brennan, started with the company last month. Brennan was previously with medical products group Smith & Nephew in Australia and had become aware of the technology while at S&N.

What is of interest is that Brennan took on the role at Polynovo because of the strong interest he has in the company's technology. Brennan said to *Bioshares* this week that the product is outstanding and that he has not seen a skin matrix product (called NovoSorb BTM) that gives such good elasticity with such a good cosmetic outcome. The product is made from a biodegradable polyurethane material.

NovoPore – An Opportunistic Application

Polynovo's lead product, NovoPore, is for use in negative pressure wound treatment. The company has completed trials with the product with a positive outcome. Polynovo is in various stages of discussions with a number of companies.

Brennan said this is an opportunistic product application for the technology. It is a very competitive market where product differentiation is not a key item and margins are lower than other product opportunities for the company. Polynovo is not expecting to invest any further in product development for the negative pressure wound treatment application.

NovoSorb BTM

The market for the treatment of full thickness wounds with the company's NovoSorb BTM product is quite different. "BTM is a completely differentiated product," said Brennan. It is used as a dermal matrix for burns and trauma wounds, and also in free flap surgical procedures, where the full layer of skin is removed and used in reconstructive procedures for other parts of the body. The lack of wound contraction delivers a very good cosmetic outcome said Brennan.

Polynovo's strategy for commercialising NovoSorb BTM is to focus on building up the regulatory package around the product said Brennan. This means conducting clinical trials in Europe and the US. The company expects to hire two dedicated regulatory staff to help manage the process.

Cont'd over

In Europe, a trial is expected to commence in the next three months, which is expected to take two years to complete, recruiting around 30 patients.

BARDA Submission

In the US, the company is waiting to receive a decision on its application from BARDA which would be a contract for Polynovo to conduct clinical studies with NovoSorb BTM. BARDA is part of the US defence organisation and is responsible for preparing for disaster management.

A synthetic, full thickness, skin matrix product would be able to address burn wounds in a large population, with the product able to be stored easily and produced on a large sale.

The US trial will be run at eight burns centres in the US. The trial is unlikely to progress without external funding from BARDA or a partner.

Other Markets

Polynovo will also be pursuing registration of NovoSorb BTM in other markets, including India, China, Brazil and South Africa. In Australia, the product is currently used in a small number of cases on a pre-authority basis.

Summary

At the end of last year Polynovo had $3.4 million in cash. It expects to have $2.6 million by mid-year. Funding will be an aspect the company will need to address this year with a little over one year's cash at hand. The company would like to see a decision on its BARDA application this year.

With respect to the company's AOD9604 asset, agreement terms for sale of that asset are being negotiated with a potential buyer.

With additions to the board last year, a new CEO and a decision to sell-off the company's non-core AOD9604 asset, the company has an improved and better focused direction in commercializing its core assets.

Polynovo is capitalised at $33 million.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

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