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Bioshares

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Edition 542

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

Companies covered: CZD, POH, RVA, 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 - Current)	60.9%
Cumulative Gain	**473%**
Av. annual gain (13 yrs)	**20.0%**

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Extract from Bioshares –

Calzada Receives FDA Approval for First Wound Healing Product

Calzada (CZD: $0.115) reached a major milestone this week with clearance received from the FDA to sell its first product into the US wound healing market. That product is the NovoPore dressing that will be used in Topical Negative Pressure (TNP) dressings, a market that is work in excess of $400 million.

Calzada's product was tested against the market leading product and gold standard, Granufoam from KCI. In an 18 patient trial, it was found that Calzada's NovoPore achieved less fragmentation into the wound and was easier to remove with less bleeding. Calzada's product also has the advantage of being biodegradable, so removing all fragments is less important that with other products. NovoPore is made from biodegradable polyurethane.

The next step in commercialising the product is to partner it with one of the existing marketers of the TNP products. There are around five major players in this field and Calzada is in discussion with most of them according to Laurent Fossaert, CEO of Polynovo Biomaterials, a fully owned subsidiary of Calzada. Calzada will seek to retain manufacturing control of the product, which is made at the company's facility in Melbourne.

In 2012 Calzada appointed David McQuillan to the board. McQuillan was formerly Senior VP of Research at KCI. Fossaert said McQuillan provides good insight on the market for this product, specifically what the market is looking for in terms of innovation, and the pressure points in the market.

In our view, a realistic timeframe for investors to look for, for the completion of a partnering deal, would be by the end of 2014.

Fossaert said the approval is a big tick in the box for the company, being important for getting the next products on the market using the same technology, and important also for potential partners. The approval lowers the risk of the entire technology platform, which can now be leveraged to bring other products to market believes Fossaert.

Cont'd over

Second product – Treatment of Donor Site Wounds

In February this year, three plastic surgeons at the Royal Adelaide Hospital were granted commercial access to the Calzada technology for the treatment of full thickness donor site wounds. This is the same hospital where the 10 patient clinical trial was completed last year with successful results. Calzada can charge for supply of the product. However, an important benefit for the company is that it will collect more data from the product's use. The name of the product for this application is NovoSorb BTM.

In that trial, it was shown that the NovoSorb BTM product could be effectively used as a dermal scaffold, in full thickness burns, with a skin graft completing the treatment once the wound was stabilised with the NovoSorb product. This was found to achieve a substantially better appearance than using a skin graft alone which results in the normal skin contraction which is obvious with full thickness wounds such as serious burns.

Burns Trials

At the end of last year, Calzada started recruitment in its burns trial in Adelaide (at the Royal Adelaide Hospital). This is a difficult trial to conduct, with the patients having serious trauma injury to 20%-50% of their body with third degree burns (where the wound extends all the way to the dermis). Similar to the donor site trial above, the NovoSorb BTM product will be used to immediately close the wound and to fill the wound site with the biodegradable polymer material. Once the patient has been stabilised, skin grafts will be taken to complete the wound treatment.

The aim of this trial is to achieve an improvement in final wound appearance with less contraction (scarring), to see how well this polymer product can be integrated into the wound, and how easily the NovoSorb BTM product can be delaminated. (The NovoSorb BTM includes a temporary epidermal seal that must be removed just before the skin graft is applied.) It was for this application for wound healing that the technology was originally developed.

A second burns trial is expected to start later this year (second half likely) in France. The size of that trial is unknown. The work of plastic surgeon John Greenwood, who is driving the clinical adoption of this product, has attracted interest from France, with one of the aims being to gain an independent assessment of use of the NovoSorb BTM.

Board Strengthened

Last month Calzada announced the appointment of David Williams to the board. Williams is a welcomed addition. He is currently Chairman of Medical Developments International (ASX: MVP) and also of the board of IDT Australia (IDT) and has an investment banking background. In November last year Chairman David Franklyn stepped down and was replaced by Dr Roger Aston.

Summary

Calzada is capitalised at $48 million. It had $5.3 million in cash at the end of December. The company is making solid progress with its technology, with its application in several areas being pioneered by Adelaide plastic surgeon John Greenwood.

After the surprise retirement of David Franklyn from the board last year, the new board appointment of David Williams is a noteworthy event and which may flag other corporate developments ahead.

Milestones to monitor will be progress in the current burns trial, filing the NovoPore product for approval in Europe, and a commercial distribution agreement for NovoPore in the US.

Bioshares recommendation: **Speculative Buy 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

Corporate Subscribers: Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Antisense Therapeutics, Benitec BioPharma, Admedus, Calzada, Invion, Circadian Technologies, Imugene, Analytica