

In this edition...

The GFC continues to play havoc with company earnings. API manufacturer IDT Australia posted a half year loss with revenues cut in half from the previous period. Cellestis, which has previously recorded strong sales growth saw sales fall 9% for the period. However, we also provide updates on two established biotechs, Biota and Starpharma which are lessons in how to build a business with short, medium and long term revenue possibilities. And when management does not achieve promised sales, it's time for a change, which is where CathRx finds itself, having replaced Neil Anderson with board member Jeffery Goodman.

The Editors

Companies Covered: BTA, CST, CXD, IDT, SPL

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - Current)	62.4%
Cumulative Gain	215%
Av Annual Gain (9 yrs)	20.0%

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Bioshares

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

Extract from *Bioshares* –

Biota Accelerates R&D

Biota Holdings (BTA: \$2.19) reported a net profit of \$33.5 million for the six months to 31 December 2009, up from \$7.2 million in the previous corresponding period. Indicative expected Relenza royalties attributed to that six months were \$56.7 million (versus \$3.8 million for the previous corresponding period). The good news for Biota shareholders is that there should be some consistency now in Relenza royalties for the next five years, until patents expire in December 2014.

Relenza is sold by **GlaxoSmithKline**. In 2009 Relenza became a blockbuster, generating sales of US\$1.1 billion for GSK, up from a mere US\$105 million in 2008. Biota receives a 7% royalty from global sales of this drug (and 10% in Australia and New Zealand).

GSK has increased production to at least 90 million courses a year, with the potential to increase to 190 million courses if required. At 90 million courses a year at a price of US\$20 per course, it represents sales of US\$1.8 billion, or to Biota, around \$140 million a year in revenue.

R&D Investment

Biota is heavily reinvesting some of this revenue it is receiving into R&D to ensure the company has a solid future after Relenza royalties end in just under five years time. Late last year the company made two acquisitions of antibiotic drug developers, **Maxthera** and **Prolysis**. In FY2009, Biota spent \$24.6 million on R&D and product development, with a significant part of this paid for by partners (\$12.5 million).

Moving forward, Biota expects to accelerate its R&D spend substantially to \$50 million a year. The two acquisitions are expected to account for \$8 million a year of spending. This signals a more aggressive strategy by the company, no doubt influenced by recently appointed chairman Jim Fox, who built up the highly successful Vision Systems from scratch, which was sold to Danaher Corporation in early 2007 for just under \$900 million. Fox understands the output value that can be achieved from investment in R&D.

Acquisition costs, of around \$13 million for the two companies, will be amortised over 10 months and falls into the R&D cost base.

This aggressive R&D investment comes at a time when more clarity and consistency is occurring in Relenza sales. CEO of GSK has recently stated that Relenza sales would now resemble more 'heads and shoulders' fluctuations that peaks and troughs. Moving forward, Relenza royalties of around \$140 million a year should be sustainable.

Driver of Relenza Sales

The main driver now of Relenza sales is an acknowledgement from several governments, including America, that the antiviral drug stockpiling should be distributed evenly between Relenza and Tamiflu. At the moment, many governments, particularly the US, have heavily stacked stockpiles in favour of Tamiflu (ratio 80/20).

Cont'd over

The recent influenza pandemic outcome was milder than expected. However the effectiveness of having an antiviral war chest that was widely utilised has been appreciated by government health bodies. The deficiencies in the stockpiles has also been noted and these points will continue to see demand for Relenza into the future. We believe GSK is currently running at maximum production (90 million courses) with an ability to move to 190 million courses under a pandemic situation.

Distribution to Shareholders

Biota will continue to distribute surplus funds to shareholders. The company currently has about \$40 million of tax losses and it should make use of all of those losses to offset against profits in this financial year. In FY2011, the company should start to pay normal tax rates, with franked dividends to shareholders to be expected.

R&D Programs

LANI

Biota has a joint program with **Daiichi Sankyo** in Japan to develop a long acting flu treatment, using a compound that produces an active similar to Relenza. The treatment only requires one dose every five days versus twice daily for Relenza and Tamiflu.

The product has been filed for approval in Japan and approval is expected within 12 months if all goes well. The seasonal market is worth around US\$160 million a year and we estimate Biota will receive around a 4% royalty. Biota is seeking to find a licensing partner for this drug for the rest of the world. Phase III bridging studies would still be required. Biota's CEO Peter Cook remains confident that a licensing deal can be transacted by mid year. Biota would be entitled to half of all proceeds to be shared with Daiichi Sankyo, where we estimate royalty rates of up to 20% could be negotiated with a partner.

The core patent around this drug candidate expires from 2017, however there are additional patents around the inhalation device and generic players would need to repeat Phase III studies to bring any copies to market. General industry standard contracts contain clauses that around 70%-80% of royalties can be maintained past patent expires if there are no generic copies on the market.

Rhinovirus

Biota is seeking to partner the rhinovirus program. The company is seeking to develop this therapy for people with existing complications such as asthma that are infected with the rhinovirus, which is the most common cause of the common cold. The company successfully completed Phase IIa proof of concept studies in June 2009.

Hepatitis C

Biota has an early stage development partnership with **Boehringer Ingelheim** for this program. Biota has completed all of its preclinical work on the program although no development milestones have been paid to date.

Respiratory syncytial virus (RSV)

Biota previously had a development partnership with **AstraZeneca** for RSV. AstraZeneca handed back the program to Biota when the lead compound was shown to have too narrow a therapeutic window (i.e. too narrow room for error to achieve therapeutic effect). Biota believes it can improve the therapeutic window of its drug candidates and AstraZeneca remains a potential future partner. Biota expects the drug could be back in the clinic in 2011 after a lead candidate is chosen this year.

Summary

Biota has become a profitable business with a more predictable revenue outcome over the next five years. This allows the company to find a happy medium of distributing excess funds to shareholders whilst accelerating future investment in R&D to ensure a viable business is maintained past 2014. It's a sensible strategy. The company's strong financial position also allows it to take advantage of a continuing shortage of funding for global drug development assets, as seen through the acquisitions last year of Prolysis and Maxthera, to build a more prominent global biotech business.

Bioshares recommendation: **Speculative Buy Class A**

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.

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

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