ISSN 1443-850X

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%**

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

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Individual Subscriptions (48 issues/year)
$350 (Inc.GST)
Edition Number 348 (19 February 2010)
ISSN 1443-850X

Bioshares

19 February 2010
Edition 348

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

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 years 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 in 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 off 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 f**or 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 predicable 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

Breadth in the Pipeline is the Starpharma Appeal

Starpharma Holdings (SPL: 74.5 cents) signed its third drug delivery deal earlier this month, this time with **Eli Lilly**, for the enhancement of pharmaceuticals using Starpharma's dendrimer scaffolds.

It follows on from a similar deal signed with **Elanco** (the animal health division of Eli Lilly) in May last year to achieve the same outcome with animal health products, a collaborative agreement signed with **Stiefel Laboratories** (now GlaxoSmithKline) in 2007 to apply the same technology for improving dermatology drugs, and an agricultural product deal signed last year with an undisclosed group to apply the technology to improve effectiveness of pesticides. The interest in the application of dendrimers is gaining speed as it looks set to become the new pegylation technology for improved drug development.

Pegylation Technology

Pegylation has been one of the most successful methods of increasing the size of pharmaceutical products, mainly protein drugs, with the object of increasing the half-life in the body. And importantly, it also extends patent protection with new composition of matter patents. Developed in 1970s and commercialised initially by **Enzon Pharmaceuticals**, PolyEthylene Glycol (PEGylation) was first used in a pharmaceutical product in 1990 in the Adagen product. Pegylated drugs to follow include pegylated interferon alpha (Pegasys and Pegintron), Neulasta (pegylated G-CSF), pegylated EPO and even cancer drug Doxil (pegylated doxorubicin). Over US$6 billion in annual sales are generated from pegylated drugs. In 2002, Enzon licensed the rights to the technology to **Nektar Therapeutics**.

The pegylation technology has some limitations that Starpharma's dendrimers seek to overcome. These include attachment of the polymer at specific sites on the pharmaceutical compound, high quality reproduction and the difficulty in producing branched pegylated drugs. Dendrimers' specific three dimensional structure and the ease of attaching functional groups potentially addresses these shortfalls of the pegylation technology.

Cancer Drug Applications

One of the applications of dendrimers for drug enhancement is with existing oncology drugs. Tumours tend to be more porous and result in what is called enhanced permeability and retention. By making existing cancer drugs larger in placing them on the dendrimer scaffold, tumours have shown an increased selection for these drugs. Reduced toxicity has also been observed, due to the site specificity of the molecules. **Ortho Biotech** and **Schering-Plough** have already shown this by bringing pegylated doxorubicin to market. In December 2008 Starpharma also showed that this could be achieved with a dendrimer-doxorubicin combination in preclinical studies, where the same efficacy could be achieved with considerably reduced cardiac toxicity.

Starpharma has also shown that another cancer drug Paclitaxel, which is almost completely insoluble in water, could achieve a 37mg/ml solubility (up from 0.8ug/lt) with its dendrimer-Paclitaxel version.

Commercial terms

We expect there will be several more drug delivery collaborations formed by Starpharma with pharmaceutical companies over the next three years. The deal with Eli Lilly involves one program at this stage and there is no limit to how many drugs Eli Lilly can apply the technology to. All agreements signed to date do not include upfront payments, but do include R&D fees, milestone payments and royalties on sales from sales of any products incorporating the technology.

Appeal of Starpharma

The appeal of Starpharma is the breadth of the company's pipeline covering different applications of the technology. Drug delivery we would argue comes in third place in terms of importance for this company. In second place would be the Vivagel stand-alone product for the treatment and then prevention of Bacterial Vaginosis. However, of greatest significance due to its proximity to market is the condom microbicide application.

Vivagel Coated Condom product

Starpharma's lead product is use of its Vivagel microbicide coated on condoms to prevent transmission of diseases. Starpharma has partnered with **SSL International**, which sells the Durex brand of condoms and has 35% of the global condom market.

The product is expected to be on the market at the end of 2010 at the earliest and Starpharma expects to begin receiving royalties in 2011. Depending on the proportion of its condoms that SSL will incorporate the Vivagel microbicide dictates the royalty income to Starpharma. If it is used in 40% of condoms, then Starpharma stands to receive around $24 million a year.

Starpharma communicates almost daily with SSL, such is the priority of this program. For SSL, innovation is a key priority to grow sales and keep the customers interested according to SSL CEO Garry Watts. The interest in the Vivagel microbicide by SSL is easily understood in this context.

Basic safety studies will need to be conducted before the product can be launched and those studies are expected to commence shortly. Starpharma's patents on this product expire in 2027.

Bacterial Vaginosis

Bacterial vaginosis describes imbalance between good and bad bacteria that occurs in women. It is estimated that 21 million women in the US are affected with this condition. The company found serendipitously when it was conducting is Vivagel studies for the prevention of herpes transmission that women were cleared of this condition following treatment with Vivagel.

The market for topical treatments alone (excluding antibiotics) with existing products is in the order of US$300-$350 million market. These treatments have poor outcomes, including less that 50% successful treatment, high rate of recurrence and adverse effects from existing antibiotic treatments which can also not be taken with alcohol and cause nausea.

Cont'd over

CathRx Appoints New CEO

Cardiac catheter manufacturer CathRx (CXD: 29 cents) this week appointed a new CEO, with board member Jeffery Goodman stepping in to takeover from Neil Anderson, a founder of the company. Anderson will continue to contribute to company but at a technical level.

Goodman was appointed to the CathRx board in March 2008. He brings extensive experience in the medical devices industry to the position, including 25 years with **Baxter Healthcare**, where he rose to the position of President of its Biotech North American Division and went on to head **Boston Scientific**'s International Division, with a staff of 4,000, from 1999 to 2008. Goodman was also a director of **Ventracor** and serves as a director of **PFM Cornerstone Ltd**, alongside Denis Hanley (the chairman of CathRx and **Pharmaxis** and **Universal Biosensors** (UBI) board member), Andrew Denver (the chairman of UBI and fellow CathRx board member) and Colin Adam (board member of UBI).

Anderson has been disappointed with the recent progress. He acknowledged in February that sales forecasts made for FY2010 in May 2009 would not be met. The company had originally expected sales of $5.4 million for FY2010, but has revised that to approximately $600,000. As a founder of the business, co-inventor of the technology and a substantial shareholder of the business, no doubt he supports the new appointment.

CathRx has stated that with the appointment of Goodman as a CEO, its immediate focus will be to revise the operations and strategies of the company. According to Goodman, the company will need to raise additional funds to support the development of the business. At the end of December it had only $5.4 million in cash remaining and the company is spending $10 million a year making another fund raising is very likely.

Goodman is conscious of the challenge the company has in selling its range of modular catheters, in the face of dominance of the market by larger firms such as Biosense Webster. Goodman sees an opportunity to work alongside companies that reprocess catheters, (e.g. **Remed**, part of the **Vanguard Healthcare Group** in Europe and **Ascent Healthcare Solutions** and **Sterimed Inc** in the USA). Approximately 70% of the German market uses reprocessed catheters. CathRx's modular catheters are designed for re-use, and may sit well with the logic of the reprocessing industry. However, such a concept of alignment with reprocessing firms is very much in early stages of discussion. That said, Germany could well be CathRx's most important market with purchasing decisions resting more with hospital administrations and less with surgeons.

Goodman, who is 61 years of age, does not see his role as CEO to last for not more than a couple of years, but presumably long enough to put the company on a stronger footing and make it a more attractive opportunity for a future CEO. We speculate that the company's efforts to transition the CEO role is made somewhat more difficult by the need to manage activities in both Australian and Europe, with an Australian based CEO looking at having to take on extensive travel obligations. It should be noted that CathRx has appointed a President of European operations, however, such a senior role does not diminish the requirement to also engage in market development activities in Europe.

Although the company is valued at only $18 million, expect the possibility of further price weakness when funds are raised. CathRx has the potential to become a very successful business, however there is still considerable work to be done before that occurs.

Bioshares recommendation: **Speculative Hold Class A**

– Starpharma cont'd

In November last year Starpharma raised $15.6 million to fund the development of this program through Phase II and Phase III studies. It will take two and a half years to complete requiring about 500 patients. At the end of these studies, Starpharma will potentially have a pharmaceutical product that it can register for approval to compete in a US$300 million plus market that is poorly served.

Starpharma intends to out-license the product if clinical studies are successful, just before registering the product for approval. It should be able to achieve a 20%-25% royalty plus an upfront and milestones. The Phase II study is expected to start in this half in 108 women in the US, Europe and Australia. Recruitment is not anticipated to be difficult.

Other programs

Starpharma is also seeking to develop Vivagel as a topical standalone product for the prevention of HIV and genital herpes. Longer efficacy studies will be required for the product to gain approval for these indications.

Small safety studies have been completed. Vivagel has shown to offer greater than 90% viral inhibition for three hours following application, making it a potentially very useful product to prevent the transmission of sexually transmitted diseases.

Summary

Starpharma has now built a portfolio of early, middle and late stage programs. It expects to start generating revenue from its Vivagel condom coating next year which could be around $25 million a year in future years. It is generating revenue from sales of laboratory reagents (around $1.5 million a year), it has a Phase II program in bacterial vaginosis, the potential to sign several more drug delivery product collaborations, and further applications of the Vivagel product in the prevention of HIV and herpes. It is an appealing biotech investment option that has the potential to generate outstanding medium and long term gains.

Starpharma is capitalised at $177 million with $24 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

Half Yearly Results: Cellestis and IDT Australia

With life science firms reporting their results for the half year ending December 31, 2009, signs of tough market conditions are showing through in the reports submitted by some companies.

IDT Australia

IDT Australia, a manufacturer of active pharmaceutical ingredients, supplier of drug chemistry services and clinical trial services posted a loss for the half year of $0.6 million, a fall of 119% from the previous half year period. Sales slumped by 51% from the previous period, coming in at $6.3 million.

Double-Whammy

IDT Australia's financial performance is a direct effect of the contraction in the local drug development sector, for which it had positioned itself as a services provider. Also at play in the IDT Australia figures is the impact of the GFC on its pharmaceutical clients, which we assume have either cancelled or reduced orders for the manufacture of API.

Recently key customer **Pfizer** elected not to proceed with a potential long term API contract for which it has commissioned and spent $20 million on facilities at IDT Australia's Boronia facility. The facility is to be handed over to IDT for no upfront cost.

In a remarkable change of heart, IDT Australia has said that it will undertake a number of projects for which it would have a proprietary position. We assume this means the company will look to invest in higher-risk/higher-reward drug development assets for which it has traditionally provided development services.

Celestis

CMP	$3.32
Capitalisation ($M)	$319
PE (Annualised)	55

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Revenue ($M)	$7.5	$11.3	$14.5	$20.0	$18.2
% ch, prev. period		*50%*	*28%*	*38%*	*-9%*
EBITDA ($M)	$0.6	$1.5	$4.8	$5.2	$3.8
% ch, prev. period		*173%*	*215%*	*7%*	*-26%*
Depreciation	-$0.2	-$0.2	-$0.2	-$0.3	-$0.2
EBIT ($M)	$0.3	$1.4	$4.6	$4.9	$3.6
% ch, prev. period		*312%*	*241%*	*7%*	*-27%*
Tax ($M)	$0.0	$0.0	-$0.2	-$1.1	-$0.7
NPAT ($M)	$0.3	$1.3	$4.4	$3.8	$2.9
		311%	*229%*	*-14%*	*-23%*

IDT Australia

CMP	$1.08
Capitalisation ($M)	$46
PE (Annualised)	N.A

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Revenue ($M)	$14.3	$17.2	$13.7	$13.0	$6.3
% ch, prev. period		*20%*	*-20%*	*-6%*	*-51%*
EBITDA ($M)	$5.3	$7.1	$5.6	$5.7	$0.3
% ch, prev. period		*35%*	*-21%*	*2%*	*-94%*
Depreciation	-$1.2	-$1.0	-$1.2	-$1.1	-$1.3
EBIT ($M)	$4.1	$6.1	$4.4	$4.6	-$1.0
% ch, prev. period		*50%*	*-27%*	*4%*	*-121%*
Tax ($M)	-$1.2	-$1.8	-$1.4	-$1.2	$0.3
NPAT ($M)	$2.8	$4.3	$3.1	$3.3	-$0.6
		52%	*-28%*	*9%*	*-119%*

Options

The company has announced the issue of free options on the basis of one option for each ten shares, with a exercise price of $1.00 during March 2011.

Comment

IDT finds itself in extremely challenging circumstances, with the fall off in demand for its services by both small start-up biotechs and large pharma likely to remain weak for these two business sectors for the medium term.

One marker of small drug development business sector activity are IPOs. There were none in 2009 and only one so far this year. Investment focus has been on supporting existing businesses while they mature. It may be some time before we see IPO numbers pick up significantly.

IDT Australia competes globally providing undifferentiated services, competing on price and quality. The recognition that it should invest in proprietary products may have come too late with returns from such an investment some years away. We point to our commentary on **Starpharma** (see page 3) which is building a business with short, medium and long term income based from proprietary products. However this has involved more that decade of development to build this base.

IDT Australia should now be considering other options which include halting the payment of dividends, revitalising its management and also merging the company with another firm that can enrich the company at the board and management level and also strengthen the income producing asset base of the merged entity.

Bioshares recommendation: **Hold**

Cellestis

The very strong growth rates charted by TB diagnostic company Cellestis now look to be under some pressure, with the its half year sales of $18.2 million weakening by 9%. Net profit after tax fell by 23% from the previous six months.

The company is trading on an annualised price earning ratio of 55, which is hard to justify when the rate of sales growth for the company is easing considerably.

The company has suggested a number of positive factors ahead that should lift revenues. However based on current sales growth rates and the company's capitalisation, the stock appears overvalued. It remains a very solid business.

Bioshares recommendation: **Sell**

Bioshares

Bioshares Model Portfolio (19 February 2010)

Company	Price (current)	Price added to portfolio	Date added
Tissue Therapies	$0.23	$0.21	January 2010
Biodiem	$0.16	$0.15	October 2009
QRxPharma	$0.88	$0.25	December 2008
Hexima	$0.37	$0.60	October 2008
Atcor Medical	$0.17	$0.10	October 2008
CathRx	$0.25	$0.70	October 2008
Impedimed	$0.72	$0.70	August 2008
Mesoblast	$1.82	$1.25	August 2008
Circadian Technologies	$0.59	$1.03	February 2008
Patrys	$0.14	$0.50	December 2007
Bionomics	$0.30	$0.42	December 2007
Cogstate	$0.28	$0.13	November 2007
Sirtex Medical	$5.83	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.29	$0.66	September 2007
Starpharma Holdings	$0.75	$0.37	August 2007
Pharmaxis	$2.49	$3.15	August 2007
Universal Biosensors	$1.71	$1.23	June 2007
Probiotec	$1.83	$1.12	February 2007
Acrux	$2.01	$0.83	November 2004
Alchemia	$0.62	$0.67	May 2004

Portfolio Changes – 12 February 2010

IN:
No changes.

OUT:
No changes.

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

Corporate Subscribers: Pharmaxis, Cytopia, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd, Tissue Therapies

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