

In this edition...

The week has been turbulent for Biota Holdings as volatile Relenza sales sparked a sell-off in the company's shares, which lost about a third of their value this week.

Relenza sales will continue to be lumpy and this provides entry (and exit) opportunities as investors over-buy and over-sell the stock.

We provide an update at Cogstate, where lumpy revenue has also caused a weakness in that company's shares, however the outlook for that company remains very promising.

We also provide an end of quarter cash analysis. And next week, Bioshares will be providing coverage of the annual BIO conference in Chicago, highlighting the key trends that are occurring in the global biotech industry.

The Editors

Companies Covered: BTA, CGS, Quarterly Cash Flow Summary

	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)	57.5%
Cumulative Gain	206%
Av Annual Gain (9 yrs)	19.4%

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au

David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph: (03) 9671 3222
Email: pachacz@bioshares.com.au

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Bioshares

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

Biota Holdings Share Price Comes Under Pressure With Volatile Relenza Sales

Biota Holdings has been a volatile stock over the last 18 months. Hitting a low of 29 cents in late 2008, the Mexican swine flu outbreak in March 2009 saw demand accelerate substantially as governments and the public stockpiled Relenza (and the other flu drug Tamiflu) for protection against the deadly pandemic flu strain.

And indeed it was a deadly strain. One frightening aspect of that strain was that 36% of deaths occurred in the normally health population of 18-35 year olds. This was reminiscent of the deadly 1918 flu pandemic that also killed indiscriminately unlike the standard seasonal flu virus that preys on the old and the sick. The arsenal of these neuraminidase inhibitors, which are effective against all flu strains, no doubt saved many lives and helped contain the spread of this pandemic outbreak.

While the world has survived this pandemic outbreak, without the millions of deaths that occurred in 1918, governments' flu drug stockpiles still poorly protect the broader populations. In the US the government has sufficient stockpiles for one week's treatment for 22% of the population (and is moving towards 25% coverage). In the UK that figure is 35% of the population and is moving to 50%. Australia currently has sufficient stockpiles to protect 55% of the population. About 60 countries currently stockpile or intend to stockpile the flu drugs, which need to be replenished every five to seven years.

Around US\$8 billion worth of flu drugs has been stockpiled, which suggests an annual replenishment market worth at least US\$1 billion a year. Although those stockpiles have consisted of an estimated 80% Tamiflu and 20% Relenza, we would argue that replenishment of the stockpiles should be at least 50% Relenza given the resistance issues and side effect profile of Tamiflu. To date 28 H1N1 pandemic virus strains has been shown to be resistant to Tamiflu with the same mutation that remains susceptible to Relenza treatment.

The seasonal market for influenza drugs grew considerably in FY2009 to around US\$800 million, compared to around US\$600 million in the previous year and from around US\$100 million in 2003. Combined with the stockpile and stockpile replenishment market, the total market for these drugs should be at least US\$1.8 billion a year. If we assume Relenza captures 30% of the seasonal market and half of the stockpile replenishment market, then **GlaxoSmithKline**, which sells Relenza, should be generating around US\$740 million in an unexceptional year. From that, Biota should receive approximately US\$52 million in royalties.

The excitement at Biota came last year when GlaxoSmithKline announced it was increasing its annual production capacity to 190 million treatment courses. At US\$20 a course, this would translate to US\$266 million in royalties for Biota if it matched that production capacity with orders.

Biota's share price fell sharply this week (down 34%) as GSK released its quarterly sales results. Relenza sales were down significantly, with Biota standing to receive only \$9.7 million in royalties for the quarter, not bad for most biotechs, but down from \$32.6 million from the December quarter. In the first nine months of this financial year, Biota has accrued \$66 million in royalties.

At the end of this financial year Biota has indicated it expects to have around \$100 million in cash. It has around four years remaining on its patents which should see at least US\$210 million of revenue to Biota if seasonal use doesn't grow and based on the above stockpile replenishment rates (and assuming no growth in the stockpile market).

Stockpile sales to governments should be expected to be lumpy as governments place orders for Relenza. Biota, in conjunction with its Japanese partner, **Daiichi Sankyo**, could see the next generation flu drug, CS8958, on the market in Japan by year's end. CS8958 is delivered as one dose which lasts for the whole week, compared to Relenza (and Tamiflu) which need to be taken twice a day for five days. In Phase III studies, CS8958 taken once was as effective as Tamiflu taken twice daily for five days.

Biota is currently seeking to partner CS8958 for the rest of the world (outside of Japan) where it equally shares the rights with Daiichi Sankyo. In Japan, Biota receives will receive a royalty from sales, which we estimate to be around 4% of sales. The Japanese market is the largest in the world, making up just under US\$500 million of the global US\$800 million seasonal flu drug market.

In recent weeks, Biota had its second collaboration cancelled in eight months with **Boehringer Ingelheim** ending the early stage Hepatitis C collaboration. In August last year **Astrazeneca** ended the collaboration with Biota for development of a drug to treat the respiratory syncytial virus.

In November last year, Biota beefed up its preclinical program, acquiring development assets from two companies, **MaxThera** and **Prolysis**, working on novel antibacterial drugs.

Summary

Biota's is capitalised at \$242 million. The share price fall this week looks excessive. The company will have \$100 million in cash at the end of this financial year. We expect it to continue to generate revenue from Relenza royalties in excess of US\$50 million a year for the next four years. Its long acting flu drug candidate, CS8958, may see its way onto the Japanese market by year's end and there are rest-of-world rights for this drug candidate for which Biota is currently seeking to license.

Bioshares recommendation: **Buy**

Bioshares



Cogstate - Investing for growth

Although some service providers to the pharmaceutical industry in this sector have experienced some difficult trading conditions as the global financial crisis has been passing through, Cogstate has enjoyed a stellar run in sales growth for the last three years. Sales for the first nine months of this financial year have increased 35% over the previous corresponding period to \$7.5 million (or a 67% increase in US dollars, with the US contributing to the majority of the company's sales).

However, with a major contract signing deferred towards the end of this year, sales in the current quarter will slow to around \$1.5 million. The company expects revenues to pick up in the second half of the year with \$4.3 million of revenue already locked in for future work.

The result has triggered a slight sell off in Cogstate shares which represents a better entry point for investors. The expected dip in the current quarter sales has resulted also from three major customers to move away from the schizophrenia area, which has been a reasonable market for the Cogstate cognitive testing system for clinical trials. Nonetheless, the other key application, in cognitive testing in the Alzheimer's space, is growing well.

The company also expects cognitive testing in the HIV space to become an increasingly important revenue source. In 2009 its test was not used in this application at all.

This comes at a time where Cogstate is investing in growth. At last report the company had around 31 employees. This has now increased to 43 people. Some of this increase has come from additional clinical trial management staff. However the company is also investigating building the use of the product outside of the clinical trials market. Other cognitive testing products the company sells are Cogstate WorkPlace, for testing cognitive testing in the workplace, and a concussion management product, Cogstate Sport.

For this financial year, the company expects to achieve a small loss or marginal profit. The latest dip in sales is also disappointing because the company had achieved an operating profit in the first nine months of \$1.08 million.

Cogstate is well placed with \$3.6 million in cash (and a further \$1.5 to be received in trade debtors) to expand the applications of its cognitive testing platform and having established a strong growth business (generating sales of around \$9 million a year) in the clinical trials market alone.

The company is now capitalised at \$17 million. Of interest to note is the recent \$500,000 purchase of shares in the company by its CEO, Brad O'Connor, obviously confident of the prospects for the business.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

4.7B Reporting Companies – Cash Balances March 31, 2010

Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Cash End 31/3/10 (\$M)	Survival Index	Events since Mar 31; other comments
1	PCC Probiomics	\$1.155	\$0.292	A	Not App
2	ACR Acrux	\$55.483	\$61.483	A	Not App
3	BRC Brain Resource Corp	\$3.839	\$12.588	A	Not App
4	CTE Cryosite	\$5.509	\$2.016	A	Not App
5	CBB Cordlife	\$18.757	\$7.856	A	Not App
6	HGN Halcygen	\$21.575	\$14.503	A	Not App
7	NDL NeuroDiscovery	\$1.985	\$1.779	A	Not App
8	PAA Pharmaust	\$1.448	\$5.283	A	Not App
9	RHT Resonance Health	\$1.552	\$2.348	A	7.0
10	SPL Starpharma	\$4.115	\$23.716	A	6.5
11	SOM Somnomed	\$7.321	\$3.109	A	5.9
12	BPH Biopharmica	\$0.002	\$7.865	A	5.8
13	OBJ OBJ	\$0.005	\$5.556	A	5.3
14	ACL Alchemia	\$0.027	\$19.633	A	4.3
15	XCD Xceed Capital	\$2.174	\$1.467	A	3.9 \$US196 K convertible note; \$1.146 put option
16	HXL Hexima	\$0.000	\$23.981	A	3.4
17	NAN Nanosonics	\$0.583	\$22.901	A	2.9
18	TIS Tissue Therapies	\$0.000	\$6.561	A	2.7
19	UBI Universal Biosensors	\$1.00	\$27.77	CY	2.6
20	CDY Cellmid	\$0.000	\$2.441	A	2.4
21	CUV Clinuvel Pharmaceuticals	\$0.000	\$29.539	A	2.4
22	PRR Prima Biomed	\$0.000	\$15.578	A	2.4
23	PXS Pharmaxis	\$0.968	\$95.904	A	2.3
24	AVH Avita Medical	\$2.155	\$4.202	A	2.2
25	BNO Bionomics	\$2.447	\$14.362	A	2.2
26	PBT Prana Biotechnology	\$0.000	\$6.862	A	1.7
27	AVX Avexa	\$0.000	\$28.299	A	1.6
28	BIT Biotron	\$0.000	\$2.473	A	1.5
29	MSB Mesoblast	\$0.003	\$12.605	A	1.5
30	SLT Select Vaccines	\$0.01	\$0.3	CY	1.5
31	ANP Antisense Therap.	\$1.801	\$2.019	A	1.4
32	LBT Labtech Systems	\$0.000	\$1.981	A	1.2
33	ACW Actinogen	\$0.013	\$1.133	A	1.2
34	PAB Patrys	\$0.025	\$8.496	A	1.2
35	VLA Viralytics	\$0.000	\$3.257	A	0.9 Access to US\$3.25M Convertible Note
36	SHC Sunshine Heart	\$0.251	\$6.063	A	0.9
37	SIE Scigen	\$2.85	\$4.13	CY	0.9
38	TDX Tyrian Diagnostics	\$1.026	\$4.187	A	0.9
39	GBI Genera Biosystems	\$0.033	\$2.942	A	0.9
40	GTG Genetic Technologies	\$6.406	\$4.058	A	0.8
41	KSX KarmelSonix	\$0.119	\$3.791	A	0.8
42	IMU Imugene	\$0.000	\$1.237	A	0.8
43	UCM USCOM	\$0.929	\$1.500	A	0.8
44	PYC Phylogica	\$0.411	\$2.479	A	0.7
45	ADO Anteo Diagnostics	\$0.218	\$1.614	A	0.7
46	LCT Living Cell Technologies	\$0.222	\$4.090	A	0.7
47	AYX Austofix	\$2.259	\$0.091	A	0.6
48	QRX QRxPharma	\$0.000	\$16.667	A	0.6
49	MVH Medic Vision	\$0.340	\$0.398	A	0.6
50	HCG Helicon Group	\$0.000	\$0.397	A	0.6
51	ACG Atcor	\$5.370	\$1.715	A	0.5
52	BLT Benitec	\$0.171	\$0.935	A	0.5 Access to US\$6M Convertible Note
53	NEU Neuren Pharmaceuticals	\$0.00	\$2.39	CY	0.5
54	BDM Biodiem	\$0.003	\$1.490	A	0.4 Rights issue underway to raise \$7.5M
55	IPD Impedimed	\$2.801	\$4.712	A	0.4 Raising up to \$20.1M
56	HTX Healthlinx	\$0.071	\$1.034	A	0.4 Access to est. \$9M Convertible Notes

4.7B Reporting Companies – Cash Balances March 31, 2010

Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Cash End 31/3/10 (\$M)	Survival Index	Events since Mar 31; other comments
57	BPO BioProspect	\$0.000	\$0.931	A	0.4 SPP underway
58	STI Stirling Products	\$0.206	\$1.560	A	0.4
59	ALT Analytica	\$0.000	\$0.337	A	0.2
60	CXD CathRx	\$0.294	\$2.461	A	0.2 \$6.3M raised, up to \$4.9M being raised
61	SLA Solagran	\$0.465	\$1.734	A	0.2 Can access \$1.4 M debt facility
62	MGZ Medigard	\$0.000	\$0.124	A	0.2
63	BOD BioMD	\$0.000	\$0.319	A	0.2 \$1.3M being raised - underwritten
64	ACU Acuvax	\$0.000	\$0.074	A	0.1 Access to \$10M draw down facility
65	FLS Fluorotechnics	\$2.622	\$0.186	A	0.0 Raising \$2.1M
66	IMI IM Medical	\$0.215	\$0.024	A	0.0
67	BNE Bone Medical	\$0.000	\$0.007	A	0.0 To issue Con Notes; min \$400k
68	ATW Atos Wellness	DNR	DNR	A	DNR Suspended fom quotation
69	EMS Eastland Medical Systems	DNR	DNR	A	DNR
70	GIA Giaconda	DNR	DNR	A	DNR

DNR: Did Not Report

Commentary

Of the 67 companies in the sector that reported their quarterly cash flow statements for the end of March, eight had six months or less cash, down from 13 companies three months earlier. The convertible note option is becoming more popular with some biotechs to secure ongoing funding. Benitec recently announced it secured funding from a US\$6 million convertible note facility through La Jolla Cover Investors. Viralytics also has a convertible note facility with the same group for further access to US\$3.25 million.

Healthlinx has access to two convertible note facilities, one being through the Spring Tree Opportunity Fund (for \$7.23 million from last year) and the other from City West Corp (with up to \$2.25 million more available).

It is a busy time for fund raising since the end of March. Biodiem is currently conducting a \$7.5 million rights issue. Impedimed has raised \$10 million through a placement with up to \$10.1 million more to be raised through an entitlement offer. CathRx has raised \$6.3 million through a rights issue and is seeking to place those shares not taken up in the offer to raise a further \$4.9 million. BioMD is in the process of raising \$1.3 million through an underwritten rights issue and Fluoretechnics is raising \$2.1 million through a rights issue with shareholder Hunter Hall agreeing to contribute its share of \$1.2 million.

Small cap life science companies that are not required to comply with the 4.7B Rule include: Advanced Medical Design and Manufact., Agenix, Imuron., Biota Holdings, Cogstate, Cellestis, Circadian Technologies, Clovercorp, Compumedics, ChemGenex Pharm., Cyclopharm, Telesso Technologies, Ellex Medical Lasers, Ascent PharmaHealth, IDT Australia, ITL Corp, Calzada, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Phosphagenics, Sirtex Medical and Virax Holdings.

Re-domiciled companies, Psvida and Heartware International no longer comply with the 4B Rule.

Legend:

Not App. : The SI calculation for these companies is not calculated due to the companies reporting positive operational cash flows, or in some cases marginally negative operational cash flows.

A: The SI calculation for these companies is based on the last two quarter's figures, annualised.

CY: The SI calculation for these companies is calculated using latest full year's figures.

Each quarter, the majority of ASX listed biotech companies are required to report their cash positions. In turn, a key analytical measure we present each quarter is the 'Survival Index' (SI). The index measures how many years those cash reserves will last, based on a company's recent spending patterns. It is limited because it does not account for companies that may increase spending in the next period of activity.

The index is derived for this quarter by dividing the annualised net operational cash flows (NOCF) for the last half year into each company's cash assets as recorded at March 31, 2010. For companies that report on Dec 31 full year basis, the index is based on the full year NOCF figure. The NOCF is the net of receipts and outgoings incurred in support of operational activities.

As a rule of thumb, companies that present with an SI of less than one are likely to be raising funds to support their activities, or are in the process of doing so. A healthy SI is either two or more. Companies with SIs of less than 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

Bioshares Model Portfolio (30 April 2010)

Company	Price (current)	Price added to portfolio	Date added
Tissue Therapies	\$0.20	\$0.21	January 2010
Biodiem	\$0.16	\$0.15	October 2009
QRxPharma	\$1.21	\$0.25	December 2008
Hexima	\$0.31	\$0.60	October 2008
Atcor Medical	\$0.14	\$0.10	October 2008
CathRx	\$0.18	\$0.70	October 2008
Impedimed	\$0.70	\$0.70	August 2008
Mesoblast	\$1.94	\$1.25	August 2008
Circadian Technologies	\$0.74	\$1.03	February 2008
Patrys	\$0.13	\$0.50	December 2007
Bionomics	\$0.31	\$0.42	December 2007
Cogstate	\$0.26	\$0.13	November 2007
Sirtex Medical	\$5.75	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.23	\$0.66	September 2007
Starpharma Holdings	\$0.61	\$0.37	August 2007
Pharmaxis	\$3.07	\$3.15	August 2007
Universal Biosensors	\$1.65	\$1.23	June 2007
Probiotec	\$1.65	\$1.12	February 2007
AcruX	\$1.97	\$0.83	November 2004
Alchemia	\$0.54	\$0.67	May 2004

Portfolio Changes – 30 April 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, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd, Tissue Therapies, Viralytics

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