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In this edition...
The analysis of a future drug market can be a challenging affair. A good example is how the cards may fall for Alchemia's injectable anticoagulant fondaparinux. There looks to be some stiff competition headed the way of the injectable anticoagulants from a raft of new oral drugs. However, Alchemia may still be well placed to collect a respectable income stream, such is the size and complexity of the market.
We report on the March quarter cash flow positions for a large number of biotechs. It comes as no surprise that a number of biotechs are in a state of financial stress. And unusually for these times, we report on a biotech IPO, Genera Biosystems, which is developing a HPV diagnostic.

The editors
Companies covered: ACL, Genera Biosystems, Mar Q Cash Analysis

	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 (from 4 May '07)	-36%
Cumulative Gain	**108.0%**
Av Annual Gain (6 yrs)	**26.8%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. The company also provides market and company analysis of the Australian pharmaceutical and biotech industries for local and international funds management institutions, venture capital funds and other related industry groups. For further details contact David Blake (see details below).

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Bioshares

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

The Potential for Alchemia's Fondaparinux

It is anticipated that Alchemia's (ACL: 42 cents) marketing partner, **Dr Reddys**, will shortly file an Abbreviated New Drug Application with the FDA for fondaparinux, a generic version of the anticoagulant Arixtra, marketed by **GlaxoSmithKline**. Approval should be received by year's end or in early 2009 with a market launch immediately thereafter. With the market in the US for Arixtra expected to be worth around US$240 million a year in 12 months time and with Alchemia having developed the only known forthcoming generic, the investment market is factoring in some upsets along the way.

However, if those upsets do not occur, then Alchemia may be in a position this time next year to be receiving in the order of $35 - $40 million a year from its profit share with Dr Reddys. If that occurs, Alchemia's share price (current market capitalisation of $67 million) should see significant appreciation in this time.

Stumbling blocks?

So what are the possible stumbling blocks? Our understanding is that the manufacturing risk has been largely diminished, allowing Dr Reddys to file for approval in this half of the year. Bioequivalence studies are not required because the drug is injected directly into the bloodstream, with bioequivalence studies only required for oral, transdermal or inhaled generics.

Being the first generic, Alchemia (Dr Reddys) will be entitled to a 180-day exclusivity from other generics if it is the first to file. This is generally a highly profitable six months for generic companies. Generic substitution is very high in the US, particularly for injectables sold into the hospital market. There is a risk that another group may file an ANDA first, but given that the market exclusivity for Arixtra ended in December 2006, that risk is low.

There is the possibility of a patent challenge, but given that the drug was sold under market exclusivity protection to the end of 2006, that risk should also be low, and Alchemia does not believe it is infringing any Arixtra patents.

There is a risk that once a generic fondaparinux comes onto the market, that GSK will reduce its marketing efforts in the US. There is a reasonable chance this will happen, however by the time Alchemia's drug is approved in the US, the market is expected to be worth US$240 million by our estimates, as mentioned. Alchemia is expected to launch its drug into Europe in 2012.

Cont'd over

Some Price Erosion

There will be some price erosion, conservatively 20% but more realistically for a market where there is only one generic, around 10% price erosion can be expected. If Alchemia's fondaparinux can achieve certain sales milestones, then Alchemia will receive a 60% profit share from sales, translating to around 40 cents from every dollar of sales. With a 10% price erosion and capturing 45% of the market, Alchemia stands to receive US$38 million a year from fondaparinux sales (based on a market size of US$240 million).

Recall of heparin product batches

The global heparin market is valued at US$4.6 billion a year. Heparin products are divided into three main categories: unfractionated heparin, for which the global market is relatively small; low molecular weight heparin (e.g. Lovenox), which has the lion's share of the heparin market; and synthetic heparin (Arixtra - fondaparinux) which is generating global sales on an annualised basis of US$280 million (US$152 million in the USA, up 73%).

Unfractionated heparin is sourced from pig intestines. Heparin from Chinese processing facilities has recently been identified as the cause of 81 deaths. There is some speculation now that the product may have been intentionally contaminated. More recently last month the TGA in Australia recalled five batches of Lovenox (sold as Clexane) in Australia due to detection of impurities. It is unclear whether these batches were also sourced from China.

These unfortunate contamination issues may increase the demand for the purely synthetic heparin form, fondaparinux, sold by GSK and Alchemia/Dr Reddys from next year. Of interest will be the sales of Arixtra in the current quarter which may see a stepped increase due to the recent contamination issues.

Risk of new entrants

In our view, it is inevitable that the stronghold **Sanofi-Aventis** has over the heparin market will end. Based on the first quarter sales, Sanofi Aventis is generating annualised sales of US$4.4 billion a year from Lovenox, an increase of 21.5%. The global market for unfractionated heparin is worth around US$400 million a year and GSK is generating global annualised sales for Arixtra of US$280 million.

Lovenox is expected to come under pressure from generic versions. **Momenta Pharmaceuticals** is expected to file its generic versions with the FDA in the third quarter of 2008.

Competition

There will be significant competition from oral anticoagulants Pradaxa (**Boehringer Ingelheim**), rivaroxaban (**Johnson & Johnson** and **Bayer**) and a number of other potential products including Apixaban.

In March this year the European Medicines Agency approved the use of Pradaxa (a thrombin inhibitor) for clot prevention in total hip and total knee replacement surgery. Pradaxa is expected to reach the US market in 2010. Pradaxa has shown to have a similar efficacy in preventing major bleeds post surgery to Lovenox. Another oral anticoagulant, Apixaban (a factor Xa inhibitor), is in Phase III trials and is being jointly developed by **Bristol-Myers Squibb** and **Pfizer**.

Rivaroxaban (a direct factor Xa inhibitor) was submitted for approval in Europe last year and is expected to be submitted for approval in the US this year. Rivaroxaban has shown in a Phase III study to have a significant improved efficacy over Lovenox (and presumably over fondaparinux).

Rivaroxaban will likely have a strong competitive edge over Lovenox in the homecare setting. In the hospital use market, it is unlikely Lovenox will be overthrown easily. That **Momenta Pharmaceuticals**, which is developing a generic Lovenox version, is capitalized at US$500 million supports the view that the enoxaparin (Lovenox) market will be around for some time to come. There are also a number of indications within the anticoagulant market. Arixtra is still not approved for the treatment of Acute Coronary Syndrome with GSK expected to resubmit its product for ACS approval by mid year. (Rivaroxaban is currently in Phase II trials for ACS).

An injectable delivery has advantages over oral delivery in the hospital care setting including better patient compliance (patients coming out from under anaesthetic commonly feel nauseous and an orally delivered drug would not be suitable). However, the threat of oral anticoagulants to the injectable heparin market is very real.

Summary

There is a strong chance that Alchemia could be generating profit share revenue from sales of its generic fondaparinux of close to $40 million this time next year. That revenue stream may increase for a year of two, however the arrival of oral anticoagulants such as Pradaxa and rivaroxaban are likely to limit the growth. It should be expected that sales of fondaparinux globally would start to decline within two to three years if the oral competing products prove to be very successful.

The heparin market overall is in a very dynamic state with expected competition from generic Lovenox, Alchemia's generic fondaparinux and the oral anticoagulants. However, it is almost a US$5 billion a year market and changing healthcare practise in a very established market will take time. In the process, Alchemia looks set to enjoy a reasonable income stream over the coming years. How large and how long that will last is largely out of Alchemia's control.

Bioshares recommendation: **Speculative Buy Class A**

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Thredbo Biotech Summit

July 25-26, 2008
Thredbo Village, NSW, AUSTRALIA
www.bioshares.com.au/thredbo2008.htm

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Key Note Speaker
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Former FDA Commissioner

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New Biotech IPO Braves Waters

Genera Biosystems in Melbourne is challenging the nervous capital markets through a planned IPO of its diagnostic development business. Genera Biosystems is looking to raise $5 million at 50 cents a share which would capitalise the company at $25 million upon listing.

Genera Biosystems was formed in 2001 with R&D conducted at WEHI, AGRF and the University of Melbourne. The company has developed a novel DNA analysis technology using microscopic silica beads labelled with dye and oligonucleotides that are imaged using a flow cytometer and interpreted using proprietary software.

The company's lead diagnostic is a HPV screening test that will compete directly with the Digene (Qiagen) HPV test. Digene was acquired by Qiagen last year for US$1.6 billion, largely for the company's HPV diagnostic product, which generated just under US$200 million of sales a year.

Genera's test differs from the Qiagen test in that its test allows pathologists to detect the sub-variant strain of HPV where the Qiagen test informs pathologists only of whether there is a HPV infection or not. Some HPV strains, such as HPV 16 and HPV 18 for which the Gardasil vaccine protects against, are more strongly linked to the progression of cervical cancer.

The company plans to use its diagnostic platform to commercialise other diagnostic products, including tests for chlamydia and gonorrhoea.

Genera plans to sell its test directly to pathology providers. The company has an agreement with **Sonic Healthcare** whereby Sonic will conduct larger trials for the company with a view of getting the product approved for use in the USA. If successful, Genera will supply the test to Sonic for use in its pathology centres.

There are several patent applications in place over the technology which will assign to Genera following the IPO.

The test and technology platform is potentially very valuable. Having a commercialisation partner such as Sonic is crucial to the success of this product. Risks remain for the company. These include the successful completion of larger scale testing by Sonic to confirm the accuracy of the technology. There is the risk of intellectual property infringement and protection. An ongoing risk is funding risk. The company expects to be selling its test in early 2009.

Shareholders in the company include **Sonic Healthcare**, **Gateway Capital**, **Orbit Capital**, **QIC** and **Domain Capital Biotech Investments**.

The offer period has been extended to 15 May. Investors are required to read the prospectus prior to subscribing to the offer.

A prospectus can be downloaded from www.generabiosystems.com

Bioshares

March Quarter Survival Analysis

Each quarter, the majority of ASX listed biotech companies are required to report their cash positions.

Following on from this, a key analytical measure we present each quarter is the 'Survival Index' (SI) (see tables on the following pages). The index measures how many years those cash reserves will last, based on the 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 firstly by annualising net operational cash flows for the last nine months. This annualised figure is then divided into each company's cash assets as recorded at March 31, 2008.

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 then 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

For the March quarter 38 of 93 reporting companies reported SIs of less than one and 23 companies reported SIs of less than 0.5 (less than six months cash.)

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Bioshares Clinical Trials Survey 2008

Corrections:

In our 2008 Clinical Trials Survey, published in *Bioshares* 260, we omitted survey data supplied by NeuroDiscovery. NeuroDiscovery has three clinical trials underway in pain indications. The trials include a Phase I trial for NSL-043, with results expected in July 2008, and two Phase II trials for NSL-101, with results also expected in July 2008.

This bring the total number of trials planned or underway to 85.

Also, compounds for three trials being conducted by Progen were incorrectly attributed to PI-88. Trials 47-01-001 and 47-01-002 relate to relate to compound 11047, and trial CFZ101 relates to PI-166.

We apologise to both companies for these errors and omissions.

An updated version of Appendix A can be our on the Bioshares website, www.bioshares.com.au/bcts08aa .

If not available, please contact David Blake at blake@bioshares.com.au .

4.7B Reporting Companies – Cash Balances Mar. 31, 2008

Sorted by Survival Index

	Code	Company	Cash End 31/03/08 (AUD $M)		Survival Index	Events since Mar 31; other comments
1	ACR	Acrux	$37.0		**18.3**	
2	RHT	Resonance Health	$2.3		**12.5**	Mar Qtr CF+ve due to new Novartis clinical trial contract
3	AOS	Advanced Ocular Systems	$2.2		**10.1**	
4	HXL	Hexima	$36.6		**7.8**	
5	CUV	Clinuvel Pharmaceuticals	$53.0		**7.1**	
6	ACW	Actinogen	$2.6		**6.1**	
7	ABI	Ambri	$4.3		**5.5**	
8	PXS	Pharmaxis	$116.2		**5.2**	
9	PSD	pSiVida	$19.8		**4.8**	
10	HGN	Halcygen	$12.7		**4.8**	
11	LBT	Labtech Systems	$4.0		**3.9**	
12	NAN	Nanosonics	$26.3		**3.9**	
13	MSB	Mesoblast	$15.6		**3.2**	
14	PAB	Patrys	$19.4		**3.1**	
15	QRX	QRxPharma	$35.4		**3.1**	
16	UBI	Universal Biosensors	$37.0	CY	**2.9**	
17	CXD	CathRx	$22.3		**2.9**	
18	HTW	Heartware	$24.9		**2.8**	
19	CCE	Clinical Cell Culture	$10.2		**2.8**	
20	AYG	Austofix	$3.3		**2.7**	
21	OBJ	OBJ	$1.6		**2.7**	
22	BPO	BioProspect	$4.4		**2.6**	
23	SOM	Somnomed	$5.8		**2.5**	
24	FER	Fermiscan	$19.6	CY	**2.5**	
25	SRX	Sirtex Medical	$7.5		**2.2**	
26	AVS	Avastra	$2.7		**2.2**	Projecting full yr rev. of $37-$40 M and EPS of 1.3-1.5 CPS
27	AVX	Avexa	$53.5		**2.1**	
28	ACL	Alchemia	$17.7		**2.1**	
29	CBB	Cordlife	$8.5		**2.1**	
30	LCT	Living Cell Technologies	$12.7		**2.0**	
31	HCG	Helicon Group	$2.1		**1.8**	
32	XCD	Xceed Capital	$3.8		**1.8**	
33	UCM	USCOM	$3.0		**1.7**	
34	SPL	Starpharma	$8.9		**1.5**	
35	BIT	Biotron	$2.3		**1.5**	
36	BDM	Biodiem	$6.6		**1.4**	
37	BOD	BioMD	$1.6		**1.3**	
38	IPD	Impedimed	$10.2		**1.3**	
39	GBL	Genesis Biomedical	$1.3		**1.3**	
40	ANP	Antisense Therap.	$4.7		**1.2**	
41	ALT	Analytica	$1.1		**1.2**	
42	BZI	Brainz	$3.0	MY	**1.2**	
43	BNO	Bionomics	$7.6		**1.2**	
44	NDL	NeuroDiscovery	$2.4		**1.1**	
45	SLT	Select Vaccines	$1.6	CY	**1.1**	R&D tax refund excluded from SI calculation
46	IMU	Imugene	$1.7		**1.1**	
47	PXL	Proteome Systems	$6.9		**1.0**	
48	SBP	Solbec Pharm.	$1.7		**1.0**	
49	VLA	Viralytics	$3.0		**1.0**	
50	PRR	Prima Biomed	$1.5		**0.9**	
51	ACG	Atcor	$3.7		**0.9**	
52	PYC	Phylogica	$4.3		**0.8**	
53	BPH	Biopharmica	$1.1		**0.8**	
54	STI	Stirling Products	$1.6		**0.8**	
55	STC	Stem Cell Sciences	$6.8	CY	**0.8**	
56	IMI	IM Medical	$2.2		**0.8**	
57	BLT	Benitec	$2.5		**0.8**	
58	SHC	Sunshine Heart	$6.6		**0.7**	
59	ATW	Atos Wellness	$1.6		**0.7**	Formerly Medec, focused on 'wellness' services; f/c FY08 revs of $19.8M
60	CGS	Cogstate	$0.9		**0.7**	
61	MGZ	Medigard	$0.2		**0.6**	
62	KSX	KarmelSonix	$3.3		**0.6**	
63	ICV	Incitive	$1.0		**0.6**	
64	DIA	Dia-B Tech	$1.6		**0.6**	Has $3.5M in convertible note funding available
65	PAA	Pharmaust	$1.4		**0.6**	Has placed manufacturing business in voluntary administration
66	MTY	Medical Therapies	$0.8		**0.5**	
67	PBT	Prana Biotechnology	$6.1		**0.5**	
68	BLS	Biolayer	$0.6		**0.5**	Raised $3.7M through U/W right issue
69	BOS	Biosignal	$1.5		**0.5**	Expects US$1.5M on finalisation of outlicensing agreements
70	ACU	Avantogen	$0.6		**0.5**	
71	UNI	Unilife	$3.4		**0.4**	Reported 40% q-on-q growth in qtrly receipts

4.7B Reporting Companies – Cash Balances Mar. 31, 2008

Sorted by Survival Index

	Code	Company	Cash End 31/03/08 (AUD $M)		Survival Index	Events since Mar 31; other comments
72	EMS	Eastland Medical Systems	$1.1		0.4	
73	CAU	Colltech	$0.8		0.4	Raising up to $1.16M through Non. Ren. Rights Issue
74	HTX	Healthlinx	$0.6		0.3	Raising up to $4M through Non. Ren. Rights Issue
75	OMI	Occup.& Medical Innov.	$0.9		0.3	In litigation with Retractable Technologies Inc Corp
76	AOP	Apollo Life Sciences	$2.3		0.3	Under self appointed wind-up of business
77	NEU	Neuren Pharmaceuticals	$4.1	CY	0.3	
78	RTL	RTL Corp	$0.0		0.3	Under reorganisation
79	MVH	Medic Vision	$1.0		0.3	Rec'd $750K order March Qtr, which will will appear in June Qtr figures
80	SLA	Solagran	$0.6		0.2	ANZ now major shareholders: good luck guys!!
81	NAL	Norwood Abbey	$0.6		0.2	S'hold. in Norwood Imm.now reduced to 21%; $258 K remains in credit standby
82	GIA	Giaconda	$0.4		0.2	
83	PLD	Portland Orthopaedics	$1.1		0.2	Post 31/3, rec'd $220K from SPP
84	BNE	Bone Medical	$0.5		0.2	
85	RBY	Rockeby Biomed	$0.3		0.1	$5M equity standy facility; drew down $123K in April
86	PCC	Probiomics	$0.0		0.0	Change of business, acquiring Minomic International
87	TIS	Tissue Therapies	$0.1		0.0	Can access $1.5 million in convertible note finance
88	NLS	Narhex Life Sciences	$0.0		0.0	Negotiating $400K funding; seeking tax conc. of $192 K
89	BRC	Brain Resource Corp	$19.6		**Not App.**	
90	CST	Cellestis	$13.2		**Not App.**	
91	CTE	Cryosite	$1.8		**Not App.**	
92	GTG	Genetic Technologies	$15.3		**Not App.**	
93	SIE	Scigen	$5.7	CY	**Not App.**	

Legend:

Not App. : The SI calculation for these companies is not calculated due to the companies reporting positive operational cash flows.

CY: The SI calculation for these companies is based on the latest 3 months figures, annualised.

MY: The SI calculation for these companies is based on the latest 12 months figures.

Small cap life science companies that are not required to comply with the 4.7B Rule include:

Advanced Medical Design and Manufact., Agenix, Anadis, Arana Therapeutics, Biota Holdings, Circadian Technologies, Clovercorp, Compumedics, ChemGenex Pharm., Cyclopharm, Cytopia, Telesso Technologies, Ellex Medical Lasers, Genepharm, IDT Australia, ITL Corp, Life Therapeutics, Metabolic Pharmaceuticals, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Polartechnics, Phosphagenics, Sirtex Medical, Ventracor and Virax Holdings – (27 companies). * This company elects to report.*

Bioshares Model Portfolio (2 May 2008)

Company	Price (current)	Price added to portfolio	Date added
Cellestis	$2.63	$2.27	April 2008
IDT	$2.18	$1.90	March 2008
Circadian Technologies	$0.96	$1.03	February 2008
Patrys	$0.30	$0.50	December 2007
NeuroDiscovery	$0.14	$0.16	December 2007
Bionomics	$0.38	$0.42	December 2007
Cogstate	$0.13	$0.13	November 2007
Sirtex Medical	$3.79	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.43	$0.66	September 2007
Starpharma Holdings	$0.36	$0.37	August 2007
Pharmaxis	$1.80	$3.15	August 2007
Universal Biosensors	$0.85	$1.23	June 2007
Biota Holdings	$1.03	$1.55	March 2007
Probiotec	$1.18	$1.12	February 2007
Peplin Inc	$0.49	$0.83	January 2007
Arana Therapeutics	$1.02	$1.31	October 2006
Chemgenex Pharma.	$0.93	$0.38	June 2006
Cytopia	$0.28	$0.46	June 2005
Optiscan Imaging	$0.27	$0.35	March 2005
Acrux	$0.85	$0.83	November 2004
Alchemia	$0.42	$0.67	May 2004

Portfolio Changes – 2 May 2008

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: Phylogica, Pharmaxis, NeuroDiscovery, Biotech Capital, Cytopia,Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima

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