

In this edition...

In the absence of products and sales, investors can evaluate biotechs by the partnering deals they do. In the case of Xceed Biotech, its investee company PolyNovo has signed on another large US devices firm, Biomet, following the development deal it struck last year with Medtronic. This is very positive news not only for PolyNovo, but for the sector.

We also explain why Alchemia's stock price has surged, note clinical trial go-aheads for Neuren and Living Cell Technologies and provide a summary of the latest quarterly cash balances for 88 4.7B reporting life science firms.

The editors

Companies covered: ACL, LCT, NEU, XBL

	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 (from 5 May '06)	20.7%
Cumulative Gain	236%
Average Annual Gain	27.3%

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Bioshares

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

Alchemia's Share Price Surges

Alchemia's share price (ACL: \$1.20) has surged over the last week by 40%. Favourable research reports released by two stockbrokers are partly responsible. Approval from the FDA for Arixtra (fondaparinux), which is sold by **GlaxoSmithKline**, for the indication of Acute Coronary Syndrome is expected to be imminent (Alchemia is commercialising the only generic version of Arixtra). And strong rumours of an impending takeover of the company has added further interest to this stock. M&A discussions have been denied by the company.

Quarterly sales figures from GSK for Arixtra are due to be released on 8th February. IMS data for October and November suggests Arixtra sales continue to grow at 20% a quarter. For 2006, global sales of arixtra are expected to reach US\$100 million which moves the drug away from being a niche product. Once approval for the ACS indication is received, which accounts for 30% of the heparin market, then continued healthy growth should continue. GSK received an Approvable Letter from the FDA today for the ACS indication, which means that while the scientific review process has been completed, GSK is required to submit further minor information to complete its application.

Alchemia expects to file its generic version of Arixtra for approval with the FDA towards the end of 2007. This is six months later than previously stated although is due to changes within the FDA regarding approval of generics. The changes bring about a positive aspect with a six month turnaround expected from the FDA for first generics to file, down from 15 months pre-

viously expected. The result is the Alchemia's generic version of Arixtra could be approved for sale as early as mid-2008. Alchemia's manufacturing partner, **Dow Chemical**, has started manufacturing the first commercial batch of fondaparinux.

Negotiations with potential marketing partners for the generic in the US are progressing well. We anticipate a partnering announcement can be expected in the next three months.

Alchemia is due to complete and report on a Phase II oncology study with HyCAMP, a program acquired through merger with **Meditech Research**. A smaller Phase II program is expected to be commenced if the result is positive. The company is assessing the progression/commencement of earlier clinical programs from its in-house VAST discovery program and from earlier Meditech programs.

With about a year's cash remaining, Alchemia will need to raise further funds in the next six months. If the strong share price rally continues, this could be expected to occur over the next three months.

The strong interest that appears to have resulted from the increasing coverage of this stock may see the share price continue to appreciate in coming weeks. Other drivers from upcoming milestones include an announcement of a US marketing partner and further approvals for Arixtra in the US. Alchemia is capitalised at \$168 million.

Bioshares recommendation: Speculative Hold Class A

Neuren Ready to Launch Phase III Study

Neuren Pharmaceuticals (NEU: 56 cents) passed a major milestone this week, receiving approval from the FDA to commence a Phase III study with its lead compound, Glypromate. In a 520 patient study, the company will test the ability of Glypromate to prevent cognitive impairment following major cardiac surgery. If successful, the compound will be the first in market for this indication that is estimated to be valued in excess of US\$1 billion a year in sales.

The trial is expected to take 18 months to complete and will be conducted by a contract research organisation. The first patient is expected to be dosed in March or April. The sites in the US and New Zealand have been selected and clinical trial sites in Australian are currently being arranged. Neuren has managed to design the trial such that trial costs will be limited to only \$10 million, which is an exceptional achievement for a 500 patient Phase III trial.

The company completed a Phase I study with its second compound, NNZ-2566, for protection of brain function in patients who have experienced traumatic brain injury. This trial was being conducted in conjunction with the US Army. A Phase II study is expected to begin in mid 2007.

Neuren is capitalised at \$73 million and had \$9.5 million in cash at the end of last year. With a Phase II and III program expected to be underway this year, and with a number of preclinical assets, the company remains a very attractive investment proposition.

Bioshares recommendation: **Speculative Buy Class A**

Living Cell Technologies to Start Cell Transplant Trial in Russia

Another New Zealand biotech also received positive news this week. Living Cell Technologies (LCT: 21.5 cents) was given the green light to commence clinical trials with its cell transplant technology in patients with type I diabetes in Russia. This is also a major milestone for the company. The company is also awaiting approval to start similar trials in New Zealand.

LCT's technology uses islet cells from an isolated and highly pure pig herd that are encapsulated with an alginate and injected into patients using a laparoscope. The procedure is expected to take one hour to complete.

Previous animal trials in mice, rats and primates have all shown that the technology delivers a reduced level of insulin requirements. The objective of this potential product is not to fully remove the need for insulin in patients with diabetes, but to reduce the daily dosage levels and reduce the occurrence of hypoglycaemic episodes that can be difficult to control and can have fatal consequences.

Preclinical studies suggest the technology has a strong chance of success. Six patients have been selected for the Russian trial which will be managed by an international contract research organisation. The New Zealand trial is expected to involve up to 12 patients. Patients will receive two injections, six months apart. A measure of initial efficacy from the trial can be expected towards the end of this year.

In Russia, rabbit islet cell transplants are currently available and cost approximately \$30,000 per treatment course. Concerns over transmission of viruses from other animal species to humans has delayed the start of clinical studies. Positive results from Russian and New Zealand studies will help support an application to begin studies with the technology in the US. LCT is also seeking to commercialise porcine cell therapy technology for the treatment of hemophilia and Huntington's disease.

LCT also announced this week that it will be raising \$3 million through a fully underwritten Share Purchase Plan. The company's founder and CEO, David Collinson, is stepping down for health reasons and will be replaced by Dr Paul Tan, who currently manages New Zealand operations. LCT is currently capitalised at \$30 million and had \$0.9 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Xceeds' PolyNovo Biomaterials Signs Deal with Biomet Inc

Xceed Biotechnology's (XBL: 19.5 cents) 60% owned subsidiary **PolyNovo Biomaterials** has announced a third partnering deal for its novel polymer technology. PolyNovo reached an agreement with **Biomet Inc** covering the development of applications of the NovoSorb technology in the separate areas of cartilage repair applications and cranial and facial bone repair applications.

Biomet is a Nasdaq listed medical devices companies, capitalised at US\$10.4 billion and recording sales on a trailing twelve months basis of US\$2 billion. Biomet markets hip and knee implant products and is probably better known to Australian investors as one of a number of competitors to Australian hip and knee company, Portland Orthopaedics.

However, Biomet's interest in dealing with PolyNovo lies in the 'surgical glue' like properties the NovoSorb technology. NovoSorb biodegradable polymers can be designed to incorporate different mechanical properties and different rates of degradation. In the instance of cranial application, the piece of skull that has been removed to allow access to the brain would be re-fixed with the polymer like glue with 'glue' cured or set using a light source. The opportunity for Biomet is that the process does not use pins and plates and may enable a new approach to be tried in the pediatric surgery market, where cranial surgery is much more limited for a number of reasons.

A second application area is for the use of Novosorb polymers to help rebuild the misshapen heads of children with major deformations, which typically involves risky and time-consuming surgery. The potential advantage of the Novosorb technology is that its glue-like properties (and biodegradability) would speed up the surgical process and reduce the time these children spend under anaesthetic. This application may also benefit from a speedier regulatory approval and hence a quicker path to market.

Other alliances

Previously, PolyNovo has partnered with **Medtronic** (January 2006) to develop coronary and other stents, and in June of 2006 established the NovoSkin joint venture with Professor John Greenwood of the **Royal Adelaide Hospital** to develop coverings and mesh for use in treating burns patients (see our interview with Dr Greenwood in Bioshares 182)

Deal terms

Terms of the partnering deal with Biomet include undisclosed up-front and milestone payments and high-single digit royalties on product sales, terms similar to the deal struck with Medtronic. Going forward, Biomet is responsible for the vast bulk of the development and clinical trial costs, with PolyNovo responsible for a small amount of materials.

Spin-out possibility

Now that PolyNovo has achieved a second partnering arrangement with a major US medical devices firm, the chance of PolyNovo being spun out and listing in its own right is now distinct, and in our view, a timely possibility. A key reason for a separate listing of PolyNovo is that it would increase the likelihood of attracting investors with a specific interest in Polynovo, but not the parent entity and its associated interest in **Boron Molecular**. Secondly, PolyNovo has now achieved a measure of success, profile and maturity as an investee company of another listed company, and its passage to a full listing is likely to be undertaken on a surer footing, with a track record of deals completed with major firms. However, a publicly listed PolyNovo still would still need to meet the challenge of creating an expanded and well rounded board and management with the appropriate depth and experience to do justice to the promising polymer technology.

Our estimate of the current value ascribed to Polynovo is \$16 million. Xceed Biotechnology is capitalised at \$17 million. Deducting cash held in the group of \$3.8 million and ascribing a value of \$3 million (~ 1 X sales) to Boron Molecular, leaves a residual value for Xceed's 60% share of PolyNovo of \$13.2 million. On a grossed up basis, the market value of PolyNovo is therefore in the order of \$22 million.

Summary

Xceed's investment in PolyNovo is maturing in an extremely favourable fashion, with the deal with Biomet concrete validation of the prospects for the CSIRO-invented polymer technology. With PolyNovo being seriously studied as an IPO offering, there looks to be considerable value locked up in Xceed at present, and investors would do well to remember that **Avexa** was de-merged from **Amrad** in 2004 with a technology value of \$12 million, but now has achieved a technology value of \$126 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Xceed's Deals and Collaborations

Partner	Announced	Terms	Application	Royalties
Medtronic (Cap. US\$61b)	21/01/2006	World-wide, exclusive	Coronary stents	High single digits
NovoSkin	19/06/2006	Joint venture with Dr John Greenwood, Royal Adel. Hospital	Easy Application Synthetic Epidermis; Bioresorbable Temporising Matrix (for Severe Burns)	
Biomet (Cap. US\$10b)	1/02/2007	World-wide, exclusive	Cartilage Repair	High single digits
		World-wide, exclusive	Cranial and facial bone repair	High single digits

4.7B Reporting Companies – Cash Balances December 31, 2006 Commentary

For the December quarter 2006, we have tabulated the cash positions of 88 listed life science companies (see the next page), and calculated their respective Survival Indices.

For four companies, it was not appropriate to calculate Survival Indices – **Cryosite**, **GenePharm**, **PharmAust** and **Eastland Medical** – because these companies recorded positive net operational cash flow or in have recorded a relatively small operational loss whilst recording solid revenues.

There are 127 life science companies listed in Australia. Of the 88 4.7B reporting companies, 35 recorded SIs of less than one, and 18 had, at December 31, less than 6 months cash at hand.

The company with the greatest cash balance was **Pharmaxis**, which held \$86 million in cash, sufficient for 3.9 years of operations. Behind Pharmaxis was **Peplin** with \$40 million (2.3 years), and **Clinuvel** with \$38 million. Investors should note that of the top ten companies (by cash balances), five companies, including **Heartware**, **Avexa**, **Alchemia**, **Clinical Cell Culture** and **Mesoblast**, had SIs between 1 and 1.5 and may therefore be looking to raise funds in the next six months if market conditions are favourable.

Top Ten Cash Balances Company

Company	Cash End 31/12/06 (\$M)	Survival Index
Pharmaxis	\$86.1	3.9
Peplin	\$39.5	2.3
Clinuvel Pharmaceuticals	\$38.2	4.1
Heartware	\$21.7	1.0
Avexa	\$20.4	1.1
Acrux	\$17.0	2.1
Alchemia	\$16.5	1.1
Clinical Cell Culture	\$16.1	1.5
Mesoblast	\$15.7	1.4
Sunshine Heart	\$15.1	2.7

Companies in Stress

A number of companies that are in financially stressed positions have subsequent to December 31, either raised capital or announced plans to raise capital.

Apollo Life Sciences, which recorded an SI of 0.1 has since December 31, received the proceeds of a \$10 million capital raising, which would move its SI, an adjusted basis, closer to 1.5.

Medical Therapies, with an SI of 0.2 looks to have raised \$1.2 million through a convertible note offering, which would give it an adjusted SI of 0.6, which realistically does not advance that company's financial position that far.

The majority of listed life science companies are required to file cash flow statements with the ASX on a quarterly basis. This provides investors with a means to monitor the financial health of cash depleting biotech firms on more timely basis than is available through half yearly and annual reporting requirements.

A key analytical measure we present is the 'Survival Index' (SI). The index is derived for this quarter by dividing a company's annualised latest half year net operational cash into the company's cash balance. 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 ramp up spending in the next period of activity.

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 should therefore be investigated cautiously by investors.

Share Purchase Plans (SPP)

Living Cell Technologies has announced an SPP which is to be underwritten by Taylor Collison, to raise \$3 million. Analytica is also conducting an SPP.

Reasonable footing

Tissue Therapies which recorded an SI of 0.2, this week announced a world-wide supply agreement with a major laboratory reagents firm, **Invitrogen**. It is likely that income from this arrangement will positively offset Tissue Therapies' future operational outgoings. It should also be noted that a significant one off expenditure was made by Tissue Therapies in the first half of FY2007 on process development and manufacturing of GMP grade components for use in clinical trials and for inventory for the Invitrogen arrangement.

Cause for concern

A number of companies have SI figures that point to difficult times ahead, unless some fairly rapid moves are made to secure new funding or control costs. These companies include **Solbec Pharmaceuticals** (0.2), **pSiVida** (0.2), **Probiomics** (0.2), **Norwood Abbey** (0.2), **RiTract** (0.1) **Advanced Ocular Systems** (0.1) and **Advantogen** (0.0).

4.7B Reporting Companies – Cash Balances December 31, 2006 Sorted by Survival Index

Life Science Companies - Cash Balances Dec Q 2006

Code	Company	Cash End 31/12/06 (\$M)	Survival Index
1	CTE Cryosite	\$1.5	Not Appl.
2	EMS Eastland Medical Systems	\$2.7	Not Appl.
3	GAA Genepharma	\$11.6	Not Appl.
4	PAA Pharmaust	\$0.5	Not Appl.
5	ANP Antisense Therap.	\$9.2	4.3
6	CUV Clinuvel Pharmaceuticals	\$38.2	4.1
7	CST Cellestis	\$12.4	3.9
8	PXS Pharmaxis	\$86.1	3.9
9	BPH Biopharmica	\$2.5	3.5
10	OBJ OBJ	\$2.5	2.8
11	BDM Biodiem	\$5.6	2.8
12	SHC Sunshine Heart	\$15.1	2.7
13	GTG Genetic Technologies	\$9.5	2.5
14	SIE Scigen	\$9.7	2.4
15	PEP Peplin	\$39.5	2.3
16	FER Fermiscan	\$6.0	2.3
17	BLS Biolayer	\$1.0	2.2
18	ACR AcruX	\$17.0	2.1
19	ICV Incitive	\$2.3	2.0
20	RHT Resonance Health	\$2.8	2.0
21	GBL Genesis Biomedical	\$1.8	2.0
22	AVS Avastra	\$8.4	2.0
23	EGX Evogenix	\$8.5	2.0
24	SPL Starpharma	\$11.2	1.9
25	BRC Brain Resource Corp	\$3.8	1.9
26	CXD CathRx	\$7.6	1.8
27	BPO BioProspect	\$1.4	1.7
28	ABI Ambri	\$6.1	1.6
29	BNO Biomomics	\$7.0	1.6
30	OMI Occup. & Medical Innov.	\$2.2	1.6
31	CCE Clinical Cell Culture	\$16.1	1.5
32	ACG Atcor	\$8.8	1.5
33	BOS Biosignal	\$5.0	1.5
34	MSB Mesoblast	\$15.7	1.4
35	KSK KarmelSonix	\$1.2	1.4
36	XBL Xceed Biotech	\$3.8	1.4
37	PYC Phylogica	\$4.5	1.3
38	UCM USCOM	\$5.6	1.3
39	CYN Cygenics	\$6.3	1.3
40	MAA Medec	\$3.3	1.3
41	SOM Somnomed	\$4.1	1.3
42	GIA Giaconda	\$3.1	1.2
43	PXL Proteome Systems	\$6.9	1.2
44	IMU Imugene	\$1.9	1.1
45	PLD Portland Orthopaedics	\$7.1	1.1
46	AVX Avexa	\$20.4	1.1
47	ACL Alchemia	\$16.5	1.1
48	RBY Rockeby Biomed	\$2.764	1.1
49	NDL NeuroDiscovery	\$1.8	1.1
50	BOD BioMD	\$1.8	1.1
51	PBT Prana Biotechnology	\$11.5	1.0
52	AVP Acuron	\$1.4	1.0
53	IMI IM Medical	\$2.7	1.0
54	HTW Heartware	\$21.7	1.0

Life Science Companies - Cash Balances Dec Q 2006

Code	Company	Cash End 31/12/06 (\$M)	Survival Index
55	CGS Cogstate	\$1.6	0.9
56	SLT Select Vaccines	\$2.5	0.9
57	STI Stirling Products	\$1.8	0.9
58	VLA Viralytics	\$3.2	0.8
59	CMQ Chemeq	\$13.7	0.8
60	NEU Neuren Pharmaceuticals	\$9.5	0.8
61	VSG Visiomed	\$1.4	0.7
62	NLS Narhex Life Sciences	\$2.9	0.7
63	CAU Colltech	\$2.0	0.7
64	PBI Premier Bionics	\$1.8	0.6
65	MGZ Medigard	\$0.3	0.6
66	DIA Dia-B Tech	\$1.9	0.6
67	LBT Labtech Systems	\$0.9	0.6
68	BLT Benitec	\$1.0	0.6
69	BIT Biotron	\$2.4	0.5
70	PRR Prima Biomed	\$2.1	0.5
71	SLA Solagran	\$1.0	0.4
72	UNI Unilife	\$3.3	0.4
73	ALT Analytica	\$0.1	0.4
74	MDM Medical Monitors	\$0.5	0.3
75	BNE Bone Medical	\$0.8	0.3
76	MTY Medical Therapies	\$0.7	0.2
77	HTX Healthlinx	\$0.5	0.2
78	EQX Eqitx	\$0.2	0.2
79	TIS Tissue Therapies	\$1.1	0.2
80	SBP Solbec Pharm.	\$0.6	0.2
81	PSD pSiVida	\$5.4	0.2
82	PCC Probiomics	\$0.3	0.2
83	LCT Living Cell	\$0.9	0.2
84	NAL Norwood Abbey	\$0.9	0.2
85	AOP Apollo Life Sciences	\$1.0	0.1
86	RTL RiTract	\$0.4	0.1
87	AOS Advanced Ocular Systems	\$0.5	0.1
88	ACU Avantogen	\$0.1	0.0
Total		\$574.9	
Average		\$6.5	
Median		\$2.7	

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

Agenix, Anadis, Biota, Circadian, Clovercorp, Compumedics, Chemgenex Pharmaceuticals, Cytopia, Eiffel Technologies, Ellex Medical Lasers, IDT Australia, ITL Corp, Life Therapeutics, Metabolic Pharmaceuticals, Medical Developments International, Novogen, Optiscan Imaging, Panbio, Progen Industries, Polartech, Phosphagenics, Peptech, Sirtex, Ventracor and Virax Holdings - (25 companies).

Also, Brainz was not included in this survey due to its quarterly reporting periods occurring on different months.

Portfolio Changes

Sirtex Medical has been removed from the portfolio at \$3.45, after being added at \$1.95. The company appears well valued at \$192 million, with sales growth appearing to slow, as suggested by its recent cashflow statement. Receipts from customers in the last quarter were \$6.5 million, a 21% increase from the previous corresponding period. Bioshares has changed its recommendation to **Lighten**.

IDT was forecasting strong growth ahead when it reported its full year results last year. In response to the ASX recently over its share price increase, the company stated that results for the six months just passed should be more in line with the trend shown in 2002, 2003 and 2004, suggesting a less optimistic growth outlook than indicated six months earlier. We have removed the stock from the portfolio and place a **Lighten** recommendation on the stock.

Bioshares Model Portfolio (2 February 2007)

Company	Price (current)	Price added to portfolio
Acrux	\$0.81	\$0.83
Alchemia	\$1.20	\$0.67
Bionomics	\$0.27	\$0.210
Cogstate	\$0.22	\$0.18
Cytopia	\$0.68	\$0.46
Chemgenex Pharma.	\$0.58	\$0.38
Evogenix	\$0.88	\$0.47
Optiscan Imaging	\$0.48	\$0.35
Metabolic Pharmaceuticals	\$0.96	\$0.53
Neuren Pharmaceuticals	\$0.56	\$0.70
Peplin	\$0.78	\$0.83
Peptech	\$1.55	\$1.31
Phylogica	\$0.44	\$0.42
Prima Biomed	\$0.054	\$0.09
Progen Industries	\$7.15	\$3.40
Sunshine Heart	\$0.23	\$0.19
Ventracor	\$0.94	\$0.92

The Bioshares 20 Index

<i>Change from June 30, 2006</i>	48.0%
<i>Change from Dec 31, 2006</i>	17.2%
<i>Change - week ago</i>	2.9%

Nasdaq Biotech Index

<i>Change from June 30, 2006</i>	10.9%
<i>Change from Dec 31, 2006</i>	3.2%
<i>Change - week ago</i>	1.3%

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, Neuren Pharmaceuticals, Pharmaxis, NeuroDiscovery, Prima Biomed, Biotech Capital, Cygenics, Psivida, Cytopia, Biodiem, Peptech, Starpharma Holdings, Cogstate, Xceed Biotechnology, Healthlinx, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals

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