

Bioshares

6 November 2009
Edition 336

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

In this edition...

This week in Australian biotech ended on an upbeat note with Acrux appointing Credit Suisse as corporate advisor to assist Acrux in the "execution of the partnering process (for Axiron) as well as optimising strategic options associated with Axiron". We speculate that the company is being groomed for acquisition as much as for a partnering deal.

Pharmaxis also filed Bronchitol for approval in Europe, an event of much significance for that company. And a number of other companies are set to pass major milestones in 2010. However, our analysis of quarterly cash flow statements also confirms the weak financial position of many smaller firms with 40 companies calculated to be holding less than one year's cash for operational activities.

The Editors

Companies Covered: MSB

	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)	75.9%
Cumulative Gain	242%
Av Annual Gain (9 yrs)	21.5%

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Pharmaxis Files Bronchitol For European Approval...Acrux Appoints Commercial Advisor...Biotech Bull Run Continues

In a major milestone for the Australian biotech sector, **Pharmaxis** this week filed its drug candidate, Bronchitol, for approval in Europe for the treatment of cystic fibrosis. The interest in the local sector has been strong for all of 2009, and this biotech bull market is showing signs it may continue to at least the end of 2010 with an unprecedented level of later stage commercial activity underway. These drivers are expected to continue to drive consistent interest both from retail and institutional investors, at a time when the broader market experiences high volatility due to uncertain economic conditions.

In September this year, **Chemgenex Pharmaceuticals** completed the filing of its lead drug candidate, Omapro, for regulatory submission with the FDA, and **Acrux** is expected to file its drug candidate, Axiron, with the FDA by year's end for the treatment of testosterone deficiency in men. **Biota Holdings'** partner, **Daiichi Sankyo** is expected to file the long acting influenza drug candidate, laninamivir, for approval in Japan in coming months. Biota shares equal rights to this drug outside of Japan and will receive a single digit royalty from Japanese sales. And **Clinuvel Pharmaceuticals** anticipates filing its lead drug candidate, afamelanotide, for EPP, a skin condition characterised by absolute intolerance to UV light.

In early 2010, we should see the product launch of **Universal Biosensors'** glucose monitoring diagnostic product through its partner **Lifescan**, the potential approval and launch of Chemgenex Pharmaceutical's Omapro for the treatment of chronic myeloid Leukemia and the potential approval of Pharmaxis's Bronchitol product in Europe. **Starpharma**, through its partner **SSL International**, is aiming to get its microbicide-coated condoms into commercial use by the end of 2010.

Mesoblast's stem cell therapy for the treatment for non-union long bone fracture should see its way into use in Australia next year through the Special Access Scheme. With major clinical study results expected in 2010, Mesoblast should be in a position to report several Phase II studies from its adult stem cell therapy next year, having this week reported positive interim results from its sister company, Angioblast, using its adult stem cells to expand cells in bone marrow transplantation. (see page 2).

Bionomics should release data out from both its second Phase I trial of BNC210 for the treatment of anxiety (with the aim being to deliver an improved Prozac or Valium to the market), and some interim data from its Phase II cancer studies with BNC105.

The progress of **Biota Holdings**, **Cellestis** and **Sirtex Medical** in generating income should continue draw attention as product sales or royalty streams accelerate. For Biota Holdings, the northern hemisphere flu season which is now underway will increase demand for Relenza.

Cont'd over

– from page 1

Acrux has appointed **Credit Suisse** as a corporate adviser to assist with the commercialization of the company's Axiron product. That Acrux has selected Credit Suisse rather than a more traditional biotech investment bank would suggest that an outright acquisition of the company is more likely than a licensing deal for Axiron. It would also seem to suggest that the interest in Axiron and in Acrux is escalating and that the company needs assistance to negotiate the sale or license of company assets.

In September in *Bioshares* 328 (Acrux share price \$1.45) we posed the question whether Acrux was up for sale. Our view was that this would depend on the share price the company was trading at. At current levels, we view an acquisition of the entire company remains a reasonable proposition.

Most companies approaching market, such as Chemgenex, Acrux and Universal Biosensors can be considered acquisition targets. If the sector sees its third \$300 million plus acquisition with 12 months, following on from **Arana Therapeutics** and **Peplin** earlier this year, then the biotech bull run is very likely continue with much vigour for the next 12 to 18 months.

Bioshares

Bioshares Top 5 Stock Picks: November 2009

Company	CMP	Cap'n. (M)
Acrux	\$2.06	\$329
Chemgenex Pharmaceuticals	\$0.88	\$249
Alchemia	\$0.70	\$113
Universal Biosensors	\$1.72	\$270
Sirtex Medical	\$6.19	\$345

Mesoblast – Positive Data With Angioblast Study May Allow Progression To Phase III In 2010

Mesoblast's (MSB: \$1.20) investee company Angioblast (of which Mesoblast owns 38%) released further results from a Phase II clinical study using the company's adult stem cell technology. The company is trialing the adult stem cells in a bone marrow transplant application.

The adult stem cells have shown an ability to expand haematopoietic stem cells used in bone marrow transplant by up to 40-fold. The adult stem cells are thought to secrete growth factors that help the haematopoietic cells grow.

In the first 18 of the 30 patients in the trial who have now been treated, the time taken for neutrophil (white blood cell) recovery

was only 18 days in the patients following chemotherapy, compared to around 30 days which has been achieved in the past using unexpanded cord blood. For recovery of platelets following chemotherapy, the medium time was only 38 days when the Angioblast stem cells were used to expand the cord blood, versus the historical reported average of over 90 days.

At the completion of this Phase II clinical study, Angioblast may be in a position to move into pivotal Phase III studies, which may involve as few as 100 patients, in 2010.

Bioshares recommendation: Speculative Buy Class A

Mesoblast/Angioblast Clinical Trial Results To Date

Date	Disease	Patients	Centre	Results
November 2009	Expansion of haematopoietic stem cell sin bone marrow transplant	18	MD Anderson Cancer Center, Texas	Neutrophil recovery 16 days (vs 30 days published data) and 38 days platelet recovery (vs over 90 days published data)
May 2009	Heart Failure	20	Arizona, San Diego, Minneapolis, Texas	37% increase in ejection fraction after 3 months (vs 11% decline in control group)
August 2008	Non-healing long bone fractures	11	Royal Melbourne Hospital	Union of bones in 9 from 11 patients after 10 months of non-union pre-treatment

4.7B Reporting Companies – Cash Balances September 30, 2009 Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Cash End 30/09/09 (\$M)	Survival Index	Events since Sept 30; other comments
1 CBB	Cordlife	\$5.2	\$8.8	A	Not App
2 LBT	Labtech Systems	\$0.0	\$2.8	A	Not App
3 RHT	Resonance Health	\$0.7	\$2.8	A	Not App
4 IMU	Imugene	\$0.0	\$1.9	A	Not App
5 CTE	Cryosite	\$1.9	\$1.5	A	Not App
6 UNI	Unilife	\$9.1	\$4.6	A	Not App
7 PAA	Pharmaust	\$0.6	\$4.0	A	Not App
8 SIE	Scigen	\$10.6	\$5.6	CY	Not App
9 BRC	Brain Resource Corp	\$0.2	\$13.7	A	Not App
10 NDL	NeuroDiscovery	\$0.4	\$1.2	A	6.4
11 SLT	Select Vaccines	\$0.3	\$0.4	CY	5.3
12 BPH	Biopharmica	\$0.0	\$2.9	A	4.4
13 PXS	Pharmaxis	\$0.3	\$113.4	A	3.9
14 HXL	Hexima	\$0.0	\$27.1	A	3.4
15 SOM	Somnomed	\$2.4	\$3.8	A	3.3
16 ACW	Actinogen	\$0.0	\$1.6	A	2.6
17 SPL	Starpharma	\$1.3	\$10.2	A	2.3
18 ATW	Atos Wellness	\$5.8	\$2.3	A	2.1
19 UBI	Universal Biosensors	\$0.3	\$17.9	CY	2.0
20 MSB	Mesoblast	\$0.0	\$15.8	A	2.0
21 HGN	Halcyon	\$0.0	\$7.6	A	1.8
22 BNO	Bionomics	\$0.9	\$9.0	A	1.8
23 CUV	Clinuvel Pharmaceuticals	\$0.0	\$19.2	A	1.7
24 ACG	Acor	\$1.8	\$2.3	A	1.6
25 PAB	Patrys	\$0.0	\$12.3	A	1.5
26 AVH	Avita Medical	\$0.8	\$5.1	A	1.4
27 NAN	Nanosonics	\$0.2	\$12.1	A	1.4
28 UCM	USCOM	\$0.4	\$1.5	A	1.4
29 SHC	Sunshine Heart	\$0.0	\$10.2	A	1.4
30 GTG	Genetic Technologies	\$2.0	\$6.6	A	1.4
31 PBT	Prana Biotechnology	\$0.0	\$8.8	A	1.3
32 BDM	Biodiem	\$0.0	\$2.7	A	1.2
33 ACR	Acrux	\$0.2	\$10.9	A	1.2
34 ANP	Antisense Therap.	\$1.8	\$3.7	A	1.0
35 OBJ	OBJ	\$0.0	\$1.1	A	1.0
36 ACL	Alchemia	\$0.0	\$6.7	A	1.0
37 TDY	Tyrian Diagnostics	\$0.3	\$6.4	A	0.9
38 ALT	Analytica	\$0.0	\$1.0	A	0.9
39 LCT	Living Cell Technologies	\$0.1	\$5.0	A	0.9
40 XCD	Xceed Capital	\$0.7	\$0.7	A	0.9
41 BOD	BioMD	\$0.0	\$0.9	A	0.8
42 QRX	QRXPharma	\$0.0	\$13.5	A	0.8
43 SLA	Solagran	\$0.1	\$3.4	A	0.8
44 BPO	BioProspect	\$0.0	\$1.5	A	0.8
45 IPD	Impedimed	\$0.8	\$9.5	A	0.8
46 GBI	Genera Biosystems	\$0.0	\$2.6	A	0.8
47 CXD	CathRx	\$0.1	\$8.1	A	0.8
48 BLT	Benitec	\$0.1	\$1.6	A	0.7
49 HCG	Helicon Group	\$0.0	\$0.6	A	0.7
50 EMS	Eastland Medical Systems	\$2.7	\$1.5	A	0.7
51 NEU	Neuren Pharmaceuticals	\$3.1	\$2.5	CY	0.7
52 KSX	KarmelSonix	\$0.0	\$2.2	A	0.6
53 PYC	Phylogica	\$0.0	\$2.1	A	0.5
54 PRR	Prima Biomed	\$0.0	\$1.4	A	0.5
55 AVX	Avexa	\$0.0	\$15.0	A	0.4
56 ACU	Acuvax	\$0.0	\$0.4	A	0.4
57 PCC	Probiomics	\$0.4	\$0.1	A	0.3
58 VLA	Viralytics	\$0.0	\$1.0	A	0.3
59 BNE	Bone Medical	\$0.0	\$0.4	A	0.3
60 BIT	Biotron	\$0.0	\$0.5	A	0.3
61 TIS	Tissue Therapies	\$0.0	\$0.6	A	0.3

4.7B Reporting Companies – Cash Balances September 30, 2009 Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Cash End 30/09/09 (\$M)	Survival Index	Events since Sept 30; other comments	
62	ICV	\$0.0	\$0.3	A	0.3	Not acq. V-Patch Medical Systems; agreement to place \$750K
63	MVH	\$0.0	\$0.3	A	0.2	
64	MTY	\$0.0	\$0.3	A	0.2	
65	ADO	\$0.1	\$0.4	A	0.2	Raised \$0.8M from rights issue
66	GIA	\$0.0	\$0.1	A	0.2	
67	RBY	\$0.2	\$0.3	A	0.2	Liquidating two subsids. companies; intends to de-list
68	MGZ	\$0.0	\$0.1	A	0.2	
69	FLS	\$0.9	\$0.7	A	0.2	
70	STI	\$0.0	\$0.4	A	0.1	Raised \$1.6 M from SPP
71	FER	\$3.6	\$0.7	CY	0.1	Suspended from trading; board is pursuing alternatives
72	PLI	\$0.0	\$3.2	A	0.1	Shareholders have approved acq by Leo Pharma AS
73	HTX	\$0.0	\$0.2	A	0.1	Received \$750k grant; Access to \$7.2M line of finance
74	IMI	\$0.0	\$0.1	A	0.1	Acquiring radiology business
75	AYX	\$0.3	\$0.1	A	0.1	
76	OMI	\$1.0	\$0.0	A	0.0	Suspended from trading; Auditors cite 'going concern' issues

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 average of the last five quarters' figures, annualised.

CY: The SI calculation for these companies is based on the average of the latest three quarters' figures, annualised.

Advanced Medical Design and Manufact., Agenix, Imuron, Arana Therapeutics, Biota Holdings, Cogstate, Cellestis, Circadian Technologies, Clovercorp, Compumedics, ChemGenex Pharm., Cyclopharm, Cytopia, Telesso Technologies, Ellex Medical Lasers, Ascent PharmaHealth, IDT Australia, ITL Corp, Metabolic Pharmaceuticals, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Phosphagenics, Sirtex Medical and Virax Holdings – (25 companies).

Re-domiciled companies, Psvida and Heartware International no longer comply with the 4B Rule, although Peplin Inc elects to report.

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 average of net operational cash flows (NOCF) for the last five quarters into each company's cash assets as recorded at September 30, 2009. For companies that report on Dec 31 full year basis, the index is based on average last three quarters of NOCF, annualised. 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.

Commentary

The number of companies monitored on a 4.7B reporting basis fell from 81 in the June quarter, to 76 in the September quarter, as companies have continued to enter administration or be re-capitalised and applied to business activities in other economic sectors.

At September 30, 2009, for 40 of 76 reporting companies we calculated SIs of less than 1.0 and for 22 companies we calculated SIs of less than 0.5, or less than six months cash, although the cash positions of some companies will have improved since this date. A year ago we calculated 37 out of 89 companies with an SI of less than 1.0 and 26 with an SI of less than 0.5.

The latest figures indicate that the number of listed biotech's will fall even further, with **Rockeby biomed** looking to de-list, **Fermiscan** in a wind-up mode, **Peplin** now to be acquired by **Leo Pharma** and **Cytopia** by **YM Biosciences**.

Although **Fluorotechnics** and **Austofix** look to be companies in stress, these two companies are trading and generating turnover from sales and their positions should improve in the medium term, so long as economic conditions improve.

Bioshares Model Portfolio (6 November 2009)

Company	Price (current)	Price added to portfolio	Date added
Biodiem	\$0.19	\$0.15	October 2009
QRxPharma	\$1.15	\$0.25	December 2008
Hexima	\$0.60	\$0.60	October 2008
Atcor Medical	\$0.20	\$0.10	October 2008
CathRx	\$0.60	\$0.70	October 2008
Impedimed	\$0.70	\$0.70	August 2008
Mesoblast	\$1.20	\$1.25	August 2008
Circadian Technologies	\$0.75	\$1.03	February 2008
Patrys	\$0.15	\$0.50	December 2007
Bionomics	\$0.36	\$0.42	December 2007
Cogstate	\$0.30	\$0.13	November 2007
Sirtex Medical	\$6.19	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.30	\$0.66	September 2007
Starpharma Holdings	\$0.59	\$0.37	August 2007
Pharmaxis	\$2.55	\$3.15	August 2007
Universal Biosensors	\$1.72	\$1.23	June 2007
Probiotec	\$2.40	\$1.12	February 2007
Chemgenex Pharma.	\$0.88	\$0.38	June 2006
Acruz	\$2.06	\$0.83	November 2004
Alchemia	\$0.70	\$0.67	May 2004

Portfolio Changes – 6 November 2009**IN:**

No changes.

OUT:

No changes.

Correction:

In the Model Portfolio published last week, Alchemia was accidentally omitted from the table.

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

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