

**In this edition...**

What a turnaround for the Australian biotech sector! Only nine months ago, the prospects for the sector overall looked miserable. Today capital has well and truly started to flow back into the sector, triggered by the third consecutive quarter of strong share market gains.

One of the drivers for biotech stock prices is the excellent progress being made by the leading biotechs. Acrux is now ready to license and file its testosterone drug, Axiron. It may be one of the largest commercial deals that Australian biotech has seen.

And even some of the smaller biotechs, such as Biodiem, continue to see their programs advanced and create some appealing value opportunities for investors.

**The Editors**

**Companies Covered: Quarterly Review, ACR, BDM**

	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)	48.0%
<b>Cumulative Gain</b>	<b>187%</b>
<b>Av Annual Gain (9 yrs)</b>	<b>18.4%</b>

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

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

Individual Subscriptions (48 issues/year)

\$320 (Inc.GST)

Edition Number 331 (2 October 2009)

ISSN 1443-850X

Copyright 2009 Blake Industry and Market Analysis Pty Ltd. ALL RIGHTS RESERVED.  
Secondary electronic transmission, photocopying, reproduction or quotation is strictly prohibited without written consent of the publisher.

# Bioshares

2 October 2009

Edition 331

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

## Quarterly Review

### **Strong Support for Biotech Stocks Continues Through the September Quarter**

Investors intensified their interest in listed Australian biotech stocks in the September quarter, pushing the **Bioshares Index** 33.1% higher. After the sell-down of 2008, a year in which the Bioshares Index fell 60%, the Bioshares Index has recorded three positive quarters, with the latest figure being the biggest quarterly gain recorded since the index series commenced at the end of 2004.

The Bioshares Index out-performed the **Nasdaq Biotech Index**, which rose 12% for the quarter and the **Bioshares Large Cap Index**, which increased by 4.2% over the same period. The Bioshares Index also out-performed the **ASX 300 Index**, which posted a healthy gain of 20.1% for the September quarter.

Although 78 stocks registered positive price movements in the September quarter, two stocks in particular exerted a strong influence on the movement of the Bioshares Index. These were **Biota Holdings**, which rose 128% for the quarter and was capitalised at \$478 million as of September 30, and **Unilife Medical Solutions**, which increased by 345% for the quarter (Capitalisation – \$306 million).

The driver behind the Biota share price has been an anticipated licensing of the rights to long acting neuraminidase inhibitor laninamivir, outside of Japan and Northern Asia, and the prospects of substantial royalty revenues from sales of Relenza. Unilife commenced production of syringes in the US. It also announced plans to re-domicile in the USA.

Shares in **Peplin** rose 72% in the quarter, with the company in the process of being acquired by **Leo Pharma** for US\$278 million. **Acrux** also finished the quarter on a strong note, posting a 50% gain for the quarter, supported by positive results from its Phase III trial of a testosterone product for hypogonadal men. And **Starpharma**, now capitalised at \$118 million, saw its share price rise 68% in the quarter.

The ASX listed life sciences sector was capitalised \$34.9 billion at September 30, representing 117 companies. The 111 companies that comprise the Bioshares Index were capitalised at \$6.7 billion.

#### Index performances by Quarter

	Q3 2008	Q4 2008	Q1 2009	Q2 2009	Q3 2009
Bioshares Index	-10.9%	-26.1%	16.0%	20.3%	33.1%
Nasdaq Biotech Index	5.4%	-12.7%	-6.4%	9.8%	12.0%
Bioshares Large Cap Index	12.4%	-8.1%	-3.8%	1.1%	4.2%
ASX 300 Index	-12.0%	-19.3%	-3.6%	10.6%	20.1%

## Capital Raisings by Australian-listed Biotech Companies Q3 2009

Company	Investment Manager or Investor	Type of raising	Funds raised (\$M)
1 Heartware		Placement	\$75.00
2 Bionomics		Placement	\$12.80
3 Bionomics		SPP (u/w)	\$2.20
4 Probiotec		Placement	\$12.00
5 Sunshine Heart		Rights Issue	\$8.10
6 Phosphagenics	BBY	SPP (u/w)	\$7.00
7 Patrys		Rights Issue	\$6.80
8 Prana Biotech	Rodman & Renshaw , Peregrine Corporate	Placement	\$6.00
9 Solagran	Salim Group	Placement	\$5.54
10 CathRx	Wilson HTM	Rights Issue (u/w)	\$5.30
11 Tyrian Diagnostics	Patersons Securities	Rights Issue	\$4.98
12 Nusep		SPP	\$3.75
13 Holista Colltech		Placement	\$2.50
14 Halcygen Pharm.	Patersons Securities	Placement (Tranche 1) u/w	\$2.28
15 Sunshine Heart		Placement/Rights Issue	\$1.75
16 Prima Biomed	SpringTree Special Opportunities Fund	Convertible Loan Funding (est)	\$1.50
17 Imuron		SPP	\$1.30
18 Fluorotechnics			\$1.23
19 USCOM		SPP	\$1.10
20 Agenix		Convertible Notes	\$1.00
21 Neuren Pharm.		SPP	\$0.82
22 OMI		SPP	\$0.61
23 Holista Colltech	Mercatus Capital	Placement	\$0.50
24 Genesis R&D		SPP	\$0.39
<b>Total</b>			<b>\$164.4</b>
<b>Total raised in Q2 2009</b>			<b>\$132.7</b>
<b>Total raised in Q1 2009</b>			<b>\$27.4</b>
<b>Cumulative Raise - 2009</b>			<b>\$324.6</b>

### Capital raisings

Capital inflow into biotechs listed on the ASX continues to increase. If the third quarter of this year \$164 million was raised, up from \$132 million in the second quarter. The climate for capital raising is starkly different from the fourth quarter in 2008, when only \$18 million was raised in the sector by 11 companies, and still only \$27 million from 17 companies in the first quarter of 2009.

The most significant raising came from **Heartware**, which raised US\$60 million after its merger with **Thoratec** was stopped by the US Federal Trade Commission. **Bionomics** has received commitments to raise \$15 million, which is an impressive raising in what remain tentative capital markets.

Total funds raised for the year total \$324 million, and does not include yet the total funds to be raised by **Halcygen Pharmaceuticals** to fund its acquisition of **Mayne Pharma International**. In

this quarter, it's of interest to note that 24 companies raised money, with a positive sign that the funding doors are starting to open for the smaller companies in the sector.

Bioshares

## Selected Clinical Trial Developments - September Quarter 2008

	Company	Code	Product/Therapeutic	Event
1	Acrux	ACR	Axiron (testosterone deficiency in males)	Announced Phase III trials results (155 hypogonadal males); 84% of patients recorded normal levels of testosterone after four months, which exceeded the FDA's benchmark of 75%.
2	Avita Medical	AVH	Recell (Wounds and burns)	Completed US pilot study in 14 pts in lead up to larger US Army funded study
3	Biodiem	BDM	LAIV (SCH900795)	Recruitment for Phase I trial completed (120 healthy volunteers).
4	Biota	BTA	Laninamivir (CS-8958) (Influenza)	Reported results from Phase III study (1000 pts). Laninamivir, single inhaled dose, was shown to be as effective as Tamiflu administered twice a day for five days.
5	Living Cell Technologies	LCT	Diabecell (diabetes)	Commenced NS Phase IIIa trial (8 pts)
6	Mesoblast	MSB	Revascor	Completed enrollment for second group of 20 out of 60 patients in heart failure pts
7	Peplin	PLI	PEP005 Gel (non-cancerous skin lesions)	Commenced and completed enrollment in second non-head (ie trunk and extremities) Phase III trial in pts with actinic keratoses. Trial to enrol 200 pts. [REGION-Ib trial]
8	Pharmaxis	PXS	Bronchitol (cystic fibrosis)	Announced the achievement of target of 300 pts in second pivotal Phase III trial
9	Phosphagenics	POH	Transdermal Oxycodone Matrix Patch (Pain)	Completed Phase I trial
10	Phosphagenics	POH	Topical Diclofenac (anti-inflammatory)	Commenced Phase II/III trial
11	Progen	PGL	PG11047 (monotherapy) (advanced solid tumours)	Completed Phase I study in 46 pts; MTD established at twice the dose used in other earlier trials
12	Progen	PGL	PG11047 (Combination study) (advanced solid tumours)	Announced Phase Ib study recruitment was on schedule, 131 patients recruited and five of seven arms have been enrolled.
13	Psivida	PVA	Iluvien (fluocinolone acetonide) (diabetic macular edema)	Reported interim 18 month data from PK study in 37 pts
14	QRxPharma	QRX	MoxDuo IR (Pain Therapy)	Commenced Phase II comparative proof of concept study for MoxDuo IV versus morphine IV, following hip replacement surgery
15	Sirtex Medical	SRX	Sir-Spheres (liver cancer)	Published results of 25 pt study of Sir-Spheres used in combination with irinotecan. Median overall survival of 12.2 months was reported, with three pts still alive at time of reporting.
16	Sunshine Heart	SHC	C-Pulse (heart assist device)	Four out twenty pts now implanted in US feasibility trial
17	Tissue Therapies	TIS	VitroGro (wound healing)	Reported that 8 pts in Canadian trial had been recruited to date, from an original target of 30. Patient recruitment had been "disappointingly slow"; company intends to open more trial sites.
18	Virax Holdings	VHL	VIR201 (HIV)	Completed enrolment in South African trial

## ***Acrux – Ready to License***

As expected, Acrux has delivered positive results from its Phase III trial for its male testosterone transdermal product. The results were stunning, achieving FDA specifications within only 15 days of use, and being well within the requirements after four months of use. The safety profile was excellent as well as patient compliance.

Acrux's CEO, Richard Treagus, is confident a licensing deal will be effected in this financial year together with the receipt of an upfront payment. It has the potential to be the largest licensing deal in Australia's biotech history. The market for male testosterone products is in excess of US\$1 billion a year. Most of that market (82%) is in the US, and most of it is for transdermally delivered products. The overall market is growing at 20% a year.

That Acrux appears to have a product that is by far better than any competing products on the market puts the company in possession of "an extremely valuable asset", in the words of Treagus, and we would fully agree. Existing products need to be smeared over a large area on the upper torso and take twice as long to dry as the Acrux product, called Axiron. The Axiron device is applied to a small area under each arm, similar to a deodorant roll-out product.

This week will also have been the first time potential licencees or acquirors will have seen the data as well, starting off an auctioning process for the product, or at the current share price, the entire company. Whilst the company would like to make this an ordered process to maximize value for its shareholders, there is a good chance that will not be the case with the possibility of a preemptive bid placed on the company whilst it continues to trade at current prices.

A licensing deal for the US could be worth in the order of US\$300 million, including an upfront payment of US\$50 million. However with the company capitalised at only US\$247 million, it's easy to see why bids may be made for the entire company.

It's also worth noting that the Acrux share price has now passed \$1.60, which is the price at which \$22.5 million was raised to fund the development of Axiron in July 2007. This may result in less resistance now in the share price moving forward.

*Bioshares* recommendation: **Speculative Buy Class A**

*Bioshares*

### **The Axiron Product**

Axiron is a testosterone solution delivered via an applicator under the arm. The testosterone solution is combined with Acrux's proprietary delivery system which allows enhanced delivery of drugs across the skin. Its drying time is less than half that for competing drugs on the marketed with a substantially lower application area required (under the arm rather than across the upper torso).

The global market for testosterone products is currently worth US\$1.04 billion and is growing at 20% per annum. The leading product, Androgel, a transdermal gel, generated sales of US\$550 million in the US in the 12 months to March this year. The large and growing market size for testosterone products is attributed to an aging population and increasing awareness of male sexual health products such as Viagra.

North America makes up 82% of the testosterone product market. Countries such as India, China and Brazil are largely untapped.

Last month **ProStrakan** struck a US\$210 million deal with **Endo Pharmaceuticals** for US rights alone for its testosterone gel product which is currently being reviewed by the FDA. We would argue Acrux has developed a product with a superior delivery profile.

The Phase III trial just completed was conducted in 155 men with low testosterone at 26 sites. The primary endpoint showed that 84% of men reached normal testosterone levels (300ng/dl-1050ng/dl) at 120 days. The average level achieved was 504ng/dl. This

was well within the FDA requirements of 75% of trial participants achieving a normal range of testosterone levels.

Secondary endpoint changes included:

- A 13% improvement in mood
- A 26% decrease in negative moods
- A 79% increase in sexual desire
- A 104% increase in sexual desire

No serious adverse events were reported with Axiron use.

All the results were clearly statistically significant. At present, between 5%-10% of men with testosterone deficiency in the US are being treated with testosterone products. Current testosterone treatment costs approximately US\$260 per month in the USA.

94% of patients surveyed rated Axiron as being better over existing gels in reducing transfer of testosterone to others.

Acrux has manufactured three regulatory batches of its Axiron product through Orion Corporation in Europe. Commercial validation batches will be manufactured in the middle of 2010.

Acrux expects to file its Axiron product for approval in the USA by the end of 2009 and be on the market in early 2011. It is seeking to license the drug to a marketing partner by mid 2010.

*Bioshares*

## Update – Biodiem

Biodiem (BDM: \$0.15) is a biotech that has received little attention over the last two years. However, the company's core asset is quietly progressing and the next 12 months may see some value recognition occur.

Biodiem's main asset is an intranasal live attenuated influenza vaccine (LAIV) that should next progress into Phase II clinical trials shortly. The vaccine technology emanated from the **Institute of Experimental Medicine in Russia** (IEM), which has also prepared a H1N1 pandemic version of its LAIV, which should start Phase II trials this month and may be released for use in early 2010.

### Seasonal Vaccine (Non Pandemic Version)

The LAIV program is now being commercialised by **Nobilon**, which is part of **Schering Plough**. It will soon be a part of **Merck**, with Merck to acquire Schering-Plough at year's end for \$41 billion. This follows the acquisition of **Organon** (including Nobilon) in 2007 by Schering-Plough.

It's of interest that Biodiem initially licensed the program to Merck, which handed it back to Biodiem and now it is back in the hands of Merck. However, there have been considerable advances and developments that make this arguably a more important asset for Merck.

Nobilon first licensed the technology from Biodiem in 2004. Since that time it will have made a considerable investment into this program – we would estimate in excess of \$50 million – through licensing payments to Biodiem (US\$7 million received to date), developing a cell-based manufacturing process for the vaccine (rather than the laborious chicken egg production system), completing preclinical testing and it has completed a 120 person Phase I study.

A Phase II trial could begin this month, with immunogenicity results out as early as late 2009. The product is expected to reach the market in 2013, however this could be earlier depending on the situation with the influenza pandemic. The relevance of influenza vaccines in light of the influenza pandemic threat seen this year, and the progress the vaccine has made under Nobilon, should see this program receive greater priority from Merck.

Under the commercial arrangement with Nobilon, Biodiem maintains North American rights (as well as Russia and the CIS) to the vaccine, rights in Japan are shared, and Nobilon has the rights to commercialise the vaccine in all other regions, from which Biodiem will receive a 'healthy royalty'.

One unresolved issue that will require action, very possibly in the next 12 months, is that of the commercial rights to the vaccine in North American markets. As the vaccine progresses, the value of these rights will increase, particularly now that the product is in the clinic. For Biodiem, which is capitalised at only \$11 million, this could be a major share price driver in the next 12 months.

### Advantages of Biodiem's LAIV

The LAIV has multiple advantages over existing injectable influenza vaccines. Because it stimulates a local immunity (in the nose) at the place of infection, it is arguably a more effective vaccine. This characteristic of the vaccine is why it has shown, in school-age children studies, lower infection rates in children *not* immunized with the vaccine, as the virus does not spread because of the immediate immune response in the upper airways.

Another advantage is that Nobilon has developed this vaccine using a cell-based manufacturing process, whereby the vaccine is produced in a biotech reactor vessel, where millions of vaccine doses can be produced rather than the cumbersome traditional process of injecting antigens into millions of chicken eggs.

(Note, where the chicken egg production process is employed, which is the case of the pandemic vaccine strain, the production yield of the LAIV is far higher than that of the inactivated current influenza vaccines, giving it appeal, particularly where a quick response to a pandemic strain is required.)

The live attenuated vaccine products such as Biodiem's and AstraZeneca's Flumist, are believed to provide broader immune protection in antigenic shifting strains, and they are inhaled and so do not require injection.

Biodiem's vaccine has been in use in Russia for many years now and Flumist (developed by Aviron which was acquired by MedImmune which was subsequently acquired by AstraZeneca), which was first approved in 2003 and is approved for use in people aged 2-49 years. Biodiem's scientist, Professor Larisa Rudenko, argues that its LAIV strain induces a stronger immune response than Flumist because Flumist is developed from a more mutated strain.

### Pandemic Vaccine Product

In May this year, Biodiem and Nobilon made an agreement with the World Health Organisation to allow access to its LAIV to develop a pandemic strain (H1N1 swine flu) for use in developing countries. Pandemic vaccine trials are expected to begin shortly in Thailand and India, with trials already having commenced in Russia. Once approved, the vaccines will be made available for use free-of-charge in those countries for public healthcare use. That could occur within several months time following the Phase II studies, which are due to begin imminently.

The first registration of the pandemic vaccine is expected to be in Thailand. The trial will involve around 200 people in Thailand. The vaccine includes no adjuvants, which is another benefit of the vaccine.

The impact of this free access for developing country public use is twofold. Firstly it will build a safety record for this type of vaccine, paid for by the WHO. Secondly, use of the vaccine outside of Russia for the first time will increase the profile of this vaccine. This should benefit the development of the seasonal LAIV by

*Cont'd over*

– *Biodiem cont'd*

Merck. Nobilon will be able to sell any registered pandemic vaccine into private markets, which are considerable in size in India and China, and Biodiem would then receive a royalty from those private market sales.

As noted above, another attractive feature for WHO is that the LAIV production yield is far higher than the traditional killed vaccine, giving health authorities a quicker response to a pandemic threat.

### Management

Biodiem has recently installed a new and experienced CEO, Julie Phillips, who was previously CEO at Select Vaccines briefly and before that at Psiron. Under the chairmanship of Hugh Morgan, the company has progressed through the turbulent financial market conditions over the last 12-18 months seemingly unaffected. The company has access to a highly experienced and highly credentialed non-executive director, Dr John Brown, who also has a consultancy agreement with the company to assist with the BDM-E program and in assessing new programs. However his services come at a significant price, costing the company \$508,000 in FY2009.

### Summary

Biodiem's lead program is partnered with Nobilon and the company can dictate its own R&D spending rate on other projects based on available funding. This includes the BDM-E peptide, which continues to generate positive preclinical data in each model tested. Sufficient data may have now been generated on different animal models and mechanism of action studies to partner the program.

Biodiem had \$4 million in cash at June 30 and generated a net loss in FY2009 of only \$1.5 million. Potential funds could be received from achievements of milestones with the Nobilon LAIV program, and negotiation of US LAIV rights with Merck.

There are several drivers for this stock over the coming 12 months. These are:

- Commencement of H1N1 vaccine trials in Thailand and India
- Results from H1N1 trial in Thailand
- Registration of H1N1 LAIV in Thailand
- Results from Nobilon seasonal vaccine Phase I trial
- Start of Phase II seasonal trial by Nobilon/Merck
- Results from Phase II seasonal study
- Negotiation of North American rights to Merck (possible) for seasonal LAIV

Biodiem appears well undervalued at present with a capitalisation of only \$11 million. With major milestones due to be reached in the year ahead, it makes an appealing speculative investment at its current price.

**Bioshares recommendation: Speculative Buy Class B**

*(Biodiem has been added to the Bioshares Model Portfolio)*

**Bioshares**

#### Bioshares Model Portfolio (2 October 2009)

Company	Price (current)	Price added to portfolio	Date added
<i>Biodiem</i>	\$0.15	\$0.15	October 2009
QRxPharma	\$0.94	\$0.25	December 2008
Hexima	\$0.55	\$0.60	October 2008
Atcor Medical	\$0.16	\$0.10	October 2008
CathRx	\$0.34	\$0.70	October 2008
Impedimed	\$0.64	\$0.70	August 2008
Mesoblast	\$1.05	\$1.25	August 2008
Circadian Technologies	\$0.73	\$1.03	February 2008
Patrys	\$0.14	\$0.50	December 2007
Bionomics	\$0.28	\$0.42	December 2007
Cogstate	\$0.24	\$0.13	November 2007
Sirtex Medical	\$4.72	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.33	\$0.66	September 2007
Starpharma Holdings	\$0.60	\$0.37	August 2007
Pharmaxis	\$2.35	\$3.15	August 2007
Universal Biosensors	\$1.30	\$1.23	June 2007
Probiotec	\$2.50	\$1.12	February 2007
Chemgenex Pharma.	\$0.73	\$0.38	June 2006
AcruX	\$1.79	\$0.83	November 2004
Alchemia	\$0.53	\$0.67	May 2004

#### Portfolio Changes – 2 October 2009

##### IN:

We have added Biodiem to the portfolio. With solid progression of its flu vaccines, and capitalised at only \$11 million, the company has several large milestones to look forward to in the coming year. (See update on page 5).

##### OUT:

Cellestis and Biota Holdings have both made strong gains this year. We will take some profits and remove them from the portfolio. Cytopia has still not addressed its funding requirements and has also been removed from the portfolio.

**The Australian Listed Life Sciences Sector**  
**September 30, 2009: Capitalisation \$34.9 billion, 117 companies**

## Bioshares Large Cap. Index

Company	Code	Cap. \$m	Principal Activities	Change - Quarter	Change - Year	Price 30/09/09
CSL	CSL	19,590	Manufactures pharmaceutical products including vaccines and human plasma fractions	4%	-10%	\$33.46
Resmed Inc.	RMD	3,921	Manufactures diagnostic and treatment equipment for sleeping disordered breathing	0%	-4%	\$5.19
Cochlear	COH	3,753	Manufactures cochlear hearing implants	16%	13%	\$66.76
Sigma Pharmaceuticals	SIP	932	Pharmaceutical manufacturing and wholesaling	-13%	-11%	\$1.07
<b>Capitalisation Total</b>		28,195				

## Bioshares Index

Company	Code	Cap. \$m	Principal Activities	Change - Quarter	Change - Year	Price 30/09/09
Pharmaxis	PXS	523	Marketing a lung function test, Aridol, and developing the Bronchitol product to treat cystic fibrosis, bronchiectasis and COPD.	0%	7%	\$2.40
Biota	BTA	478	Commercialised Relenza anti-flu drug and flu diagnostic kits. Now developing an improved version, laninamivir with partner Daiichi Sankyo.	128%	299%	\$2.73
Heartware International	HIN	392	Developing a mechanical heart pump (LVAD).	9%	55%	\$0.96
Blackmores	BKL	336	Manufactures vitamin, mineral and herbal supplements and skin & hair products in Australia and N.Z.	27%	17%	\$20.34
Cellestis	CST	324	Marketing a diagnostic for latent tuberculosis	12%	57%	\$3.38
Unilife Medical Solutions	UNI	306	Developer of retractable syringes.	345%	376%	\$1.38
Peplin	PLI	275	Developing a plant derived compound, PEP005, to treat non-melanocytic skin cancers. <b>Acquisition by Leo Pharma pending.</b>	72%	108%	\$0.90
Acrux	ACR	272	A Pooled Dev. Fund commercialising a drug delivery technology that uses sunscreen penetration enhancers to aid transdermal drug delivery.	50%	81%	\$1.71
Sirtex Medical	SRX	270	The company's core technology uses radioactive particles to irradiate tumours in the liver. Approved for use in most major regions.	44%	135%	\$4.84
API	API	219	Pharmaceutical wholesaler	49%	34%	\$0.85
Universal Biosensors	UBI	210	Development, manufacture and commercialisation of a range of in vitro diagnostic tests for point-of-care use.	43%	91%	\$1.34
ChemGenex Pharmaceuticals	CXS	208	Developer of the drug Omacetaxine, which has potential to treat CML patients that develop the T315i mutation.	13%	4%	\$0.74
Mesoblast	MSB	142	Developing therapies based on mesenchymal pre-cursor stem cells, with applications in cartilage regrowth and heart and bone repair.	24%	-6%	\$1.03
Probiotec	PBP	138	Manufacturer, marketer and distributor of a range of over the counter (OTC) pharmaceuticals, complementary medicines and speciality ingredients	19%	72%	\$2.49

## Bioshares Index

Company	Code	Cap. \$m	Principal Activities	Change - Quarter	Change - Year	Price 30/09/09
Starpharma Holdings	SPL	118	Developer of pharmaceutical applications of chemical scaffolds known as 'dendrimers'.	68%	111%	\$0.57
Clinuvel Pharmaceuticals	CUV	102	Developing an analogue of the alpha-MSH protein as a photo-protective agent	20%	46%	\$0.34
Nanosonics	NAN	96	Developing a novel disinfection technology. The first product is a point of care ultrasound probe disinfection unit.	23%	158%	\$0.49
Alchemia	ACL	92	Commercialising new solid phase carbohydrate synthesis technology. First product, a synthetic heparin, to be launched by Dr Reddy's in 2009/10.	61%	159%	\$0.57
pSiVida	PVA	91	Developing drug delivery technologies, with a special focus on ophthalmic applications	146%	148%	\$4.95
Aveva	AVX	78	Developing antiviral therapies for HIV and Hepatitis B and a novel antibiotic.	0%	-28%	\$0.12
Institute of Drug Technology	IDT	76	Manufacturer of pharmaceutical ingredients to international standards for major pharmaceutical groups.	23%	-13%	\$1.77
Bionomics	BNO	75	Developing drugs to treat cancer and CNS diseases, and has also developed a gene diagnostic for epilepsy.	29%	-16%	\$0.27
Novogen	NRT	75	Developing analogues of naturally occurring phenolic hormones to treat cancers and other conditions.	40%	-34%	\$0.73
Prima Biomed	PRR	74	Developing the CVac immunotherapy.	250%	2400%	\$0.18
Impedimed	IPD	72	Develops devices that aid the diagnosis of secondary lymphoedema, muscle wasting and other disorders	3%	-8%	\$0.66
Rockeby Biomed	RBY	70	Research, development and marketing of rapid testing technologies for infectious diseases in animals and humans.	24%	675%	\$0.03
QRxPharma	QRX	69	Developing a 'dual opioid' drug to treat moderate to severe pain.	135%	53%	\$0.92
Scigen	SIE	66	Developer and manufacturer of biopharmaceuticals. Company is based in Singapore and was spun out of Sonic Healthcare in 2002.	-40%	79%	\$0.12
Phosphagenics	POH	64	Commercialising a drug delivery technology improving the delivery of vitamin E and existing pharmaceutical products through phosphorylation.	-29%	45%	\$0.10
Living Cell Technologies	LCT	62	Developing cell therapies for diabetes, haemophilia and Huntington's disease.	31%	52%	\$0.24
Ascent PharmaHealth	APH	59	A generic pharmaceutical manufacturer and distributor.	81%	18%	\$0.24
Prana Biotechnology	PBT	55	Developing drugs to treat CNS diseases such as Alzheimer's and Parkinson's	88%	-45%	\$0.24
Hexima	HXL	51	Research and development of genetic technologies that can enhance the resistance of crops to insects and fungal pathogens.	57%	-27%	\$0.55
Holista Colltech	HCT	50	Has developed a novel technology for the extraction of collagen from sheepskins. Acquired Holista Biotech (Malaysia); 1:10 consolidation	55%	3%	\$0.16



## Bioshares Index

Company	Code	Cap. \$m	Principal Activities	Change - Quarter	Change - Year	Price 30/09/09
Genera Biosystems	GBI	47	Develops, manufactures and distributes advanced molecular diagnostic tests, with a particular focus on women's health.	51%	344%	\$0.80
Solagran	SLA	46	Developing complementary medical compounds called Bioeffectives.	74%	-61%	\$0.16
Halcygen	HGN	39	Developing an improved dosing anti-fungal drug, Subazole, based on drug delivery technology developed by Mayne Pharma.	150%	53%	\$0.45
Cordlife	CBB	37	Rolling out tissue banking services in Australia and Asia	18%	14%	\$0.40
Progen Pharmaceuticals	PGL	36	A developer of cancer therapeutics	-29%	-17%	\$0.60
Circadian Technologies	CIR	35	Developing drugs, including antibodies, around the VEGF C and VEGF D targets.	7%	-3%	\$0.78
USCOM	UCM	33	Marketing a non-invasive heart output function monitor.	4%	122%	\$0.80
Clovercorp	CLV	33	Development and production of omega-3 food additives from tuna oil.	-7%	-26%	\$0.20
KarmelSonix	KSX	32	Respiratory and pulmonary devices company	35%	123%	\$0.06
Compumedics	CMP	30	Develops, manufactures and markets sleep diagnostic and monitoring equipment.	32%	23%	\$0.19
Southern Dental Industries	SDI	30	Manufacture & distribution of amalgam (fillings) & other dental materials and product R&D.	11%	32%	\$0.25
Antisense Therapeutics	ANP	29	Developing antisense compounds to treat multiple sclerosis and acromegaly	35%	-6%	\$0.05
CathRx	CXD	28	Developing novel modular cardiac catheters for the diagnosis and treatment of abnormal heart rhythms	0%	-45%	\$0.40
Patrys	PAB	26	Developing human antibody therapies for the treatment of lung, pancreatic, gastric and colon cancers	8%	-38%	\$0.14
Sunshine Heart	SHC	25	Developing the C-Pulse heart assist device. The C-Pulse wraps around and compresses the aorta, increasing blood flow through the body.	-6%	-53%	\$0.05
Brain Resource Corp	BRC	25	Development and commercialisation of functional brain analysis techniques.	0%	-28%	\$0.27
Somnomed	SOM	23	Commercialising an oral device for the treatment of sleep apnea and snoring.	30%	43%	\$0.03
Eastland Medical Systems	EMS	23	Developing retractable syringes, ClipOn and VetLock, and anti-malarial product ArTiMist.	97%	-52%	\$0.07
Phylogica	PYC	22	Developing phylomer (protein fragment shapes) compound libraries for use in human therapeutics.	79%	-5%	\$0.10
Genetic Technologies	GTG	20	Provides DNA paternity testing services and holds broad patents relating to the use of non-coding DNA.	22%	-20%	\$0.06

## Bioshares Index

Company	Code	Cap. \$m	Principal Activities	Change - Quarter	Change - Year	Price 30/09/09
Imugene	IMU	19	Developing animal products such as antibiotic alternatives used in the stock feed industry using a vaccine and gene therapy approach	99%	121%	\$0.14
Bone Medical	BNE	18	Developing treatments for bone and joint degenerative diseases such as arthritis and osteoporosis.	-15%	-40%	\$0.17
Avita Medical	AVH	17	Markets ReCell, a skin repair product	70%	209%	\$0.17
Atcor Medical	ACG	17	Markets the SphygmoCor device, a noninvasive technology that provides information regarding the functioning of the cardiovascular system	-11%	70%	\$0.17
Benitec	BLT	17	R&D company focusing on gene silencing, specifically DNA delivered RNAi, technology.	84%	-2%	\$0.05
Imuron	IMC	16	Specialises in R&D of hyper-immune bovine colostrum products for therapeutic use in animals and humans.	177%	3%	\$0.07
Cogstate	CGS	16	Marketing cognitive performance diagnostic products.	2%	53%	\$0.25
Tissue Therapies	TIS	16	Developing the VitroGro product for ulcer and wound healing	28%	141%	\$0.21
Ellex Medical Lasers	ELX	15	Develops, manufactures and markets solid state ophthalmic lasers used to treat secondary cataracts and retinal disorders.	38%	-28%	\$0.18
Labtech Systems	LBT	15	Developing the MicroStreak technology for the automation of microbiology laboratory processing	20%	-3%	\$0.15
Biotron	BIT	15	Developing a compound to treat HCV	65%	0%	\$0.14
Acuvax	ACU	15	Holds interests in various therapeutics and vaccines	-21%	-54%	\$0.02
Biopharmica	BPH	14	Managing cancer treatment and detection and bacterial DNA diagnostic projects. Portfolio investment approach.	582%	305%	\$0.15
Advanced Surgical Design & Manufacture	AMT	14	A developer and manufacturer of prosthetic implants and medical devices	43%	11%	\$0.40
Biodiem	BDM	13	Focused on the development of LAIV influenza vaccines	97%	59%	\$0.18
Cyclopharm	CYC	13	A nuclear medicine company that markets the Technegas lung imaging system	-7%	-42%	\$0.08
Optiscan Imaging	OIL	13	Manufacture of confocal microscopes for clinical diagnosis	168%	-39%	\$0.11
Fluorotechnics	FLS	12	Development and sale of scientific equipment and consumables, including fluorescent stains.	-20%	0%	\$0.40
Tyrian Diagnostics	TDX	11	Formerly Proteome Systems. Developer of diagnostic products.	-12%	-67%	\$0.02
Virax Holdings	VHL	11	Developing a therapeutic and prophylactic vaccine for HIV.	106%	112%	\$0.07

## Bioshares Index

Company	Code	Cap. \$m	Principal Activities	Change - Quarter	Change - Year	Price 30/09/09
BioProspect	BPO	11	Developing insecticides from naturally occurring molecules	35%	21%	\$0.02
Neuren Pharmaceuticals	NEU	10	Developing neuroprotective therapeutics	50%	-49%	\$0.04
Giaconda	GIA	10	Developed novel (patented) combinations of registered drugs for the treatment of gastrointestinal disorders.	352%	-3%	\$0.14
Cytopia	CYT	10	Small molecule drug development company with a focus on kinase targets. Lead program, CYT997 is at the Phase II level of development.	64%	-25%	\$0.12
ITL	ITD	10	Develops and distributes medical devices such as safety equipment to prevent needle stick injuries and sterile preparation kits.	-3%	-23%	\$0.08
Austofix	AYX	10	Manufacturer and developer of orthopaedic fixation devices	0%	0%	\$0.85
Metabolic Pharmaceuticals	MBP	10	Holds a 60% stake in PolyNovo, a polymer chemistry company.	19%	0%	\$0.03
Fermiscan Holdings	FER	10	Commercialising the use of x-ray diffraction to aid in the screening of breast cancer.	-32%	-78%	\$0.07
Viralytics	VLA	10	Developing a cancer treatment based on the application of viruses (oncolytic virus technology).	-9%	-42%	\$0.03
Healthlinx	HTX	10	Detecting novel functions of known and new protein and peptides for therapeutic purposes.	214%	175%	\$0.09
PharmAust	PAA	9	Operates Epicchem and PharmAust Manufacturing, which provide products and services to biotech and pharma companies	80%	80%	\$0.04
Vita Life Sciences	VSC	9	Development, manufacture and distribution of prescription and OTC medicines as well as complementary and alternative medicines, dietary supplements and health foods.	-10%	20%	\$0.18
Analytica	ALT	8	A medical devices company that has developed a retractable syringe	0%	10%	\$0.02
Medical Developments	MVP	8	Commercialising the Penthrax inhaler for temporary pain relief. Used widely in ambulances across Australia.	14%	-27%	\$0.16
Medigard	MGZ	8	Developed retractable syringe technology and other safety medical products.	41%	71%	\$0.12
BioMD	BOD	7	Developing a tissue engineering technology, termed ADAPT	32%	-36%	\$0.06
Agenix	AGX	7	<b>Currently suspended from trading.</b> Developing Thromboviev, a blood clot diagnostic imaging agent.	0%	0%	\$0.02
Helicon Group	HCG	7	Exploiting niche market opportunities for medical products in China and other Asian markets.	196%	167%	\$0.08
Occupational & Medical Innovations	OMI	7	Developing safety devices used in the healthcare industry, including safety syringes.	16%	-42%	\$0.15
IM Medical	IMI	6	Markets the Intelliheart Cardiovascular Diagnostic System. Now acquiring a radiology and imaging business.	0%	-33%	\$0.004

## Bioshares Index

Company	Code	Cap. \$m	Principal Activities	Change - Quarter	Change - Year	Price 30/09/09
Stirling Products	STI	6	Development of R-Salbutamol based products and the Immunoxell immune modulator	-36%	-64%	\$0.01
Medical Therapies	MTY	6	Developing therapies that target the midkine protein	50%	-48%	\$0.03
Resonance Health	RHT	5	Marketing the FerriScan technology, a non-invasive tool for measuring liver iron levels	7%	15%	\$0.02
Medic Vision	MVH	5	Currently suspended from trading. Marketing training software and hardware for surgeons.	0%	-40%	\$0.05
Cryosite	CTE	4	Provides specialised storage services, especially for umbilical cord blood	-10%	-31%	\$0.09
Probiomics	PCC	4	Proprietary ownership of a unique probiotic strain	71%	0%	\$0.01
Anteo Diagnostics	ADO	3	Developer of a biological coatings technology that can be applied to immunoassays, bio-separations, drug delivery and other medical devices.	-10%	-64%	\$0.01
OBJ	OBJ	3	Developing transdermal drug delivery technologies	0%	-60%	\$0.00
Incitive	ICV	3	Has acquired V-Patch Medical Systems.	-11%	-73%	\$0.01
NuSep	NSP	3	Manufacture and sale of protein separations technologies.	240%	240%	\$0.17
Actinogen	ACW	3	Early stage developer of antibiotics that show activity against MRSA and VRE bacteria	-26%	-7%	\$0.07
Narhex Life Sciences	NLS	3	Currently suspended from trading. Developed a low cost protease inhibitor for treatment of HIV in Chinese market.	0%	0%	\$0.02
Telesso Technologies	TEO	2	Funding a trial of US company Vascular Pathways' guidewire assisted peripheral catheter, with view to acquisition.	25%	-11%	\$0.04
NeuroDiscovery	NDL	2	Provides electrophysiology services to biotech and pharma, and is developing range of compounds for treating neuropathic pain.	11%	-54%	\$0.04
Atos Wellness	ATW	2	Manages wellness centres in Singapore, Malaysia, India, Australia, Austria and Germany	-8%	-70%	\$0.01
Genesis Research & Development Corp.	GEN	2	Developing RNAi based therapeutics. Interests in agricultural biotechnologies.	20%	-25%	\$0.06
Select Vaccines	SLT	1	Development and commercialisation of infectious diseases diagnostics, vaccines and therapeutics for hepatitis-related diseases	33%	-56%	\$0.00
<b>Capitalisation Total</b>		<b>6,737</b>				

## Listed Biotech Investment Funds

Company	Code	Cap. \$m	Principal Activities	Change - Quarter	Change - Year	Price 30/09/09
Biotech Capital	BTC	20	A Pooled Development Fund investing in unlisted Australian biotech companies and in public biotechs, including Alchemia, Starpharma, Neurodiscovery and Phylogica.	50%	66%	\$0.24
Xceed Capital	XCD	3	Holds a 25.5% stake Polynovo and owns 100% of Boron Molecular, a chemistry services company.	30%	-60%	\$0.03

**Capitalisation Total** 20

**Capitalisation Total - All Indexs** 34,951

**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, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx

**Disclaimer:**

Information contained in this newsletter is not a complete analysis of every material fact respecting any company, industry or security. The opinions and estimates herein expressed represent the current judgement of the publisher and are subject to change. Blake Industry and Market Analysis Pty Ltd (BIMA) and any of their associates, officers or staff may have interests in securities referred to herein (Corporations Law s.849). Details contained herein have been prepared for general circulation and do not have regard to any person's or company's investment objectives, financial situation and particular needs. Accordingly, no recipients should rely on any recommendation (whether express or implied) contained in this document without consulting their investment adviser (Corporations Law s.851). The persons involved in or responsible for the preparation and publication of this report believe the information herein is accurate but no warranty of accuracy is given and persons seeking to rely on information provided herein should make their own independent enquiries. Details contained herein have been issued on the basis they are only for the particular person or company to whom they have been provided by Blake Industry and Market Analysis Pty Ltd. The Directors and/or associates declare interests in the following ASX Healthcare and Biotechnology sector securities: ACL, ACR, ADO, BNO, BTA, CGS, CSL, CST, CXD, CYT, CUV, CXS, FLS, HGN, HXL, IDT, IMU, MBP, PAB, PBP, PLI, PXS, SHC, SPL, TIS, UBI. These interests can change at any time and are not additional recommendations. Holdings in stocks valued at less than \$100 are not disclosed.

**Subscription Rates (inc. GST)**

48 issues per year (electronic distribution): **\$320**

For multiple email distributions within \$550 2-3 email addresses  
 the same business cost centre, our \$750 4-5 email addresses  
 pricing structure is as follows: \$950 6-10 email addresses

To subscribe, post/fax this subscription form to:

**Bioshares**  
**PO Box 193 Richmond VIC 3121**  
**Fax: +61 3 9671 3633**

I enclose a cheque for \$ \_\_\_\_\_ made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card \$ \_\_\_\_\_ MasterCard  Visa

Card Number

Signature \_\_\_\_\_ Expiry date \_\_\_\_\_

**Subscriber details**

Name \_\_\_\_\_

Organisation \_\_\_\_\_

Ph ( ) \_\_\_\_\_

Emails \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_