ISSN 1443-850X

Bioshares

11 September 2009
Edition 328

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

In this edition...

The gates look to have opened for biotech capital markets coinciding with strong market performance of many biotech stocks not just in recent weeks but for the large part of this year. The announcement of the second $300 million plus M&A deal for the sector recently in the acquisition of Peplin is perhaps a tangible example of the value that can be created from drug development.

At this point we have put together the Bioshares Biotech Industry Score Card. The results are surprising.

We have also provided an update on Fluorotechnics. And is Acrux the next takeover target in the sector?

The Editors

Companies Covered: ACR, FLS

	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)	42.6%
Cumulative Gain	**177%**
Av Annual Gain (9 yrs)	**17.8%**

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

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Individual Subscriptions (48 issues/year)
$320 (Inc.GST)
Edition Number 328 (11 September 2009)
ISSN 1443-850X

Gates Open For Biotech Stocks

For a third consecutive quarter, we expect Australian biotech stocks will deliver strong gains, as measured by the **Bioshares Index**. Sentiment towards biotech seems have changed positively and rapidly, not only locally but in the US as well. Australian biotechs, on a confidence measure, are global leaders if recent gains in local stocks are any indication. A key measure in coming months will be the biotech IPO market, which has opened in the US for more advanced companies in the last two months, and should open in Australia before year's end. A field of ten-to-fifteen private companies could begin the process of writing and filing prospectuses over the next twelve months.

In this month alone, **Pharmaxis** is expected to file its cystic fibrosis drug for approval with European regulators, **Acrux** is due to announce Phase III data from its Axiron trial, **Alchemia** may receive news regarding its ANDA submission with the FDA, and **Chemgenex Pharmaceuticals** has announced it has completed the filing of its lead oncology drug with the FDA.

By our estimates, we are one-third of the way into what may be a two year bull market for the Australian biotech sector. In Australia the turnaround in interest in biotech has been driven by two things: two $300 million plus acquisitions announced this year, of **Arana Therapeutics** and **Peplin**, and the proximity to market for a dozen or so leading biotechs. This is a period that has been anticipated for the last three years and is the culmination of a 10 year investment cycle.

With funding access for biotechs improving for not just Tier-1 biotechs but also for the smaller companies in the sector, the Tier-2 biotechs have the opportunity to reconsider their commercial options in light of the more favourable funding climate that appears to be arriving.

Bionomics has announced it has secured follow-in funding of $7 million from **Start-Up Australia**, with an additional placement of $5.8 million made to other investors and a $2.2 million share purchase plan underwritten by **Linwar Securities**. All up, an impressive raising of $15 million.

Prana Biotech this week announced a capital raising of $6 million and **Sunshine Heart** is completing a $8.1 million rights issues following a $1.75 million placement. Patrys has completed a right issue, raising $5 million, with another $1.8 million to be taken up by the underwriter. **CathRx** completed a rights issue in July, raising $5.3 million and **Phosphagenics** has raised $7 million. The biggest sum raised in this quarter to date has been a US$60 million (~$75 million) follow-on round with **Heartware International**. The rolling total for the September quarter now stands at $137 million, compared to $133 million for the June quarter. With such a growing and positive interest at play for biotechs it is not difficult to see rights issues or placements now being seriously considered by many other companies in the sector.

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Bioshares Biotech Industry Score Card

With the announcement of the acquisition of **Peplin** by **Leo Pharma A/S**, valued in excess of $300 million, it appears the sector is sitting on the edge of a golden age. Following the acquisition of **Arana Therapeutics** by **Cephalon**, there is real evidence that value is starting to be crystallised, both through M&A and also through healthy profit growth. These occurrences are right on track and are consistent with the roughly decade long investment horizon that relates to biotech investments.

Has this investment into biotech delivered positive returns as measured by industry value creation? To answer this, we calculated capital supplied to biotech companies whose public market origins for the most part date from 1999-2000. We have excluded the businesses previously established, such as **CSL**, **Resmed**, **Cochlear** and **Sigma Pharmaceuticals**, but included companies such as **Biota**, **Novogen**, **Circadian** and **ChemGenex Pharmaceuticals**.

We then calculated the value of the successful businesses that have been created in this sector over the last 10 years and compared this value with the gross and aggregate investment made. The successful businesses we have put into three categories: (a) profitable businesses; (c) companies with products on the market or that have filed their products for approval with profitability anticipated in the next three years; and (c) companies that have been acquired.

We have included acquisitions that have been made by interna-

The Bioshares Biotech Industry Scorecard

Successful Biotech Businesses

Profitable companies		
Company	**Market Cap ($M)**	**Comments**
Biota Holdings	$378	$38 million profit in 2009
Cellestis	$335	Maiden profit in 2008
Sirtex Medical	$267	$18.2 million profit in 2009
Probiotec	$123	$8.9 million profit
Ascent Pharma Health	$46	-
Clover Corporation	$32	-
Compumedics	$32	-
Cogstate	$15	Maiden profit in 2009
Imugene	$14	Maiden profit in 2009
Labtech Systems	$14	Maiden profit in 2007
Ellex Medical Lasers	$14	-
Medical Developments	$11	-
Sub-total	$1,281	
Companies with products on market or filed for approval		
Company	**Market Cap ($M)**	**Comments**
Pharmaxis	$530	Main product Bronchitol filed for regulatory approval
Acrux	$242	Evamist on market with Axiron to be filed for approval in 2009
Chemgenex Pharmaceuticals	$211	OMAPRO filed for approval in US
Nanosonics	$91	First product released 2009
Alchemia	$80	Fondaparinux filed for approval
Impedimed	$65	Products on market
CathRx	$29	First product released 2008
Genetic Technologies	$19	Operating genetics testing business
Atcor Medical	$17	Products on market
Sub-total	$1,284	
Acquired business (or being acquired)		
Company	**Acquisition Value ($M)**	**Comments**
Arrow Pharmaceuticals	$800	Acquired by Sigma in 2005
Vision Systems	$791	Acquired by Danaher Corportation 2006
Peplin	$350	To be acquired by LEO Pharma 2009
Arana Therapeutics	$329	Acquired by Cephalon 2009
Axon Instruments	$186	Acquired by Molecular Devices in 2004
Amrad	$100	Acquired by CSL in 2006
Gropep	$96	Acquired by Novozymes in 2006
Panbio	$41	Acquired by Inverness Medical Innovations in 2007
Bresagen	$21	Acquired by Hospira in 2006
Enterix	$57	Acquired by Quest Diagnostics in 2006
Stem Cell Sciences	$7	Assets acquired by Stem Cells Inc in 2009
Sub-total	$2,778	
Total	**$5,343**	

– Scorecard cont'd

tional companies, or by local companies CSL and Sigma Pharmaceuticals, which have made acquisitions but are not included in the performance measure as they were previously established businesses.

This list of successful businesses so far only consists of around 30 companies. For inclusion into this category, these companies are required to have raised capital on the ASX in the last 10 years for product development. The list may not be exhaustive but seeks to capture the majority of the value of successful businesses that have been built over the last decade. Our expectation is the list will grow over the next three years.

In terms of funds raised, we totalled the capital raisings over the last decade (10.5 years) both from IPOs and follow-on placements, although for the years 1999-2001 inclusive, our records are only for capital raised from IPOs. (We estimate this would make up the majority of funds raised during that period. At the start of 1999, there were only 24 listed life science companies, with 49 companies listing in the sector in the period 1999-2001.)

Funds raised by Australian biotechs 1999-2009

Year	Funds raised ($M)
2009 (to June 30)	$160
2008	$183
2007	$943
2006	$613
2005	$638
2004	$504
2003	$570
2002	$99
2001*	$91
2000*	$379
1999*	$61
VC investment 1999-2009 (est.)	$420
Total	**$4,661**

** IPO raisings only*

We have also added an estimate for the level of venture capital that has been invested into private companies. Our rule-of-thumb is that venture capital investment into private companies accounts for about 10% of the funds invested through public equity markets.

The Results

In total, we estimate that over the last decade, just under $4.7 billion has been invested into the development of biotech programs in Australia in biotech (life science) companies. The peak of this investment occurred in 2007, when $943 million was raised by Australian listed biotechs, with the up-tick attributed to the funding requirements for several Phase III studies.

Approximately 12 profitable businesses have been formed in the last decade which continue to trade on the ASX. The most noteworthy of these are **Biota Holdings**, **Sirtex Medical** and **Cellestis**.

A further nine companies have products on the market or have filed their drugs for approval (**Pharmaxis**, **ChemGenex Pharmaceuticals** and **Alchemia**) and we would argue these businesses are approaching profitability in the next three years.

There have been 10 life science companies acquired in the last decade that we have recorded for which information is publicly available. The largest acquisition was of **Arrow Pharmaceuticals** by **Sigma** for $800 million, then followed by the acquisition of **Vision Systems** in 2006 for $791 million by **Danaher Corporation**, the proposed acquisition of **Peplin** for $348 million, and the acquisition of **Arana Therapeutics** earlier this year for around $330 million (figures are approximate because of currency movements and changes in acquirer's stock price). The acquisition of **Mayne Pharma** in 2006, which was a previously established business, has not been included.

The current tally for the net value of these 30 successful Australian life science businesses is $5.3 billion, $682 million more than what has been invested in the sector over the last decade.

This measure includes the high profile failures in the sector such as **Chemeq**, **Metabolic Pharmaceuticals**, **Ventracor** and **Progen Pharmaceuticals** but does not include the biotech companies that remain in the development phase and have yet to bring their products to market for have them filed for approval.

Comments

As a second wave of Australian biotechs move into a value crystallisation phase, it is a very promising sign that current value of the successful businesses that have been formed in the last decade exceeds the investment made over that period, currently by $682 million.

This equation does not take into account the time value of money or the investment return over this period that should be expected. It also does not take into consideration the benefit of investment cash flow as an internal dynamic in the sector.

However, given that more companies in the sector are approaching value realisation points on the technology commercialisation curve, this will be an interesting measure to monitor over the next three years. Our expectation is that the cumulative value of successful businesses, by capitalisation or acquisition value, will far exceed the investment that has occurred.

It is of interest to note also that the value of the companies acquired ($2.8 billion) comes close to matching the value of successful existing businesses ($2.5 billion) that remain listed on the ASX.

Note that the value of government investment into this sector through grants has not been measured. The output from government investment is presumably measured through exports, employment and taxes returning to the government from creation of profitable businesses.

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Fluorotechnics to Launch New Product – 'The Flat Top Tower'

Fluorotechnics (FLS: $0.44) develops and markets genomics, cell biology consumables and proteomics (or protein) research workflow products. The company has operations in Sydney, San Francisco, and Tübingen in Germany. It employs 27 people, including 5 in Australia, and deploys a sales force of 10 personnel. The company represents the merger of three businesses. Fluorotechnics from Sydney contributed fluorescence-based consumables, ETC Elektrophorese-Technik GmbH in Germany contributed high-end electrophoresis pre-cast gels, consumables and equipment and The Gel Company in San Francisco contributed cell culture, DNA-sequencing, proteomics and microarray consumables and equipment. Although the company retains the name Fluorotechnics for corporate reason in Australia, it has now adopted 'gel company' as its global corporate brand and identity.

The Proteomics Workflow

The proteomics workflow begins with sample preparation and quantification and followed by a separation step. This step has been performed using gel electrophoresis (1D or 2D) although other methods such as chromatography are also used. Fluorotechnics sells the Lava prep kit for the preparation step, and a variety of products that fit within the separation step, including gels, blotting membranes (Western format), cassettes and electrophoresis units.

New Product – The Flat Top Tower

Fluorotechnics has recently developed a horizontal high performance electrophoresis unit (a 'flat top tower') that combined with the company's proprietary polyacrylamide gels, is expected to provide a new level of performance in protein separation. The unit can run four gels simultaneously.

A flat top unit means that a higher voltage can be run through the gels. However, the reason that flat top units have not been successful in the past is because the standard gels burn. Fluorotechnics, through its acquisition of ETC Elektrophorese-Technik GmbH, has a plastic gel that does not burn at higher voltages. In addition, the plastic gels offer a superior sensitivity to traditional gels because they contribute far less background 'noise'.

A perennial problem for proteomics researchers is the identification of rare or low abundance proteins. Innovations that enable improvements in the separation phase of protein research should be met positively by research customers.

The flat top system, which includes the unit itself, gels, stains and accessories, is being launched this month at an annual proteomics conference in Toronto. The list price of the system is approximately $22,000 (€13,000), a figure that sits within the purchasing limits of most lab heads. Nine prototypes have been sold to reference sites to date.

Fluorotechnics' objective is to capture market share from other suppliers to the electrophoresis market. Fluorotechnics estimates the market for consumables in the electrophoresis segment is US$600 million per annum.

One element of the proteomics work flow that Fluorotechnics does not have under its own badge is an IPG (isoelectric polyacrylamide gel) strip. However, the company is working to incorporate this product into its lineup.

Competitors

The big workflow solution companies are **Biorad**, **GE** and **Life Technologies** (formerly **Invitrogen**). However, a major competitor in the gels market are scientists who make their own gels (DIY). However, where DIY gels may compete on price, their weakness is in quality, with a significant percentage of DIY gels being disposed of due to imperfections.

Financials

Fluorotechnics reported sales of $3.3 million for FY2009, and posted a loss of $5.6 million after forecasting a FY2009 sales figure of $7.5 million. The company now anticipates generating sales in FY2010 from proteomics systems of $8.2 million, with overall sales guidance of $10-$12 million for FY2010.

Investment Points

There are several points about Fluorotechnics that increase the appeal of this company as an investment proposition.

Hunter Hall and share register

The largest single shareholder of Fluorotechnics' stock is value investor Hunter Hall. Following a recent $1.3 million capital raising Hunter Hall now owns 26% of the firm. Board and management hold about 35% of the company. Hunter Hall's long position in stocks, unfettered by the time constraints can be a benefit to companies such as Fluorotechnics that are in early stage of entrenching themselves in the market.

Cash flow generating business

Fluorotechnics sells an extensive catalogue of products, including third party items, of over 600 products and consumable items. The company is a cash generating business and is not a development stage biotech. As the company moves to profitability, we expect the stock to begin to appeal to a wider range investors with an interest in profitable industrial stocks.

An established customer base

The acquisition of The Gel Company brought a base of 800 customers into the expanded Fluorotechnics business.

Summary

Fluorotechnics disappointed investors when it failed to meet revenue forecasts for the financial year just ended. The company is going out on a limb again with forecasts for FY2010. However, with economic conditions easing after the tumult that engulfed economies the world over in the second half of 2008, we expect the company has a more reasonable chance of meeting its targets for FY2010. Fluorotechnics is capitalised at $13 million.

Bioshares recommendation: **Speculative Buy Class B**

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Acrux for Sale?

We expect M&A activity in the Australian biotech sector to continue for the next 12-24 months. One company that is very likely to be in the sights of larger suitor is **Acrux** (ACR: $1.45). With one product, Evamist, already on the market in the US and due to be released in other major markets in the next 12 months through distributors, animal health products expected to gain approval in the next 12 months through Eli Lilly, and potentially a highly valuable product in Axiron (a testosterone gel for males) due to be filed for approval by year's end pending favourable Phase III data (to be announced this month), Acrux is a highly rated takeover target.

What will bring the issue to the foreground is an expected licensing deal for Axiron, which we anticipate should occur in the next three to six months. A potential deal for this product could be worth as much as US$300 million in up front and future milestone payments (FDA approval and achievement of sales targets). The market for male testosterone is valued at US$1 billion a year and is growing annually at 20%. Acrux appears to have a potentially superior product to its competitors, including Androgen which generates sales of US$550 million a year.

Acrux is currently capitalised at $230 million. At a share price of between $2.30 - $2.40 a share, Acrux could be acquired for $370 million - $400 million, which translates to a 60%-70% premium to its current share price. At these prices, an outright acquisition would likely be more appealing than a straight licensing deal in the order of US$300 million for just the one product in one market.

As mentioned last week, only two weeks ago **ProStrakan Group** signed a US$210 million deal with **Endo Pharmaceuticals** for an inferior product which is virtually at the same stage of development as Axiron.

Whether Acrux is acquired or out-licenses Axiron has likely more to do with the company's share price. If it were trading at $2.50 a share ($400 million market cap), then a minimum sale price of $600 million - $680 million could be set for the company, in which case, a major licensing deal would more likley be successfully transacted.

Acrux is currently a standout opportunity, with the stock potentially set to achieve a 50%-70% gain by year's end, pending positive Phase III data for Axiron, where we would judge the risk profile to be relatively low for speculative investment.

Bioshares recommendation: **Speculative Buy Class A**

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Bioshares Model Portfolio (11 September 2009)

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$0.83	$0.25	December 2008
Hexima	$0.52	$0.60	October 2008
Atcor Medical	$0.17	$0.10	October 2008
CathRx	$0.41	$0.70	October 2008
Impedimed	$0.59	$0.70	August 2008
Mesoblast	$1.09	$1.25	August 2008
Cellestis	$3.49	$2.27	April 2008
Circadian Technologies	$0.73	$1.03	February 2008
Patrys	$0.12	$0.50	December 2007
Bionomics	$0.28	$0.42	December 2007
Cogstate	$0.23	$0.13	November 2007
Sirtex Medical	$4.78	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.30	$0.66	September 2007
Starpharma Holdings	$0.46	$0.37	August 2007
Pharmaxis	$2.43	$3.15	August 2007
Universal Biosensors	$1.36	$1.23	June 2007
Biota Holdings	$2.16	$1.55	March 2007
Probiotec	$2.45	$1.12	February 2007
Chemgenex Pharma.	$0.75	$0.38	June 2006
Cytopia	$0.14	$0.46	June 2005
Acrux	$1.52	$0.83	November 2004
Alchemia	$0.50	$0.67	May 2004

Portfolio Changes – 11 September 2009

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, 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

Subscription Rates (inc. GST)

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

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