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In this edition...
Some cash is on the way to loyal Biota shareholders who backed the company in the early days of its litigation with GSK. While representing an attempt to act in a consistent manner, perhaps the more significant event this week was the handback of its RSV compound partnered to AstraZeneca. Biota has comfortably absorbed this 'setback' and we may yet see an improved version of the drug re-licensed in a year or two.
Another company where patience has been the key is Alchemia, whose generic version of GSK's anti-coagulant Arixtra edges closer to market. Approval may be gained as soon as September. We also include updates on Mesoblast and ASDM and contributed discussion by Craig Hickman of Asset Selection Advisers.

The Editors
Companies Covered: ACL, AMT, BTA. 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)	23.9%
Cumulative Gain	**140%**
Av Annual Gain (8 yrs)	**14.7%**

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Bioshares

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Edition 324

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

A Vindication for the Biota Business Model

Biota Holdings (BTA: $2.08) issued three announcements to the market this week. The first announcement was that **Astra Zeneca** had returned the respiratory syncytial virus drug candidate BTA9881. The second announcement declared the results from the Phase III trial of CS-8958, now termed laninamivir, conducted by partner **Daiichi Sankyo** in Japan, Taiwan, Hong Kong and Korea. The third announcement revealed Biota's intent to return $20 million to shareholders.

The Phase III trial enrolled about 1,000 subjects who tested positive for influenza A or B. The subjects were administered either 20mg or 40mg of laninimivir as a single inhaled dose, or were administered 75mg of oseltamivir (Tamiflu capsule) twice daily for five days. Laninimivir was found to be non-inferior to oseltamivir at both the 20mg and the 40mg dose. The 40mg dose of laninimivir was found to be more effective than the 20mg dose and both doses were well tolerated.

Laninimivir has been developed as along acting neuraminidase inhibitor, a next generation version of zanamivir (Relenza). The benefits that could acrue from laninimivir are significant, with only one dose required versus 10 for Relenza and Tamiflu. The reduction in drug material also has beneficial implications for stockpiling and drug pricing.

Daiichi Sankyo expects to file a new drug application this year in Japan and the drug may be on the market in that territory in time for the 2010/11 northern hemisphere flu season. The rest-of-world (ex-Asia) rights for laninimivir remain available for license. As many as ten companies from the anti-infectives or respirator disease space could prospective partners, with **GlaxoSmithKline** and **Roche** the most obvious candidates given their hold on the market with Relenza and Tamiflu respectively. Now that the Phase III results from the Asian study are available, it is reasonable to expect that one of the next major events for Biota is to secure a rest-of-world licensee. Biota and Daiichi would share equally in milestone payments and royalties from such a license.

Biota has in excess of $85 million cash at hand. We expect these cash resources to grow significantly as GlaxoSmithKline ramps up production and sales of Relenza. GSK recently announced increasing Relenza production to 190 million treatment courses (90 million Diskhaler format and 100 million Rotohaler format), a decision that could see in excess of $300 million in royalties flow to Relenza, if such production levels are sustained on an annual basis. Note that in 2006 GSK was producing 15 million courses a year and in the second half of 2007 it had increased annual production to an implied 26 million courses. Note also that the Relenza patents expire in 2014 in most major regions.

With the prospect of substantial revenues, it is relatively easy to comprehend how Biota's board has reached a decision to initiate a capital return of $20 million, worth 11 cents per share.

Cont'd on page 4

Only 2 Weeks To Go!

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We have a few remaining accommodation-registration packages available. Contact events@bioshares.com.au

We look forward to seeing you there!

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Alchemia Drug Moves Closer To Approval

Alchemia's (ACL: 49.5 cents) generic version of **GlaxoSmithKline's** blood thinning drug Arixtra (generic name fondaparinux) is expected to receive FDA approval (ANDA) by year's end, potentially by 13 September, six months after filing its drug for approval. The FDA may have some further questions that will need to be answered by Alchemia's partner **Dr Reddy's**. Anticipation of approval, with this date approaching, has been the reason for the increased interest in this stock this week.

Once the ANDA is received, Dr Reddy's will start to sell the drug immediately. It has already contacted the 10 major hospital purchasing groups in the US as well as major retail pharmacy chains. Once the company has clarity on the timing of availability of the drug, it will start to lock in sales contracts with these groups.

Many major purchasers of Arixtra will likely want to stock a generic version of Arixtra, if only to have two different suppliers of the drug should one not be available for any reason. So we expect take up of Alchemia's fondaparinux to be rapid.

Expected profit share for Alchemia

In the most recent quarter (Q2, 2009), GSK sales for Arixtra were US$52 million in the US. US sales are the important figures to watch, because this is where Alchemia's fondaparinux will be sold first. The US also has the highest drug prices, so it is the most lucrative market. Based on this figure, we expect Alchemia to receive a profit share of $33 million a year. This assumes generic fondaparinux achieves 40% of the market with a 20% price discount. (Its market share could be higher and the price discount could be less, say 10%).

Over the last three years, Arixtra's annual sales growth has been consistent, increasing by US$31 million in 2006, by US$51 million in 2007, and by US$54 million in 2008. Arixtra sales continue to grow and we anticipate sales to be tracking at over US$60 million a quarter this time next year (US$240 million a year). At this sales level, we calculate Alchemia's profit share income should be around $38 million based on the same assumptions listed above.

Switching from Lovenox to fondaparinux?

Fondaparinux has the potential to show continued and consistent sales growth as has occurred over the last three years. An oral anticoagulant drug Xarelto from **Bayer** has yet to make any significant inroads into the blood thinning market to break the Lovenox market stranglehold, although they are still early days for Xarelto. Within two years time, Alchemia's profit share could approach $50 million a year if the market for fondaprinux continues to experience similar growth.

An unknown is if switching will occur from Lovenox to fondaparinux if there is a cheaper fondaparinux available. The price for daily treatment using Arixtra is between US$24-US$25 in the prevention of DVTs and PEs following knee or hip surgery (online pharmacy prices and prices to major hospital prices will be different but this gives an indication of the pricing dynamics). Following knee replacement, Lovenox is prescribed twice daily (30mg), which costs around US$22 a day. The advantage with Arixtra is that patients need to inject only once a day but the price is slightly higher.

Following hip surgery, Lovenox therapy can be as prescribed as above (30mg twice daily), or a higher dose (40mg) once a day, depending on the prescribing physician. The price for this latter treatment is around US$14.50 a day (from the pharmacy), which is significantly cheaper than Arixtra.

The question is whether a less expensive generic form of fondaparinux, selling at a 20% discount, at say US$20 a day, will see some switching from the 30mg twice daily Lovenox group (US$22 a day) to Alchemia's fondaparinux. We would anticipate there will be some switching but this will be modest.

Summary

The Arixtra drug has now secured close to 10% of the heparin market for GSK, with Lovenox maintaining the lion's share. To date there has not been significant pricing erosion, with **Sanofi-Aventis** prepared to allow GSK to take some market share without cannibalizing the market. The entry of a third player, a generic fondaparinux from Alchemia/Dr Reddy's, we suspect will be allowed to also gain its share in this market without destabilising the market through severe price cutting.

From this Alchemia should start to benefit quite well in 2010 – from a business plan that was formed at the start of this decade and remains largely unaltered – when its drug becomes the first, and at this stage, the only known generic version of Arixtra. According to Peter Smith, Alchemia's CEO, fondaparinux is one of the most difficult drugs to synthesize. Alchemia's technology reduces the number of manufacturing steps by about half, we estimate, providing a barrier to entry for other generic players.

Alchemia is capitalized at $80 million and held $8.3 million in cash at the end of June.

Bioshares recommendation: **Speculative Buy Class A**

Mesoblast Update

Mesoblast (MSB: $1.17) has added another clinical trial to pipeline in assessing the benefits of its adult stem cell therapy through its investee company Angioblast Systems. The trial will see Angioblast's stem cells injected into patients undergoing an LVAD (heart pump) implant procedure for bridge-to-transplant, using the Thoratec LVAD system.

The aim is to see if these patients, who are awaiting a heart transplant and are being supported by the mechanical heart pump, will benefit from adult stem cells injected directly into the heart muscle. If the therapy works, potentially the patients could benefit sufficiently to not require a heart transplant and have the LVAD removed. Given that the patients are already undergoing heart surgery, delivery of the cells into the heart should be straightforward.

It should be noted that these patients have severe heart disease (Stage IV) and to repair these heart muscles will be extremely difficult. However if there are obvious signs of benefit from the stem cell therapy in this patient group, then it's expected the therapy would be more easily acievable in less ill patients.

The trial is being sponsored and funded by the **National Institutes of Health** with Principal Investigators managing the trial from the **Mount Sinai School of Medicine** in New York, and the **Columbia University Medical Center** also in New York. The trials will be conducted across 16 sites in the US with final data expected to be out in September 2010.

This trial brings to seven the number of trials assessing Mesoblasts MPC therapy, with six currently recruiting (see table). Mesoblast owns 38% of Angioblast Systems. The company is capitalised at $160 million with $16 million in cash at the end of June. The risk with Mesoblast is that all product applications are based on the one class of therapeutic cells.

Bioshares recommendation: **Speculative Buy Class A**

Mesoblast's Trials

Indication	Phase	Location	No. Patients	Status
Spine fusion (lumbar)	Phase I/II	Texas	24	Recruiting
Spine fusion (lumbar)	Phase I/II	Massachusetts	40	Recruiting
Knee osteoarthritis after ACL reconstruction	Phase II	Melbourne	24	Recruiting

Angioblast Systems' Trials

Indication	Phase	Location	No. Patients	Status
Heart failure	Phase II	Arizona, California, Minnesota & Texas	60	Recruiting (all sites)
Heart attack (using Cordis Biosense catheter)	Phase I/II	Minnesota & Texas	25	Recruiting (both sites)
Combination with LVAD implant	Phase II	USA, 16 sites	80	Not recruiting
Bone marrow reconstitution	Phase II	Texas (MD Anderson Center)	20	Recruiting

Source: ClinicalTrials.gov

– Biota cont'd

However, the Biota board is also attempting to maintain consistency with its decision to raise funds in October 2004 ($20 million) and October 2005 ($31 million). One of the reasons behind the October 2005 raising was to reinforce the company's balance sheet while it was in litigation with **GlaxoSmithKline**. With that legal dispute now out of the way, grounds exist to return some of that capital to shareholders. The reality is, however, that capital returns (or dividends) only make sense when there is a genuine surplus of capital over what a business needs to continue in a sustainable fashion. More precise details of the capital return are pending a ruling by the ATO.

Perhaps the most significant of the three announcements made this week was the most negative, that of the RSV drug handback by AstraZeneca. Counter-intuitively, the event provides evidence that the Biota drug development model (really its business model) works. The company aims to manage the risk involved in drug development by shifting this risk to partners much earlier in the development stage (pre-clinical or Phase I), and with more frequency. Biota spent perhaps $15-$17 million on developing BTA9881 but received through milestone payments, upfront fees, territory payments and fee for service income, an estimated $34 million in revenues. In other words Biota shareholders, in crude terms, have made nearly a 100% return on this project to date.

According to Biota, AstraZeneca did not think the drug had a wide enough therapeutic window. Biota now intends to invest a further $3 million in BTA9889 to improve the drug's profile. It is possible that AstraZeneca was being ultra-conservative in assessing the drug, but doing so in the context of an ever increasingly safety conscious FDA. However, Biota is of the view that the market opportunity in RSV is such that this further investment in the drug is warranted.

Handbacks have occurred before with Australian biotechs, including **Allergan** handing back PEP005 to **Peplin**, **Merck** handing back the LAIV to **Biodiem**, and **Serono** handing back LIF to **Amrad**. Peplin and Biota have demonstrated that it does not mean the end of the company, although in that case the stock price remained weak for months. The Biota experience now serves to demonstrate that specialisation and program breadth is integral to building a successful drug development business, provided that capital is available to cover the costs of half a dozen pre-clinical projects at any one time.

Biota is capitalised at $364 million. The stock continues to hold upside for investors.

Bioshares recommendation: **Buy**

Advanced Surgical Design and Manufacturing – Update

Advanced Surgical Design and Manufacturing (ASDM) (AMT: 39.5 cents) is a Sydney-based firm that specialises in manufacturing orthopaedic implants and surgical products and devices. The company holds the world-wide manufacturing rights to Allvascular Pty Ltd's peripheral access device (PAD), a device invented by Dr Ronald Lane, a vascular surgeon at Sydney's Royal North Shore Hospital.

This week, the PAD was approved by the TGA as a Class IIa device, which allows the device to be used to trial isolated limb and organ chemotherapy. The PAD enables a treatment termed 'isolated perfusion therapy' to be conducted, in which a limb or organ's blodd vessels are isolated as a closed circuit. Anti-cancer compounds can be delivered at higher doses to the effected limb or organ and other sensitive organs can be spared the drugs. A benefit of the PAD is that repeat treatments can be performed with far greater convenience than current ballon catheter method.

Obtaining TGA approval for the PAD as a Class III device and hence for use for hyperperfusion therapy has proven more demanding, with the company looking to conduct a trial with at least 15 patients, and up to 25. The trial is expected to be completed in 12 months, using several different surgeons at several sites in Australia. ASDM will fund the trial.

A pilot study that enrolled 18 patients has been completed. However, results from this pilot trial have not been published.

Hyperperfusion therapy involves isolating the veins and arteries in a limb, commonly a limb of a diabetic patient that is gangrenous and at risk of amputation, and pumping the blood back through the leg at a higher pressure. The higher-pressure blood flow promotes blood vessels growth in the limbs.

The objective of the trial is to demonstrate that the device is safe, to show that the PAD does not leak at high pressure, that there is no infection, and that blood flows without causing clotting.

ASDM is capitalised at $14 million. The company expects to report an improved net cash position for the six months ending June 30, 2009, compared to the previous six months.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (14 August 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	$0.40	$0.30	December 2008
QRxPharma	$0.62	$0.25	December 2008
Hexima	$0.57	$0.60	October 2008
Atcor Medical	$0.19	$0.10	October 2008
CathRx	$0.30	$0.70	October 2008
Impedimed	$0.57	$0.70	August 2008
Mesoblast	$1.17	$1.25	August 2008
Cellestis	$3.55	$2.27	April 2008
IDT	$1.64	$1.90	March 2008
Circadian Technologies	$0.74	$1.03	February 2008
Patrys	$0.10	$0.50	December 2007
Bionomics	$0.22	$0.42	December 2007
Cogstate	$0.26	$0.13	November 2007
Sirtex Medical	$4.15	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.32	$0.66	September 2007
Starpharma Holdings	$0.38	$0.37	August 2007
Pharmaxis	$2.56	$3.15	August 2007
Universal Biosensors	$0.90	$1.23	June 2007
Biota Holdings	$2.13	$1.55	March 2007
Probiotec	$2.21	$1.12	February 2007
Peplin Inc	$0.56	$0.83	January 2007
Chemgenex Pharma.	$0.66	$0.38	June 2006
Cytopia	$0.08	$0.46	June 2005
Acrux	$1.20	$0.83	November 2004
Alchemia	$0.49	$0.67	May 2004

Portfolio Changes – 14 August 2009

IN:
No changes

OUT:
No changes

Contributed Discussion

Observations of a Biotech Investor

by Craig Hickman

There I was, a couple of weeks ago, rushed to Monash Medical Centre following a pretty bad seizure. After various tests I finally got to see the neurologist. Some more tests and the recommendation of an MRI and medication. Upon prescribing medication he asked "do you want the generic brand?" "No thanks," was my reply. "I'm a biotech investor, I want to pay for all the years of R&D that went into the drug."

I've been following biotech for some time now having been engaged to provide corporate governance advice to institutional investors a few years back. Corporate governance and biotech may seem like a bit of an anathema but as an investor one thing I like is 'skin in the game', management and directors feeling the pain as much as me when the share price gets hit!

When I started investing in the sector I noted commentary in analyst reports including 'not for the faint hearted' or speculative buy. That should be enough to cause an investor to shy away from the sector given other opportunities available in the share market, especially on a risk adjusted basis. Those opportunities have become more apparent due to the GFC. That approach, I believe, misses the point. Biotechs provide diversification in a portfolio. Moreover, you've got to be in it to win it. Have a look at Biota. Biota was languishing at around 50 cents for what seemed like an eternity. The stock had surged to above $2.00 recently largely on the back of the swine flu pandemic and potential sales of Relenza and increased royalties from GSK. I note that analysts have largely removed 'speculative' from their Buy recommendations.

Believe it or not you can make money trading biotech. That's right, trading biotech! As other investors in the sector and management of biotech often lament, the liquidity of biotech stocks is terrible. However, for those in the know, that illiquidity can provide wonderful trading opportunities or even good entry points for long term investors. Recently there have been some large blocks of stock coming out of transition portfolios where a large fund has redeemed its portfolio from a fund manager. The transition portfolio is typically advertised to the market by the broker and dealt at the Volume Weighted Average Price or VWAP. The problem for the transition manager is that there is little or no volume in the biotech stock [and other small cap stocks] so they sell at a discount to clear the line. Investors and traders have been able to purchase some late stage biotechs at large discounts to market to clear the line and slowly sell that line at a profit in a timely manner or hold the stock with an attractive entry price.

There has been significant discussion in biotech articles about the two tiered market for Biotechs; "the haves and the have nots." Many of the 'haves' are conducting Phase III trials and have sufficient cash either from a partnering deal or a recent capital rasing. The 'have nots' are a different matter. Brokers suggest that if the company's market cap is less than $50 million it's difficult to attract institutional support largely due to the illiquidity of the stock and an apparent willingness to want to remain below the 5% substantial shareholder disclosure threshold. I think such apathy presents a wonderful opportunity for long term professional investors including those who run SMSF's to acquire stakes of some microcap companies at very low enterprise values, if any! Many of the microcaps are trading at cash backing or just above cash and that valuation does not reflect the technology value of the company. Moreover, and possibly due to a perceived seller of stock or potential capital raising, the market capitalisation of one biotech company may appear glaringly cheap when compared to another with similar technology and importantly similar cash levels and cash burn rate. Although hard to fathom, such discrepancies may provide opportunities for those with a long term time horizon.

Despite the warnings about investing in biotech, the opportunities can be significant. And wouldn't it be great to think that our capital was being deployed to improve the quality of life or to supply a drug to a disease where there is presently an unmet medical need.

Craig Hickman is a Principal of ASSET SELECTION ADVISORS Pty Ltd, a boutique financial advisory firm. All client portfolios have an allocation to biotech stocks. Craig can be contacted at CraigHickman@optusnet.com.au

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

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