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# Biosshares

12 August 2011
Edition 420

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

**In this edition...**

Enter stage left, a new character in the Alchemia story. In this case an Authorised Generic of GSK's Arixtra has emerged, with GSK permitting Canadian company Apotex to sell a generic version. The decision will cut into Alchemia's profit share from its manufacturing and marketing partner Dr Reddy's. The move triggers questions about the future funding of its Phase III oncology program.

Market volatility has seen a slight easing in the AUD/USD exchange rate. A lower exchange rate can be expected to benefit a bevy of life science stocks and we briefly discuss three: Acrux, Cogstate and Sirtex Medical.For biotech bargain hunters we highlight four stocks that have fallen to attractive levels from 52 week highs.

**The Editors**

**Companies Covered: ACL, ACR, BTA, CGS, GTG, NAN, QRX, SRX**

| | 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 - May '10) | 49.2% |
| Year 10 (May '10 - May'11) | 45.4% |
| Year 11 now commenced | -18.1% |
| **Cumulative Gain** | **245%** |
| **Av Annual Gain (10 yrs)** | **21.2%** |

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## *Alchemia – Time to Temper Expectations as Authorised Generic Surfaces*

Alchemia (ACL: 35 cents) shareholders were surprised this week when news surfaced that a second generic, in fact what's called an authorised generic (AG), appeared for Arixtra, a synthetic heparin drug sold by **GlaxoSmithKline**. An authorised generic comes from the branded pharmaceutical company, in this case GSK, and is a way for the pharmaceutical company to take some of the generics revenue as well by licensing it to a generics player, in this case Apotex. CEO Pete Smith said it was an unexpected development but not surprising.

In our view it is surprising because it could have been a comfortable duopoly. However, according to a report from the FTC released in 2009 we have recently viewed, on average 61% of the revenue from the branded generic market goes to the generic company when there is only one generic. When that independent generic (Alchemia and its partner Dr Reddy's in this case) is joined by an authorised generic, the independent generic receives only around 32% of the original total market value (so in Alchemia's case that would translate to 32% of the current US$340 million a year in Arixtra sales). (See table below.)

**Average Relative Wholesale Expenditures on the ANDA Generic (by pharmacies)**

*Source: Federal Trade Commission Report on Authorized Generics, June 2009*

| | | Month of Exclusivity | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 6 | |
| ANDA only | Mean | 42.4% | 71.7% | 59.7% | 62.8% | 69.5% | 65.0% | 61.1% |
| | *SE* | *4.9%* | *10.7%* | *6.6%* | *3.9%* | *6.0%* | *4.8%* | *2.7%* |
| ANDA+AG | Mean | 35.6% | 35.0% | 28.7% | 32.3% | 30.4% | 34.4% | 32.7% |
| | *SE* | *0.035* | *0.03* | *0.017* | *0.017* | *0.021* | *0.026* | *0.01* |

*SE= Standard Error*

*ANDA = First generic (in this case)*

*Note, the above table relates to cases when there is only one generic on the market under the 180 exclusivity period.*

With only the independent generic on the market, prices fall around 20%. When an AG is introduced, the price for generics can be expected to fall by around 30% from the original price.

Assuming a 30% price drop which causes gross margins to fall to 55%, and a profit share of 50% (down from 60% because there are now two generics on the market, which was the arrangement with Dr Reddy's), this equates potentially to a profit of $29.6 million a year to Alchemia from fondaparinux sales based on current Arixtra sales of US$340 million a year. However before Alchemia can start to collect its profit share from fondaparinux sales, Dr Reddy's needs to deduct around $8-$9 million in development costs from profit share payments.

*– Cont'd over*

# Three Companies to Benefit from a Lower AUD

With the Australian dollar falling in recent weeks against the US dollar, many Australian biotechs, including large caps such as CSL and Cochlear, will benefit. Across the smaller companies, Sirtex Medical, Cogstate and Acrux are three that life gets a lot more comfortable when the local currency is trading at parity with the US dollar.

### Sirtex Medical

Sirtex Medical (SRX: $5.37) has returned to solid growth, with full year dose sales of the company's liver cancer treatment increasing by 19.3% over the year. Overall sales have increased by around 30% and should be just over $80 million when the company releases its annual report. The stronger result in dollar sales over unit sales was due to the price increase achieved for the US market, which makes up 65% of its total sales.

The treatment is currently used to mostly treat for secondary cancers that have spread to the liver from the colon. The company received some very positive results from a study in 325 patients with primary liver cancer. Although there was no control group to compare to (note: there are two major randomised controlled trials underway), the comments were very favourable from the chair of the group that conducted the study.

The treatment allowed the disease burden to be reduced and potentially allowed the patient's length and quality of life to be extended. The Sirtex treatment was found to have applications (and warrant routine use) in four different groups of patients with primary liver cancer. The treatment may also have synergistic benefit with a new liver cancer drug, sorafenib, with a large study underway to investigate this approach.

*Bioshares* recommendation: **Buy**

### Cogstate

Cogstate generates most of its revenue from the US. The company has recently lost $1.5 million in margins due to an appreciating Australian dollar. The company has introduced strong cost cutting measures in the last nine months, which has been necessary due to the strong rise in the local currency. Any weakening in the Australian dollar has a profound impact on the company's bottom line. The company understands it needs to be profitable regardless of the changes in the currency.

One of the key drivers for Cogstate is take up of the company's cognition test in sport. The US has been driving awareness of the dangers of concussion in sport, and of relevance to Cogstate, the dangers of returning players to the field too soon, exposing that player to a second and more major injury because of delays in response times brought about from the first concussion.

Australia has been quick to catch on, with Toyota sponsoring the rollout of the test to 130 local Australian Rules football clubs and the test has been adopted by all AFL and ARL professional teams. In the US, the Mayo Clinic has sponsored the Cogstate test (sold through a joint venture called Axon Sports) to all athletes playing contact sports in the state of Arizona.

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

### Acrux

Acrux (ACR: $4.00) stands to receive a further US$195 million in milestone payments from Eli Lilly should its testorone product, Axiron, achieve certain milestones. These milestones we understand are very achievable. The movement of the Australian dollar has a sizeable impact on future milestone and royalty payments.

Axiron sales we forecast should reach US$800 million. Its royalty stream should equate to US$160 million a year at those sales figures. No doubt Acrux shareholders will be hoping the Australian dollar continues to fall. If that does happen, an outright bid for the company also becomes a more appealing option for Eli Lilly.

Bioshares recommendation: **Speculative Buy Class A**

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*– Alchemia cont'd*

One point to note is that the FTC report relates to oral generics, not injectables like fondaparinux. The assumptions also do not support predicting whether the overall fondaprinux market in unit sales (from GSK, Apotex and Dr Reddy's) grows or declines. Fondaparinux is sold in similar volumes through hospitals and pharmacies, although many of these pharmacies are located within hospitals.

The take-up rate of new generics is also of interest. The report shows that by the third month , the first generic (referred to as ANDA) gets 47.4% of the market on average by the third month of sales when there is both the ADNA and the AG on the market. This moves up to an average 55.7% of the market by month six.

### Temper Expectations

There have been quite a few surprises and disappointments for Alchemia shareholders over the years; the change in manufacturers from Dow Chemical in the US to Dr Reddy's in India, a four year delay in getting this product to market as a result of the change in manufacturing and large backlogs at the FDA, and now the surfacing of an authorised generic.

Although there still remains the potential for Alchemia to generate revenue of around $30 million from fondaparinux sales, we suggest investors temper their expectations and wait to see how quickly Dr Reddy's can penetrate the hospital and retail market in the US for fondaparinux. Management has indicated that it will not be known until well into next year how effectively this product can break into the fondaparinux market.

### The Future of Alchemia's Oncology Program?

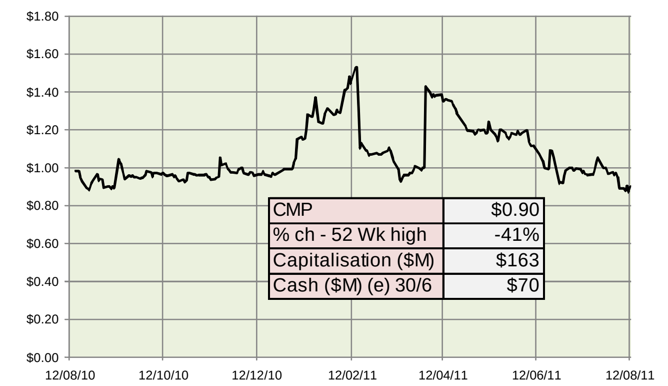
Another issue for the company becomes funding, with Smith saying a straight equity issue is not the preferred option at this stage (given the company has a market capitalisation of only $67 million). The company had only $5.5 million at the end of June. Without further funding the company can not launch its HA-Irinotecan Phase III study and we expect there may be some uncertainty at

*– Cont'd on page 4*

# *Four Picks in a Weak Market*

Wider market weakness has played through to the biotech sector, causing large price decreases for many stocks. By the end of this week some stocks had recovered some losses. However, several stocks stood out as attractive offerings, especially when the decrease from their 52-week high was taken into consideration. We present four of these stocks.

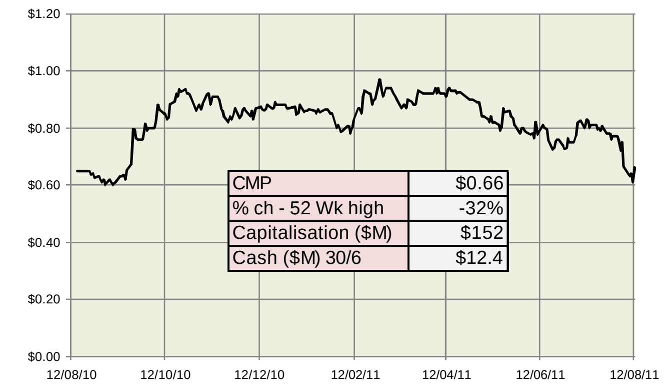
*Price Chart – Biota (BTA)*




The Biota share price recovered markedly when it announced in May that it had been granted a contract for US$231 million by BARDA, a US public health body, to develop C-8958 (laninamivir) for the US market under US regulatory conditions.
The BARDA contract will consume Biota's focus for the next five years. However, two outstanding issues are that BARDA did not award Biota a supply contract for CS-8958 and that the formalisation of Rest-of-World rights between co-owner Daiichi Sankyo and Biota has yet to occur.

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

*Price Chart – Nanosonics (NAN)*

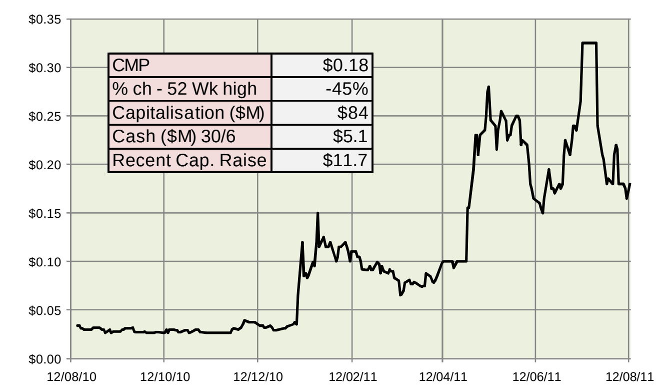



Nanasonics has moved much closer to getting traction and scale for sales of its Trophon EPR, a disinfection unit for ultrasound probes used in gynecology.

Exclusive North American distributor General Electric Healthcare placed an initial $2.4 million order in May, with units now being shipped to a number of high level medical institutions. The order is expected to be the first of many, assuming the product meets customer expectations.

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

*Price Chart – Genetic Technologies (GTG)*

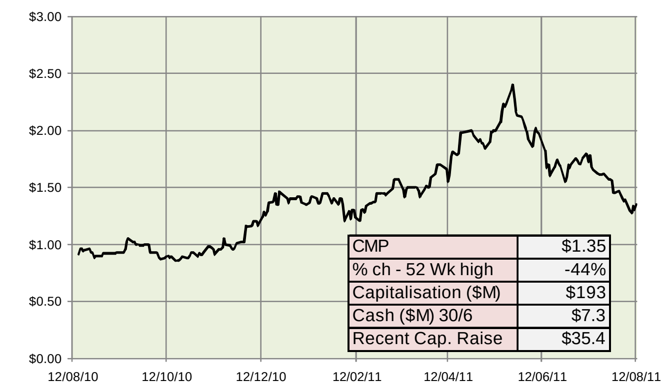



Genetic Technologies (GTG) launched Brevagen, a diagnostic for non-familial breast cancer in June in the US. The company estimates an addressable market for the test of 1.25 million tests per annum. However, volumes of this magnitude will take many months to achieve. The company has established Phenogen Sciences to hold the US business and has now employed eight US-based sales staff.

While Brevagen can be expected soak up capacity at GTG's Fitzroy labs, investors can take comfort with an improved cash position following a capital raising of $11.7 million in July.

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

*Price Chart – QRxPharma (QRX)*




QRxPharma has developed MoxDuo IR, a pain drug which combines the opioids morphine and oxycodone, in a 3:2 ratio. The first therapeutic focus is the relief of moderate-to-severe acute pain.

The company submitted its New Drug Application for four different forumulations of MoxDuo (in the 3:2 ratio) to the FDA in July, with an FDA response expected in 10-12 months time. Also in July, the company completed a $25 million placement and announced a rights issue to raise up to $10.4 million, rejuvenating its June 30 cash balance of $7.3 million.
The next major milestone for QRxPharma is to sign on a strategic partner, expected towards the end of this year.
*Bioshares* recommendation: **Speculative Buy Class A**

**Bioshares Model Portfolio (12 August 2011)**

| Company | Price (current) | Price added to portfolio | Date added |
|---|---|---|---|
| Genetic Technologies | $0.18 | $0.18 | August 2011 |
| Acrux | $4.00 | $3.37 | June 2011 |
| Psivida | $4.02 | $3.95 | May 2011 |
| Bioniche | $0.85 | $1.35 | March 2011 |
| Somnomed | $1.29 | $0.94 | January 2011 |
| Phylogica | $0.068 | $0.053 | September 2010 |
| Sunshine Heart | $0.040 | $0.036 | June 2010 |
| Biota Holdings | $0.90 | $1.09 | May 2010 |
| Tissue Therapies | $0.49 | $0.21 | January 2010 |
| Atcor Medical | $0.08 | $0.10 | October 2008 |
| Impedimed | $0.59 | $0.70 | August 2008 |
| Bionomics | $0.50 | $0.42 | December 2007 |
| Cogstate | $0.15 | $0.13 | November 2007 |
| Sirtex Medical | $5.37 | $3.90 | October 2007 |
| Clinuvel Pharmaceuticals | $1.75 | $6.60 | September 2007 |
| Starpharma Holdings | $1.34 | $0.37 | August 2007 |
| Pharmaxis | $1.10 | $3.15 | August 2007 |
| Universal Biosensors | $0.91 | $1.23 | June 2007 |
| Alchemia | $0.35 | $0.67 | May 2004 |

## *Portfolio Changes – 12 August 2011*

**IN:**
Genetic Technologies' share price has fallen to attractive levels as a result of recent financial market volatility and has been added to the portfolio at 18 cents.

**OUT:**
Patrys has been removed from the portfolio, with a focus towards stocks with later stage assets.

*Alchemia*

### The FTC Report

In 2009 the Federal Trade Commission completed and published a report on the impact authorised generics have on the pharmaceutical market, obviously considering the impact of a branded pharmaceutical company releasing its own generic has on the take up and pricing of other generic products.

In this case, the report looked at the period where there was only one generic competing with an authorised generic (AG) and the branded drug. In these cases, a 180 day market exclusivity period is granted to the generics company for being the first generic on the market (excluding the branded generic). A 180 day exclusivity period is granted to a generics company when it successfully argues a patent is invalid, which was not the case with Alchemia's fondaparinux.

In Alchemia's case, specifically around the drug Arixtra to which it has developed the first and only non-authorised generic to date, a reasonably good estimate can be made on the above expenditure rates. The expenditure rates (see table page 1) are how much pharmacies pay wholesalers for the first generic (ANDA). Arixtra is currently generating sales of US$340 million. If there is an AG on the market, Alchemia's partner can be expected to generate 32.7% of US$340 million, which equates to US$111 million. (It would have been US$207 million had GlaxoSmithKline not licensed an AG to generic company Apotex.)

The introduction of an authorised generic causes faster and more pronounced brand erosion. Whilst some of those sales are shared with a generics company, the volume quantities of drug sold by the branded and the authorised generic company is more than the first-to-file generic company. According to the FTC report, one reason that an AG may be released is that the branded company expects it will lose relatively more sales for particular drugs and issuing an AG is one way to retain some of those sales.

– *Alchemia cont'd*

this stage whether this program continues. A Phase III study will cost around $20 million.

Alchemia did not want to raise funds for the Phase III oncology program until fondaparinux had gained approval, presumably because it would be less dilutionary for shareholders. However, the oncology program may now have increased in importance for the company, relative to the fondaparinux income stream, with the company possibly now needing to contemplate calling on shareholders to fund the program.

*Bioshares* recommendation: **Speculative Hold Class B**

**Bioshares**

## 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. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

### Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

| | |
|---|---|
| **Buy** | CMP is 20% < Fair Value |
| **Accumulate** | CMP is 10% < Fair Value |
| **Hold** | Value = CMP |
| **Lighten** | CMP is 10% > Fair Value |
| **Sell** | CMP is 20% > Fair Value |

(CMP–Current Market Price)

### Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

***Speculative Buy – Class A***

These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

***Speculative Buy – Class B***

These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

***Speculative Buy – Class C***

These stocks generally have one product in development and lack many external validation features.

***Speculative Hold – Class A or B or C***

***Sell***

**Corporate Subscribers:** Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Circadian Technologies, Biota Holdings, Mayne Pharma Group, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida



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