

**In this edition...**

Should companies revise their product development plans? The answer is yes if current plans call for heading into disease indications that turn out to be non-competitive. This is why Clinuvel has dropped the Solar Urticaria indication for its photo-protective drugs Afamelanotide.

AcruX says it remains on track as investors wait for an Axiron deal.

Following a strong year for biotech in 2010, we bring readers up to date on what several biotech analysts in broking firms think about where the sector is headed in 2010.

**The Editors**

**Companies Covered: ACR, CUV, Analyst Views 2010**

	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)	62.0%
<b>Cumulative Gain</b>	<b>215%</b>
<b>Av Annual Gain (9 yrs)</b>	<b>19.9%</b>

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# Bioshares

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

## **Clinuvel Pharmaceuticals – EPP A Clear First Market For Afamelanotide**

As Clinuvel's (CUV: 26.5 cents) drug candidate Afamelanotide approaches registration, the commercialisation strategy for the company is being optimized for the most appropriate path to market and key markets for its drug candidate. Afamelanotide is an analogue of alpha-MSH, a naturally occurring peptide in the body which stimulates the production of melanin in melanocyte cells in the skin. This causes an increased pigmentation of the skin which Clinuvel is seeking to prove has photo-protective properties and which may be particularly useful for people intolerant to direct sunlight exposure.

The lead clinical and commercial application for Afamelanotide is in the treatment of EPP (erythropoietic protoporphyria), which is characterised by severe toxicity to sunlight. There are around 5,000 people identified as having this disorder in Europe (of an estimated 11,000 in Europe in total) and around 4,000 in the US according to CEO Philippe Wolgen. Daily life is severely restricted in people with this disorder with liver toxicity a complication.

### **EPP Phase III Study CUV017 in Europe – 100 patients**

A 100 patient Phase III trial is underway in patients with EPP. Interim results have shown a clear statistically significant result on the two primary outcomes at the four month mark. The level of reduction in phototoxic reactions was not listed but there was a clear significant difference in patient pain scores between treatment groups (p=0.006 95% CI)

The trial is a double-blinded placebo controlled trial. Interim results were decided to be taken to ensure the trial design for the subsequent trials was correct. Twelve month data from the trial should be released next month.

### **EPP Phase III study CUV029 in Europe – Estimated 40 patients**

A second Phase III study has started in Europe. Two from seven centers in Europe have started to enroll patients. The trial will be conducted over the European spring/summer and is expected to be completed by the end of September. The company plans to file a new drug approval with the EMA (European drug regulator) by year's end. This will be a tight schedule for the company which Wolgen believes the company can meet.

### **EPP Phase III study CUV030 in Europe – Estimated at least 100 patients**

Clinuvel is waiting to gain approval for a Phase III trial to start in the US in at least 100 patients to be conducted in the forthcoming spring/summer period. Completion of this trial this year will also allow the company to potentially file the drug for approval in the US in the first half of 2011 for this indication.

Clinuvel prefers to manage its own clinical trials rather than operate through clinical research organisations. This allows the company to stay closer to the patient, understanding their needs, and any delays cannot be blamed on third party trial coordinators. The planned trial in the US will cost between \$8 million - \$11 million.

*Cont'd over*

### Core clinical programs

Clinuvel has identified five different potential medical indications that may benefit from treatment with Afamelanotide. The SU (solar urticaria) application has been halted for the moment. The reason for this is that there is currently a very inexpensive treatment available - antihistamines - which while not very effective, mean that clinical path to market is more difficult compared to where no treatment (effective or otherwise) exists. Clinuvel had 12 centres ready to start a Phase III trial in 75 patients in March. This trial has now been stopped.

PDT (photodynamic therapy) has also been sidelined for the time being, with recruitment for these patients having shown to be very difficult given the poor health of the patients who are terminally ill. Phase II trial results (in 12 patients) reported a 'positive trend'.

The three core programs now for the company are in EPP (lead), non-melanoma skin cancers in transplant patients who have a much higher chance of developing skin cancer because of their immune suppression treatment, and in patients with PLE (polymorphic light eruption). With PLE, a rash develops from exposure to sunlight, which then hardens the skin after about two months.

PLE is not as severe condition as EPP. In a Phase III trial reported last December in 36 patients, statistical significance was not met although there was a 'trend toward reduction'. (In drug development, the term 'trend' is euphemism for we'll get there next time.) A Phase III trial in up to 50 patients with PLE will start next month.

### Strengthens communication with FDA

Wolgen has developed a close communication with FDA officials. One of the benefits of having a CEO with a medical specialists' background, is that communication with key opinion leaders, clinical trial investigators and regulators can be conducted from a position of medical authority and clarity. This is showing to be crucial for meeting enrolment timelines for patients in clinical trials. Mesoblast founder Silviu Itescu is another example of a credentialed and knowledgeable CEO that has enabled that company to achieve a very impressive enrolment rate into its clinical studies.

### Positive request from EMA

Clinuvel has received a very positive sign from the European drug regulator. The EMA has encouraged Clinuvel to also develop a smaller dose version of Afamelanotide for children. Clinuvel will oblige and expects to have a kids' dose available for trial by mid 2010.

Clinuvel is also making the drug available to 120 patients in Europe with EPP on compassionate use grounds at no charge to the patient.

### Patient awareness

Clinuvel has been extremely active in communicating with patients about the diseases it is trying to treat and the progress Afamelanotide is making. The company provides access to a blog and twitter on its website, and many patients are now communicating through internet forums such as Facebook. The company estimates that about 80% of patients diagnosed with EPP are aware

of the Afamelanotide program. The company also hosts a UV light disorder awareness sight.

The company has a number of interviews on its website with EPP sufferers, including with an Australian family who have two children afflicted with EPP. It is worth taking 15 minutes to watch and understand the severity and pain this disease causes in children and in adults for which there is no current treatment.

### Funding

At the end of last year Clinuvel had cash and financial assets of \$32.4 million. It spent only \$4.4 million in the first half of this financial year. The funds are expected to be sufficient to allow the company to complete its Phase III programs and file its drug for approval.

### Risks

Clinuvel is a one compound company. This should be an acknowledged as risk by investors. A second risk is production of illegal, untested versions of the alpha-MSH peptide that are being produced in China and sold to people outside of China for tanning. These are sold as powders that are dissolved in water and injected by some people very determined to have tanned skin. Any adverse event from even illegal Chinese versions of this drug could cause problems with regulators down the track.

### Summary

Bringing Afamelanotide to market is an extremely challenging task, given the possibility that the drug could be abused outside of its intend use (as a tanning agent). Clinuvel is making excellent progress in developing this product. Registration of this drug candidate in Europe is now within sight. It has the potential to be a very successful product, however quantifying that success is difficult because there is no current market for these disorders. On the positive side, the EPP condition is an important unmet clinical need with signs indicating that regulators (at least in Europe) are now very interested in potential of this drug candidate. Clinuvel is capitalized at \$87 million.

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

## Acrux Update

The market is awaiting news for a commercial deal regarding Acrux's (\$1.80) Axiron program, a topical testosterone treatment for men with low testosterone levels. The company's share price is holding up relatively well, with many biotech stocks being sold down in the last two weeks. According to management, the company is progressing well and is on track.

Last month the company filed its new drug application for Axiron with the FDA. Testosterone gels are currently generating sales of US\$700 million a year in the US. Acrux's product offers distinct advantages over existing products on the market.

The company has set a target date for a commercial agreement in the current financial year. We remain confident that a significant deal will be achieved in this timeframe, and our expectation is that the company may be able to report a successful transaction in this first quarter. It will be a much needed transaction for the sector.

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

## Contributed Discussion

### Analysts Comment on the Year Ahead

We invited a number of analysts to answer the following questions, or to generally discuss the thematic for the sector for 2010.

*Are biotechs set to repeat the gains they made in 2009 or will it be a year of sedate and steady progress?*

*What continues to be the major weaknesses of Australian biotech companies, and hence sources of investment failure?*

*If a biotech is looking to IPO, what five criteria would you use to judge it by and what criteria might you have once used but no longer think are relevant?*

*What are your two or three standout picks for 2010 and why?*

#### Tom Duthy – Taylor Collison

We believe the key thematic for the sector in CY10 will be the delivery of commercial milestones. A number of companies have progressively transitioned from research/development into fully fledged commercial businesses. As such, there will be growing investor interest in revenue generation, and potentially, profits.

We anticipate a transition from blue sky valuation of late stage R&D, which has certainly expanded/accelerated during CY09, into market values based on more traditional valuation principles, including multiples relating to EV/Sales, EV/EBITDA and P/E.

On this basis, we feel there will be some pressure to maintain and grow market values for those seeking to launch new products/technologies onto the market in CY10, as any market related sales disappointment is likely to see a significant shareholder reaction and pricing pressure.

We have seen a significant level of capital raisings during CY09, commensurate with an improved sector generally and increased risk appetite. The majority of the larger cap biotech/device companies (ACL, ACR, BTA, CST, CXS, HGN, HIN, IPD, NAN, PXS, QRX, SPL, SRX, UBI, UNI) remain relatively well capitalised. This underlies our rationale that CY10 will be all about delivery, not capital.

#### Tanya Solomon and Scott Power – RBS Morgans

With many investors left licking their wounds following a tumultuous 2008, the life science sector started 2009 in the wilderness. Impacted by severe economic conditions and a general aversion to risk, funding wasn't available for many companies, resulting in some forced exits from the sector. Despite this, several key milestones were achieved over the year with clinical, regulatory and commercial goals being kicked by the more advanced companies, driving interest in the sector. These achievements, admittedly when combined with oversold share prices, resulted in significant gains being recorded in 2009. For example from a 12 month low to a high, Biota was up 732%, ChemGenex was up 289%, Acrux was up 504% and Alchemia was up 636%. Strong share price appreciation also saw companies tap the market for capital to strengthen balance

sheets. Most recently, QRxPharma raised A\$21.6m, Alchemia raised \$15.5m, Avexa raised \$22.9m and Tissue Therapies raised \$8.3m. M&A activity was also a highlight of 2009. The likelihood that the significant gains over the last 12 months will continue in 2010 will depend on not just the ability of companies to continue to meet development targets, but also broader market conditions.

With that in mind, a number of the Tier-1 companies are quickly approaching key commercialisation milestones, such as major clinical end points, regulatory feedback, or the negotiation of licensing deals, which in some instances will result in revenue (and profit) generation. We believe these achievements will set the tone for the sector over the year ahead. Delivering on expectations will see interest in life science stocks increase, increasing the possibility that more traditional investors will be attracted to the space. We note that this thesis is dependent on progressive economic recovery, which is the RBS Morgans House View. Conversely, if major milestones are missed early on, the sector will likely be relegated to the back burner for the remainder of the year. So assuming the recovery continues, individual company's share prices will rise or fall on the achievement of milestones.

Although the percentage increase may not be as impressive as 2009, we remain confident that individual companies will meet targets and believe the sector will deliver solid gains in 2010. Furthermore, we do not rule out the possibility of M&A activity becoming an ongoing trend. The key events we are focused on include:

- Alchemia's partner Dr Reddy's Laboratories gaining approval for generic fondaparinux
- Acrux successfully negotiating a licensing deal for Axiron and moving to profitability
- Pharmaxis achieving positive results for its Phase 3 trial of Bronchitol for cystic fibrosis
- Biota securing a global licensing deal for its long acting version of Relenza
- ChemGenex receiving FDA regulatory approval for Omapro
- ImpediMed receiving a satisfactory reimbursement category for the L-Dex U400

While meeting commercialisation targets is critical, a company's ability to do this is often hampered by access to long-term capital. In our view, this is the major weakness facing the sector in recent years. Over the last ten years, a select number of Australian institutions have provided ongoing, patient capital by anchoring numerous, and in many cases, repeat funding rounds. As the sector matures and the prospect of revenues and profits is more realistic and near-term, raising additional capital, by definition, becomes easier. But, at the risk of sounding repetitive, the achievement of key milestones remains critical. Unfortunately, we often watch as companies miss set timelines with the resultant share price falls alienating current and future investors. We suggest management help themselves, by setting considered and realistic timelines with significant buffers built-in to cope with delays.

To this end, we continue to remind companies of the importance of effective communication with the market. This should involve

*Cont'd over*

both "user-friendly" explanations of technology, the commercialisation pathway and timely ongoing management of investor expectations towards near-term milestones. We can not emphasise this point enough.

Given our emphasis on strong balance sheets for listed companies, it is timely to consider whether or not the IPO window will re-open in 2010. We again believe this will be dependent on broader market conditions and existing companies delivering on market expectations. With investors wary of companies with early stage projects with long lead times and or large capital requirements, we look for the following qualities in a company contemplating whether to list:

- A strong management and solid board with good corporate governance in place. Furthermore, it doesn't hurt to have management and/or board members with skin in the game.
- The support of key opinion leaders; while an industry player or an experienced reputable investor on the register can also assist in providing third party endorsement or validation.
- An exit strategy for investors needs to be considered and may include building a sustainable near term profit stream.
- Solid fundamentals; including, a clear market opportunity, a solid IP position, manufacturing capability, a sound and realistic regulatory strategy and path to commercialization.
- The ability to recognise that, for life science companies, cash is king. Therefore it is important to focus on the bigger picture and not just valuation.

In conclusion, RBS Morgans is looking forward to an exciting 2010. It is make or break time for a number of companies and much will depend on their ability to deliver on expectations.

### Shane Storey – Wilson HTM

*Are biotechs set to repeat the gains they made in 2009 or will it be a year of sedate and steady as she goes progress?*

I personally cannot see biotech outperforming in 2010 as a sector. The re-rating we witnessed in 2009 followed such a poor year, that one has to doubt some of its authenticity. If a proportion of that re-rating was undeserved, as I suspect was the case for many individual stocks in the group, and the broader outlook for equities remains shaky, which I also think is valid, then probabilities point to underperformance in 2010.

Obviously there will be clear exceptions where companies can deliver an undeniable catalyst. For outperformance, investors are really relying on companies overcoming binary events this year; somewhat unexpectedly. I think most of the late stage companies already have FDA/EMEA approvals and first sales factored into their share prices.

Late stage is actually a tricky place to be invested this year because the next step in those investment stories will be about sales and earnings. If you are not convinced there will be a big bang on product launch - look elsewhere. To my mind there is better value in earlier stage companies this year, where investors can back binary outcomes, in an educated way, at low prices. I also think it

is a smart idea to take some biotech profits from 2009 levels and switch them into healthcare where multiples are attractive now, such as CSL and PRY.

*What continues to be the major weaknesses of Australian biotech companies, and hence sources of investment failure?*

Most companies do entertain a very sector-centric view of themselves and don't realise that when they pitch for fund managers' time/capital, they are being compared against resources, renewable energy, small industrials et al. Many of these alternative investment sectors have similar risk, earnings potential and timelines to biotechs. But in the main, they do a better job of describing their end-markets. If companies do not talk about their end markets in great detail, in a credible manner, investors conclude the company does not know what they are doing.

*If a biotech is looking to IPO, what five criteria would you use to judge it by and what criteria might you have once used but no longer think are relevant?*

No changes in the way I look at this issue

1. Does the company know its market? Can they describe demand for their product by year, patient group, geography and reimbursement practice?
2. Intellectual property description must go well beyond the usual "what is a patent?" guff seen in Prospectuses. It is useful and possible to see patent rights described accurately in plain English. Use USPTO or WIPO descriptors - not Australian patent office reference numbers.
3. Plan - investment has to get the company to an unambiguous value uplift, comfortably, with spare cash in the bank. Attention to newsflow profile also important.
4. Team has to be believable and can be put in front of institutional investors.
5. Register. Illiquidity is unattractive.

*What are your two or three standout picks and why for 2010?*

AcruX (ACR). Share price suggests that the market thinks something good will come of AcruX's AXIRON programme - but my expectation is that this one will surprise to the upside from where it is priced.

HeartWare (HIN). This company has grown its capabilities in every dimension since the FTC killed the Thoratec bid for them last year. They have raised US\$120M in less than six months, at good prices, meaning they will be financially secure for the remainder of their development programme. I think they have the best clinical assets in the heart failure field.

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**Matthijs Smith – Shaw Stock Broking*****Crisis? What crisis?***

2009 will go down in history as the year where the brave and the foolish made an obscene amount of money from biotechnology stocks. This time last year, we all believed the planet was on the brink of financial extinction, the sky was falling down and we were all about to be naturally selected.

You may not remember, but that was how many people felt...and the gut-wrenchingly low prices of all of our favourite little biotech stocks reflected that feeling. We no longer made incredulous hooting noises at shares that were trading below cash backing, but instead earnestly furrowed our brows while contemplating what discount to cash backing was actually appropriate.

While CEO's of biotech companies were wearing out their worry beads wondering if their existing cash would get them through the unending financial desert (or at least to a friendly oasis) and frantically announcing "prudent cash management strategies" to the market, the brave and the foolish were deliriously picking up shares at emaciated prices.

And lo' and behold, with a couple of claps of thunder, a few, glitzy flashes of lightning, a gentle shower, and it was all over...apparently. The biotech shares that were trading this time last year at long-time lows, steadily started to push through the dirt and return to something resembling a more rational value.

As a consequence, if you had a penchant for biotech stocks, a six-pack of kevlar-coated abdominal muscles, had avoided exposure to any form of media, and had a deep and profound ignorance of economics; today you would be describing the returns from your share portfolio, not in terms of percentages, but in terms of multiples.

However, we are not likely to see such a dramatic change in value across the entire sector again in 2010. That is not a reflection of the lack of value in the current market, it simply reflects the fact that at this time last year, the biotech sector had been thoroughly hung, drawn and quartered...at least from a valuation perspective. Much of the uplift that those brave or foolish investors enjoyed during 2009 was not due to material progress within companies; it was more due to recovery of the market and a re-pricing of risk for those stocks that actually owned something of substance.

Despite this, in 2010 we are expecting to see one of the most exciting years the sector will ever experience. Several companies that have been developing truly innovative and commercially attractive products will be either launching these products or putting the finishing touches on their development this year. This makes these companies ripe for significant uplifts in their share price as our nostrils are gently tickled with the pungent, but alluring, smell of cash.

Thus while there are not likely to be too many 5- or 10-baggers lurking about on our screens this year, several biotech companies are expected to hit high-value milestones that should translate into returns which would make most holders of the industrial stocks blush.

***Never Mind The Bollocks***

Now that all the fundamental and structural issues with the global economy have apparently all been solved or gone away, the biotech sector can re-emerge from its gentle, wet-shave with Ockham's razor a little stronger and wiser than it was before. There were a few deaths and exits along the way however nothing too spectacular and, if we are honest, nothing that will be greatly missed. The relatively brief vision of what a financial apocalypse could look like, however, did highlight a number of key issues for companies in the biotech sector.

First, biotech companies need to be realistic about where they fit in the world. The entire Australian biotechnology sector, that is all 100+ listed companies, only comprises around 0.35% of the ASX. Furthermore, for the most part, these companies are at the risky, speculative, cash-hungry, revenue-blind, un-PE-able part of the market. This is the part of the market that gets royally slammed when the waste products hit the air redistributor.

While these relativities are not going to change in a hurry, it does highlight the need for biotech companies to offer a compelling, comprehensible and competitive investment thesis in order to attract support in the market. There are many, many places that investors can put their money and if a company does not make sense, or cannot be understood, the market for that company is going to be wafer thin.

Furthermore, for biotech stocks, it is almost nonsensical to talk about "the market" in the context of a collective sentiment of thousands of investors that is resolved on a minute-by-minute basis through electronic trading and is quantifiably measured by the current share price. The reality is trading of most biotech stocks on most days is done by a handful of investors for a variety of reasons; some of which have nothing to do with the company itself. That's just the way it is.

Secondly, it has become increasingly clear that the companies which are going to deliver in the next few years are those which have had clear focus on their products. Real products. Products that it is possible to talk about what their benefits are over what else is available and can understand how and why people are going to buy them.

Investors in the sector have now seen enough companies that do have such products and, for the most part, made good money out of them. The bar has been raised. It is no longer acceptable to turn up with the cast of Big Bang Theory, ridiculously inflated and unspecific numbers about the cancer or autoimmune markets, and an incomprehensible rationale as to how you are going change the world. If the product cannot be defined, the value of the opportunity cannot be quantified; and if the opportunity cannot be quantified, on what basis are investors expected to make their investment decision?

*Cont'd over*

Finally, the companies that have been successful in attracting ongoing investor attention away from the remaining 99.65% of the market are those who have done a consistent job of managing and meeting the expectations that they themselves set.

For some reason, there are still companies that believe the worse things get, the more they should promise, even though the likelihood of delivery gets further and further away. Eventually the tsunami sneaks up on them though. That is what tsunamis do. While everyone is aware of the unpredictability of a development program, the asymmetry of this unpredictability (ie; things always get worse and hardly ever get better) tends to awaken the inner sceptic that inevitably resides in each one of us.

**Remain In Light**

Fortunately, the investment community is getting more discerning and more biotech savvy. While there was a frantic flurry of successful capital raisings in the fourth quarter of 2009, there were also a few companies of questionable merit that failed to get the funding they were after. This is a good thing. The last thing we need is more ailing aunties suffering from some protracted but clearly terminal illness turning up on our doorstep wanting to be looked after. We already have a living room full of such relations. However, in 2010, we also have some insanely athletic looking relatives with nicely oiled skins and rippling muscles ready to perform feats of great wonder during the course of the year. Some of the companies that we are watching with bated breath are:

Starpharma (SPL): continues to deliver partnership deals around its dendrimer technology platform, has a royalty deal in place with

the leading condom manufacturer that looks better every day, has a good chance of securing additional funding for its microbicide product and will commence clinical testing for a second indication. How much more do you want?

Pharmaxis (PXS): by the end of the year, we are expecting PXS will have approval in place to sell Bronchitol in Europe, will have released data from its second Phase-3 trial (which given what we have seen to date should be good) and will have filed for marketing approval with the FDA. And they have a really snazzy spray drier.

Acrux (ACR): from a development perspective, everything is on track for their male testosterone replacement product Axiron™. The commercial potential of this product is unambiguous with clear therapeutic and user advantages that should translate into strong sales. Sometime, before the end of FY10, we are expecting a transaction (either licensing or corporate) that will reflect the considerable commercial potential of Axiron™.

Nanosonics (NAN): this should be a big year for NAN with the rollout of its ultrasound probe disinfection device, the Trophon™. The market appetite for this product appears robust and is supported by a need for practitioners to comply, in most markets, with recently revised recommended guidelines. If NAN is able to convert this demand into revenue, the company should be posting very healthy sales figures by the end of the year.

**Bioshares**

<b>Bioshares Model Portfolio (12 February 2010)</b>			
<b>Company</b>	<b>Price (current)</b>	<b>Price added to portfolio</b>	<b>Date added</b>
Tissue Therapies	\$0.22	\$0.21	January 2010
Biodiem	\$0.16	\$0.15	October 2009
QRxPharma	\$0.78	\$0.25	December 2008
Hexima	\$0.39	\$0.60	October 2008
Atcor Medical	\$0.17	\$0.10	October 2008
CathRx	\$0.28	\$0.70	October 2008
Impedimed	\$0.59	\$0.70	August 2008
Mesoblast	\$1.77	\$1.25	August 2008
Circadian Technologies	\$0.62	\$1.03	February 2008
Patrys	\$0.16	\$0.50	December 2007
Bionomics	\$0.30	\$0.42	December 2007
Cogstate	\$0.31	\$0.13	November 2007
Sirtex Medical	\$5.98	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.27	\$0.66	September 2007
Starpharma Holdings	\$0.70	\$0.37	August 2007
Pharmaxis	\$2.48	\$3.15	August 2007
Universal Biosensors	\$1.75	\$1.23	June 2007
Probiotec	\$2.20	\$1.12	February 2007
Acrux	\$1.80	\$0.83	November 2004
Alchemia	\$0.65	\$0.67	May 2004

**Portfolio Changes – 12 February 2010**

**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**

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