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Biosshares

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

In this edition...
The recent Bioshares Biotech Summit brought together a number of Australia's biotech stock analysts in the one room. The panel session in which these analysts and several corporate finance directors participated highlighted the fact that biotech struggles for attention from investors who are more attracted to defensive stocks. However, several analysts were bullish on the longer term outlook for the sector. pSivida's prospects may take turn for the better if its licensee Alimera Sciences resubmits an NDA for Iluvien with the FDA. Biota's proposed merger with Nabi received a message of disapproval (via a Proxy Statement) from Nabi investor Mangrove Partners. Novogen has announced a merger with sleep apnea device company Kai Medical.
Companies Covered: BTA, NRT, PVA

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - current)	-12.7%
Cumulative Gain	**201%**
Av. annual gain (11 yrs)	**17.8%**

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2012 Bioshares Biotech Summit Report (Part 2 – Analysts Session)

This year's investment panel session at the *Bioshares* Biotech Summit in Queenstown comprised of Michael Lusis (Business Director, **Wilson WTM**), Graeme Wald (Investment Director, **Octa Phillip Bioscience Managers**), Tom Duthy (Analyst, **Taylor Collison**), Matthijs Smith (Analyst, **Shaw Stockbroking**), Stuart Roberts (Analyst, **Bell Potter Securities**) and Scott Power (Senior Analyst, **RBS Morgans**).

The first question put to the panel was: *Do investors accept the biotech sector as one that is investment grade and one where they should have an exposure?*

Stuart Roberts opened with "I think people get it now, I don't think they got it in 2007, but some time in the last two years they realised that this was something to wake up and pay attention to. There are one or two big success stories such as Starpharma (which is here) which makes people sit up and take notice."

Matthijs Smith was of the view that there a lot of people who still are not convinced. "There are the converted and those who say we don't play in that space. You can preach until you are blue in the face. A number of institutions say you may be good, you may be right, you might have a great track record but we just don't go there. There's people who have made a lot of money and there's people who have lost a lot of money. (And) there's people who just say it's too hard."

To Michael Lusis the most frustrating aspect is the lack of depth and the lack of institutions that invest in the sector. "The issue is to expand that investor pool. Once we get more companies with earnings, that will expand the institutional investor interest in this space. The interest (from institutions) is still very small and very thin."

Tom Duthy said retail interest at the moment for brokers is terrible. "Investors have more interest in stocks such as Telstra at the moment." Duthy said the people funding a lot of these businesses are coming from off-shore, citing examples of **Reva Medical** and **Osprey Medical**. "The Model going forward should be to think abroad if we are trying to raise money or seek new listings."

Scott Power agreed that the mood in the market is poor. "It does come in cycles. Bear markets tend to last about five years and you can probably argue that we are coming towards the end of that. And bull markets tend to have a seven year cycle. At the moment investors are very much focused defensively, so they are parking their money in defensive stocks, if they are parking their money at all (in shares), otherwise they are putting their money in fixed interest (facilities)."

RBS's view is that crisis in Europe is a banking crisis. "Banks are getting recapitalised so at least it's not getting worse. China is slowing down, but it will be a managed slow down.

We are expecting a better end to the year. The last six months has been as bad as ever for the broking community. Money will come out of the defensive stocks very quickly, perhaps in the next six months, into the growth stocks," stated Power.

Graeme Wald believes that Europe is a complete 'basket case'. "There are examples now of pharmaceutical companies not being paid in various provinces in Italy which is a concern. Pricing (of products) is still a very big issue for companies. The German government recently issued some bonds with a negative yield. I don't even understand how that works. It's more than a banking crisis."

"You are effectively paying the government to look after your money. If there is such a risk averse mentality, then that has to have an impact on companies and on valuations. Plus the strengthening of the Australian dollar again recently will have implications for local companies."

One interesting appeal of the sector to at least one investor, according to Wald (who Wald says is a quantitative investor) was that that investor is able to get uncorrelated alpha by investing in biotechs.

Stuart Roberts proposed that technology has a life of its own that runs apart from the broader economy, citing a number of cases in history. "A lot of the current woes could be argued is the new economy killing off the old economy, and we're (biotech) playing in the new economy. Our economy is going up when a broader economy is going down. I think there's cause to be optimistic for where we are travelling"

"We could be in the first genuine biotech boom since 2007. Every 20 years there is a genuine boom and everyone looks around and says where the heck did that come from. It started nine years ago and the foundations are here now. Big Pharma is having a productivity crisis, we have an aging population. The next Poseiden Boom will be the biotech boom," Roberts stated.

The next topic of discussion was whether any of the broking houses had any biotech listings they were working on at the moment.

"There are a couple in process now, (including) one that **JP Morgan** is working on," said Smith. "There is appetite out there for new listings, as we demonstrated with Osprey Medical. This is a tough market, you have to be very pragmatic about valuations. People aren't going to pay premiums. Osprey was valued at what had been put in. (There was) very little upside for the VC investors there who will make their money down the track," said Smith. "Companies coming along with high valuations are going to struggle. If you have a decent value proposition then there is appetite for it."

For Michael Lusis one of the concerns is the small cap resources space. "The small caps (resources) are down 30% in the last quarter. There is some investor cross over in these sectors. The risk meter has been turned suddenly off," said Lusis. "It's very hard to sell anything at the moment. It's all of the defensive stocks such as Telstra, Rio Tinto and BHP. Previously you may have, for instance, lost money in biotech and made it up in the resources boom. But resources have recently really turned nasty. Resources is suffering and it's bigger than biotech". And that is impacting speculative investor interest in biotech stocks. The one positive aspect for Lusis is the maturing of the biotech sector.

Graeme Wald, who has moved from Wilson HTM to become an Investment Director with the Octa Phillip group, agreed that valuations are a big issues. "There's no getting away from the risk aversion in the market at the moment," argued Wald. "The offering has to be very keenly priced and the story must be excellent."

Smith said the good side to that is that investors should be writing their cheques now. "Two years ago you may have paid twice as much for the same deal. If you are brave enough, there is a lot of (potential) upside from investing now."

Stuart Roberts suggested that if it's good enough it can get away in any market conditions. Lusis disagreed. Last year Wilson HTM was close to listing a healthcare industrial stock, but the market fell 5% over night and that killed the momentum. "There's such a long period from start to finish to do an IPO. With the big swings it's hard to keep investors stable through that process," argued Lusis. "The problem is getting that steady window."

Smith also agreed with Lusis. Shaw Stockbroking managed the Osprey Medical listing earlier this year. Ventus Medical tried to float two weeks later but the float was pulled. If Shaw had gone out with Osprey two weeks later it would have been difficult too said Smith.

The next question for the analysts was: *What was to be learned from companies going through the final stage of regulatory approval? (There have been five regulatory setbacks in the last three years for Australian biotechs - Chemgenex Pharmaceuticals, Pharmaxis, pSivida, Mayne Pharma and most recently QRxPharma.)*

Duthy conceded that maybe it's a good option to wait until the product is approved beefier investing. "Invest after approval, but reimbursement is a key issue as well."

Wald said that Acrux is a good example of a stock that has attracted significantly more institutional investor interest post product approval.

Scott Power believed the smartest money made in this sector is by investors who have a core position in the company and then they have a trading position, dependent on whether it does or doesn't hit milestones. "They do pretty well, particularly if they are unemotional". From a trading perspective, technical analysis tools can also be very helpful believes Power.

The biggest issue for investors according to Lusis is that they still need to be educated to have a portfolio. "It's a risky sector, let's face it. Some institutions have only one biotech, it blows up and then they leave the sector. Too many people still don't spread their risk."

Cont'd over

Is a US$25 Million Milestone Payment Back on the Table for pSivida?

pSivida's (PVA:$2.30) licencee of its eye drug Iluvien, the Georgia-based **Alimera Sciences,** revealed at an analysts day that it intends to resubmit Iluvien to FDA, presumably for the approval for the indication of *chronic* diabetic macular edema (DME), which is a subset of the *broader* indication of DME.

In November 2011, Alimera received a second Complete Response Letter from the FDA in response to its New Drug Application for Iluvien for the indication of DME, with the FDA saying that Alimera had not provided "sufficient data to support that Iluvien is safe and effective in the treatment of patients with DME," and that the "risks of adverse reactions shown for Iluvien in the FAME Study were significant and were not offset by the benefits demonstrated by Iluvien in these clinical trials."

Since then, however, Alimera has received preliminary approval in Europe in February 2012 for the indication of *chronic* DME where patients are insufficiently responsive to available therapies. Specific country approvals have followed for France, Portugal, Austria, the UK, and Germany with approvals pending in Italy and Spain.

Iluvien is a single implant which delivers submicrogram quantities of the corticosteroid fluocinolone acetonide (FAc). The low dose, long term release steroid combats inflammation in the eye. The implant is designed to last three years. In a Phase III trial, Iluvien was found to deliver 15 or more letters improvement (a visual test score measure) to 34% of chronic DME patients over 36 months compared to 13.4% for patients on standard of care therapy.

Alimera has also announced a capital raising through the sale of US$40 million of convertible preferred stock. It intends to apply the funds to the rollout of Iluvien in Europe. An assumption now available to pSivida investors is that the capital raising may cover the US$25 million Alimera is obliged to pay pSivida if it gains regulatory approval for Iluvien in the US. However, this assumption must be contrasted with Alimera's statement that sales and marketing costs for four EU countries would initially be in the order of US$18-$20 million a year.

Alimera is waiting for the official minutes of a recent meeting with the FDA in which it discussed a proposed pathway for Iluvien, ostensibly for use in *chronic* DME patients. The company may be in receipt of these minutes in August, after which it could articulate a new time line to market. The FDA would most likely provide a decision about six months following a re-submission date.

Alimera is aiming to commence sales in Europe in 2013 Q1. Alimera has given guidance on EU sales, and is expecting peak sales of US$400 million in four years time. The net price for Iluvien in Europe has been estimated by Alimera to range from €3500 to €5500 per treatment (injection).

pSivida is entitled to 20% of net profit on product sales, which equates to sales net of discounts, rebates, vouchers and taxes and less cost of goods and less commercialisation expenses (per territory).

Summary

pSivida's income and growth prospects are closely tied to those of its licensee Alimera. Investors now have an important event to monitor in August for if and when Alimera confirms a new submission strategy for Iluvien with the FDA, the upside being a date for a US$25 million milestone payment for pSivida upon FDA approval.

Bioshares recommendation: **Speculative Buy Class B**

– Analysts Session cont'd

Stock Picks for Next 12 Months

The Analysts Session concluded with analysts and bankers offering two stock picks for the next 12 months.

One of Smith's top picks was **Pharmaxis**. Stocks take a while to recover after being hit by a major share price correction. Smith believes it will correct but that may take longer than any of us want. Smith's second pick was **Starpharma**, which he believes should get a positive Phase III trial result with Vivagel in bacterial vaginosis. "It's a unique product and should get a re-rating (post results)."

Graeme Wald's two top picks for the year ahead were **Pharmaxis** and **Nanosonics**.

To the pleasure of the audience, Stuart Roberts said "I'm a bull on the whole sector!" Roberts said there is big news ahead for many of the companies in the sector, including Mesoblast and Starpharma. "It's rare for this to be happening. I think we're all going to have a good year." **Neuren** is his top pick. "They have a perfect storm of data coming out in the next year. Their drug just got tested in the wrong indication the first time."

"The other one to watch out for is **Alchemia**. Remember cancer stem cells are real. We have known about cancer stem cells since the 1930s but only in the last five years there has been an explosion of knowledge in the cancer stem cell space". And the CD44 receptor linked with cancer stem cells is the area Alchemia's technology is operating in.

Tom Duthy's top two picks were **Sirtex Medical** and **Atcor Medical**.

Scott Power chose **Alchemia** and **QRxPharma**. A stock he doesn't cover but liked the sound of at the conference was Cogstate.

Echoing Stuart Roberts, Michael Lusis said he liked a lot of the stocks in the sector. His favourites are unquestionably **Pharmaxis**, which has a "lovely grand vision on strategy which has stayed consistent," and that is important for Lusis. "It has a rich set of milestones coming through in the next 12 months." His second selection was **Universal Biosensor**s. It is validated by its partnerships with Johnson & Johnson and Siemens. It will have sales this year for investors to follow and the approval the PT/INR test partnered with Siemens is expected next year.

Bioshares

Bioshares Model Portfolio (27 July 2012)

Company	Price (current)	Price added to portfolio	Date added
Nanosonics	$0.500	$0.495	June 2012
Osprey Medical	$0.40	$0.40	April 2012
QRxPharma	$0.72	$1.66	October 2011
Mayne Pharma Group	$0.385	$0.435	September 2011
Somnomed	$0.83	$0.94	January 2011
Phylogica	$0.038	$0.053	September 2010
Biota Holdings	$0.66	$1.09	May 2010
Tissue Therapies	$0.49	$0.21	January 2010
Atcor Medical	$0.06	$0.10	October 2008
Bionomics	$0.25	$0.42	December 2007
Cogstate	$0.250	$0.13	November 2007
Sirtex Medical	$6.40	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.63	$6.60	September 2007
Pharmaxis	$1.10	$3.15	August 2007
Universal Biosensors	$0.60	$1.23	June 2007
Alchemia	$0.485	$0.67	May 2004

Portfolio Changes – 27 July 2012

IN:
No changes

OUT:
No changes

Stock Briefs

Biota – Mangrove Partners Files Proxy Statement

Biota Holdings (BTA:$0.66) is currently undertaking a merger with the Nasdaq listed Nabi Biopharmaceuticals, announced on April 13, 2012.

A shareholder of Nabi Pharmaceuticals, The Mangrove Partners Fund, L.P., has released a Proxy Statement in which it says it does not believe the proposed transaction (i.e. the merger of Nabi with Biota) is in the best interest of shareholders.

Mangrove Partners argues that a superior alternative is for all cash held by Nabi to be returned to Nabi shareholders through a special dividend, along with an orderly wind-down of Nabi. Under the merger plan US$54 million of Nabi's cash would stay with the merged entity with between US$25 and US$30 million being returned to Nabi shareholders.

Mangrove Partners also expressed significant reservations about the merger. It said Nabi "did not properly consider all available alternatives for maximizing the value of Nabi and engaged in a sales process that appears to be influenced by potential conflicts of interest."

Mangrove Partners hold a 5.65% stake in Nabi Biopharmaceuticals, which is a Delaware-registered corporation. Under Delaware law, 50.1% of shareholder votes by shareholding are needed to approve a merger.

Mangrove Partner's disagreement with the proposed merger is a sign that the path in front of both Nabi and Biota may become increasingly difficult. We have already identified several issues of relevance to the proposed merger, including a lack of clarity regarding the ownership of the Rest-of-the-World rights to laninamivir, which are ostensibly shared between Biota and Daiichi Sankyo.

Bioshares recommendation: **Hold**

Novogen – To Merge with Kai Medical

Novogen (NRT: $0.077) has announced that it intends to merge with US sleep apnea therapy company Kai Medical. Kai Medical's Kai Apnea device has received a CE mark (European clearance) and is awaiting an FDA clearance.

Novogen undertook a backdoor listing through Norvet in 1997. The company was accepted for listing on the Nasdaq in late 1998. Novogen was established to develop natural products from isoflavones derivatives (phenolic hormones) found in red clover herbs. The company set up an OTC business and also ran trials of pharmaceutical formulations, including phenoxodiol, in various cancer settings such as prostate and ovarian cancers.

Novogen spun out selected pharmaceutical assets, including phenoxodiol, into Marshall Edwards Inc (now MEI) in 2001.

Novogen intends to sell its glucan assets to TR Therapeutics.

Novogen will also undertake a capital reduction and arrange an *in specie* distribution of Novogen's shareholding in MEI.

Bioshares recommendation: **Under Review Pending Provision of Merger Information**

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, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies, Calzada, Bioniche

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