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**In this edition...**

The Bioshares Biotech Summit is an intense affair as far as conferences go. This year's event saw attendees hear speakers from Biota, Universal Biosensors, Acrux, Cogstate, QRxPharma, pSivida, Phylogica, Alchemia, Phosphagenics, Sunshine Heart, Neuren Pharmaceuticals, Bioniche and Genetic Technologies as well as a half a dozen private companies.

And four leading biotech analysts discussed their two current top stock picks.

This edition of Bioshares brings you coverage of a number of those presentations, with more to follow next week.

**The Editors**

| | Bioshares Portfolio |
|---|---|
| Cumulative Gain | 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 | -4.4% |
| **Cumulative Gain** | **303%** |

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# Bioshares

**25 July 2011**
**Edition 417**

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

## *The 7th Bioshares Biotech Summit – Report*

The 7th Bioshares Biotech Summit was held in Queenstown over Friday July 22 and Saturday July 23, with approximately 120 people in attendance. The conference program ranged from presentations on what follows once a company has launched a product and begun to generate revenues, the use of cash flow businesses to fund higher margin products, on biotech company strategy from the earliest days in the life of a biotech, a walk through Alchemia's fondaparinux approval, the role of patient capital in biotech, to a suite of presentations from a group of biotechs that might be considered to be on the 'cusp of success'.

In this edition we report on several presentations made at the summit, with more to follow in a later edition.

*Two companies, Biota and Universal Biosensors were invited to address the topic 'The Next Step - The Transformation from R&D to Products, Profits and Dividends?"*

### Biota – BARDA Contract the Main Game

Biota CFO Damian Lismore provided several key updates, on the RSV program and the BARDA (Biomedical and Advanced Research Development Authority) funded laninamivir program. BARDA is a component of the US Public Health Emergency Counter Measures Enterprise (PHEMCE). BARDA has funded 29 contracts and two grants, totalling US$4.1 billion, to develop measures to manage seasonal and pandemic influenza. In April 2011, Biota announced that had been contracted over five years to develop laninamivir under FDA guidance for the US. The value of the contract, structured on a cost plus fee basis, is US$231 million.

Laninamivir is a long acting neuraminidase inhibitor which was approved in Japan in September 2010 for the treatment of influenza.

What emerged from the Biota presentation was that the BARDA funded laninamivir program has been placed front and centre of all of Biota's activities. One piece of evidence for this argument is that number of staff involved in product development is forecast to grow from 12 in 2010 to 50 in 2016, whereas research staff numbers will see a decline from 73 to 60 over the same period.

Lismore said that BARDA solicited proposal as in 2008 for therapies and prophylactics to manage seasonal and pandemic influenza. The solicitation sought FDA approved products. However, the swine flu epidemic saw the solicitation put on the back-burner. However, it resurfaced with more criteria added in, including a requirement for commercial manufacturing based in the US and a plan for dealing with surge capacity.

Phase II trials will commence next winter. However, when Phase III trials commence, it is expected that they will be supplied by a US manufacturing operations. Lismore said

*– Cont'd over*

it was important to note that BARDA was not only paying for clinical trials but also for manufacturing line development and for the transfer of expertise from Japan to the USA.

The US clinical development program will include Phase II trials in elderly and pediatric patients, Phase III registration studies and Phase I studies (in parallel) designed to demonstrate cardiac safety.

One interesting administrative challenge for Biota is must adopt an Earned Value Management System, which is a long term project management system used by the US military, as well as adhering to US Federal Acquisition Regulations and US Health & Human Services Acquisition Regulations and submitting to audits from the US Defence Contract Audit Agency.

Lismore said that Biota will have working capital requirements of 45 days. A big issue for Biota will come in Year 3 of the contract when $80 million in working capital will be needed.

Lismore added that the BARDA contract only covers treatment as opposed prophylaxis (prevention) of flu and he remains hopeful that a contract for prophylaxis will be achievable (maybe $100 million).

The benefits of the BARDA contract to Biota include Rest of World commercial entitlements for laninamivir and the right to buy back the manufacturing line at a written down value.

Lismore concluded his presentation with a fascinating comparison of Biota with Nasdaq listed SIGA, which was awarded a US$55 million contract by BARDA in 2008 to develop a smallpox antiviral. It was then selected as a smallpox antiviral supplier and in May 2011 BARDA awarded the company a five year contract. In June 2011, BARDA ordered 1.7 million courses valued at US$433 million. That company is currently capitalised at US$433 million.

Lismore made the point was that at some point BARDA can be expected to place a request for supply.

"We are quite happy to sacrifice anything to get lani through - the financial metrics for lani are so strong no matter which way you look at it. It is a market of 20 customers globally that Biota can access itself, worth $2 billion a year" concluded Lismore.

### Universal Biosensors – Focus Now On PT/INR Product

The CEO of Universal Biosensors Paul Wright placed his company in the camp where earnings will be reinvested into new product development. The focus of his talk was on the development of a point-of-care Pro-Thrombin/International Normalised Ratio (PT/INR) product and the manufacturing resources and assets that accompany it.

The Prothrombin Time test measures clotting tendency of blood. The test is predominantly used by patients on warfarin therapy, following orthopeadic surgery, or post-operative or atrial fibrillation.

However, the need is to stay in a particular range, with clotting on one end of the range and bleeding on the other end. PT/INR testing is carried out in hospitals and at home but is ultimately is managed by a doctor.

The PT/INR market is was worth an estimated US$400 million in 2008, and Wright sees as a good growth opportunity from several angles. Wright expects warfarin used to continue, despite warfarin substitutes emerging, with a growth expected to occur in the point-of-care setting, including patient self care market where a greater than 20% growth rate is anticipated. Reimbursement for warfarin treatment has expanded in the US, from 2008, to include coverage of 2 million atrial fibrillation patients and 2 million venous thromboembolism patients, and 400,000 mechanical heart valve patients. In 2009, Medicare reimbursement was set at US$5.53 per test (per week). This opened up a US$1 billion opportunity from reimbursement.

"The more testing you do the certain you are in the appropriate range", he said and moving from an eight weekly test to a once a week test has significant multiplier effect on the number of diagnostic tests being performed.

Wright highlighted the UBI PT/INR product, citing advantages of cost per test from much lower cost of strips, improved features and ease of use.

The strip's cost advantages stem from being able to manufacture large batch sizes to a high degree of reproducibility. The strips themselves use inexpensive chemistry components and have a small electrode area, with low wastage rates occurring for metal components.

Wright offered a scoping outline of indicative annual earnings per strip in the PT/INR setting, assuming 7 million warfarin patients worldwide and 100% of this market. With testing done every eight weeks, figures ranged from $23 million at 50 cents per strip, to $68 million at $1.50 per strip. With testing done every week, figures ranged from $182 million at 50 cents per strip to $546 million per strip at $1.50 per strip. Wright emphasized that the figures were illustrative only and were not earnings forecasts.

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*Genetic Technologies CEO Paul MacLeman spoke in the session entitled 'Using Cash Flow Businesses to Fund Higher Margin Products'.*

### Genetic Technologies – The Brevagen Story

While the GFC was terrible for many companies around the world, one company that may turn out to be a beneficiary is Genetic Technologies (GTG), through its acquisition of a test for non-familial breast cancer called Brevagen. Genetic Technologies' CEO Paul MacLeman described how GTG obtained the asset and the market strategy for the product in the US.

GTG was a shareholder in a US genetics company **Perlegen**. The stake was gained as a consequence of patent infringement enforcement of GTG's non-coding DNA patents. GTG was there-

*– GTG cont'd*

fore familiar with the Perlegen's fiscal status, and the product development status of the Brevagen test. Perlegen had expended US$320 million in the course of its life, of which a large portion was devoted to the development of Brevagen.

GTG had in 2009 approached Perlegen in 2009, seeking the rights to the product for Australia and New Zealand. Perlegen was unable to obtain funding in late 2009 and simply ran out of cash, after a potential funder decided to withdraw a funding offer at the last minute.

MacLeman secured an option over Perlegen's assets, including the Brevagen asset through the payment of Perlegen's outstanding IP bill and the cost of a CLIA certificate. The deal was finally settled for less than $1.5 million in March 2010.

After analyzing companies such as **Myriad Genetics**, **Genomic Health** and **Response Genetics**, MacLeman decided to push GTG down the path of being a 'direct sales force, single test product' company. On the staffing front, the GFC and labour market weakness in the US offered further benefits, by enabling very good hires to be made. The GFC also saw a competitor, **DeCode Genetics** leave the field, and drop their breast cancer stratification product, after losing 'cash assets' held in mortgage backed securities.

A concern for GTG was how to pay for its plan to build a US sales force. In Australia, savings were made from staff cuts, reagents costs and rent reductions. A new round of IP assertion suits also delivered $14 million in non-dilutive revenue, although MacLeman qualified this revenue as not a part of the Brevagen strategy.

In addition to hiring staff, GTG spent money pre-market development. GTG invested in focus group research, so that the company could set the most appropriate label claim for the test. The company also spent time on the discovery of product advocates and 'anti'-advocates, seeking especially to 'neutralise' the opponents of the product.

GTG also hired a number of US service firms such as Premier Source, a specialist molecular diagnostics reimbursement house, which helped with reimbursement strategy and do billing and appeals process. MacLeman said that process of understanding the US reimbursement system was "mind-numbing".

MacLeman said that risk-mitigation and honesty was key to the process he and the company went through in getting Brevagen to market. You have to lay the strategy out on the table and say "where are the warts?" he said. According to MacLeman, quantification of risks mattered so that one could get "a real handle on the relativities of the annualized loss or the annualized benefit for each component of the strategy". It's not so much the numbers that matter but the ranking in the stack, to help you know where to focus time and attention, he concluded.

Brevagen was finally launched three weeks ago in the US.

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## Alchemia's Fonda Approval

Alchemia CEO Peter Smith became a late addition to the speaker line-up, following the recent FDA approval of fondaparinux, a generic version of **GlaxoSmithKline**'s Arixtra.

Smith said the Alchemia story is one of incredible tenacity. Smith looked appropriately relieved and delighted that the company's generic fondaparinux (fonda) was finally approved in the US.

Global sales for fonda are now tracking at close to US$0.5 billion a year. Smith believes that there will eventually be competitors but not for at least three to four years. Smith was very disappointed that there was a six month delay in getting its partners manufacturing facility inspected in India. Alchemia was in fact lucky, because that delay is now three years!

Alchemia was unfortunate because when after scaling up from 100g batches to 1kg batches, an impurity surfaced that took 18 months to remove. Before it filed for approval, the generic approval time was only 18 months, and nine months for first generics. However, the flood of new generic applications from India and China and the fears stoked from fatal heparin products from China made the FDA a lot more cautious and Alchemia ran into a log jam at the FDA.

Alchemia originally had **Dow Chemical** making fonda however because of the difficulty in making the drug, the cost was three times the original quote, with Alchemia deciding to move manufacturing to India. The drug took the original co-developer of the drug, **Sanofi**, at least 10 years to work out how to make it. Alchemia's process provides some efficiencies in the process but both Sanofi and GlaxoSmithKline did not believe Achemia could make the drug said Smith. Obviously they were wrong. Smith stressed that whilst the difficulty in making the drug has delayed the launch, it's also a very good barrier to entrants.

Smith said that first generics generally get around 50%-60% of the market, with only an 18%-20% price erosion when there is only one generic. The launch is imminent, said Smith, with syringes of fonda available in the US.

Smith said that the company had a rifle shot with its oncology program. Using hyaluronic acid with irinotecan, called HA-irinotecan, the company is ready to enrol patients in September in a Phase III trial in colorectal cancer. This will be a very important trial, according to Smith. If it works, then it will validate the platform. Alchemia will use the technology with a range of other cancer drugs, including 5-fu and doxorubicin.

The initial market for irinotecan is not small. **Pfizer**'s branded version, Camptosar, generated sales of $1 billion before it went off patent in 2008. Smith believes its HA-irinotecan could recapture that premium pricing.

Patents on this platform in the US go out to 2022 (plus maybe a couple of extra years) and in Europe there is data exclusivity protection out to 2020.

**Bioshares**

### Investor Panel Session – Stock Picks

Four analysts were asked for their top two picks in the Investor Panel Session. Tom Duthy from **Taylor Collison** picked Sirtex Medical and Cogstate. For Duthy, Sirtex offers profitability and dividends, but with high growth potential that most standard industrials lack. Duthy said it's a stock that should be in every biotech portfolio. The blue sky is in the later stage trials that may move this treatment from a third line salvage therapy to a first line therapy, thereby increasing the market fourfold.

Scott Power from **RBS Morgans** picked **Impedimed** and **Alchemia**. Power said the market is assigning no value to Alchemia's oncology assets. He believes Impedimed is at a tipping point in terms of product take up in the US. He views **Phylogica** as a smaller cap stock with the greatest potential share price appreciation ahead.

Matthijs Smith from **Shaw Stockbroking** picked **Starpharma** and **Nanosonics**. He said that Starpharma has so many opportunities that makes it very difficult to value. However he said that if one, two or three of its products make it, the company's current market cap is an absolute fraction of what it will be worth.

**Wilson HTM** analyst Graeme Wald said **Universal Biosensors** was his top pick, and Wald was also sticking behind **Pharmaxis** as another favourite although he said this really is a binary outcome now. That Lifescan has stated it will make the Universal Biosensors' strip the basis of its entire diabetes franchise makes it a very appealing company, he said. With respect to Pharmaxis, Wald said the argument from the European regulator just does not stack up. Of particular interest was that both Wald and Duthy indicated that in recent months there had been interest from a number of US companies considering listing in Australia after the listing of **Reva Medical** and **Bioniche** here in December last year and January this year. However, that interest has now subsided.

**Bioshares**

*pSivida VP-Investor Relations Brian Leedman spoke in the session entitled 'Biotechs on the Cusp of Success'*

### pSivida – A Frank History

In one of the most revealing and entertaining presentations at the conference, Brian Leedman provided a very frank history of **pSivida**'s corporate history as well as the potential ahead for that company as it approaches the cusp of success after 10 years of drug development.

Leedman has now become the longest standing shareholder in pSivida and the last remaining employee in Australia. He joined the company in 2005.

pSivida was formed on the back of biosilicon technology that come out of the UK. However, that drug delivery technology was never successfully commercialised and never progressed into clinical studies as a drug delivery technology. To speed up commercialisation the company decided to move into ophthalmology applications by acquiring a later stage company called **Control Delivery Systems** (CDS) at the end of 2005. That acquisition today underpins the core assets of pSivida.

The acquisition occurred because CDS could not list in the US and needed access to funds. At the time CDS had just started a Phase III trial with **Alimera Sciences** in 1,000 patients with diabetic macular edema. The arrangement was a 50/50 partnership however even after being acquired, pSivida could not fund its share of the very expensive three year Phase III trial.

So the deal was renegotiated to a 20/80 profit share arrangement which is how it stands today. Under that renegotiation, pSivida received $20 million and Alimera took over all development costs of the drug Iluvien for DME, which the FDA will now give a decision on around the 12th November this year.

While it has been a very fruitful acquisition for the company, it had several, major financial challenges to overcome around 2006 that had very serious implications for the survival of the business.

In 2006 the company had taken out a $20 million convertible note facility, which Leedman said went toxic real fast. This was a very dangerous time for the company, resulting in the management resigning and half of the board being replaced. However, in late 2006 and early 2007, Leedman raised $8 million for the company, which was enough to get it out of trouble until the company's fortunes changed for the better. Half of those funds were raised in the US, with the company's NASDAQ listing proving very useful.

Very correctly, Leedman stated that all businesses need a little bit of luck and for pSivida that came in March 2007 and the turning point for the company. pSivida signed a $167 million licensing deal with Pfizer for another ophthalmic program. On the back of that deal and the company's technology, pSivida was able to raise $45 million which then allowed it to remove its toxic debt facility.

*Cont'd over*

**Bioshares Model Portfolio (22 July 2011)**

| Company | Price (current) | Price added to portfolio | Date added |
|---|---|---|---|
| Acrux | $4.22 | $3.37 | June 2011 |
| Psivida | $4.50 | $3.95 | May 2011 |
| Bioniche | $0.86 | $1.35 | March 2011 |
| Somnomed | $1.34 | $0.94 | January 2011 |
| Phylogica | $0.075 | $0.053 | September 2010 |
| Sunshine Heart | $0.044 | $0.036 | June 2010 |
| Biota Holdings | $1.05 | $1.09 | May 2010 |
| Tissue Therapies | $0.60 | $0.21 | January 2010 |
| Atcor Medical | $0.13 | $0.10 | October 2008 |
| Impedimed | $0.73 | $0.70 | August 2008 |
| Patrys | $0.09 | $0.50 | December 2007 |
| Bionomics | $0.67 | $0.42 | December 2007 |
| Cogstate | $0.17 | $0.13 | November 2007 |
| Sirtex Medical | $5.04 | $3.90 | October 2007 |
| Clinuvel Pharmaceuticals | $1.83 | $6.60 | September 2007 |
| Starpharma Holdings | $1.61 | $0.37 | August 2007 |
| Pharmaxis | $1.10 | $3.15 | August 2007 |
| Universal Biosensors | $1.19 | $1.23 | June 2007 |
| Alchemia | $0.69 | $0.67 | May 2004 |

### *Portfolio Changes – 22 July 2011*

**IN:**
No changes.

**OUT:**
No changes.

However, that wasn't the end of the company's financial problems. Raising those funds meant that pSivida became 51% US owned. That meant it needed to become incorporated in the US.

But then in mid 2008, the company's share price fell to below $1, which meant it would be delisted. The company undertook a four-for-one share consolidation in the US and a forty-for-one consolidation in Australia. That decision still impacts the company today, with very low liquidity in the stock on the ASX.

At the end of last year, the company had a setback from the FDA, with the regulator asking for more data before it would approve Iluvien. Although a two year endpoint had been agreed upon, the company was three months away from three year data which the FDA wanted to see. Those results have shown that at 30 months the effect is significantly better. In November the company will find out where or not the drug gets approved, and if it is successful it will receive $25 million from its partner, Alimera.

pSivida has developed the only FDA approved drug delivery systems for the eye, with two products on the market, Vitrasert and Retisert. While these have not made much money for the company, they have provided a basis for the company to develop the next generation product that targets a billion dollar market for which there are no approved drugs at the moment (Roche's Lucentis is at a similar stage of development to Iluvien for DME). According to Leedman, analysts in the US are forecasting peak sales for Iluvien of between $250-$800 million.

The share register has been cleaned up now with only 21 million shares on issue. The company has $23 million in cash and recently signed another deal with Pfizer. Leedman says the company is in a good cash position and is not looking to raise funds. However, it has been an arduous and rollercoaster journey for pSivida and its shareholders.

## 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***

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