

In this edition...

As the world was engulfed in financial market chaos this week, investors probably need to accept that high volatility in the sharemarket is with us to stay for the next few years. This means investors need to take profits when solid gains have been made, and to take advantages of attractive opportunities when irrational fear takes control of the markets as we saw on Friday. At Bioshares, we will continue to provide stock specific research so investors can be well equipped to take advantages of the pendulum swinging stockmarket that has become a normality.

In this edition we provide updates on Bionomics, Phylogica and Bluechiip and introduce investors to private company Photonz.

The Editors

Companies Covered: BCT, BNO, PYC, Photonz

	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	-16.8%
Cumulative Gain	250%
Av Annual Gain (10 yrs)	21.2%

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Bioshares

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

Bionomics Phase II BNC105 Results – In Line With Expectations

Bionomics (BNO:\$0.53) delivered interim results from its Phase II BNC105 cancer trial studies. The results were in line with our expectations. The interim renal cancer study results showed that the combination of BNC105 with Afinitor was safe and that study will now move into evaluating the drug's efficacy. The second study in mesothelioma was always going to be a tough indication. BNC105 showed only a small response. However there were some encouraging signs.

Renal Cancer Interim Study Results

This study investigated the safety of combining BNC105 with an existing renal cancer drug, Afinitor, in 15 patients. The Phase I study characterized the safety profile of BNC105. However its safety profile given with Afinitor was yet to be investigated which is why the safety of the combination of the two drugs needed to be established.

Although no evidence of efficacy has been assessed in this trial, it is encouraging that some patients have remained on treatment, and are ongoing, for more than 12 cycles (one cycle lasts 21 days, so 8.4 months of treatment). If patients continued to progress with disease then their treatment of this experimental regiment would stop.

The Phase II study will enroll 152 patients in total. It will seek to complete enrolment by the end of 2012 with results out in June 2013. This trial is comparing Afinitor and BNC105 against Afinitor alone. The primary measure is the change in six month progression free survival (PFS) of the combination therapy versus Afinitor alone. CEO Deborah Rathjen said that Afinitor was approved with only a four month improvement in PFS over previous incumbent therapies.

Mesothelioma Trial Results

The mesothelioma trial yielded some interesting results. A total of 24 patients have been treated. This was a very difficult patient class, with the median expected survival time being only 1.5 months.

The drug was seen to have an effect in one quarter of the patients, with five having achieved a stable disease status, and a stunning result in one patient, with a 57% reduction in overall tumour size. All patents were progressing when they enrolled in the trial. A further three patients need to have their disease status confirmed, at this stage looking like they may have achieved stable disease.

Bionomics has decided to stop this trial rather than continuing to enroll the planned 60 patients. It plans to conduct preclinical work on combining BNC105 with other cancer drugs, possibly Alimta and cisplatin. BNC105 is known to combine well with platin-based cancer therapies.

There has been an argument by some that vascular disrupting agents (VDAs) such as

– Cont'd over

– *Bionomics cont'd*

BNC105 required a combination therapy approach. Whilst the VDAs destroy the tumour from the inside, there are residual smaller tumours remaining that would benefit by being 'mopped up' by a cytotoxic cancer drug.

Other information that came out of this trial was that a dosage level of 16mg/m² was shown to be safe, which will allow dosage in the renal cancer trial to move up from 12mg/m² to 16mg/m².

The main side effect from BNC105 was fatigue in patients. There was no off-target effect observed and no cardio-toxicity, which has been seen with other VDAs.

Additional Study – Ovarian Cancer

Bionomics will progress with the renal cancer Phase II study and has now decided to commence a Phase II study with BNC105 in women with ovarian cancer in the first half of next year. BNC105 has shown to be effective in *in vitro* and *in vivo* models of ovarian cancer.

Oxigene had previously completed a Phase II study in ovarian cancer with its VDA. Bionomics has developed a much more potent VDA and this gives it another reason for exploring this option. Oxigene enrolled 44 patients with a 25% response. Bionomics will look at conducting a larger trial.

Summary

Oncology is a very difficult area of drug development. Success depends on being sufficiently funded to investigate a number of indications simultaneously in a manner that can deliver strong evidence of efficacy. Investors need only to look at the impact one positive Phase III trial Genentech had with Avastin in May 2003. Bionomics is now in that position, having sufficient funding for two and a half years for these programs, retaining \$17.5 million at the end of June.

The company is also in partnering discussions for its anti-anxiety drug candidate, BNC210. An outcome there may occur by year's end. With regard to BNC105, the company will likely look to see results from the Phase II renal cancer study before it seeks to partner that drug candidate.

Bionomics is capitalised at \$183 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Corrections and Clarifications:

In the table in Bioshares 418 "4.7B Reporting Companies – Cash Balances June 30, 2011", the column headed "Cash End 31/3/11 (\$M)" should have read "Cash End 30/6/11 (\$M)".

Phylogica on Track for Further Partnering Deals

One of the ongoing themes in the Australian biotech sector is that many companies in this sector have been steadily developing their products and services over much of the last decade, such that some are now in fact on the cusp of success. This represents an inflection point for the biotech sector that is increasing its appeal to a broader range of investors.

Phylogica (PYC: \$0.06) is one such company where R&D has begun to translate into commercial success after eight years of operation. In 2009 Phylogica changed its business model to focus on revenue generation rather than seeking to bring products into clinical development on its own. Since December 2009, the company has signed three drug discovery deals, with Roche, MedImmune (AstraZeneca) and Pfizer, as well as striking a second deal with Roche to expand its original collaboration.

At this year's *Bioshares* Biotech Summit, Nick Woolf, CFO & VP of Corporate Development at Phylogica, said the company was in fact talking with most of the top 10 global pharmaceutical companies, and all are showing interest in the Phylogica technology. The remaining top 10 pharmaceutical groups that Phylogica has not signed a deal with so far are Johnson & Johnson, GlaxoSmithKline, Novartis, Sanofi-Aventis, Abbott, Merck, Bayer and Eli Lilly.

Phylogica has developed peptide libraries derived from biodiverse bacterial genomes. The peptides are being tested by partners against a range of targets, offering a new way to block human diseases. Over the last few years the company has also improved the quality of its libraries and the ease at which they can be accessed for particular indications.

The company has an aggressive target to sign three pharmaceutical deals this year. Woolf believes that's an achievable goal with the company getting closer to signing its next pharmaceutical discovery deal.

After the company had signed its first two deals, we said the company was one deal away from validating the utility and interest in its drug discovery platform. After completing its third deal, we believe interest in the platform has been validated. This represented both a turning point for investors, but also for other potential pharmaceutical partners.

There is no doubt that having signed four pharmaceutical deals (including two deals with Roche) in 18 months with three major customers, Phylogica is generating increased interest from other potential partners and subsequent deals should be becoming easier to sign. This perhaps explains the company's confidence in securing further deals in the next five months. The company is also in a position to sign more favourable deals in terms of the immediate fee-for-service work and the downstream future payments.

The longer term value for the company is future milestones and

– *Cont'd on page 5*

Bluechiip – Adding Value in the High-End Biomedical Storage Sectors

Bluechiip (BCT: \$0.17) listed on the ASX in June 2011, raising \$3 million. The company has developed a tracking technology for use with medical samples. The technology has been developed in its first "solution design" for the bio-medical industry to include a miniaturized mechanical component (a chip), a wand style reader and software. This suite of products is called the Bluechiip Tracking Solution.

The micro-chip is made up of 56 beams that can be made to vibrate on excitation. The beams can be disabled by being fused or tethered. The chip is digital, in that each resonating beam corresponds to a "1" or "0" depending on whether or not it can vibrate freely.

IPO Funds used for Key Equipment Purchase

The IPO funds have been used in part to acquire specialised laser equipment from **ST Microelectronics** in Italy, to program its chips. The equipment gives each chip a unique ID, using 32 of 56 bits on the chip. Up to 4.2 billion unique addresses can be created.

The company has contracted with ST Microelectronics to produce programmed chips, which will then be sent to third parties to be embedded in their products.

Features of the Chip

The chip can be embedded in tubes and vials because it is a mechanical rather than electronic device. It can survive temperatures as low as to -196 °C and as high as 200 °C, be autoclaved, gamma-radiated and be incorporated into plastics manufactured by injection moulding. These features are the basis of the competitive offering of the technology.

An additional feature is that one of the beams on the device can be used as a reference point for temperature. This means that temperature changes can be tracked, and can alert if the temperature has changed potentially altering the integrity of the sample.

Business Focus

Bluechiip's primary goal is to generate commercial returns by selling and integrating with storage systems and solutions used in the healthcare and biomedical sectors, and to have it adopted as the standard for those industries.

It is avoiding expansion into other areas such as aerospace and defence until it has demonstrated commercial proof-of-principle in an initial industrial setting.

Competition – Barcodes

The main competition for the Bluechiip technology is bar code technology. However, problems for barcodes begin to occur in inventory management setting. Biological samples are stored frozen resulting in barcodes frosting over. Uncovering the bar code can take time, creating the potential for defrosting, which then can lead to integrity issues for the samples. A further risk is that bar codes can fall off the tube or vial, or be mis-read.

Managing Risk in IVF and Cord Blood Storage

An important opportunity for the company lies in risk mitigation in the cord blood storage and IVF and assisted reproduction businesses (stored semen and ova).

What could drive the adoption of the Bluechiip system in these sectors is where the technology can improve the reliability of identification of samples, decreasing, for example, the chance of a woman receiving incorrectly fertilised eggs, and improve the audit quality of cord blood samples, which are meant to be stored for many years.

Strategy

The company is in dialogue with liquid nitrogen tank (pressure vessel) suppliers, such as **Chart MVE** and **Taylor Wharton** and refrigeration suppliers (such as **ThermoFisher** and **Sanyo**) to the biomedical industry as well as the companies that supply tubes and vials (such as ThermoFisher).

An objective of Bluechiip is to have its chip integrated into vials and tubes to make "smart" tubes and vials, with these smart tubes positioned premium end of the storage market, where prices range in the dollars per tube or vial but not used in the 5-10 cents range such as in general pathology.

Bluechiip is aiming to have its chips used in IVF, cord blood and stem-cell storage, and pharmaceutical compound management.

Cont'd on page 5

History

The company was founded by Brett Schwarz and Dr Ron Zmood in 2003, after an Australian poultry products supplier experienced a spoilage issue. The producer wanted a low cost temperature sensor that could be used to check individual chicken carcasses.

The company was previously known as Mems-ID, inferring an association with radio-frequency identification (RFID) technology.

However RFID is an electronics term and the fundamental technology in Bluechiip is not electronic, but mechanical.

RFID cannot be incorporated into tubes and vials plastics (injection moulding) because they are too sensitive to heat and can't be sterilised.

Therefore the company changed its name to Bluechiip, seeking to leverage the common word "blue-chip" which denotes quality, reliability, continuity, longevity and revenues. The redesign of the corporate identity was also done in the hope that the solution name "bluechiip" could one day be used as a verb that describes the process of identifying a stored biological (or other) sample.

Photonz – Manufacture of Pharmaceutical-grade EPA

Below we take a look at a very interesting private New Zealand company that presented at the IPO Preview session at the 2011 Bioshares Biotech Summit recently.

Photonz is a company that investors may see listing on the ASX in the next 12 months. It has developed a world leading position in the manufacture of EPA, a polyunsaturated fatty acid, for pharmaceutical applications.

According to Photonz CEO Greg Moss-Smith, the demand for very pure EPA is growing very strongly but to date the only source has been from oil obtained from fish. However, this source is not sustainable, he said. The key concern is that the supply of fish oil peaked twenty years ago and has not expanded. Furthermore, prices of fish oil have increased at three times the rate of inflation for a decade.

Moss-Smith said that fish don't make EPA. Instead it is made by microscopic plants (micro-algae) and concentrated up the food chain. "Photonz has learnt how to ferment the appropriate micro-algae to cut the fish out of the process," he said.

Photonz has developed a prototype 600 litre fermentation reactor, achieving stable production at that scale, and is now aiming to get industrial scale and produce pharmaceutical grade drug substance by 2012.

Market Rationale

The market for a cholesterol lowering class of drugs, statins, is very large with more than 20 million prescription users in the US alone. Clinical evidence now exists to show that adding high purity EPA to statin therapy is beneficial. For Photonz, this represents a large market opportunity, where existing channels can be used to access patients. The scale of demand is potentially for thousands of tonnes of high purity EPA.

Moss-Smith estimates that based on what is known about the combination drug products that are entering or set to enter the statins drug market, that high purity EPA drugs end up accounting for about two thirds of the market, with one third being represented by the low purity LOVAZA-type drug substance and another third met by the high purity EPADEL-type drug substance.

Photonz is aiming to capture 25% of the high purity EPADEL-type drug substance, which represents about 6 million prescription users. It is also aiming to introduce its own generic version of EPADEL, as part of this strategy.

Pharmaceutical demand for fish oil is reaching the point of taking 40% of what is actually available. While pharmaceutical companies can pay more for fish oil, the concern is that higher prices stimulate overfishing, leading to over-fishing and ultimately collapse of fish stocks.

Addressing Supply Chain Risk

The Photonz technology is the only technology that can address these supply risks and Photonz's goal is position itself as the second source of EPA in the supply chain. "As the secure second

source supplier we are looking at sales of US\$500 million and potentially as much as \$1 billion (per annum)," said Moss-Smith.

EPA Fermentation Productivity

Photonz has now the broken industry ceiling for production yields and is on track to meet process targets by the end of 2012, in time to transfer the process to a chosen contract manufacturer to take it up to a 20,000 litre pilot industrial scale. Photonz is aiming to achieve an EPA productivity target of 30-35 mg/l/hr, having crossed the 20 mg/l/hr barrier in the last twelve months.

Moss-Smith emphasized that the key task was to derive an economically viable fermentation process, since downstream purification processes are essentially conventional and proven. "It's a pretty low risk development once you have the fermentation sorted out," said Moss-Smith.

Lead Product

Photonz's lead product is a generic version of EPADEL (**Mochida**, Japan) which is 96% EPA. EPADEL has been on sale since 1990 and has annual sales of US\$420 million. However EPADEL now is being converted to an over-the-counter format, which could see demand increase but without the underlying capacity in place to meet that demand.

Amarin, which is developing another EPA product, has released positive Phase III results for MIAXION and it is expected that product will be launched in 2012.

Protection

Photonz chose to naturally breed micro-algal strains instead of applying genetic engineering to solve the yield problem. Moss-Smith argued the strain development approach creates long lead time barriers to entry. Photonz has been working on its strains for six years. The company hasn't patented the strain, but has patented all the essential intermediate compositions down the process path.

"The trick is not just making a lot of EPA, its making a lot of EPA you can purify. We have worked out how to distort the fatty acid metabolism of the strain so that you maximize the EPA yield and minimize all the interfering compounds, which gives you a very economic purification downstream. It has meant that the cost of goods is similar to that for fish oil because the purification is so efficient," said Moss-Smith.

Commercial Relationships

Moss-Smith said Photonz had formalised a relationship with **DSM** as a potential contract manufacturer, had signed a fractionation agreement with **Separex** and a purification agreement with **Novasep**.

Next Funding Round

Photonz has raised US\$8 million to date and now intends to raise US\$12.5 million in first half of 2012, with one of its options to achieve this being via an ASX listing.

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Bioshares Model Portfolio (5 August 2011)			
Company	Price (current)	Price added to portfolio	Date added
Acrux	\$3.73	\$3.37	June 2011
Psivida	\$3.86	\$3.95	May 2011
Bioniche	\$0.85	\$1.35	March 2011
Somnomed	\$1.25	\$0.94	January 2011
Phylogica	\$0.060	\$0.053	September 2010
Sunshine Heart	\$0.035	\$0.036	June 2010
Biota Holdings	\$0.89	\$1.09	May 2010
Tissue Therapies	\$0.44	\$0.21	January 2010
Atcor Medical	\$0.11	\$0.10	October 2008
Impedimed	\$0.59	\$0.70	August 2008
Patrys	\$0.07	\$0.50	December 2007
Bionomics	\$0.53	\$0.42	December 2007
Cogstate	\$0.17	\$0.13	November 2007
Sirtex Medical	\$5.37	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$1.50	\$6.60	September 2007
Starpharma Holdings	\$1.39	\$0.37	August 2007
Pharmaxis	\$1.09	\$3.15	August 2007
Universal Biosensors	\$1.00	\$1.23	June 2007
Alchemia	\$0.62	\$0.67	May 2004

Portfolio Changes – 5 August 2011

IN:
No changes.

OUT:
No changes.

– Bluechiip cont'd

A Contributor to Productivity

Bluechiip is similar to **LBT Innovations** in inventing a technology that, like LBT Innovations' Microstreak agar plate streaking technology, can deliver workflow productivity gains.

Managers of biomedical storage businesses could expect to see costs decrease if the Bluechiip systems are adopted, by delivering labour costs savings where improvements are made to occupational health and safety.

Patents

Bluechiip has established IP that includes ten patent families. Patents have been awarded in the US (7,434,737) and in Europe and key EU countries that describe and set out the invention in its first instance.

Risks

Risks with an investment in Bluechiip are grouped around the ability of the company to secure channel partners and drive adoption of the technology by its target markets. A slower rate of take-up could weaken the company's financial position.

Summary

We expect Bluechiip to be stock of interest to not only investors in the biotech sector but also outside the biotech sector because it is a platform technology company with multiple industry opportunities. This potential however, will not become apparent until it secures repeat sales in the biomedical samples storage industry.

Bluechiip is capitalised at \$13 million and held cash of \$1.4 million at June, 2011.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

– Phylogica cont'd

royalties if its discovery partnerships progress into clinical trials and products on the market. In terms of bio-dollar deals, the company currently has potential milestone payments of US\$235 million, however this has the potential to rapidly accelerate over the next 12 months according to Woolf. The reality is if there is such strong and widespread demand for access to the technology, an acquisition in the next three years has a reasonably high likelihood of occurring.

Woolf said the company's work with MedImmune is progressing well, which is focused on discovering novel antibiotic peptides targeting *p. aeruginosa* and the drug resistance to this bacterium. The primary screen has gone well and if the company is the successful, there is the potential to expand this work into a broader collaboration.

One of Woolf's goals has been to build the international share register in Phylogica. In March the company raised \$5 million from funds such as Ascent BioMedical Ventures in New York (which now owns 5% of the company, and NAOS Asset Management in Sydney (which has a 10% stake in the company). These funds will be used to increase the R&D capacity of the research facility in Perth, including the purchase of additional robotic screening systems. The company had \$5.2 million in cash at the end of June.

Phylogica's medium term goal is to become profitable from its deals. It generated revenue of \$2.5 million in 2010 calendar year and revenue of \$5 million this year is a reasonable target, if it can secure three additional deals by the end of the year. Its operating costs for this year are expected to be \$6 million. The company is looking to move into cash flow sustainability in 2012.

Bioshares recommendation: **Speculative Buy Class A**

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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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