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In this edition...
Canadian biotech Bioniche listed on the ASX in February. The human and veterinary health business has long standing Australian links, including shareholders and local operations. Bioniche is developing a treatment for bladder cancer. The market opportunity in bladder cancer is substantial and Urocidin offers improvements over the current BCG therapy, especially in the area of product handling and disposal.
Biota will be a stock to watch in coming months, especially if funding from an unspecified agency is made available to support the development of Inavir for markets outside of Japan.
Starpharma has two key milestones coming up, including the launch of Vivagel coated condoms and the conclusion of a Phase II bacterial vaginosis trial.
The Editors
Companies Covered: BNC, BTA, SPL

	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 - Current)	26.8%
Cumulative Gain	**267%**
Av Annual Gain (9 yrs)	**18.5%**

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Bioshares

18 March 2011
Edition 400

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

Bioniche – The Urocidin Story

Bioniche (BNC: $1.35) is a Canadian biotechnology company that was founded in 1979 as Vetrepharm Animal Health. The company listed on the Toronto Stock Exchange in 1992, and listed on the ASX in January of this year, raising $12.5 million through its Australian IPO in conjunction with a C$15 million raising in Canada. The company has sought a listing in Australian given a long standing Australian shareholder base, veterinary business operations located in Armadale, NSW and connections to stockbroker Taylor Collison. The CEO, President and Chairman of the firm, Graeme McRae is also Australian.

Bioniche is a developer of human therapeutics, veterinary and food safety products. Its vet business generated sales of C$27 million in 2010, down 19% from C$33.3 million in 2009. Sales for the half-year ending December 31, 2010 were C$12.8 million, roughly on par with C$12.9 million for the previous corresponding period.

The company has veterinary operations in the US, Canada and Australia, with 60 products on offer. It utilises distributors for other parts of the world. The company employs 230 people.

Lead Human Health Program – Urocidin

Bioniche has developed a therapeutic product candidate called Urocidin for the treatment for non-muscle invasive bladder cancer or superficial bladder cancer. The current standard-of-care treatment for this cancer indication is BCG therapy (bacillus Calmette-Guerin), derived from live attenuated mycobacterium bovis. BCG therapy delivers about a 50% disease free survival rate at two years.

BCG was originally developed as a vaccine to prevent tuberculosis in humans. The origins of BCG as a bladder cancer therapy date back to the 1970's when a Canadian urologist, Dr Alvaro Morales, proposed that infecting the bladder with BCG would stimulate the immune system to respond to the presence of cancer cells. Dr Morales has been intimately involved with the development of Urocidin, which takes its lead from the BCG vaccine. Other immune stimulants exist such as beta-glycan and lipopolysaccharide, however, toxicity issues have limited their exploitation.

For carcinoma in situ (CIS) bladder cancer, which effects about 7% of bladder cancer patients, the current treatment begins with transurethral resection of the bladder tumour, followed by one or two courses of immunotherapy with BCG.

There are several issues with BCG treatment. One is that between 35-50% of patients become refractory (i.e. cease to respond) to BCG treatment. Another is the risk imposed on patients and healthcare workers of potential infection from the live BCG vaccine, leading to tuberculosis infection. Product handling and disposal of treatment solution impose burdens on clinical staff.

– Cont'd over

How Does Urocidin Work?

Similar to BCG therapy, Urocidin (otherwise known as mycobacterial cell wall DNA complex) stimulates an immune response. It is comprised of 120 different components of the mycobacterium cell wall including 90 different proteins. The mycobacterium from the complex is sourced from *m. phlei*, a non-pathogenic organism, which is not associated with infection in humans or animals.

What Bioniche has found is that when components of the cell wall of *m. phlei* are complexed with the DNA of *m. phlei*, a strong response is obtained. The complex initiates the cell death cycle in cancer cells. Secondly it induces an immune response by elevating levels of surveillance and responder immune system molecules that track down and destroy cancer cells.

Clinical Program for Urocidin

A Phase II trial of Urocidin conducted in 55 patients evaluated two different doses of the formulation, being 4mg and 8mg respectively. A complete response at weeks 12 and 26 weeks of 27% was observed for the 4mg dose group of 25 patients. A complete response at weeks 12 and 26 weeks of 46% was observed for the 8mg dose group of 25 patients. A complete response rate is defined as no evidence of disease as determined by cystoscopy, biopsy or cytology.

As a matter of contrast the two marketed forms of BCG, TheraCys (Sanofi Pasteur) and TICE (Organon - Schering Plough), are dosed at 81mg and 50 mg respectively. Urocidin does not have the safety issues of TB infection that these existing products have.

First Phase III Trial

Interim results of Bioniche's first Phase III trial were released recently at the Annual Congress of the European Association of Urology in Vienna.

The purpose of the study was to evaluate Urocidin (8 mg) for its safety and efficacy in an open-label single arm study in patients who were refractory to BCG therapy but were at a high risk of progression.

The primary efficacy endpoint was the disease free survival rate at one year on the intent to treat population.

The study enrolled 129 patients between November 2006 and April 2009. Of the 129 patients, 91 had carcinoma in situ (CIS) and 38 had papillary tumours.

The overall disease free survival rate at 12 months was 25%. In the CIS tumour group, the disease free survival rate was 21% and in the papillary tumour group the disease free survival rate was 35%.

Two serious adverse events were reported, being a case of hematuria and a urinary tract infection.

Second Phase III Trial

Bioniche licensed Urocidin to **Endo Pharmaceuticals** in 2009 (see next page), which is funding and managing a second Phase III trial. Enrolment for this 450 patient trial commenced in February of this year and the trial is scheduled to be completed in 2013. Unlike the first Phase III trial, this is a randomized trial which will see Urocidin compared to Mitomycin C, a chemotherapy with a history of use in treating early stage bladder cancer.

The trial will recruit both patients who have failed BCG therapy and patients who have seen their bladder cancer recur.

Comment

The Urocidin product has probably achieved its response rates of ranging from 20% to 46% because it is an immune system stimulant that has been delivered with an appropriate periodicity and frequency to allow the immune system to react to the vast pool of antigenic matter in the MCC complex. Its short apoptotic effect

– Cont'd over

Selected Clinical Trials - Urocidin (EN3348) (mycobacterium cell wall DNA complex (MCC))

Trial	Description/Title	Num. Pts	Dosing	Design	Results/Comments
Phase II	Intravesical Mycobacterial Cell Wall-DNA Complex in the Treatment of Carcinoma In Situ of the Bladder After Standard Intravesical Therapy Has Failed	55	6 weekly intravesical instillations of **4mg** or **8mg** MCC followed by 3 weekly instillations at weeks 12 and 24	Dosing study	Complete response* rate 4mg group (n=25) was **27%** at weeks 12 and 26; for the 8mg group (n=30) the response rate was 4**6%**
Phase III	Treatment of patients with NMIBC at high risk of progression and refactory to BCG	129	6 weekly intravesical instillations of **8mg** MCC followed by 3 once weekly instillations at 3,6, 12,18 and 24 months	Open label, single arm	One year disease free survival rate - **25%**; carcinoma in situ group - **21%**, papillary tumour group - **35%**
Phase III [with Endo Pharmaceuticals]	Efficacy and Safety Evaluation of EN3348 (Mycobacterial Cell Wall-DNA Complex [MCC]) as Compared With Mitomycin C in the Intravesical Treatment of Subjects With BCG Recurrent/Refractory Non-muscle Invasive Bladder Cancer (EMBARC-RF)	450	6 weekly intravesical instillations of **8mg** MCC followed by monthly instillations to month 12	Control arm - Mitomycin C	Enrollment commenced Feb 2011. Est completion date - Nov 2013

*Complete response rate defined as no evidence of disease as determined by cystoscopy, biopsy or cytology

courtesy of the DNA construct would appear to have a tumour disruption benefit that destabilises the disease in the short term.

What may warrant further investigation are variations on the dosing regimes tried to date for Urocidin, including longer term dosing schedules.

What is the Market Opportunity for Urocidin?

Bioniche says that 70% of bladder cancer cases are the non-muscle invasive form which are suitable to treatment with its product.

Each year approximately 135,000 patients are diagnosed globally, of which 50,000 are at high risk of progressing to more advanced stages of the disease or are refractory to BCG treatment. Each year 215,000 patients will have a recurrence of bladder cancer.

From these two groups, Bioniche believes that a combined group of new but high risk patients, coupled with some of the recurrence group, would offer an initial addressable opportunity of 130,000 patients per year globally.

One patient subset of patients with the non-muscle invasive form of bladder cancer that may be particularly attractive to Bioniche and Endo Pharmaceuticals is those with papillary form of the cancer. BCG therapy cannot be used in that group because of the risk of BCG causing tuberculosis infection through the blood.

Endo Partnership

In July 2009, Bioniche licensed the North American rights to Urodicin to Endo Pharmaceuticals, a US based pharmaceutical firm. Endo sells a range of pain management products. It entered the bladder cancer space when it acquired **Indevus Pharmaceuticals** in 2009. Endo is capitalised at US$4 billion. It posted revenues of US$1.7 billion for the year ended 31 December 2010.

Endo markets Valstar (valrubicin), a product approved for the treatment of BCG-refactory bladder carcinoma in situ. This product garnered sales of US$14.1 million in 2010 and US$3.4 million in 2009 after being relaunched in 2009. Valstar (valrubicin), is semisynthetic analog of the anthra-cycline doxorubicin. In a 90 patient trial with bladder cancer carcinoma in situ, 18% of patients recorded a complete response at six months.

Endo paid an upfront fee of US$20 million to Bioniche in 2009 for the North American rights to Urocidin. In February 2011, Endo extended the deal to take up world-wide rights to the product. This brought the total of upfront and milestone payments of $38 million. Bioniche stands to gain another $92 million should certain development milestones be met. Bioniche is entitled to a royalty on net sales in excess of 20%.

What is perhaps of equal significance to the royalty rate is that Bioniche has retained manufacturing rights by putting a supply agreement in place with Endo, which offers additional revenue to Bioniche which we estimate equates to the company earning revenue at the rate of around 30% of net sales. Through its manufacturing facility, Bioniche is currently able to supply 3500 doses per annum. However, the company is building additional capacity to supply one million doses of Urocidin per annum.

Risks

The company faces the risk of delays to the Phase III trial being conducted by Endo Pharmaceuticals, primarily if recruitment is slower than expected. This risk is of moderate grade given that the global prevalence of bladder cancer is high.

Although not determined, the final pricing of Urocidin will be an important factor in determining the take-up rate of the therapy. A key consideration will be how much urologists will be able to earn from administering the treatment. The total cost of a course of treatment will then have to be assessed from a health economics perspective to secure reimbursement.

While the company is in possession of options and warrants that could trigger a capital inflow of more than C$8 million, an ongoing risk with the firm is it's capacity to address working capital requirements. Weak economic conditions saw the company experience a 19% drop in sales in 2010, and growth was flat in the latest half year. If weak market conditions persist, there is a possibility that the company would need to raise additional funds.

A risk for investors taking up stock in international firms that list in Australia is that their visibility in the market, as generated by roadshows and investor meetings and other activities, has a far greater chance of waning. This is a function of the need to travel significant distances on a regular basis. The appointment of an Australian-based executive tasked with investor relations responsibilities could mitigate this risk.

Investment Opinion/Summary

Bioniche is an attractive investment opportunity for several reasons. The Urocidin program is well advanced and de-risked from a funding point of view through the Endo partnership. The clinical evidence in favour of Urocidin warrants close inspection and monitoring as the second Phase III trial moves towards completion in 2013. Of particular note, the company's decision to retain manufacturing rights for Urocidin means that should the product successfully reach the market, then the monetary reward for shareholders appears to be sizeable.

Bioniche is capitalised at $136 million and holds cash assets of approximately $27 million.

Bioshares recommendation: **Speculative Buy Class A**

(Bioniche has been added to the Bioshares Model Portfolio at $1.35.)

Bioshares

Biota Holdings – Looming Agency Funding Decision Will Be Significant Share Price Driver If Successful

There will be some big changes for Biota Holdings (BTA: $0.96) in the months ahead. The company is waiting on a decision from a US agency to see if it can get its long acting flu drug program (called Inavir in Japan) funded to get the product registered in major markets. If that doesn't occur, then the company is considering a range of other options to progress the program, including raising the funds from overseas investors, an M&A transaction, or still partnering the program with a pharmaceutical group. Either way, Biota looks determined to crystallise some of the substantial potential value that Inavir has in commercialising the product outside of the Japanese market.

Inavir is the most recent neuraminidase inhibitor (flu drug) to gain approval by regulators (in Japan). It is competing with Relenza and Tamiflu in Japan. However it has a clear delivery advantage over incumbent products, needing only to be taken once as apposed to twice daily for five days for Relenza and Tamiflu. It was released at the end of Japan last year and in the first two months it generated sales of $34 million. Of particular interest will be the sales generated over the first quarter of this year, which is the peak flu period in Japan.

To get Inavir commercialised outside of Japan will cost between $250-$300 million. The figure is high because it will also include the registration of a new delivery system (inhaler). In Japan the requirements are lower in getting a flu drug to market, needing only to show there is no inferiority to an existing drug (Tamiflu). Outside of Japan, the drug will need to be compared to a placebo arm which will take longer and cost more.

Biota has been in discussions will a health funding agency for a significant period to access funding to bring Inavir to market outside of Japan. If it's successful, that grant would fund the full program and would therefore be a very substantial grant. We believe there is a reasonable chance that the company may be successful in its submission. If it's not successful it will need to progress the other funding options.

The global market for these flu drugs is estimated at $1.4 billion a year. That's only the seasonal market and there is also a market for stockpiling by governments or more specifically replenishing these stockpiles. Governments around the world have built up an $8 billion stockpile to protect against any future flu pandemics.

In 2012 there will be a significant amount of flu drug stockpiles that will need to be replaced. That is positive for Biota in the short term because it's expected that stockpiles in the future will become more balanced with Relenza and Tamiflu. Current stockpiles are around 85% Tamiflu/15% Relenza and this should move to a more 50/50 position with the two drugs. The reason for this is resistance issues that have emerged with Tamiflu and not Relenza. Biota will continue to receive Relenza royalties until 2014 in major markets and importantly until 2019 in Japan.

The market for flu drugs is very large and having access to the best drug around is a clear reason for Biota to hold on to Inavir for longer, potentially bringing the drug to registration stage on its own. It could even potentially sell the drug directly to governments for stockpiling given there are only a small number of customers representing a massive market. Inavir would also have storage and logistic advantages being only once only treatment.

One of the items the company still needs to resolve around commercializing Inavir outside of Japan is the contractual rights to the drug with Daiichi Sankyo, with which it shares equal ownership. Once Biota decides to invest significantly in the commercialisation of the drug, then that ownership structure will have to change, and those rights will need to be negotiated.

Another item to be considered is the impact on the flu drug market when generic competitors emerge to Tamiflu after 2015. Generic versions of Relenza will take longer to reach the market because it is an inhaled drug and there is also patent protection in place around the inhaler.

Other Programs

The RSV program is progressing well for the company. Biota has changed the drug scaffold on its previous drug candidate which had a peculiar toxicology issue that was unresolved. The company believes it is well positioned to re-licence this program, with discussions underway. The Phase IIb rhinovirus program will now not be completed until next year (results). The company is spending $25 million on this trial.

Summary

Inavir is largely de-risked as a drug development program and the company believes it would be leaving a lot of money on the table if it licensed the program now. It's good evolution for the company that it should be seeking to take products further on its own and increase its portion of future gains.

Investors in Biota need to understand that there will be periods of high volatility in this stock. Biota will receive only $3.3 million in Relenza royalties from sales in the first half of this financial year, compared to $63.7 million in the 12 months of FY 2010. Relenza royalties will pick up again. And Inavir sales should continue to grow in Japan.

There are other significant events for the company over the next 12 months, including licensing of the RSV program and results from the rhinovirus Phase IIb trial. More immediately will be a decision regarding agency funding for Inavir in coming months and how it will source the significant funds to develop Inavir if agency funding is not secured. With agency funding not factored at all into the company's share price, we would expect strong share price gains if the company was successful in a major grant.

Biota is capitalised at $174 million. It had $77 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

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The 7th annual Bioshares Biotech Summit will be held in the picturesque location of Queenstown, New Zealand, this year on July 22-23. For the past six years, this event has brought together the leading investment and biotech managers to discuss the key issues involving the Australian biotechnology sector.

The Bioshares Biotech Summit is built around an intense and highly relevant two-day conference program. It is also one of the best high-level networking events on the Australian biotech calendar. The conference is well attended by biotech CEOs, directors and senior managers, biotech investment managers, venture capital groups, analysts and stockbrokers. The conference is also highly relevant to international investment groups seeking to increase their exposure to the Australian biotech sector.

With a number of Australian biotech companies enjoying stunning success and moving through a transformational period, the conference promises to be a not-to-missed event, where reasons fo such success are discussed and examined.

And once the conference is over, delegates may want to take the time to further enjoy the magnificent attractions of Queenstown. We look forward to seeing you there!

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Bioshares Model Portfolio (18 March 2011)

Company	Price (current)	Price added to portfolio	Date added
Bioniche	$1.35	$1.35	March 2011
Somnomed	$1.05	$0.94	January 2011
Phylogica	$0.070	$0.053	September 2010
Sunshine Heart	$0.035	$0.036	June 2010
Biota Holdings	$0.96	$1.09	May 2010
Tissue Therapies	$0.65	$0.21	January 2010
QRx Pharma	$1.50	$0.25	December 2008
Hexima	$0.35	$0.60	October 2008
Atcor Medical	$0.10	$0.10	October 2008
Impedimed	$0.75	$0.70	August 2008
Patrys	$0.10	$0.50	December 2007
Bionomics	$0.40	$0.42	December 2007
Cogstate	$0.19	$0.13	November 2007
Sirtex Medical	$5.21	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.85	$6.60	September 2007
Starpharma Holdings	$1.05	$0.37	August 2007
Pharmaxis	$2.35	$3.15	August 2007
Universal Biosensors	$1.31	$1.23	June 2007
Acrux	$3.45	$0.83	November 2004
Alchemia	$0.67	$0.67	May 2004

Portfolio Changes – 18 March 2011

IN:
Bioniche has been added in at $1.35

OUT:
No changes

Starpharma – Major Milestones Pending

Starpharma's (SPL: $1.05) first major product is still expected to be launched this year, the Vivagel-coated condom, to be sold by the largest condom manufacturer in the world, **Reckitt Benckiser**, which has 42% global market share.

The Phase II results from the bacterial vaginosis (BV) trial of Vivagel are expected by mid year. The trial involves 132 patients in the US. In a serendipitous discovery from an earlier trial, it found that several women were cured of BV when taking Vivagel as a treatment to prevent sexually transmitted diseases.

Topical agents alone represent a BV market of $300-$350 million a year, which excludes antibiotic use. The existing options poorly serve the market with many shortcomings. Rather that wiping out all bacteria with antibiotics, Vivagel selectively reduces the bacteria causing the condition whilst supporting the growth of healthy bacteria. The Phase II study should also deliver some clear results.

In mid 2011, the company will start another BV trial that will look at preventing BV. It will be a similar sized trial. Around 50% of women with BV find the condition returns. Therefore recruitment should not be difficult, similar to the first trial where recruitment has gone very well. That recruitment is not an issue is a very clear indication of the potential demand for the product. Results from this trial should be available by the end of the year.

Other Developments

Starpharma was awarded $250,000 in funding from the Victorian Government to expand the use of its dendrimers in improving agricultural products. This can include improving the way agrochemicals adhere to leaves or making the chemicals more soluble, extending the product's effect, or controlling the release. Simply increasing the solubility of the active chemicals could mean the equivalent product could be shipped in 2.5 litres for instance rather than 50 litres of chemical. The top 10 agrochemicals sell around $9 billion of product a year.

Starpharma is also working with an undisclosed major agrochemical manufacturer to develop similar improved products for its partner. This technology uses an industrial, cheaper form of the company's dendrimers, called Priostar. The dendrimers would not be synthesized to the agrochemical, but simply mixed in with the chemicals to deliver improved performance.

As is being seen with more biotechs now, Starpharma not only has patents around its technology, but for an enabling manufacturing assets, importantly it has trade secrets over the manufacturing of Priostar dendrimers that have not been disclosed. This means it will more difficult for illegal versions of the ingredient (the dendrimer) to be manufactured and distributed.

Other Milestones

Other items for investors to look out for include negotiation of Japanese rights for the condom microbicide product. Under the Reckitt Benckiser licensing deal, Starpharma has indicated it expects to receive royalties of up to $30 million a year if product inclusion is high through its SSL range of condoms, between $12-$24 million if the inclusion is medium, and around $6 million in royalties if the product inclusion is low. Starpharma has a long patent life around the technology, out to at least 2027.

Starpharma is capitalised at $256 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

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

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

(CMP–Current Market Price)

Group B

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

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

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

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

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