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Bioshares

22 August 2014
Edition 565

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

Companies covered: BNO, IMC, COT (The Biofusionary Corporation)

	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 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 -)	13.0%
Cumulative Gain	**409%**
Av. Annual gain (14 yrs)	**17.0%**

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Bionomics Books Its First Profit

Drug discovery and development company Bionomics (BNO:$0.58) has posted its first profit since its foundation in 1996. The company recorded a profit of $3.2 million for FY2014, on the back of revenues and other income of $27.5 million.

This positive change in Bionomics' financial result for FY2014 was due to the company booking an upfront milestone payment of US$20 million from Merck, following the signing of a research collaboration and licensing deal in June for BNC375. A further US$486 million may be received in development related milestones, in addition to royalties, which Bionomics CEO Deborah Rathjen described as "very solid, very meaty royalties".

The company also received $7.6 million in refunds under the Commonwealth Government's R&D Tax Incentive scheme.

BNC375 is a compound that has potential to treat a range of cognitive impairment conditions, for example Alzheimer's disease. The molecule represents a novel approach to treating cognitive impairment, which is one of the reasons that ostensibly drew Merck's attention to it. Many of drugs that have been developed to treat Alzheimer's disease have, for example, been designed to mitigate the effects of amyloid plaque or 'tangled' tau proteins, but to date none of these have been successful.

In contrast, BNC375 acts on a specific (the alpha-7) acetylcholine receptor (an ion channel). BNC375 is neither an antagonist (blocker) nor an agonist (activator). Instead it simply amplifies the natural agonists which maintain vital signaling patterns in the brain. Bionomics produced pre-clinical data which showed that BNC375 increased cognition in scopolamine-induced, cognition-impaired rodents.

In these animal studies, BNC375 compared favourably to the drug donepezil (Aricept), a drug approved in the late 1990's for the treatment of mild-to-moderate Alzheimer's disease and mild cognitive impairment. The difference between BNC375 and donepezil is that BNC375 has a wide dose range (ranging from 0.1 to 10 mg kg) but equally important, it does not desensitize the alpha-7 receptor. Aricept comes in 5mg, 10mg and 23mg dose forms.

Prior to signing its research and collaboration deal with Bionomics, Merck separately studied BNC375, both reproducing and extending Bionomics' studies. These studies generated very strong interest by Merck in BNC375.

Cash Resources

We estimate Bionomics now has cash at hand of approximately $30 million. This gives the company sufficient funds to comfortably support more than two years of activities at its current burn rate of $11 million per annum.

Bionomics has accumulated losses of $70 million.

Cont'd over

– Bionomics cont'd

Main Implication of the Merck Deal

The main implication of the BNC375 deal is that it is the first transaction in the company's history to reduce its dependence on shareholders for capital to fund drug discovery and development programs. In our view, there is a more than reasonable likelihood that the next few milestone payments will come through, further consolidating Bionomics' cash position.

While the detail of any future milestone payments is not known, convention suggests that they could be connected to events such as an IND filing with the US FDA, the initiation of Phase I, Phase II, and Phase III trials, the submission of a New Drug Application with the FDA and finally the approval of the drug candidate by the FDA.

The company should be well positioned to cushion the effects of actual or potential setbacks from its other programs, including with its cancer drug BNC105, which has struggled in clinical trials to date, although the company believes that it demonstrated positive activity in subsets of patients in the Phase II kidney cancer trial.

One out-licensed program, the anxiety drug BNC210/IW-2143, has from our point of view been a cause for concern, due to the very low level of visibility into the program, which is managed by partner Ironwood Pharmaceuticals. It is worth noting that Ironwood makes no mention of IW-2143 in its R&D pipeline table as posted on its website.

Bionomics announced in December 2012 that Ironwood had commenced a Phase I trial of BNC210/IW-2143 in December 2012, 20 months ago.

The absence of milestones payments could be a sign that the program has struck difficulties. However, CEO Rathjen indicated that some new data relating to the program would become available at the Neurosciences 2014 meeting, to be held in Washington, DC in November.

Bionomics has continued to strengthen its IP covering anxiolytic compounds, filing a continuation patent (2013202426) of Australian patent application 2007312936 in 2013, as well as "A Crystalline Form of an Anxiolytic Compound" (2013204159).

Patents covering the crystal form of a compound are a stronger form of composition of matter, specifying colour, shape, melting point, density, hydroscopicity, solubility and dissolution rate as well as the actual crystal structure of the pharmaceutical product.

Thus the low visibility relating to BNC210/IW-2143 may in fact be related to IP strengthening activities managed by Bionomics.

Other Partnering Events Ahead

Bionomics' cash position may also be further strengthened this year should it be successful in out-licensing either its BNC105 program (which we rate as unlikely, given the unsatisfactory clinical data yielded to date), its BNC164 program (which we rate as highly likely) and the early stage BNC420 program, (which we rate as likely).

The BNC164 program, which is also known as the Kv1.3 program, was originally licensed to Merck Serono, a division of Merck KGaA, but was handed back in June 2012 because of a round of corporate restructuring which took place prior.

Although BNC164 had not entered into clinical development, significant funds were invested in the program. Bionomics has now extended the range of potential licensees to include eye drug companies as well as auto-immune companies.

The BNC420 program is a product of Bionomics' involvement with the Cancer Therapeutics CRC. This compound inhibits and is selective for the VEGFR3 receptor. The opportunity with the drug is that it works to stop the development of tumours in the lymphatic system and has the potential to treat melanoma and triple-negative breast cancer, according to Bionomics.

Bionomics is capitalised at $242 million.

Bioshares recommendation: **Speculative Hold Class A**

An updated version of the Bionomics Pipeline, as published in November 2013 in Bioshares 531 can be found on the next page

Bionomics' Pipeline - An Update of Tables Presented in Bioshares 531 [November 2013]

BNC-105	BNC-210 / IW-2143	BNC-101	BNC-375	Pain Drug Discovery Program	BNC-164	NEW BNC-420 [BL-011246]
Description						
Small molecule cancer compound; vascular disruption agent; tubulin inihibitor	Small molecule anti-anxiety agonist GABA-a receptor, with features superior to benzodiazapene drugs e.g. Valium	Humanised IgG monoclonal antibody targeting LGR-5, a marker of adult stem cells	A small molecule type 1 positive allosteric modulator of α-7 nAChR	BNOs newest program was announced as a license and option agreement with Merck in July	Small molecule targeting Kv1.3 ion channel; applicable to multiple sclerosis and auto-immune conditions	A selective inhibitor of VEGFR3 that supresses both primary tumor growth and lymph node metastasis
		Mech. of action improves selectivity of drug and increases signalling without loss of effect	BNO may receive up to US$172 M in fees and milestone payments (as well as royalties)	Target indication is chronic and neuropathic pain e.g. shingles, postherpetic neuralgia, diabetic neuropathy and fibromyalgia	Program was handed back by Serono in June 2012 due to corporate restructuring	The asset is licensed from the Cancer Therapeutics CRC
			Objective is to develop an oral drug which can improve memory function and cognition (relevant to schizophrenia)			Is complementary to PD1 inhibitors and other immune targeted cancer therapies
Status - Nov 2013						
Phase II renal cancer trial now fully recruited (139 pts); in comb. with Affinitor	BNC-210 was partnered with Ironwood Pharmaceuticals in Jan 2012 for total deal value of US$345 M plus royalties	Program was obtained through acq. of Eclipse Therapeutics in Sept 2012 for $10 M in BNO scrip	BNC-375 continues in pre-clinical development	This program is at a very early stage	Focus has now shifted to psoriasis	
Also in Phase I/II comb. Study with Carboplatin and Gemcitabine in Ovarian cancer (134 pts)	US$3 M was paid up front, with US$1 M paid since then; US$2 M could be paid as drug moves through Phase I	Program is 'going very well in all sorts of areas'		Program is inspired by pain drugs that originate as treatment for other CNS conditions e.g. Lyrica which was an improved version of the epilepsy drug Gabapentin. It is worth noting that Lyrica comes with a label warning concerning suicidal behaviour		
	BNO is 'very pleased with level of engagement with Ironwood'	Filed pre-IND submission with FDA in Oct		Lyrica comes off patent in the US in 2018		
	Ironwood has submitted an IND for IW-2143 and commenced a Phase I trial in December 2012	Gained feedback 2 months ahead of schedule				
Next Milestone						
Goal is to partner BNC-105 in 2014, once trial data is available	Initiation of Phase II studies	Complete enabling tox studies and submit IND	Positioned for partnering on 2014; BNO is also building a data package covering manufacturing and IND enabling studies	Time frame for a yield from the discovery program is two years	Goal is to partner BNC-164 in 2014	
					Asset now much more advanced in terms as a partnerable asset, benefiting from investment made by Serono	
UPDATED Status - August 2014						
Phase II renal cancer trial results released in March 2014 showed no difference in PFS between treatment arm and control arm	Company has little to say about this program while it is in the hands of partner Ironwood	Has completed IND enabling studies, including toxicology studies	Signed world-license agreement with Merck in June 2014, for up to US$506 M in milestone payments, for the treatment of cognitive impairments		Expanded data package; indication potential extended to opthalmology	Now an outlicensing prospect
BNO says market hasmisunderstood data, that "BNC105 combination treated benefited patients with more advanced disease"	Expects some new data to be available around the time of the Neuroscience 2015	Targeting IND filing and Phase I trials in 2015	Booked initial MSP of US$20 M in FY2014 accounts		Aim is still to partner this asset this year	
Phase I ovarian cancer trial has had 12/15 pts complete 6 cycles of combo therapy; dose for Phase II trial now determined						

Phase II Trial Start in Hot NASH Space Key Driver For Immuron

Immuron (IMC: $0.007) has a very large commercial opportunity for its immunotherapy product in development for the treatment of NASH (non-alcoholic steatohepatitis). Immuron is working to start a Phase II trial of IMM-124E, in a field that has relatively few players and one that has seen some very strong commercial and investor interest.

NASH (non-alcoholic steatohepatitis)

NASH is a liver disease that is caused by a high fat and sedentary lifestyle. What is driving the interest in this space is that between 4%-5% of the population have this disease.

NASH can be treated at an early stage with diet and exercise, but if it progresses, it can lead to fibrosis and cirrhosis of the liver and liver cancer. NASH is the second leading cause of primary liver cancer.

By 2025, 25 million Americans are expected to have NASH according to the Center for Disease Control. This compares with 29 million Americans who had diabetes in 2012. It is becoming a major health issue for which there are no treatments. This is what is driving the commercial interest in this space.

Immuron's Approach

Immuron has a commercial product on the market called Travelan. Travelan is a powder derived from the colostrum of cows that have been immunized against enterotoxigenic E.coli bacteria (ETEC). Colostrum is the first milk mammals give to their offspring. As a result, Immuron's colostrum contains antibodies against ETEC and the product is used to prophylactically protect against travelers' diarrhea.

E.coli is a gram negative bacteria that is rich in cell surface antigens, called lipopolysaccharides (LPS for short), which is also an endotoxin. These LPS are present not only on *E.coli* bacteria, but are endotoxins present on all gram negative bacteria. These LPS drive inflammation in the gut, which leads to leaky gut syndrome, and contribute to inflammation in the liver, which is a core driver of NASH.

The reason why Immuron's antibody approach may be effective in treating NASH is that the antibodies recognise a large range of LPS antigens on gram negative bacteria in the gut that contribute to this inflammatory-based disease. Immuron will be trialing a stronger dose of Travelan, called IMM-124E.

Immuron CEO Amos Meltzer said that LPS drives chronic inflammation, and that inflammation causes and maintains NASH. By continually removing the inflammatory agents LPS with the bovine colostrum derived IMM-124E, the inflammatory load on the liver should be reduced allowing the liver to have a better chance to repair itself, believes Meltzer.

Immuron's Phase II trial Delay

Immuron's Phase II trial in NASH is about three years behind schedule. The company first submitted its IND with the FDA in November 2011 and that trial was cleared to start in January 2012. However, the company then indicated that the trial would not start until sufficient funds had been raised, with a Phase II trial expected to cost approximately $5.0 million.

In February this year, the company finally raised the funds to conduct the trial, with $9.66 million raised before costs. Immuron is now preparing for the commencement of this trial, which Meltzer said is on track to start in the fourth quarter of this year.

The very strong market interest in Intercept Pharmaceuticals in January this year (see below) has very likely driven the increased investor interest in Immuron.

The steps involved in preparing for the clinical trial include completion of CMC processes, appointment of CROs, monitors and data management groups, and gaining hospital ethics approval. Meltzer said the company would update the market as these steps are completed.

Phase II Trial Design

The Phase II trial will recruit around 120 patients across 12-13 centres (an expected five in Australia, seven in the US and possibly one in Israel). The patients will be equally divided into the control and two active arms. The treatment arms will involve the same product as Travelan (600mg a day) but at doses three and six times greater respectively (1800mg a day and 3600mg a day).

All patients entering the study will have been diagnosed with biopsy-confirmed NASH in the last 12 months. Meltzer said that the centres involved in the trial typically manage large numbers of NASH patients although not all of these patients are expected to be eligible to participate in the trial.

Recruitment is expected to be completed within one year, with an aggressive target for completion of recruitment by the end of July 2015. Patients will be treated for six months. There will be no interim results with the trial being blinded.

The primary outcome measures for the trial will be changes in the liver enzyme ALT, which increase when the liver is stressed, and liver fat levels, as measured through MRI. All of the MRI images will be assessed and coordinated (not conducted) through a central facility, which will include procedures for imaging patients.

Secondary measures will include metabolic markers such as cholesterol levels and HbA1c levels. Changes in immunological responses, which will reflect inflammation activity, will also be measured by cytokine levels and regulatory T-cells.

The Principal Investigator of the study will be Professor Arun Sanyal, who has been involved with many of the major NASH studies.

Phase I/II results in NASH

In 2010 Immuron reported results from small Phase I/IIa trial in NASH. Patients were treated only for 30 days with 1,800mg per day of IMM-124E.

Cont'd over

– Immuron cont'd

The results showed a trend to improvement in liver function (as measured by liver enzymes), an improvement in insulin resistance, and more than half of patients showed an improvement in inflammation, as measured by regulatory T-cells.

Competitors in the NASH Space

In *Bioshares* 553, we provided a comprehensive table of the advanced groups developing a therapeutic for the treatment of NASH. There are 11 companies at last count with clinical programs in NASH and/or the earlier stage non alcoholic fatty liver disease. The three approaches to treating NASH are with modified bile acids (Shire/Lumena, Intercept), anti-inflammatory agents (including Immuron) and anti-fibrotics for later stage disease.

In May this year, Shire Pharmaceuticals paid an upfront US$260 million plus undisclosed milestone payments to acquire Lumena Pharmaceuticals. Lumena was due to raise US$75 million and list on the Nasdaq. Lumena was about to start a Phase II trial in NASH as well as having a Phase II program in a rare liver disease.

Intercept Pharmaceuticals has seen its market value increase from US$1.5 billion in January, to now US$6.1 billion following the release of positive Phase II trial data in NASH. That trial followed 283 patients with NASH and was conducted by the National Institute of Diabetes and Digestive and Kidney Diseases.

On the primary endpoint of a more than a two point decrease in NAS (NAFLD activity score), Intercept's OCA compound achieved at statistically significant improvement in 46% of patients, compared to a 21% improvement in the placebo arm. But what was particularly impressive was an improvement in fibrosis of the liver in one third of patients receiving OCA, with a result that was statistically significant (p=0.01) and in a trial that was not powered to achieve statistical significance on this measure. It is the first time that fibrosis has been improved in a meaningful proportion of NASH patients according to the company. Intercept plans to start a Phase III study in the first half of 2015.

One product of interest to investors in Immuron is the antibiotic Xifaxan, which is sold by Salix Pharmaceuticals. This product received FDA approval in March 2010 and last year generated sales of US$645 million. Xifaxan has some similarities with Immuron's product in that it is approved to treat travelers' diarrhea caused by *E.coli* (Immuron's Travelan is approved to prevent travelers' diarrhea from E.coli infection). It also specifically targets a range of bacteria in the gut to treat hepatic encephalopathy as a result of toxin overload of the liver stemming from bacteria build up in the gut; Immuron is developing IMM-124E to prevent endotoxins from bacteria in the gut (specifically LPS) from increasing the inflammatory load on the liver.

Phase II Trial in ASH Due to Commence

In 2012, Professor Arjun Sanyal received an NIH grant to conduct a Phase II trial in ASH (alcoholic steatohepatitis). In that trial patients will be treated with Immuron's hyperimmune colostrum therapeutic over 30 days. This trial is being coordinated by Professor Sanyal. The trial gained FDA approval to commence in November last year but has yet to start recruiting.

Escalating Sales of Travelan

In June last year, Immuron changed its sales approach for its travelers' diarrhea prevention product Travelan in Australia. Rather than selling to Takeda in Australia, Immuron now sells the product direct to wholesalers. This has seen sales increase from $150,000 in FY2013 to $1 million last financial year.

In Australia, Immuron is selling Travelan into around 3,500 pharmacies and is targeting an estimated more than 200 travel clinics in Australia. The product is used by tourists and business people traveling to countries such as Thailand, Indonesia and India to prevent travelers' diarrhea, or what is more often referred to as Bali Belly or Dehli Belly. Immuron has also entered into a co-promotional arrangement with the largest chemist chain in Australia, Chemist Warehouse.

The product was recently launched by Paladin labs in Canada. Over this financial year, Meltzer is aiming to have the product enter at least two of the following large markets: US, China, Russia or India.

Summary

Immuron has a product that is directed towards a very large commercial market opportunity. This is a market where there are no approved therapies, and one where there a limited competitors from compounds undergoing clinical evaluation.

The commencement of the Phase II trial this year, and the completion of recruitment into that trial in 2015 will be major drivers for the stock. Continued growth in Travelan sales and entry into new and large markets will also be more moderate drivers for the stock.

Immuron is capitalised at $21 million.

One outstanding issue that is arguably a drag on the stock is the number of shares the company has outstanding: 3 billion. A 100:1 share consolidation could be move that would open the stock up to institutional investors among others.

Bioshares recommendation: **Speculative Hold Class B (Revisit on commencement of Phase II trial)**

Bioshares

Bioshares Model Portfolio (22 August 2014)

Company	Price (current)	Price added to portfolio	Date added
LBT Innovations	$0.120	$0.130	July 14
pSivida	$4.830	$3.800	May 14
Invion	$0.079	$0.089	February 14
Impedimed	$0.325	$0.245	December 13
Analytica	$0.035	$0.025	December 13
Imugene	$0.017	$0.022	November 13
Oncosil Medical	$0.120	$0.155	September 13
IDT Australia	$0.260	$0.260	August 13
Viralytics	$0.275	$0.300	August 13
Tissue Therapies	$0.355	$0.255	March 2013
Somnomed	$1.88	$0.94	January 2011
Cogstate	$0.280	$0.13	November 2007

Portfolio Changes – 22 August 2014

IN:
No changes

OUT:
No changes

COT to Re-list as The Biofusionary Corporation

Continuation Investments (COT: $0.12) is to be renamed The Biofusionary Corporation on completion of its acquisition of The Biofusionary Corporation Inc through the acquisition of 100 million shares.

Bell Potter has been appointed to manage a capital raising for the re-badged entity. Continuation Investments held cash assets of $1.5 million in July and had 19.86 million shares on issue. The company is seeking $5 million, through the issue of 25 million shares at 20 cents. Therefore, the company's indicative capitalisation at that offer price is $29 million.

The Biofusionary Corporation has developed a suite of non-invasive medical products which use high frequency electromagnetic induction (alternating magnetic fields) to tighten skin and tissue through the application of heat.

In contrast to heat based technologies, such as lasers, which deliver heat perpendicular to the skin, The Biofusionary Corporation's Bebe generates heat internally, parallel to the surface. According to the company, this results in uniform heating, no tissue damage, stronger tightening and stronger sealing.

The company believes that tightening takes place because as collagen and other proteins in the skin are heated they become more fluid. Then as they cool, they re-associate and entangle again and in so doing pull together and tighten the skin's surface.

TBC has also developed a novel proprietary adhesive which is activated by electromagnetic induction, with potential for use in surgical tissue and wound closure.

The Biofusionary Corporation's lead product, the Bebe System, was cleared by the FDA in March 2014. It is indicated for the generation of "deep heat within body tissues for the treatment of medical conditions such as the relief of pain, muscle spasms and joint contractures, but not for the treatment of malignancies".

The company' first commercial destination is in the dermal aesthetics market in the USA, with entry timed for later this year, followed by RoW launches in 2015. This market is essentially a user pays market, which means that revenues can be gained sooner in contrast to reimbursement controlled markets.

However, perhaps the interesting longer term opportunity for the TBC technology is with muscle and tissue manipulation for treating faecal and urinary incontinence, including pelvic floor treatment.
Continuation Investments has invested $300,000 in TBC Inc to allow it to initiate manufacture of Biofusionary Bebe units at a manufacturing facility in Colorado.

Summary
The Biofusionary Corporation's technology could be the basis of a range of products that deliver noticeable improvements for customers seeking skin tightening for aesthetic purposes, including less pain and cosmetic disfigurations. The drive first into non-reimbursed settings is a positive, and earlier sales successes will provide validation of the longer term potential for the technology.

Bioshares recommendation: **Pending Completion of Capital Raise and Re-quotation of Securities**

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

Sell

Corporate Subscribers: Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Antisense Therapeutics, Benitec BioPharma, Admedus, Calzada, Invion, Circadian Technologies, Imugene, Analytica

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