Bionomics

AN UPDATE FOR OUR SHAREHOLDERS

BIONOMICS NOW

INSIDE THIS ISSUE

FEBRUARY 2012

CEO REPORT

DEAR SHAREHOLDERS

We enter 2012 full of optimism and confidence that our business model of strategic partnering is succeeding in extracting maximum value from our fertile pipeline which is generating promising drug candidates for solid cancers, central nervous system (CNS) conditions and immune diseases.

We start the year with the news that you have been eagerly waiting for, the successful negotiation of a licensing deal to take our anxiety drug BNC210 through its remaining clinical development to market. The partnering of this major program with Ironwood Pharmaceuticals has been one of our main goals for the past year. Success was contingent on building a compelling data set from a concerted, successful Phase I clinical program backed by solid preclinical data. The results were gratifying, indicating the potential for rapid action in relieving anxiety and our first clinical evidence of the lack of side effects including sedation by BNC210, in contrast to currently marketed treatments for anxiety.

Key elements of the licensing deal with Ironwood are:

- US$345 million in upfront and development and regulatory milestone payments
- Royalties on net sales of products incorporating BNC210
- US$13 million over the next 24 months, including US$3 million initial payment
- Ironwood will fund all clinical trials
- Ironwood will be responsible for the worldwide development and commercialisation of all products incorporating BNC210

Massachusetts-based Ironwood Pharmaceuticals, Inc. (NASDAQ:IRWD) is focused on the development of medicines for treating highly symptomatic disorders. It is an excellent fit for us, its talented team having strong clinical expertise and the capacity to undertake the type of development BNC210 now needs. Moreover, Ironwood is ready for BNC210, having recently filed with the FDA for marketing approval in the US for its first-in-class compound, linaclotide, a potential blockbuster treatment for irritable bowel syndrome with constipation and chronic constipation. Ironwood was looking to use its clinical and FDA experience to focus on another promising treatment for patients suffering from highly symptomatic disorders. Bionomics and Ironwood are already working closely together as indicated on our joint conference call on 5 January and this close association is an essential element of our partnership.

Ironwood BNC210

US$345 MILLION CNS DEAL WITH IRONWOOD

In the biggest deal the company has ever done and the first out-licensing deal for its clinical-stage pipeline, Bionomics could receive up to US$345 million pending achievement of certain development and regulatory milestones for anti-anxiety compound BNC210. If successful, royalties (additional to these development payments) on sales of products incorporating BNC210 will be forthcoming.

The deal represents an important milestone for the Australian biotechnology sector, as this is the largest deal achieved to date for a Phase I asset.

AUSTRALIAN PHASE I/II BIOTECH PRODUCT PARTNERING DEALS

JANUARY 2012
BIONOMICS (BNO)/IRONWOOD
PHASE I
Bionomics could receive up to US$345m in payments, as well as royalties on sales of products incorporating BNC210 and other related compounds. Over the first 24 months, Bionomics may receive up to US$13m in research funding and milestone payments, including an initial payment of US$3m.

JUNE 2011
pSIVIDA, (PVA)/PFIZER
PHASE I / II
Development of an implant to deliver latanoprost for patients with ocular hypertension and glaucoma. Pfizer will make an initial payment of $2.3m with further milestone payments of up to $167m.

FEBRUARY 2008
ANTISENSE THERAPEUTICS (ANP)/TEVA
PHASE II
ANP entered an exclusive, worldwide license agreement with Teva to develop and commercialise ATL1102. ANP receives an initial US$2m upfront payment and the potential to receive milestone payments of up to US$100m.

CEO REPORT CONT.

We expect BNC210 should follow a similar clinical and regulatory pathway to that of linaclotide. Anxiety is a common co-morbidity in a number of prevalent Gastrointestinal (GI) conditions. Anxiety and GI disorders are highly symptomatic and managed by many of the same high prescribing primary care physicians that will be called on for linaclotide.

Our BNC210 partnership is a timely one with reports in the press of dramatically increased use of anti-depressants and drugs to combat anxiety. The rise is attributed in part to more people resorting to prescription drugs to help them cope with the stresses of making ends meet in these difficult times of financial uncertainty.

Anti-depressant use in England has risen by 25% since the start of the financial crisis in 2007.
Source: The Telegraph, 30 December 2011

It is reported that 10% of people over the age of 12 in the United States take antidepressant medication, the third most widely prescribed group of drugs in the US. This represents a nearly 400% increase over the past two decades. Source: Centers for Disease Control study, October 2011.

These trends only serve to reinforce the need for new treatments with fewer side-effects, a void that we hope BNC210 can fill in the future.

BNC105 RETURNS TO CENTRE STAGE

We were able to sustain the effort required to accomplish the BNC210 deal because our cancer compound, vascular disruptive agent BNC105, was securely entrenched in its Phase II trial program and the Kv1.3 program targeting multiple sclerosis was in the safe hands of our partner, Merck Serono.

BNC105 is our most advanced program for which we will seek partnership when we have proof of efficacy in Phase II trials.

Several key milestones were reached last year. We have concluded the mesothelioma trial in 30 patients with advanced disease with an encouraging demonstration of an overall 43.3% clinical benefit. The single arm Phase II trial was conducted in Australia in patients with advanced metastatic mesothelioma, a cancer caused by asbestos exposure, who have progressed on platinum/pemetrexed (Alimta) chemotherapy.

Results reported at our AGM indicated disease stabilisation in 12 cases. An additional patient recorded a 57% reduction in tumour size. Bionomics is currently evaluating in preclinical models the possibility of further development of the mesothelioma application for BNC105 in combination treatments with Alimta and cisplatin.

Importantly, BNC105, at a dose of 16mg/m² was well tolerated in all patients in the mesothelioma trial and this dosage level is now being applied in the renal cancer trial underway in the US. The multi-centre clinical trial of BNC105 in combination with Afinitor is being evaluated in patients with metastatic renal cell cancer. Twenty two clinical trial sites across the US are now participating in the trial, up from nine in August 2011. New data from the trial will be presented to international conferences in the first half of 2012, including at ASCO-GU in February.

Buoyed by the significant commercial potential of BNC105, we announced last year a substantial expansion of the BNC105 clinical program and we are making good progress towards the start of a new trial targeting ovarian cancer. The ovarian cancer trial will evaluate BNC105 in combination with carboplatin and gemcitabine in a multi-centre randomised Phase I/II trial in Australia and the US. So watch this space as BNC105 takes centre stage this year with further clinical trial developments.

BLOCKBUSTER PIPELINE

Bionomics is in the enviable position of having an innovative pipeline comprising **"first in class"** and **"best in class"** drug candidates with block buster potential. These include our four front runner programs:

- BNC105, a potent and selective vascular disrupting agent for the treatment of solid tumours which targets a similar market opportunity to that of Avastin (sales of US $>7 billion in 2010).
- BNC210, a "first in class" drug candidate with potential for the treatment of anxiety, which affects some 40 million Americans each year and over 2 million Australians each year.
- Kv1.3 blockers: targeting the US$12 billion pa market for Multiple Sclerosis treatments.
- α7 nicotinic acetylcholine receptor modulators: targeting conditions where memory is impaired, including Alzheimers Disease.

ALPHA 7 ENTERS THE PIPELINE

By now you are familiar with our three leading programs but be mindful that there are programs further back in the pipeline, two in cancer and another two in CNS, that will be prioritised as our resources are freed up through our partnering activities.

This year you will be hearing more about our exciting program targeting the α7 nicotinic acetyl choline receptor (the "Alpha 7" program) which has potential application in Alzheimer's disease (AD), schizophrenia, ADHD and other conditions where memory loss is a problem. These are all

conditions where there exists a great need for new treatments and for which an "Alpha 7" drug holds promise.

For example, modulators of the "Alpha 7" receptor may improve memory and reduce brain inflammation in AD. Our goal is to select a drug candidate for clinical development in 2012.

An estimated 35.6 million people worldwide were thought to be affected by dementia in 2010. This number is anticipated to double every 20 years, reaching 65.7 million in 2030 and 115.4 million in 2050. In the US alone an estimated 5.3 million people have AD with 14% of people over 71 years of age affected by AD.

Source: Business Insights, May 2011, Advances in Alzheimer's Disease Drug Discovery: Innovations, challenges, and future directions.

STRONG FINANCIAL POSITION

On 30 January Bionomics released its quarterly cash flow statement. Key points from the statement were:

- Bionomics retains a strong balance sheet which has been further boosted by the licensing of BNC210.
- Cash at the end of the half year was $17.886 million.
- Subsequent to the announcement of the BNC210 license agreement with Ironwood Pharmaceuticals on 5 January 2012, the initial payment of US$3 million has been received. Over the next 24 months Bionomics may receive up to US$13 million in further payments including the initial payment of US$3 million.

I hope you share my enthusiasm as we look at the year ahead. As always there is a lot going on as our talented team gets on with what it does so well, finding better treatments for cancer, CNS and immune disorders. With the help of partners like Ironwood and Merck Serono we hope to make our treatments available to the world as quickly as possible.

Dr Deborah Rathjen
Chief Executive Officer

SHAREHOLDERS QUESTIONS ON THE IRONWOOD DEAL

1. WHY LICENSE BNC210 NOW?

Bionomics' well publicised strategy for the past two years has been to partner BNC210. The development of BNC210 now requires detailed, large clinical trials and substantial expenditure to give it the best chance of success. Bionomics had taken BNC210 to a point where it was ready for partnering. There was no reason to change the strategy or to delay partnering; the fact is there was a compelling case for Bionomics to take the Ironwood deal at this point.

Bionomics can now commit greater resources to the development of BNC105 for the treatment of solid tumours, including renal and ovarian cancers. We are also able to fast track our Alzheimer's disease (Alpha 7) program, taking into clinical trials an innovative approach to improve memory and impact the disease.

2. WHY IRONWOOD?

In assessing proposals for the licensing of BNC210, a number of factors were considered:

1. Development capability – did the potential licensee have a successful track record?
2. Strategic fit for licensee – would the licensee share Bionomics' sense of urgency in the development of BNC210?
3. Financial terms – Bionomics targeted a deal with a healthy upfront payment, where milestone payments exceeded $300 million and where significant royalty rates would apply for a successfully developed BNC210.
4. Company stability – was the potential licensee a substantial, stable company with the financial capacity to fund the development of BNC210?

Ironwood satisfied these elements. Some of Bionomics' shareholders were disappointed by the size of the upfront payment. However the size and financial terms of the overall deal with Ironwood (a US$345million Phase I partnering deal) made it compelling for Bionomics to accept.

3. WHAT IS IRONWOOD'S TRACK RECORD?

Ironwood is a dynamic specialty Pharma company with an impressive clinical development track record. It has rapidly moved lead drug, linaclotide, through the clinical trial process to the point where the FDA and EMA are now considering market approval.

Linaclotide, which has potential in the treatment of irritable bowel syndrome which has associated constipation (IBS-C) and chronic constipation (CC), has been the subject of over 10 clinical trials including four large Phase III trials in IBS-C. US analyst reports indicate that linaclotide is a potential blockbuster drug ("We estimate that linaclotide will be priced at $6/day and may result in sales in excess of $2 billion annually in the US alone". Wedbush Pacgrow Lifesciences 8 November, 2011).

Ironwood and its partners Forest Laboratories and Almirall are currently preparing for commercial launch in the US and Europe. In North America Ironwood's linaclotide sales force will be calling on high decile prescribing primary care physicians, many of whom prescribe anxiety medications.

SHAREHOLDERS QUESTIONS ON THE IRONWOOD DEAL CONT.

4. HOW WILL IRONWOOD PROGRESS BNC210?

BNC210 is likely to follow a similar clinical and regulatory path to that of linaclotide. Ironwood has worked closely with the FDA in developing the patient reported outcomes which formed the basis of the clinical endpoints successfully achieved by linaclotide. This experience will be invaluable in developing patient reported outcomes in future BNC210 trials.

Aside from the consideration of development capacity, Bionomics anticipates that BNC210 may have greater visibility in Ironwood's pipeline than in the pipeline of a larger Pharma company – a reassuring feature of the deal from Bionomics' perspective.

5. WHAT IS IRONWOOD'S FINANCIAL CAPACITY?

Ironwood is a stable company with "blue chip" investors. With its current estimated cash balance of $150 million, plus anticipated further pre-commercial linaclotide milestones of US$150 million plus the potential approval of linaclotide by the FDA mid-year, Ironwood has the financial capacity to develop BNC210. More recently, on 8 February 2012 Ironwood announced that it had commenced an underwritten public offering of 5,250,000 shares of its Class A common stock. Ironwood will grant the underwriters a 30-day option to purchase up to an additional 787,500 shares in connection with the offering. J.P. Morgan and BofA Merrill Lynch are acting as joint bookrunning managers of the offering. On 9 February Ironwood's share price was US$15.09.

6. WHAT NEXT FOR BNC210?

Ironwood shares our vision for BNC210 as a novel treatment for anxiety and has assembled a large team covering all the disciplines needed for the continued understanding and development of BNC210. A regular reporting framework for BNC210 activities is in place.

The BNC210 story has now commenced its next chapter.

ABOUT IRONWOOD PHARMACEUTICALS

Ironwood is a specialty pharmaceutical company based in Cambridge, Massachusetts. Linaclotide, the company's lead product, has a significant market opportunity – irritable bowel syndrome with associated constipation (IBS-C) and chronic constipation (CC).

- >30 million patients in the US estimated to suffer from bothersome abdominal and bowel symptoms, >10 million actively seek care and are not satisfied.

Linaclotide, which has been the subject of 10 separate clinical trials, is currently under review by both the FDA (June 2012 PDUFA) and the EMA.

- >Met all 66 US and EU primary and secondary endpoints in four Phase III trials.

Once approved, linaclotide will be co-commercialised in the US with Forest Laboratories, marketed in Europe by Almirall and marketed by Astellas in Japan.

Share price (1/2/12)	US $14.73
52wk Range	US$9.97 –US$16.50
Avg Vol (3m)	277,902
Market Cap	US$1.48B

IN THE NEWS

Ironwood Pharmaceuticals and Bionomics announce collaboration, research, and license agreement towards BNC210. Video of this Sky News Business Channel story is available for viewing on our home page at **www.bionomics.com.au**

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SEE BIONOMICS

1 MARCH, 2012
ASX Spotlight
Small to Mid Caps
New York, USA

8 MARCH, 2012
ASX Spotlight
Emerging Growth Conference
London, UK

31 MARCH - 4 APRIL, 2012
AACR
Chicago, USA

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