

ASX ANNOUNCEMENT: 25 November 2010

CEO on Company Update and BNC210 Results

Open Briefing with CEO & MD Deborah Rathjen



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In this Open Briefing, CEO & MD Deborah Rathjen discusses

- Objectives and clinical milestones unchanged by Start-up Australia's invitation for tenders
- BNC210 highly effective in preclinical models of drug-induced anxiety
- Next key steps in the development of BNC210

Open Briefing interview:

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Bionomics Limited (ASX: BNO) largest shareholder, Start-up Australia Ventures Pty Ltd has lodged an invitation for tenders for its entire 27.76 percent shareholding in Bionomics. Does this change the company's short-term objectives?

CEO & MD Deborah Rathjen

No. We are focused on reaching important clinical milestones in both our cancer (BNC105) and anxiety/depression (BNC210) programs.

We have four clinical trials in progress with data from three trials anticipated in Q1 CY2011. These trials are taking place in the US, Europe and Australia.

In parallel we are continuing business development to secure future licensing deals for BNC105 and BNC210. It is very much "business as usual" with our goal being the successful execution of Bionomics' business plan.

A recent significant development in the competitive landscape for BNC105 was the halting of development of Novartis' drug candidate ASA404. This increases the opportunity for BNC105 with potential partners looking for a well characterised, highly selective and potent vascular disrupting agent for treating solid tumours.

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Bionomics recently presented at the 2010 Society for Neuroscience Annual Meeting in San Diego, California, new data demonstrating BNC210 is highly effective in preclinical models of





drug-induced anxiety. What data was presented at the meeting and how does it demonstrate BNC210's effectiveness?

CEO & MD Deborah Rathjen

The Society for Neuroscience Annual Meeting (Neuroscience) is a large conference where the most recent breakthroughs in brain research from around the world are presented. The release of the latest BNC210 data at Neuroscience is part of maintaining a high profile for BNC210 which complements the ongoing European Phase Ib clinical trials and business development.

The poster presentation at Neuroscience focused on the ability of BNC210 to overcome druginduced anxiety in rodents. BNC210 was able to reverse and overcome the anxiety-inducing effects of agents which affect levels of serotonin, which is what Prozac does. BNC210 was shown to induce a return to normal behaviour at doses as low as 1mg/kg.

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BNC210 has demonstrated rapid onset of action in animal studies. How does this differentiate BNC210 from other drugs already used to treat chronic forms of anxiety?

CEO & MD Deborah Rathjen

Drugs currently used in long-term treatment of Generalised Anxiety Disorder, a chronic form of anxiety which can persist for several years, can take several weeks to exert their effects. Sometimes anxiety sufferers can feel more anxious when they first start treatment with these drugs. This may complicate or confuse treatment. It is a compelling competitive advantage to provide anxiety patients with more immediate relief.

Data from the testing of BNC210 in preclinical animal models have indicated that from the first dose of BNC210 there is an immediate reduction in anxiety behaviours. This is regardless of whether the anxiety is induced by stress or drugs. This characteristic of BNC210 is hugely beneficial for patients.

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How do results to date demonstrate BNC210's potential to compete with or replace current drugs?

CEO & MD Deborah Rathjen

Over the past 12 months or so, Bionomics has reported a swag of BNC210 data at major international scientific conferences. This data has indicated that BNC210 is free of the major side-effects of sedation, memory impairment and addiction. The animal results are supported by results from the completed clinical studies conducted in healthy subjects that indicated that BNC210 did not induce sedation.

In addition, longer exposure of animals to BNC210 does not induce tolerance, which is seen with some of the marketed anxiety drugs. Also, the cessation of BNC210 does not elicit symptoms such as weight loss and fluctuations in body temperature, which are associated with a withdrawal syndrome.

Together with this lack of adverse side-effects, BNC210 has demonstrated rapid and potent efficacy in a range of animal models of anxiety and depression.





The profile of BNC210 matches the needs of patients across the spectrum of acute/short-term anxiety disorders as well as more chronic anxiety and depression which require longer treatment.

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You've indicated the new data further supports the potential for BNC210 to expand its anxiolytic profile to include panic disorder. How does the data show this and what are the implications for BNC210's eventual market size?

CEO & MD Deborah Rathjen

Some of the animal testing has looked at the ability of BNC210 to overcome anxiety induced by a peptide CCK-4. Indeed BNC210 acts quickly and is very effective at reducing heightened anxiety induced by CCK-4 in rodents. These findings are very promising and, because the administration of CCK-4 also induces heightened anxiety in humans resulting in a brief panic attack, suggest that BNC210 may be effective in treating panic attacks in humans.

Panic Disorder is a sizeable chunk of the overall anxiety market. Approximately 20% of adult Americans, about 60 million people, suffer panic attacks at some point in their lives. The peak age at which people have their first panic attack is in the mid to late teens. Xanax, which is a benzodiazepine like Valium, was the first drug to be approved for the treatment of panic and in fact is the most prescribed psychiatric drug in the US. It is a surprising statistic that in 2009 one prescription for Xanax was issued every second in the US.

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What are the next key steps in the development of BNC210? Can you update us on the progress of the Phase Ib clinical trials in Europe?

CEO & MD Deborah Rathjen

The next key steps for BNC210 are in progress with the ongoing Phase Ib clinical trials in Europe. Both trials were initiated in October and are going to plan. We are on track with the anticipated release of results in the first quarter of CY2011. Just as a reminder, the first trial is evaluating the effects of BNC210 in drug-induced panic attack and the second trial is a head to head comparison of BNC210 with Lorazepam (a drug related to Valium). Both studies are being conducted in healthy subjects and are an integral part of Bionomics' BNC210 licensing strategy.

For more information about Bionomics Limited, visit <u>www.bionomics.com.au</u> or call Dr Deborah Rathjen on +61 08 8354 6101.

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ABOUT BIONOMICS LIMITED: Bionomics (ASX: BNO) is a leading international biotechnology company which discovers and develops innovative therapeutics for cancer and diseases of the central nervous system. Bionomics has small molecule product development programs in the areas of cancer, anxiety, epilepsy and multiple sclerosis. BNC105, which is undergoing clinical development for the treatment of cancer, is based upon the identification of a novel compound that potently and selectively restricts blood flow within tumours. A clinical program is also underway for the treatment of anxiety disorders and depression based on BNC210 which exhibits strong anxiolytic and anti-depression activity without side effects in preclinical models. Both compounds offer blockbuster potential if successfully developed. Bionomics' discovery and development activities are driven by its three technology platforms: Angene®, a drug discovery platform which incorporates a variety of genomics tools to identify and validate novel angiogenesis targets (involved in the formation of new blood vessels). MultiCore® is Bionomics' proprietary, diversity orientated chemistry platform for the discovery of small molecule drugs. ionX® is a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system.