

ASX ANNOUNCEMENT: 2 September 2010**CEO on BNC210 Clinical Trials**

Open Briefing with CEO & MD Deborah Rathjen

Bionomics Limited
31 Dalglish Street
Thebarton, SA 5031**In this Open Briefing[®], CEO & MD Deborah Rathjen discusses**

- Preclinical and clinical supporting data for BNC210
- Planned evaluation of BNC210 in two Phase Ib clinical trials
- Anticipated R&D spend in FY11

Open Briefing interview:**openbriefing.com**

Bionomics (ASX: BNO) recently presented preclinical and clinical supporting data for its anti-anxiety compound BNC210 at the 23rd annual congress of the European College of Neuropsychopharmacology (ECNP) conference. What were the key findings presented at the conference?

CEO & MD Deborah Rathjen

Bionomics presented two posters at ECNP covering firstly, the activity of BNC210 on chemically – induced anxiety in rodents and secondly, data from the two recently completed clinical trials of BNC210.

The ECNP congress is one of two major international conferences where we have taken the opportunity to highlight the latest data on BNC210. The ability of BNC210 in overcoming the effects of cholecystokinin (CCK) which in humans induces a panic attack, an acute form of anxiety, was reported for the first time. The findings provide further confirmation of the effectiveness of BNC210 across a wide range of animal models of anxiety, adding to the body of evidence suggesting that BNC210 may have broad utility across both acute and chronic forms of anxiety. Bionomics has also previously reported that BNC210 has demonstrated anti-depressant activity in laboratory studies.

ECNP is also the first major international conference where our BNC210 clinical trial data has been presented.

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When compared in rats treated with the panic-inducing chemical cholecystokinin (CCK), BNC210 reduced anxiety in a dose dependent manner, while Diazepam (which is used to treat anxiety and panic attacks) produced clear signs of sedation at higher doses. What are the implications of these results?

CEO & MD Deborah Rathjen

One of the major side-effects of treatment with Diazepam, aside from addiction, is that it induces sleepiness (sedation). BNC210, in contrast to Diazepam, does not induce sedation even at very high doses.

When rats were treated with CCK this difference between BNC210 and Diazepam was highlighted. Diazepam is effective in this model at 1mg/kg but by 3mg/kg the effectiveness of Diazepam is confounded by its sedative properties. By contrast, BNC210 is effective in this model at 5mg/kg, and shows no evidence of inducing sedation in animals even at levels as high as 1000mg/kg. The lack of sedative effects has also been confirmed in the clinical trials of BNC210.

In spite of its sedative properties, Diazepam is effective in reducing the symptoms of CCK-induced panic in human clinical trials. Bionomics' data suggests that BNC210 may similarly be effective in reducing the symptoms of CCK-induced panic in a clinical trial setting, without the adverse side-effect of sedation. The data provides a good foundation for evaluating BNC210 in CCK-induced panic in humans.

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You've evaluated ascending single doses of BNC210 in healthy human volunteers and found it safe and well tolerated at doses up to a 2000mg. A single oral dose saw drug levels higher than preclinical efficacy requirements and was maximal when taken after food. Why are these findings important and what will be the next step in testing the safety and tolerability of BNC210?

CEO & MD Deborah Rathjen

The toxicological evaluation of BNC210 prior to its entry to human clinical trials indicated that BNC210 is a very safe molecule and that there were no "red flags" which would impede its further development. It is encouraging that the initial clinical trials of BNC210 also indicate that it is safe and well tolerated even at very high doses.

Another important finding of the trial was that blood levels of BNC210, associated with efficacy in a wide range of animal models, were achieved in humans. In addition, the measurement of blood levels of BNC210 over the 24 hours following administration showed good exposure which would mean that BNC210 could be taken once a day. Both of these observations strongly support the product profile of BNC210.

We now know that blood levels of BNC210 are higher when it is given after a meal. This means that a lower dose of BNC210 may be effective.

The next step in the clinical evaluation of BNC210 will be the planned Phase Ib clinical trials.

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BNC210 is about to enter the next stage of clinical development with two, Phase Ib clinical trials commencing shortly. What will these trials determine and why are they important in the development of BNC210?

CEO & MD Deborah Rathjen

We are currently waiting for approval from regulatory authorities to commence the next step in the clinical trial process of BNC210. Pending approval, Bionomics plans to evaluate BNC210 in two Phase Ib clinical trials. In the first of these studies we will look more closely for cognitive impairment following administration of BNC210. Cognitive impairment is another side-effect of Diazepam. We will also evaluate the effects of BNC210 on brain activity.

The second trial will evaluate the effect of BNC210 on CCK-induced panic in otherwise healthy volunteers. We will also continue to evaluate biomarkers of BNC210 activity including the levels of stress hormones which are altered in response to anxiety and panic.

Further details of the clinical trials will be provided once we have gained approval.

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Over FY11, what will be the next key steps in the development of BNC210?

CEO & MD Deborah Rathjen

The next key steps are gaining approval to start the Phase Ib clinical trials. If this occurs as anticipated then we expect that both trials will be completed in the first half of calendar year 2011, with interim data available at the end of this year.

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How will recent clinical trial data help out-license programs for BNC105 and BNC210 in FY11?

CEO & MD Deborah Rathjen

Establishing the safety and tolerability of BNC210 represents a de-risking of the program from a licensing perspective. Identifying that the blood levels of BNC210 from a single dose are compatible with the levels required for efficacy in the animal models and that these levels are consistent with a once a day tablet are both important from a licensing perspective as they are key features of the target product profile. The next Phase I trials will build on this solid foundation.

The ongoing Phase II clinical trials of BNC105 in metastatic renal cell cancer and in mesothelioma are expected to provide interim data prior to the end of this year and in the first quarter of 2011 respectively. Both trials have the potential to provide a fast track to market approval under the protocols developed by the US FDA. Mesothelioma is an Orphan Drug indication which means that the FDA will expedite approval of promising treatments. This is of great interest to both Bionomics and potential licensees of BNC105. The strategy of pursuing Orphan Drug indications is commonly used with anti-cancer drugs to enable them to reach market as soon as possible before expansion into the treatment of other tumour types. As we know, BNC105 has the potential to treat all solid tumour types including lung, prostate and breast cancer.

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In FY10 Bionomics increased investment in the development of BNC210 and BNC105. R&D expenses for the year were \$8.6 million, up from \$8.1 million in the previous year. Will R&D costs increase in 2011? With cash of \$12.6 million as at the end of June, do you have adequate cash to fund the planned R&D program?

CEO & MD Deborah Rathjen

Based on our announced clinical trials, including the projected Phase Ib clinical trials of BNC210, our R&D spend is anticipated to reduce to below \$7.5 million this financial year. Last financial year Bionomics completed a Phase I clinical trial of anti-cancer agent BNC105, initiated and completed two Phase I clinical trials of BNC210 which is in development for the treatment of anxiety and depression as well as initiating two large multicentre Phase II clinical trials of BNC105 for the treatment of metastatic renal cell cancer in the US and mesothelioma in Australia. Clinical trial start-up costs, in particular for the Phase II clinical trials of BNC105, were responsible for the additional investment in R&D last financial year. Our current cash position of \$12.6 million is sufficient to fund both the current BNC105 cancer trials and the planned Phase Ib clinical trials of BNC210.

In addition to these core programs, Bionomics has a number of ancillary programs within its pipeline that are largely funded through external sources. Chief amongst these is the Development and License Agreement with Merck Serono to develop drug candidates (from the Kv1.3 blocker category) for Multiple Sclerosis (MS) and other autoimmune conditions. The Research term was extended in May for an additional year and the research program is fully funded by Merck Serono and is expected to generate a progress payment to Bionomics in the current financial year.

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Thank you Deborah.

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

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Factors Affecting Future Performance

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