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Date of lodgement: 16-Sep-2008

Title: Open Briefing®. Bionomics. BNC105 Clinical Trial Update

Record of interview:

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Bionomics Limited (ASX: BNO) recently provided an update on the status of the BNC105 clinical trial in its newsletter. Can you give us an overview of the trial?

CEO & MD Deborah Rathjen
The trial is designed to evaluate the safety of BNC105 in patients with advanced cancer and to establish a dose for the Phase II program. Bionomics achieved a significant milestone in gaining Investigational New Drug (IND) status from the US Federal Drug Administration (FDA) in November last year and the current trial started earlier this year. This is the first clinical trial of BNC105 and has enrolled patients with different tumour types including lung, thyroid and ovarian cancer.

Patients enrolled in the BNC105 trial are being evaluated for changes in the blood vessels of their solid tumours and changes in the overall tumour size. These investigations may provide preliminary evidence that the anti-tumour activity seen with BNC105 in animal models is also seen in human cancer patients. A number of biomarkers are also being evaluated in samples from treated patients to confirm the biological activity of BNC105.

The first patient was dosed at 2.1 mg/m^2, and as of August 2008, three dose levels had been evaluated and a fourth in progress. We anticipate a fifth dose level to commence later in September. BNC105 has been well tolerated by

patients receiving treatment with some preliminary signals of activity as measured by DCE/MRI and CT scan.

For patients enrolled, the trial begins with each patient receiving a pre-enrolment evaluation involving CT scans and DCE/MRI imaging. This evaluation enables the identification of the tumours which will be evaluated throughout the course of their treatment.

The trial comprises two cycles of treatment. Once patients are enrolled, they go into hospital as in-patients for the day and receive a 15-minute infusion of BNC105. This is repeated a week later. After a two-week interval of no treatments, on day 22, the patient returns for another two treatments a week apart. This is what we mean when we talk about two cycles of treatment.

If after two cycles of treatment the cancer doesn't progress, upon their doctor's advice patients may be able to stay on BNC105 therapy. For example, we have a patient at one of the lower doses of BNC105 who's now on his fourth cycle of treatment because his tumour is responding and he remains well.

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You mentioned that the first patient was dosed at 2.1 mg/m^2 and as of August, three dose levels were evaluated with a fourth in progress and a fifth dose level likely to commence in September. Can you explain the reason for continuing to increase dose levels?

CEO & MD Deborah Rathjen
Our goal is to identify a dose that is potentially beneficial in clinical terms and can be moved forward into Phase II clinical trials which are being planned for next year.

Escalating or increasing the dose that patients receive in steps as the trial progresses is standard practice in first clinical trials. The reason this approach is adopted is that it appropriately balances the evaluation of the beneficial properties of a drug whilst ensuring patient safety. In the ongoing BNC105 clinical trial there has been steady progress through increasing dose levels with a number of patients at each dose level.

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You anticipate that up to 30 patients will be enrolled in this trial. How are you progressing with the recruitment for the trial? What are the risks to enrolling the required number of patients into the trial?

CEO & MD Deborah Rathjen
Enrolment is continuing on track with our projections. There are three centres currently enrolling patients and we see a high level of enthusiasm amongst the centres. As we move forward we will focus on maintaining the required rate of patient enrolment. For this reason we're looking at bringing on board a fourth clinical centre to mitigate the risk that patient enrolment falls behind projections as we move into the final stage of the trial.

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You've recently completed the Good Manufacturing Practice (GMP) synthesis for BNC210. Recent data presented at a European Conference indicated that BNC210 is effective in treating anxiety in three animal models. What significance do these results have for your application for BNC210 clinical trials?

CEO & MD Deborah Rathjen
BNC210 has now been shown to be a potent anxiolytic (anxiety-reducing) in three separate species; the mouse, rat and guinea pig. This gives us confidence that the anxiolytic effect of BNC210 will ultimately be translated to humans. The new data presented recently at the European College of Neuropsychopharmacology (ECNP) Congress also indicates that a high level of the drug enters the blood when taken by mouth and that those levels persists for a long time so we can envisage BNC210 being taken orally once a day. This is a convenient treatment regime for patients with anxiety. In addition, the ongoing safety studies indicate that BNC210 is safe and well tolerated at very high levels. BNC210 therefore continues to show a profile supporting its progression into the clinic.

The completion of scale-up manufacture of BNC210 under GMP also gives us a high level of confidence that the compound can be readily made with a relatively low cost of goods.

We've now confirmed that we can make large quantities of BNC210 to the required level of purity that it's safe and well tolerated in animals at high doses, and it's indeed a potent anti-anxiety compound.

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Bionomics' revenue was $5.3 million in the year ending June 2008 up 272 percent from the previous year. This included a US$2 million upfront payment under the Merck Serono development and licensing deal and a US$1 million milestone payment from Genmab A/S. Excluding these two payments, revenue was up 21 percent to approximately $1.7 million. What were the factors contributing to the higher revenue?

CEO & MD Deborah Rathjen
As you have correctly indicated the significant increase in Bionomics' revenue was primarily driven by the Merck Serono upfront payment and the Genmab milestone payment – contributing a total of US$3 million to revenue.

In addition to this revenue our European subsidiary, Neurofit experienced an approximately 15 percent increase in its revenue as a result of changes made to the operation of the business which has seen increased demand for its services. In addition to its significant contribution to our anxiety and multiple sclerosis programs, Neurofit conducts work on a fee for service basis as a contract research organisation and has several large major pharmaceutical and biotech customers.

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What are the potential milestones in the company's pipeline for the current financial year ending June 2009?

CEO & MD Deborah Rathjen
Projected milestones include the completion of enrolment for the current BNC105 trial followed by the initiation of the Phase II clinical trial program. We expect to submit regulatory documentation for BNC210 to enable initiation of the first clinical trial.

We also see new partnerships as a potential milestone. Our strategy has been to partner our assets to realise value, and we're actively identifying potential partners for both BNC105 and BNC210. Ideally we'd like to retain BNC105 as we move forward into Phase II development because that's likely to increase the value of BNC105 significantly. For BNC210, we aim to have Phase I data before we partner that program. What differentiates Bionomics is the strength of its underlying technology and pipeline, therefore our strategy of identifying high value drug candidates and securing lucrative partnerships is sustainable.

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Thank you Deborah.

For more information about Bionomics Limited, please visit www.bionomics.com.au or call Dr Deborah Rathjen on (08) 8354 6101.

For previous Open Briefings with Bionomics Limited, or to receive future Open Briefings by e-mail, please visit www.corporatefile.com.au.

Factors Affecting Future Performance
This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this press release that relate to prospective events or developments, including, without limitation, statements made regarding BNC105 and its' drug development programs are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward looking statements, including risks related to our available funds or existing funding arrangements, a further downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, regulatory changes, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantages, as well as other factors. Subject to the requirements of any applicable legislation or the listing rules of any stock exchange on which our securities are quoted, we disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this announcement.