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BNC105 Phase II Trial for Mesothelioma

Open Briefing with CEO & MD Deborah Rathjen

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In this Open Briefing®, CEO & MD Deborah Rathjen discusses

- Plans to conduct BNC105 Phase II trial for mesothelioma
- Next steps in the development of BNC210
- Key 2010 development milestones

Open Briefing interview:

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Bionomics Limited (ASX: BNO) recently announced plans to conduct a Phase II clinical trial of its anti cancer drug, BNC105 on mesothelioma patients in Australia. What is mesothelioma and how prevalent is it?

CEO & MD Deborah Rathjen
The announcement that we have contracted the Australasian Lung Cancer Trials Group (ALTG) and National Health and Medical Research Council Clinical Trials Centre (NHMRC CTC) to conduct a Phase II clinical trial in patients with mesothelioma completes the 2009 BNC105 milestones we had foreshadowed during our successful capital raising in September. It is pleasing to report our progress in achieving important milestones for our lead compound.

Mesothelioma is a form of cancer that is usually caused by exposure to asbestos. In this disease, malignant cells develop in the protective lining that covers most of the body's internal organs. Its most common site is the outer lining of the lungs and internal chest wall.

Most people who develop mesothelioma had jobs where they have been exposed to asbestos dust fibres. A Safe Work Australia report published by the Commonwealth Government in June of this year indicated that in 2005 there were 597 new cases of mesothelioma diagnosed in Australia and that in 2006 there were 486 deaths attributed to mesothelioma. Due to the long latency between exposure to asbestos and diagnosis of mesothelioma, between 20 and 40 years, it is expected that the incidence of mesothelioma will not peak until after 2010. Outside of Australia, mesothelioma continues to increase.

Despite treatment, mainly with chemotherapy and radiation therapy, the disease usually carries a poor prognosis. This condition has virtually no effective treatments after first line chemotherapy and patients typically have a life expectancy of less than one year.

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How different is this trial from the Phase II trial you're conducting to evaluate the efficacy of BNC105 in renal cell carcinoma?

CEO & MD Deborah Rathjen
As with the renal cancer trial, the mesothelioma trial will be a multi-centre trial. It will be conducted in up to 12 clinical trial sites across Australia. The first sites to open for enrolment are anticipated to be in Sydney and Perth.

However there are differences in the trial design of the two studies. In contrast to the US renal carcinoma trial, the mesothelioma trial will be a single arm study which is anticipated to enrol up to 60 patients. An interim analysis will be performed after the enrolment of the initial 24 patients.

BNC105 will be administered as a single agent in the mesothelioma patients, who will have had prior chemotherapy, on days 1 and 8 of a 21-day cycle.

Whilst one arm of the renal cancer trial will follow this same schedule, a second arm of renal cancer trial will also evaluate BNC105 in combination with Afinitor®. The renal cancer trial will be a randomised study, with patients allocated on a random basis to the two different treatment groups.

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Can you tell us about the groups who will be conducting the clinical trial of BNC105 in mesothelioma patients?

CEO & MD Deborah Rathjen
Bionomics has contracted the ALTG and the NHMRC CTC to conduct the clinical trial in patients with mesothelioma. The ALTG is comprised of clinical oncologists dedicated to reducing the incidence, morbidity and mortality of lung and thoracic cancer and improving the quality of life of lung and thoracic cancer patients in Australia and New Zealand through the coordination and facilitation of high quality clinical research.

NHMRC CTC is a clinical research organisation which runs large multicentre investigator-initiated clinical trials, takes part in trials of national and international collaborative trial groups and contributes expertise to trials run by others. The CTC was established in 1988 as a research unit of the National Health and Medical Research Council (NHMRC). It is affiliated with the Faculty of Medicine, University of Sydney.

Both organisations have conducted large clinical trials in patients with mesothelioma in the past and we are extremely pleased to be working with them in this new endeavour. Our shareholders will recall that we have partnered in a similar way with the Hoosier Oncology Group in the US to undertake the renal cancer trial.

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What is the timeline of the Phase II trial in mesothelioma and how will the results help structure further trials and the ongoing development of BNC105?

CEO & MD Deborah Rathjen
With the contractual arrangements now in place, we have already started the process to initiate this clinical trial in mesothelioma patients. We anticipate that the trial will be initiated and start enrolling patients at the end of the first quarter/beginning of the second quarter of 2010. At this stage we anticipate that we will report interim data from this trial in the first half of 2011.

If successful, this trial will enable BNC105 to be considered for fast track approval. BNC105 may also receive Orphan Drug status for the treatment of mesothelioma. Both of these designations could see BNC105 reach market earlier than otherwise anticipated. This is an attractive proposition for both Bionomics and a licensing partner. Once approved for mesothelioma, additional clinical trials could be undertaken – for example in patients with lung, breast or prostate cancer – to further expand the use of BNC105 for the treatment of solid tumours.

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You completed the first stage of your Phase I clinical trial of anti-anxiety compound BNC210 recently. The trial showed BNC210 to be safe and well tolerated at doses that achieve blood drug levels consistent with suppression of the symptoms of anxiety in pre-clinical models. What are the next steps in the development of BNC210?

CEO & MD Deborah Rathjen
With the announcement of interim data from the first Phase I clinical trial of BNC210 Bionomics moved forward into the second stage of this trial which is being conducted in normal volunteers. The second stage of the study has involved the further evaluation of BNC210 at a higher dose level, in an expanded number of subjects. This stage also involved the measurement of blood levels of a broader range of blood markers. Treatment of subjects in stage 2 has now been completed in line with our projections and the analysis of data is underway. We anticipate that we will be able to announce the full results of this study in the first quarter of next year.

As foreshadowed in our recent capital raising we will undertake a Phase Ib study of BNC210, again in normal volunteers. This study is still being planned and full details of its design are not yet available, however it will build on the information obtained in the first clinical trial and may evaluate BNC210 in a challenge model in a setting which induces anxiety. It may also evaluate BNC210 effects on EEG brain recordings. We anticipate that the trial will get underway in the first quarter of next year and full details of the study will be made available at that time.

In parallel with these clinical activities, we are continuing our outreach to potential partners for the further development of this exciting compound in the treatment of anxiety.

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Bionomics recently presented new data showing that BNC210 is active in a rat model of depression and that discontinuation of BNC210 treatment does not produce any symptoms of physical dependence. What are the implications of this data for the ongoing development of BNC210?

CEO & MD Deborah Rathjen
This data was presented in October at the Society for Neuroscience conference by Dr Sue O'Connor the BNC210 project leader and Dr Emile Andriambeloson Head of Research at Bionomics' European subsidiary, Neurofit.

The forced swim test was used to evaluate the activity of BNC210 in a model which is one of the gold standard models for evaluating the anti-depressant activity of compounds. BNC210 showed clear anti-depressant activity in this model. It suggests that the further development of BNC210 should include an evaluation of anti-depressant activity.

The reported studies of BNC210 also included an evaluation of BNC210 in a model of stress-induced anxiety. The data showed that BNC210 treatment reduced anxiety levels of stressed rats to pre-stress or baseline levels. This expansion of the anxiolytic profile of BNC210 confirms the potent activity of BNC210 and further supports its potential in the treatment of both acute and chronic anxiety disorders.

On top of these exciting findings a further animal study indicated that BNC210 treatment was not associated with drug dependence. If this finding translates to humans it would be anticipated that BNC210 would not be addictive.

Anxiety is a common debilitating condition that is estimated to affect up to 40 million people in the US alone, with a worldwide market value of up to US$15 billion. Based on current data, BNC210 may be able to secure a substantial proportion of this market opportunity, satisfying the needs of sufferers for a treatment which is not addictive, non-sedating and fast acting.

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Following your successful $15 million fund raising earlier this year, Bionomics' cash balance at the end of December this year should exceed this amount. Further, you've indicated that Bionomics now has financial certainty for the next two years. What are some of the milestones for Bionomics moving into 2010?

CEO & MD Deborah Rathjen
For BNC105, there will be a number of key development milestones including the initiation of both the renal cancer and mesothelioma Phase II clinical trials. Our target is to be able to release interim data in the renal cancer trial by the end of the year. In addition, we will be releasing new BNC105 data at major international cancer conferences, including ASCO, during the year.

For BNC210 the early part of 2010 will be particularly active. Analysis of data from the first Phase I clinical trial is now underway. I anticipate that we will report the results of that trial in the first quarter of 2010. We will then move quickly into the next Phase I study as I have already described.

In summary, the things to watch for near term are:
Quarter 1 2010: initiation of the renal cancer Phase II BNC105 clinical trial and reporting of results in the current BNC210 clinical trial;
Quarter 2 2010: release of new BNC105 preclinical and clinical data at major US conferences and initiation of the Phase II clinical trial in mesothelioma patients. This is also the timeframe for the second of the Phase I clinical studies of BNC210.

These are key 2010 development milestones for Bionomics' compounds, with the prospect of significant value accretion built on positive clinical data.

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Thank you Deborah.

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

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