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CEO on BNC105 Update and Outlook

Open Briefing with CEO & MD Deborah Rathjen



Bionomics Limited 31 Dalgleish Street Thebarton, SA 5031

Bionomics (ASX: BNO) is a drug discovery and development company focused on new treatments for cancer and serious disorders of the central nervous system (CNS).

Current Market Cap: \$165 million

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

- Higher BNC105 dose level of 16 mg/m2 successfully cleared
- BNC105 first tumour vascular targeting agent showing safe combination with Afinitor
- Market opportunity for BNC105 and Afinitor combination therapy

Open Briefing interview:

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Bionomics Limited (ASX: BNO) recently provided an update on clinical trials for BNC105, its proprietary vascular disrupting agent (VDA) for the treatment of patients with metastatic renal cell cancer (RCC). How is the trial progressing so far?

CEO & MD Deborah Rathjen

Very well - there are 14 trial sites currently participating in this multicentre trial and it is anticipated that 21 clinical trial sites will be open by the end of October 2011. The clinical trial program has now moved to the randomised phase. This will recruit 134 patients and is due for completion in 2012.

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A higher dose level of 16 mg/m2 BNC105 has been successfully cleared. What is the significance of this milestone?

CEO & MD Deborah Rathjen

The 16mg/m2 dose level was a key target since it is a dose of BNC105 that was shown to be well tolerated in our concurrent phase II mesothelioma trial and one that reduced the target of BNC105 in cancer patients in the Phase I clinical trial. Individual patients in the trial have





now received up to 14 cycles of treatment with the combination of BNC105 and Afinitor with no increase in side-effects. All new patients enrolled into the trial will now receive this higher dose of BNC105.

BNC105 is the first tumour vascular targeting agent to show a safe combination with Afinitor, which provides further positive differentiation for BNC105 from other agents such as Avastin.

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BNC105 is being trialled in combination with Afinitor which is used as a second line treatment for progressive Renal Cell Carcinoma (RCC). What was the rationale for the combination trial format and to what extent do the results validate this approach?

CEO & MD Deborah Rathjen

Worldwide over 100,000 people die of RCC each year. It is the seventh most common cancer and the number of RCC diagnoses is increasing by close to 2% per year. Treatment options remain limited in progressive metastatic renal cancer and BNC105 has the potential to represent an entirely new treatment paradigm. It is hoped that that the combination of BNC105's vascular disruption with Afinitor's mTOR inhibiting action would cut off a tumour "survival" response and improve clinical outcome.

That the combination of BNC105 and Afinitor is safe and well tolerated is an important step towards validating our approach. Other vascular targeting agents have not combined well with Afinitor. It is also encouraging that as the trial progresses patients are receiving more cycles of treatment with the combination, increasing the opportunity for them to benefit from treatment. We are very pleased with this progress.

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Do you believe the combination of BNC105 and Afinitor will extend beyond the treatment of RCC?

CEO & MD Deborah Rathjen

The market opportunity for an effective combination therapy of BNC105 and Afinitor is not limited to renal cancer. Afinitor, which is projected to become a blockbuster drug, is currently undergoing clinical trials in other major cancer types including breast and lung cancer for which BNC105 is also likely to be applicable.

Taking into account also recent developments in the VDA competitive landscape which include the significant scaling back of the development of BNC105 competitor Zybrestat due to lack of funds, BNC105 is in an excellent position at this stage of its development.

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You have recently announced that the BNC105 clinical program will be extended to a third solid tumour type, ovarian cancer, next year. How will this enhance the commercial path for BNC105?

CEO & MD Deborah Rathjen

Earlier studies showed that BNC105 enhances the effectiveness of radiation treatment, cytotoxic chemotherapy such as cisplatin and biological agents such as Avastin suggesting its potential for incorporation into a variety of solid tumour treatment regimens.





The combination of BNC105 with platinum based drugs such as cisplatin and carboplatin has been shown to be a particularly strong combination when assessing both anti-tumour effects and survival of tumour—bearing animals in preclinical studies. In addition BNC105 is a potent cytotoxic agent, killing ovarian cancer cells which are resistant to platinum based drugs. In these laboratory tests BNC105 was 50,000 times more potent than cisplatin in killing ovarian cancer cells.

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. In addition to the data I have already discussed, Bionomics scientists have showed that BNC105 and gemcitabine also combine well to bring about a stronger anti-tumour response.

Ovarian cancer is the fifth leading cause of cancer-related death among women, often diagnosed at an advanced stage, after the cancer has spread beyond the ovary. In 2010 there were an estimated 21,880 new cases and 13,850 deaths from ovarian cancer in the US. It is estimated that approximately \$2.2 billion is spent in the US each year on treatment of ovarian cancer. In 2006 in Australia 1,226 ovarian cancer cases were diagnosed. The number of ovarian cancer cases in Australia increased by 47% between 1982 and 2006. In 2010 drugs used to treat ovarian cancer reported sales of approximately US\$3.6 billion.

Data from the RCC and ovarian cancer trials would enable consideration by the FDA of fast track designation of BNC105 for these cancer indications adding substantial value to the BNC105 licensing package.

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Bionomics' cash position at 30 June 2011 was \$16.05 million with a net loss in FY11 of \$9.36 million. Although revenues increased 5.8 percent to \$4.07 million, R&D costs were also up 5.9 percent to \$9.09 million. What factors contributed to these increases?

CEO & MD Deborah Rathjen

Revenues for the year include revenues from contract research services provided by Bionomics' wholly owned European subsidiary, Neurofit, and payments received under Bionomics' agreement with Merck Serono.

The net increase in cash outflows relative to the previous year reflects increased expenditure in core R&D activities, namely the ongoing clinical development of BNC105 and BNC210, Bionomics' promising treatment for anxiety and depression. These investments yielded significant value for shareholders with strong data coming forward from clinical trials during the year.

In July Bionomics' cash reserves were further boosted by \$4.2 million with the sale and lease back of our research facility in Thebarton. Our cash position provides Bionomics with a sound position for the continued development of its pipeline and its business.

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Thank you Deborah.





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.