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Lodgement of Open Briefing®**



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**Title:** Open Briefing®. Bionomics. New Data on BNC105

**Record of interview:**

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Bionomics Limited (ASX: BNO) today announced new preclinical data presented at the American Association for Cancer Research (AACR) Conference. BNC105 demonstrated anti-tumour activity in a model of human throat cancer. How prevalent are throat cancers globally? Can you detail the market size and opportunity?

**CEO & MD Deborah Rathjen**

Cancers of the head and neck account for approximately 6 percent of cancers seen in the US. Most head and neck cancers begin in the cells lining the mucosal surfaces such as those of the mouth, nose and throat and are therefore similar biologically. This means that agents that demonstrate efficacy against throat cancer are likely to be effective in treating other forms of head and neck cancer. In 2004, head and neck cancer was the eighth most common cancer in Australia.

Head and neck cancers are typically diagnosed at an advanced stage. Initial treatment options for patients include radiation therapy, chemotherapy combined with radiation treatment or surgery. Current chemotherapy includes the use of cytotoxic agents such as cisplatin and biological agents such as the monoclonal antibody Erbitux®.

Bionomics has previously reported that BNC105 is effective as a vascular disruption agent in an animal model of colon cancer and that BNC105 causes inhibition of colon cancer tumour growth. The sales of Erbitux® provide an indication of the potential commercial opportunity for BNC105 if successfully developed for the treatment of head and neck cancers and for the treatment of

colon cancer which has spread to other parts of the body. Bristol-Myers Squibb sells Erbitux<sup>®</sup> in the US in partnership with Eli Lilly and Co whilst Merck KGaA sells the drug in other parts of the world. Sales of Erbitux<sup>®</sup> in the US for the fourth quarter 2008 reported by Bristol-Myers were US\$182 million. In 2007 Merck KGaA reported sales of €470 million and recently reported a 20 percent rise in Erbitux<sup>®</sup> sales to €565 million in 2008.

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There was also new data on the effectiveness of BNC105 in a model of lung cancer, both as a standalone treatment but also in combination with a standard anti-cancer drug cisplatin. How important is this data?

**CEO & MD Deborah Rathjen**

Lung cancer is the leading cause of cancer death in the US responsible for one in every three cancer deaths. In 2004, lung cancer was the fifth most common cancer in Australia accounting for approximately 9 percent of all new cancer cases. Whilst in 2005, lung cancer was the leading cause of cancer deaths responsible for approximately 19 percent of all cancer deaths.

Non-Small Cell Lung Cancer is the most common type of Lung Cancer, making up nearly 80 percent of all cases.

Standard chemotherapy for lung cancer typically consists of combinations of two or more drugs incorporating an anti-cancer drug such as cisplatin. Therefore the demonstration that BNC105 enhances the anti-cancer activity of cisplatin in an animal model of lung cancer is an extremely important finding which further extends the clinical and commercial prospects for BNC105. Not only does BNC105 effectively combine with cisplatin to stop tumour growth, it also prolongs survival in this animal model.

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Are you still on track to complete the BNC105 Phase I trial? When is Bionomics likely to commence the next stage of clinical trials of BNC105?

**CEO & MD Deborah Rathjen**

The current Phase I clinical trial of BNC105 is approaching its conclusion, with confirmation of the dose to be used in the next stage of its development in Phase II clinical trials. Our clinical development team are working with a number of oncologists in the US and Australia to refine plans for Phase II. We anticipate being in a position to commence these trials in the second half of this year.

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You recently indicated in your shareholder newsletter that you will file a Clinical Trial Notification (CTN) to the Therapeutics Good Australia (TGA) to enable the first human clinical trial of your anti-anxiety compound BNC210 to be conducted in Australia. Can you outline the process to gain approval to undertake this clinical trial?

**CEO & MD Deborah Rathjen**

We have determined that the most efficient and cost-effective process for the initial human clinical trials of BNC210 is in Australia. The process involves making submissions, similar to an Investigational New Drug (IND)

application, to the ethics committee of the clinical trial centre. This application includes all the preclinical data gathered on BNC210 to date – both in terms of efficacy and safety – as well as the protocol for the clinical trial to be conducted. The ethics committee reviews this information and determines whether the proposed trial is able to proceed. Once approval to proceed has been obtained we will notify the TGA via its CTN process.

In line with projections, we have made our submission to the selected clinical trial centre. We anticipate receiving approval to commence the first human study of BNC210 this quarter.

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Are you still intending to file an IND application with the US Food and Drug Administration (FDA) to conduct clinical trials of BNC210 in the US?

**CEO & MD Deborah Rathjen**

An IND can be filed at anytime to enable clinical trials of BNC210 to be undertaken in the US. As our strategy is to partner the program prior to Phase II trials we anticipate that the licensee of BNC210 will undertake this process. They will also fund the ongoing development of BNC210.

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What is the outlook for partnering prospects for BNC105 and BNC210? Has your commercialisation strategy for these programs changed?

**CEO & MD Deborah Rathjen**

Our commercialisation strategy for our key assets BNC105 and BNC210 has not changed and we continue to work strongly with the Burrill & Co team in the US to successfully execute this strategy. In this regard, we can indicate significant interest in both programs and maintain our positive outlook on partnering prospects.

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Thank you Deborah.

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For more information about Bionomics Limited, please visit [www.bionomics.com.au](http://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](http://www.corporatefile.com.au).

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**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, BNC210 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.