

ASX ANNOUNCEMENT 11 March 2008

# **BIONOMICS ADVANCES ANTI-ANXIETY CANDIDATE BNC210**

Key points:

- BNC210 commences formal safety & tolerability evaluation program
- Anxiety program on-track for IND submission by end-2008
- BNC210 delivers on unmet need for a non-sedating and fast acting anxiety therapeutic
- BNC210 benefits from the established pathway to clinical trials developed by Bionomics for BNC105

Adelaide, Australia: Bionomics Limited (ASX: BNO) today announced the commencement of its formal safety and tolerability evaluation program in animals of BNC210, Bionomics' anti-anxiety lead candidate.

The commencement of this program is a key milestone in the drug development process, with Bionomics on track to submit an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) by late 2008. The Company will use the results of the program to identify a safe starting dose in humans for clinical trials estimated to commence in the first half of 2009.

Dr Deborah Rathjen, Bionomics CEO & Managing Director said, "We are excited to commence these studies with anti-anxiety lead, BNC210. Our plans for BNC210 closely follow the path to clinical trial already established by our lead anti-cancer candidate BNC105, which commenced Phase I trials last week."

This series of safety and tolerability studies is being conducted by WIL Research Laboratories, LLC, in Ashland, Ohio (USA) a contract research organization recognized worldwide for conducting quality Good Laboratory Practice (GLP) studies in line with FDA requirements.

"Our goal is to complete an IND submission at the end of this calendar year and we're planning for a pre-IND meeting with the FDA in mid-2008," continued Dr Rathjen.

BNC210 is a novel compound generated from Bionomics' powerful medicinal chemistry platform technology. It was the best performing anxiety drug candidate out of a focussed library of compounds that were synthesized, evaluated and tested in a range of small animal models.

The Anxiety program leader, Dr Sue O'Connor commented, "WIL Research Laboratories, LLC is a contract research organisation (CRO) that provides toxicology,

pharmacology, metabolism, and bio-analytical services to the pharmaceutical industry. They have a long-standing, strong reputation within the scientific community and we are looking forward to working with them to assess the safety and tolerability of BNC210 in the lead up to our IND submission."

Preclinical data shows that in animals BNC210 is able to reduce anxiety without the common side effects of current anxiety drugs including drowsiness, impairment of memory and motor function. In addition, BNC210 was shown to be fast-acting and effective with a single daily dose.

Anxiety is a common debilitating condition that affects 19 million patients in the US alone, and has an estimated market value \$5-\$12 billion worldwide. Many of the largest blockbuster drugs are for treating anxiety including Valium, Prozac, Paxil, Buspar and Zoloft. The issue is that most of the current anxiety therapeutics are not ideal and have a range of side effects, including sedation and loss of memory.

# FOR FURTHER INFORMATION PLEASE CONTACT:

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## About Bionomics Limited

Bionomics (ASX: BNO) 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. Bionomics' most advanced program, BNC105 for the treatment of cancer, is based upon the identification of a novel compound that potently and selectively restricts blood flow within tumours. Bionomics' discovery and development activities are driven by its three technology platforms: Angene®, the company's angiogenesis target and drug discovery platform, incorporates a variety of genomics tools to identify and validate novel angiogenesis targets. 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. Bionomics was recently ranked in the top 10 in the Deloitte's Technology Fast 50 Australian technology companies.

For more information about Bionomics, visit <u>www.bionomics.com.au</u>

#### About BNC210

Bionomics discovered BNC210 through a targeted medicinal chemistry program based upon a literature report of a known compound with newly described anxiolytic activity. Based upon this report, a focused library of compounds in novel chemical space was synthesized and screened.

BNC210 is a novel compound that has potent anxiolytic activity in a range of rodent models and has no effect on spontaneous motor activity at doses up to 100 mg/kg. The minimum dose required for anxiolytic activity in the mouse light/dark box is 1mg/kg/kg realising a therapeutic index of over 10000. BNC210 is readily absorbed and has good oral bioavailability, with a half life of 6.2 hours. Early safety assessment suggests that BNC210 is safe and well tolerated.

### **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.