

ASX ANNOUNCEMENT 21 December 2012

# IRONWOOD BEGINS PHASE I TRIAL OF INVESTIGATIONAL IW-2143 ANXIETY DRUG IN US

Bionomics Limited (ASX: BNO) (ADR: BMICY) has been advised by its licensee Ironwood Pharmaceuticals Inc (NASDAQ:IRWD) that, following the submission of an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) last month, the planned Phase I clinical trial of the investigational anti-anxiety drug candidate IW-2143 (BNC210) has begun in the US.

The trial is designed to assess the safety and pharmacokinetics of IW-2143 in healthy volunteers, using single and multi-dose administration.

"This is the first US clinical trial of IW-2143 and this news is welcomed by Bionomics as a strong signal of the progress being made by Ironwood in moving ahead with the study of IW-2143," said CEO and Managing Director of Bionomics Dr Deborah Rathjen. "As this trial progresses it is anticipated that a US\$2 million milestone payment to Bionomics by Ironwood will be triggered."

Ironwood is responsible for developing and, if approved, commercialising IW-2143 and related compounds, including paying for the costs of clinical development.

In the US, anxiety disorders affect approximately 40 million Americans each year and while there are therapies available, there remains significant unmet need.

# FOR FURTHER INFORMATION PLEASE CONTACT:

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### About IW-2143 (BNC210)

IW-2143 is a small molecule discovered by Bionomics through a targeted medicinal chemistry program. Data from several preclinical studies indicated that IW-2143 may have anti-anxiety activity and and appeared to promote neurite outgrowth *in vitro*. In a phase I study that included placebo and lorazepam control arms, healthy volunteers who took IW-2143 did not appear to experience impaired attention. Electroencephalography (EEG) data gathered on healthy subjects dosed with IW-2143 in the study provided information about the pharmacodynamic effect of the molecule.

#### **About Bionomics Limited**

Bionomics (ASX: BNO) is an Australian based 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, memory loss and autoimmune disorders, several of which are in or approaching clinical development stage. Its oncology approach includes cancer stem cell therapeutics as well as vascular disruption in solid tumours.

Bionomics' discovery and development activities are driven by its four proprietary 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®, a diversity orientated chemistry platform for the discovery of small molecule drugs; ionX®, a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system; and CSC Rx Discovery<sup>TM</sup>, which identifies antibody and small molecule therapeutics that inhibit the growth of cancer stem cells. These platforms drive Bionomics' pipeline and underpin its established business strategy of securing partners for its key compounds.

www.bionomics.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 presentation that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' development candidates BNC105, IW-2143(BNC210), our acquisition of Eclipse Therapeutics and ability to develop products from their platform, its licensing deal with Ironwood Pharmaceuticals, drug discovery programs and pending patent applications 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 downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, Ironwood's decisions to continue or not continue development of IW-2143, 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. Results of studies performed on competitors products may vary from those reported when tested in different settings.

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 presentation.