

ASX ANNOUNCEMENT 8 November 2012

# IND SUBMISSION TO FDA FOR IW-2143 (BNC210) ANTI-ANXIETY DRUG CANDIDATE

- Bionomics' licensee Ironwood Pharmaceuticals has submitted an Investigational New Drug application to the US Food & Drug Administration (FDA)
- IND is a precursor to proceeding with clinical trials on IW-2143 in the US

Bionomics Limited (ASX: BNO) (ADR: BMICY) has been advised by its licensee Ironwood Pharmaceuticals Inc that an Investigational New Drug (IND) application was submitted to the US Food and Drug Administration (FDA) for a clinical trial of anti-anxiety drug candidate IW-2143.

Ironwood intends to initiate Phase I studies with IW-2143 in healthy volunteers following the filing of the IND by the FDA. The initial Phase I US trial is designed to further assess IW-2143's pharmacokinetics.

"Ironwood has a strong team that has developed a thorough clinical development program for IW-2143," said CEO and Managing Director of Bionomics Dr Deborah Rathjen.

Preclinical studies conducted by Bionomics suggest that IW-2143 has anti-anxiety activity and promotes neurite outgrowth.

In the US alone, anxiety disorders affect 40 million Americans each year and while there are therapies available, there remains a significant unmet need. IW-2143 has the potential to fill a need in this market as an anxiety drug that may not have the sedation, withdrawal syndrome or memory impairment reported with other therapies.

# FOR FURTHER INFORMATION PLEASE CONTACT:

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### About IW-2143 (BNC210)

IW-2143 is a novel small molecule discovered by Bionomics through a targeted medicinal chemistry program. Data from several preclinical studies indicate that IW-2143 has anti-anxiety activity and promotes 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 have impaired attention. Electroencephalography (EEG) data gathered on healthy subjects dosed with IW-2143 in the study provided evidence of a pharmacodynamic effect.

#### **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. BNC105 offers blockbuster potential if successfully developed. A clinical program is also underway for the treatment of anxiety disorders and depression based on IW-2143(BNC210), a novel compound which stimulates neurite outgrowth. IW-2143 is partnered with Ironwood Pharmaceuticals.

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. These platforms underpin Bionomics' established business strategy and Bionomics is committed to 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.