

ASX ANNOUNCEMENT 14 December 2012

# **BIONOMICS NEW ALZHEIMER'S DRUG CANDIDATE**

- Highly differentiated drug candidate targeting large markets added to Bionomics drug pipeline
  - Strong evidence of efficacy, selectivity and rapid action
    Compound outperforms leading drug Donepezil in preclinical testing

Bionomics Limited (ASX:BNO, ADR:BMICY) has identified a novel compound with promising properties as a potential new treatment for Alzheimer's disease. Following validation in preclinical models of memory deficit in Alzheimer's disease, Bionomics has formally nominated BNC375 as its drug candidate. BNC375 is currently on a dual track, as Bionomics prepares for both clinical trials and strategic partnering.

BNC375 is proprietary to Bionomics and is a positive allosteric modulator of the  $\alpha$ 7 nicotinic acetylcholine receptor ( $\alpha$ 7 nAChR), an important target for the improvement of memory and learning deficits that occur in illnesses like Alzheimer's disease.

Bionomics will commence GMP manufacturing scale-up and formal toxicology studies with the objective of filing an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA), as it further enhances the licensing package around BNC375.

BNC375 has been found to be effective across a panel of animal models of impaired learning and memory. To date it has shown no signs of side-effects. Key data summarising the efficacy of several Bionomics' proprietary compounds from this class were exhibited in October at the prestigious *Neuroscience 2012* meeting in New Orleans.

In preclinical testing BNC375 outperformed benchmark compounds including Donepezil, a Pfizer product marketed as Aricept with reported US\$2.5 billion sales in 2011.

BNC375 competitive advantages include:

- Rapid onset of action combined with a high degree of selectivity
- Modulation of α7 nAChR without causing side-effects or lack of response due to receptor desensitisation
- Preservation of the normal signalling patterns of the receptor
- No potential for development of tolerance
- Suitable for concomitant use with other medicines e.g., acetylcholinesterase inhibitors in Alzheimer's disease

"Bionomics is now at the forefront of a new therapeutic approach in treating Alzheimer's disease. The  $\alpha$ 7 nicotinic acetylcholine receptor is a highly promising target for treatment of memory impairment associated with Alzheimer's disease, which contrasts with the historical focus on β-amyloid in the search for new therapies," said Bionomics' CEO Dr Deborah Rathjen.

"A new Alzheimer's drug candidate is a valuable addition to our drug development pipeline and caps off a productive year for Bionomics that includes the US\$345 million deal on the BNC210 anxiety drug candidate with Ironwood Pharmaceuticals, a new BNC105 Phase II clinical program targeting ovarian cancer and the acquisition of highly promising California-based cancer stem cell company Eclipse Therapeutics" she added.

Further information on BNC375 is provided in the appendix following this announcement.

The estimated worldwide costs of dementia, including direct and indirect costs of care, was \$604 billion with an estimated 35.6 million people worldwide affected by dementia in 2010. This is expected to double every 20 years reaching 65.7 million in 2030 and 115.4 million in 2050. In the US alone an estimated 5.3 million people have Alzheimer's disease including 14% of people over 71 years of age (Source: Business Insights, May 2011, Advances in Alzheimer's Disease Drug Discovery: Innovations, challenges, and future directions).

The α7 program targets Alzheimer's disease and other neurodegenerative and neuropsychiatric disorders which are associated with significant cognitive impairment. There is a large body of evidence implicating the α7 nAChR in the pathophysiology of several neuropsychiatric diseases. Modulation of this receptor enhances cognitive processes, for example working memory and attention, which are compromised in these disorders. It conforms to Bionomics' focus on developing well differentiated drug candidates to treat serious conditions such as Alzheimer's disease, Schizophrenia, Parkinson's disease, Attention Deficit Hyperactivity Disorder (ADHD), Bipolar Disorder and Major Depressive Disorder. For all of these conditions, co-morbid cognitive impairment represents a significant unmet clinical need in large markets.

In February 2012 Bionomics announced that a patent application covering several of its  $\alpha$ 7 compounds had entered the international phase.

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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. 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.

## **Appendix**

**Figure 1:** BNC375 improves mouse performance in the acute T-maze Continuous Alternation Task. Scopolamine is used to cause memory impairment in mice which can be overcome by the Alzheimer's drug Donepezil (Aricept). BNC375 overcomes the scopolamine-induced memory deficit with equivalent efficacy to Donepezil.

