



ABN 53 075 582 740

## ASX ANNOUNCEMENT

26 June 2019

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# RESULTS OF BNC210 CLINICAL TRIAL FOR THE TREATMENT OF AGITATION & NEXT STEPS IN DEVELOPMENT OF BNC210 FOR THE TREATMENT OF PTSD

### Investor Teleconference 11:30am AEST Today

You are invited to participate; led by Exec Chairman Errol De Souza

Conference ID **10000943**

To register [link here](#)

*Registered participants will then receive the dial in number*

**Bionomics Limited (ASX:BNO, OTCQX:BNOEF)**, a global, clinical stage biopharmaceutical company, today announced the top line results of the exploratory trial of BNC210 for the treatment of agitation in elderly patients in a hospital setting.

The results of the Agitation trial indicated that BNC210 treatment did not differentiate from placebo on the primary and secondary efficacy end points. Comparison of mean peak daily Pittsburgh Agitation Scale scores (observations of aberrant vocalisation, motor agitation, aggressiveness and resisting care) showed a gradual improvement for both BNC210 and placebo over the 5-day treatment period, but without evidence of a treatment effect.

This exploratory Phase 2 study was designed to assess the therapeutic potential of BNC210 to treat agitation in hospitalised elderly patients as a separate indication and to evaluate safety of BNC210 in the elderly patient population. The safety of BNC210 was confirmed.

“Whilst the results of the trial do not support further development of BNC210 for treatment of agitation, given BNC210’s consistent safety profile and the demonstration by pharmacometric exposure-response modelling of its potential to treat post-traumatic stress disorder, we remain confident in pursuing PTSD, provided that we can achieve the blood exposure levels predicted by the modelling analysis” said Professor Paul Rolan, Bionomics Consultant Chief Medical Officer.

In continuing to build the case for BNC210, following feedback from potential partners and investors, Bionomics will invest in a single ascending dose study in healthy volunteers to demonstrate that blood levels of BNC210 believed to be necessary to meet the primary endpoints for effectiveness in treating PTSD in any further trial, are achievable using the new solid dose formulation. The cost of this study is estimated at \$300,000 and results are anticipated to be available by early CY4Q 2019.

Dr Errol De Souza, Executive Chairman of Bionomics, said "If the proposed study with the solid dose formulation confirms that the required blood levels are achievable, and the FDA guidance supports a second Phase 2 trial of BNC210 in PTSD, then Bionomics intends to proceed with the further formulation development and preparation for a second Phase 2 trial".

Dr De Souza further commented "We believe that, a second trial of BNC210 in PTSD will be the best option available to Bionomics to rebuild shareholder value. However, it is clear that we will require funding beyond our current resources to do so. We have had expressions of interest from third parties to provide funding for the trial and have therefore decided to launch a formal process of active engagement with shareholders, partners and others, including the parties who have already approached us, to identify the best available solution in a timely manner. I look forward to those discussions."

#### **FOR FURTHER INFORMATION PLEASE CONTACT:**

##### **Australia**

Monsoon Communications

Rudi Michelson

+613 9620 3333

[rudim@monsoon.com.au](mailto:rudim@monsoon.com.au)

##### **About Bionomics Limited**

Bionomics (ASX: BNO) is a global, clinical stage biopharmaceutical company leveraging its proprietary platform technologies to discover and develop a deep pipeline of best in class, novel drug candidates. Bionomics' lead drug candidate BNC210 is a novel, proprietary negative allosteric modulator of the alpha-7 ( $\alpha 7$ ) nicotinic acetylcholine receptor. Beyond BNC210, Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada) and a pipeline of pre-clinical ion channel programs targeting pain, depression, cognition and epilepsy.

[www.bionomics.com.au](http://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 announcement that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' drug candidates (including BNC210), its licensing agreements with Merck & Co. and any milestone or royalty payments thereunder, drug discovery programs, ongoing and future clinical trials, and timing of the receipt of clinical data for our drug candidates 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 unexpected safety or efficacy data, unexpected side effects observed in clinical trials, risks related to our available funds or existing funding arrangements, our failure to introduce new drug candidates or platform technologies or obtain regulatory approvals in a timely manner or at all, regulatory changes, inability to protect our intellectual property, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantage, as well as other factors. Results of studies performed on our drug candidates and competitors' drugs and drug candidates may vary from those reported when tested in different settings.