



ABN 53 075 582 740

Investor Teleconference 11am AEST Today

You are invited to participate

Led by CEO & MD Deborah Rathjen

With Professor Paul Rolan, Bionomics' CMO and Dr Sue O'Connor, Bionomics' VP

With US PTSD Expert Professor Murray Stein

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ASX ANNOUNCEMENT

2 October 2018

Bionomics' Phase 2 Post Traumatic Stress Disorder Trial Results

- **Trial did not meet primary endpoint of decrease in PTSD symptoms as measured by CAPS-5 at 12 weeks**
- **Evidence of anti-depressant effects and anti-anxiety activity were observed in the CAPS-5 symptom clusters**
- **BNC210 treatment was safe and well tolerated**

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company, today announced top-line data from its Phase 2 clinical trial of BNC210, a novel, first in class, negative allosteric modulator of the $\alpha 7$ nicotinic acetylcholine receptor, in patients with Post Traumatic Stress Disorder (PTSD).

"This trial comprehensively assessed symptoms in 193 patients with PTSD across 25 sites in the US and Australia. We found that BNC210 showed excellent tolerability and safety. This adds to the safety picture for BNC210, administered for the first time over a prolonged 3-month treatment period. Although there was no overall treatment effect assessed by CAPS-5, we saw improvements on select components of the scale that are attributable to the mood and anxiety symptoms of the condition," said Professor Paul Rolan, Bionomics' consultant Chief Medical Officer.

"There is great unmet medical need for safe and effective treatments for the large population of patients suffering with PTSD worldwide. While challenging to find which symptoms may respond to the novel pharmacological properties of BNC210, there was great anticipation that it would show

clear beneficial effects on improving PTSD symptoms, supporting further development of the drug as a novel treatment for this condition,” said Bionomics consultant Dr. Murray Stein, Distinguished Professor of Psychiatry, Family Medicine and Public Health at the University of California San Diego. “Results of this trial do not demonstrate those broad benefits, underscoring the complexity of PTSD and the heterogeneity of PTSD symptoms across patients. Future work with BNC210 – and other novel compounds – may be best focused on a subset of symptoms, or a subset of patients, considered most likely to benefit.”

“We are extremely disappointed that the primary endpoint in this trial was not met. As we move forward we will focus on the completion of the ongoing Phase 2 trial of BNC210 in hospitalised, elderly patients suffering from agitation which is anticipated to readout in Q1, 2019. We plan to stop all other work on BNC210 until that time. In FY18 Bionomics reduced costs by closing the US operations and reducing overall headcount. In order to maintain and enhance shareholder value, we are continuing to assess our strategic options for partnering and portfolio prioritisation whilst conserving cash. We will provide an update on our strategic direction at the Annual General Meeting to be held on 14 November.” commented Dr. Deborah Rathjen, CEO & Managing Director of Bionomics.

Dr Rathjen further commented “Bionomics has ongoing drug discovery programs which are anticipated to deliver up to two new therapeutic candidates this financial year. We also have a strategic partnership with Merck & Co., (known as MSD outside the United States and Canada), assessing a cognition therapy candidate in an ongoing Phase 1 program, which entered clinical development and triggered a US\$10 million milestone payment last year. This deal has a potential value of up to US\$506 million in terms of the upfront payments, R&D payments and milestone payments, plus additional annual royalties on net sales of licensed drugs. Both the MSD partnership and our drug discovery programs reflect the robustness of Bionomics’ pipeline.”

The Phase 2 RESTORE Trial

The RESTORE trial was a randomised, double-blind, placebo-controlled Phase 2 clinical trial that enrolled 193 adult patients diagnosed with PTSD across 20 sites in United States and 6 sites in Australia. The primary endpoint of this study was a decrease in PTSD symptoms between placebo and BNC210 treatment groups as measured by the Clinician-Administered PTSD Scale (CAPS-5) at 12 weeks. The CAPS-5 is a standardised structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. Earlier versions of the CAPS were used to support the approval of the two currently marketed PTSD treatments. Secondary endpoints included measurement of effects on components of the CAPS-5 and PTSD symptom clusters, measures of anxiety and depression, well-being, sleep and safety.

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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, currently in Phase 2 for the treatment of agitation and for posttraumatic stress disorder, 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).

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, BNC101 and BNC105), 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.