Bionomics Limited

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ASX ANNOUNCEMENT
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Investor Teleconference 11:30am AEST Today
You are invited to participate
Led by Executive Chairman Errol De Souza

Conference ID **564556**

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Further Data Analysis of Bionomics' Phase 2 Post Traumatic Stress Disorder Trial Shows the Potential for Significant Patient Benefit When Drug Exposure is Adequate

- **Additional work undertaken on a drug exposure-response analysis shows a statistically significant response of BNC210 in treatment of PTSD symptoms, as measured by CAPS-5 at 12 weeks.**
- **Bionomics will now seek FDA guidance on next steps for BNC210 for PTSD including the design of a further trial and whether BNC210 is eligible for Fast Track designation.**
- **Variable absorption of the liquid formulation of BNC210 used in the PTSD trial and the requirement for the drug to be taken with food may be overcome through development of an improved solid dose formulation which has recently been evaluated in healthy human volunteers. The solid dose formulation of BNC210 is anticipated to be used in any future PTSD trials.**
- **It is intended that the data from the ongoing BNC210 trial in Agitation will be analysed by dose and by measures of exposure given the PTSD trial learnings. Consequently, this trial is anticipated to read out in Q2, 2019.**

Bionomics Limited (ASX:BNO, OTCQX:BNOEF), a global, clinical stage biopharmaceutical company, announces that an additional data analysis conducted in Sweden by Pharmetheus AB showed a statistically significant response when drug exposure versus response was measured in the Phase 2 PTSD Trial (referred to as the RESTORE trial). The exposure-response analysis uses patient blood levels of the drug, regardless of the administered dose, to relate drug exposure to the response

measured in the trial patients. The analysis demonstrated reduction in total PTSD symptoms as measured by total CAPS-5, the endpoint mandated by the US Food & Drug Administration (FDA) for PTSD trials.

“Bionomics had a solid scientific rationale for evaluating BNC210 in PTSD, based on its mechanism of action, and this has been borne out by this further analysis. At the time of the topline data announcement of 2 October 2018, the results of the complex and time-consuming drug exposure analyses were not available and could not have readily been foreseen. The results of the further analysis are meaningful for future development of BNC210 and they support its continued development for PTSD, as well as other indications, and our ongoing partnering activities,” said Dr. Errol De Souza, Executive Chairman of Bionomics.

A pharmacometric analysis has now been performed on the RESTORE trial. This analysis was conducted by Pharmetheus AB, an international pharmacometrics consulting company with extensive scientific and regulatory expertise, under the supervision of Advisor Mats O Karlsson, Professor in Pharmacometrics at Uppsala University. The analysis quantified the level of efficacy of BNC210 on the overall CAPS-5 score related to exposure (blood levels) of BNC210.

Prof Karlsson states “Exposure-response modelling has shown the potential for BNC210 to have significant benefit in PTSD provided that adequate blood levels are achieved. This analysis provides a basis for optimal design of future trials to demonstrate efficacy.”

Bionomics will now seek FDA guidance on the next steps for BNC210 for PTSD including the design of a further trial and whether BNC210 is eligible for Fast Track designation. Bionomics will continue to evaluate partnership opportunities in parallel. These new data will also form part of the ongoing strategic review being conducted by Greenhill & Co.

Bionomics has now identified an improved solid dose formulation of BNC210 with potential to overcome the “food effect” and the consequent variable blood levels that were evident in the PTSD trial where the patients were administered BNC210 in a liquid formulation. It is anticipated that the solid dose formulation will be used in any future PTSD trials.

In relation to the ongoing Phase 2 exploratory clinical trial of BNC210 in elderly patients with Agitation, Bionomics intends to conduct similar exposure-response analyses. Full recruitment in this trial is anticipated toward the end of Q1, with data expected to be available in late Q2, 2019.

The Phase 2 RESTORE Trial

The RESTORE trial was a randomised, double-blinded, 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, is a novel, proprietary negative allosteric modulator of the alpha-7 (α7) 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

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.