

**ASX ANNOUNCEMENT**  
**19 December 2022**

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## **Bionomics Reports Topline Results in PREVAIL Phase 2 Study of BNC210 in Social Anxiety Disorder**

- ***BNC210 for Treatment of Social Anxiety Disorder (SAD) Did Not Meet Primary Endpoint***
- ***Subjects with Confirmed SAD who Received BNC210 Exhibited Trends Toward Improvements Across Endpoints Compared to Placebo***
- ***BNC210 Demonstrated Favourable Safety and Tolerability Profile Consistent with Prior Experience***
- ***Company is Continuing Analysis of the Data and Evaluating Next Steps with Cash Runway into mid-2024***

Bionomics Limited (ASX: BNO, Nasdaq: BNOX), (Bionomics or Company), a clinical-stage biopharmaceutical company developing novel, allosteric ion channel modulators designed to transform the lives of patients suffering from serious central nervous system (CNS) disorders with high unmet medical need, today announced results from its Phase 2 randomised, double-blind, placebo-controlled, multi-centre, dose-ranging PREVAIL study to evaluate the safety, tolerability, and efficacy of BNC210 for the acute treatment of Social Anxiety Disorder (SAD). BNC210 has a novel mechanism of action that involves negative allosteric modulation of the  $\alpha 7$  nicotinic acetylcholine receptor. While the primary endpoint as measured by the change from baseline to the average of the Subjective Units of Distress Scale (SUDS) scores during a 5-minute Public Speaking Challenge was not met in the BNC210-treated patients when compared to placebo, the findings do indicate a consistent trend toward improvements across primary and secondary endpoints and a favourable safety and tolerability profile consistent with previously reported results. The Company is continuing analysis of the PREVAIL dataset and is assessing next steps for the development of BNC210 in SAD.

“Although the PREVAIL study did not statistically meet its primary endpoint, we have noted the consistent trends in improvement of endpoints in the BNC210-treated patients and continued strong safety and tolerability profile of BNC210 across the 13 clinical trials conducted to date,” commented Errol De Souza, Executive Chairman of Bionomics. “We look forward to welcoming our new President & CEO, Spyridon ‘Spyros’ Papapetropoulos, MD, Ph.D. who has extensive experience in CNS clinical development to work with the Bionomics team to conduct further analysis on the PREVAIL Study data and consult with key opinion leaders and regulators in order to define next steps for the program. The findings indicate that BNC210’s novel mechanism of action through allosteric modulation of the  $\alpha 7$  nicotinic acetylcholine receptor is promising and we remain committed to the ongoing Phase 2b ATTUNE Study in PTSD with topline data expected mid-2023. The strong cash position of the Company will enable delivery of these milestones along with continuing operations to at least mid-2024.”

### **About PREVAIL**

The trial enrolled 151 adult patients with diagnosed SAD and who rated  $\geq 70$  on the Liebowitz Social Anxiety Scale at 15 sites in the U.S. Study participants were randomised 1:1:1 to receive a single oral dose of either a placebo or 225 mg BNC210 or 675 mg BNC210. After dosing, there was a 55-minute rest period followed

by an introduction to the Public Speaking Challenge, a 2-minute anticipation-preparation period, and a 5-minute speech. The primary outcome measure was a self-assessment during the speaking challenge using the Subjective Units of Distress Scale (SUDS), a tool for quantifying the intensity of anxiety, fear, or distress on a scale from 0 to 100, with 0 indicating no distress and 100 representing the highest level. Secondary outcome measures included self-assessment with the State-Trait Anxiety Inventory (STAI), a commonly used measure of trait and state anxiety, and an assessment with the Negative Self-Statements During Public Speaking subscale (SSPS-N).

### **About Social Anxiety Disorder**

SAD is a significant and persistent fear of social and performance-related situations. One of the most common mental disorders in the United States, an estimated 31 million Americans will suffer from SAD at some point in their lives. SAD can interfere with a person's ability to work, make it difficult to maintain friendships, family relationships, and romantic partnerships, cause a person to avoid lifestyle activities like dining out and traveling, and make normal parts of everyday life such as grocery shopping, calling a handyman, or picking up coffee challenging.

Released on authority of the Board

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

#### **General**

Ms Suzanne Irwin  
Company Secretary  
+61 8 8150 7400

[CoSec@bionomics.com.au](mailto:CoSec@bionomics.com.au)

#### **Investor Relations**

Mr. Connor Bernstein  
VP, Strategy and Corporate Development  
+1 (650) 524-5143

[cbernstein@bionomics.com.au](mailto:cbernstein@bionomics.com.au)

#### **Investor Relations**

Kevin Gardner

[kgardner@lifesciadvisors.com](mailto:kgardner@lifesciadvisors.com)

### **About Bionomics Limited**

Bionomics (ASX:BNO, NASDAQ:BNOX) is a clinical-stage biopharmaceutical company developing novel, allosteric ion channel modulators designed to transform the lives of patients suffering from serious CNS disorders with high unmet medical need. Bionomics is advancing its lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the  $\alpha 7$  nicotinic acetylcholine receptor, for the acute treatment of Social Anxiety Disorder (SAD) and chronic treatment of Post-Traumatic Stress Disorder (PTSD). Beyond BNC210, Bionomics has a strategic partnership with Merck & Co., Inc (known as MSD outside the United States and Canada) with two drugs in early-stage clinical trials for the treatment of cognitive deficits in Alzheimer's disease and other central nervous system conditions.

[www.bionomics.com.au](http://www.bionomics.com.au)

### **Factors Affecting Future Performance**

This announcement contains "forward-looking" statements within the meaning of the U.S. federal securities laws. Any statements contained in this announcement that relate to prospective events or developments, including, without limitation, statements related to the Offering 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. The Company undertakes no obligation to publicly update any forward-looking statement,

whether as a result of new information, future events, or otherwise. Actual results could differ materially from those discussed in this ASX announcement.