
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the month of December, 2022

(Commission File No. 001-41157)

BIONOMICS LIMITED

(Translation of registrant's name into English)

200 Greenhill Road
Eastwood SA 5063
Tel: +618 8150 7400

(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b) (1):
Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101 (b) (7):
Yes No

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.
Yes No

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On December 19, 2022, Bionomics Limited (the “Company”) lodged a press release with the Australian Securities Exchange (the “ASX”), announcing the 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). The press release is furnished herewith as Exhibit 99.1 to this report on Form 6-K.

EXHIBIT INDEX

Exhibit	Description
99.1	Bionomics Reports Topline Results in PREVAIL Phase 2 Study of BNC210 in Social Anxiety Disorder EX-99.1

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

Bionomics Limited

(Registrant)

By: /s/ Errol De Souza

Name: Errol De Souza, Ph.D.

Title: Executive Chairman

Date: December 19, 2022



ABN 53 075 582 740

ASX ANNOUNCEMENT
19 December 2022

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 ≥ 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

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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:

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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

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.

