# 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 October, 2023**

**(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 October 16, 2023, Bionomics Limited (the "Company") lodged a press release, announcing Successful End-of-Phase 2 Meeting with the FDA and Solidifies Plans to Initiate the Registrational Program for BNC210 in Social Anxiety Disorder. The press release is furnished herewith as Exhibit 99.1 to this report on Form 6-K.

**EXHIBIT INDEX**

| Exhibit | Description |
| --- | --- |
| 99.1 | Bionomics Announces successful End of Phase 2 Meeting with the FDA and Solidifies Plans to Initiate Registrational Program for BNC210 in Social Anxiety Disorder |

**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/ Alan Fisher

Name: Alan Fisher.
Title: Non-Executive Chairman

Date: October 16, 2023

**Bionomics Announces Successful End-of-Phase 2 Meeting with the FDA and Solidifies Plans to Initiate the Registrational Program for BNC210 in Social Anxiety Disorder**

- ***Positive outcome of End-of-Phase 2 meeting with U.S. Food and Drug Administration (FDA) in September 2023 enables advancement of BNC210 into Phase 3 studies in Social Anxiety Disorder***
- ***Company confirms agreement with the FDA on Phase 3 clinical program and alignment on nonclinical toxicology studies required for registration***
- ***Company is on track for first patient dosed in the Phase 3 program planed for Q1'24***

ADELAIDE, Australia, and CAMBRIDGE, Mass., October 16, 2023 -- Bionomics Limited (Nasdaq: BNOX) (Bionomics or Company), a clinical-stage biotechnology company developing novel, first-in-class, allosteric ion channel modulators to treat patients suffering from serious central nervous system (CNS) disorders with high unmet medical need, today announced the successful and favorable outcomes of an End-of-Phase 2 meeting (EoP2) meeting with the U.S. Food and Drug Administration (FDA), supporting the advancement of its lead asset BNC210 for the acute treatment of Social Anxiety Disorder (SAD) into Phase 3 registrational studies based on the recently completed Phase 2 PREVAIL dataset.

"We are grateful for FDA's support and guidance and very pleased to reach an agreement on key elements of Phase 3 design and other nonclinical components required for registration", said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Bionomics. "The FDA meeting outcomes provide external and independent validation of our position on the strength and Phase 3-enabing nature of the PREVAIL dataset. BNC210's unique clinical profile seen in multiple anxiety disorders including SAD, Generalized Anxiety Disorder and in a panic model, was recently significantly enhanced by the positive results in Post-Traumatic Stress Disorder. BNC210, which has Fast-Track designation from the FDA for the acute treatment of SAD, has the potential to address a significant unmet need for the 17 million Americans suffering from SAD who currently don't have fast acting and safe treatment options."

On October 11, Bionomics received the official meeting minutes from the EoP2 meeting with the FDA held on September 13, 2023 reflecting that Bionomics has reached an agreement with the FDA on:
1) the plan to conduct two randomized, placebo-controlled studies with single administration of BNC210 during a public speaking task;
2) the use of the Subjective Units of Distress Scale (SUDS) measured during a public speaking challenge as the primary efficacy endpoint;
3) the doses of BNC210 to be studied in Phase 3;
4) the sample size assumptions for the Phase 3 controlled studies based on PREVAIL findings;
5) the design elements of the open label safety study required to support the new drug application (NDA);
6) the size of the safety database to support the NDA; and
7) the nonclinical toxicology studies needed to support the NDA.

The Company anticipates beginning the Phase 3 program in Q1'24.

**FOR FURTHER INFORMATION PLEASE CONTACT:**

**General**
Rajeev Chandra
Company Secretary
CoSec@bionomics.com.au

**Investor Relations**
Kevin Gardner
kgardner@lifesciadvisors.com

**Investor Relations**
Chris Calabrese
ccalabrese@lifesciadvisors.com

**About Bionomics Limited**

Bionomics (NASDAQ:BNOX) is a clinical-stage biotechnology company developing novel, first-in-class, allosteric ion channel modulators to treat patients suffering from serious central nervous system ("CNS") disorders with high unmet medical need. Bionomics is advancing its lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the α7 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 MSD (known as Merck & Co., Inc., Rahway NJ, USA in the US 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. Bionomics' pipeline also includes preclinical assets that target Kv3.1/3.2 and Nav1.7/1.8 ion channels being developed for CNS conditions of high unmet need. www.bionomics.com.au

**Forward-Looking Statements**

Bionomics cautions that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "potential," "continue" or "project" or the negative of these terms or other comparable terminology are intended to identify forward-looking statements. These statements include the Company's plans to advance the development of its product candidates, the timing of achieving any development or regulatory milestones, and the comparability and potential of such product candidates, including to achieve any benefit or profile or any product approval or be effective. The inclusion of forward-looking statements should not be regarded as a representation by Bionomics that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in the Company's business and other risks described in the Company's filings with the Securities and Exchange Commission (SEC), including, but not limited to, the Company's Annual Report on Form 20-F filed with the SEC, and its other reports. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Bionomics undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. Further information regarding these and other risks is included in Bionomics' filings with the SEC which are available from the SEC's website (www.sec.gov) and on Bionomics' website (www.bionomics.com.au) under the heading "Investor Center." All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.