



Bionomics Provides a Review of 2023 and of 2024 Plans

Jan 22, 2024

Positive Phase 2b data announced for BNC210 on reduction of total symptom severity and multiple symptom clusters in post-traumatic stress disorder (PTSD), with a discussion with the U.S. Food & Drug Administration (FDA) anticipated in Q2'24.

Positive End of Phase 2b (EoP2) meeting with FDA announced for BNC210 in Social Anxiety Disorder (SAD) following the Phase 3-enabling PREVAIL Phase 2 trial data readout.

The Company is actively engaged in strategic partnership discussions with interested parties for multiple pipeline assets and is evaluating options to proceed with clinical development plans for BNC210 in both PTSD and SAD.

ADELAIDE, Australia and CAMBRIDGE, Mass., Jan. 22, 2024 (GLOBE NEWSWIRE) -- 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 provided a 2023 review and its outlook for 2024.

"Bionomics continued its evolution into a U.S.-focused, late-stage clinical company last year. We finished 2023 with strong momentum from our positive readout in Phase 2b ATTUNE trial in PTSD and the successful EoP2 meeting with the FDA, paving the path to a registrational study in SAD. These two BNC210 programs generated significant interest from potential strategic partners, including the opportunity to co-develop and commercialize BNC210 in PTSD and SAD in the U.S. and abroad. We will explore such potential opportunities in parallel with other pathways that provide near and long-term value to the Company and its shareholders. Additionally, we've been receiving interest in our promising preclinical assets, KV3.1/3.2 channel activators and Pan Nav inhibitors, where we have identified lead candidates and continued our work on the 2nd generation $\alpha 7$ nicotinic receptor negative allosteric modulator (NAM) lead series," commented Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Bionomics.

2023 Highlights

Key Clinical Highlights

BNC210 in Social Anxiety Disorder and Post-Traumatic Stress Disorder

A first and best-in-class $\alpha 7$ nicotinic, Phase 3-ready NAM of the $\alpha 7$ nicotinic receptor with a unique and differentiated psychoactive profile suitable for acute and chronic dosing in multiple CNS indications:

Post-Traumatic Stress Disorder

- Positive topline results from the Phase 2b ATTUNE study were announced in September 2023, meeting the primary endpoint on reduction in total symptom severity and highlighting the potential of BNC210 to improve multiple PTSD symptom clusters with notable effects on thought intrusions, mood, trauma-related cognition, and sleep. The BNC210 program is the only non-psychedelic program with a novel mechanism of action to advance in late-stage development in recent years.

Social Anxiety Disorder

- BNC210 may become the first intermittent "as-needed" non-sedating, non-habit forming, cognitively non-impairing anxiolytic for the treatment of anxiety in patients with SAD.
- In March 2023, the Company completed, on time and within budget, the full data analysis of the Phase 2b PREVAIL study demonstrating that BNC210 reduced anxiety during a public speaking challenge and provided support for further evaluation in Phase 3 clinical trials.
- A successful EoP2 meeting with the FDA in September 2023 confirmed the Phase 3 enabling nature of the PREVAIL dataset and clarified the plans for the registrational program for BNC210 in SAD, including the number of trials, trial designs, endpoints, sample sizes, size of the safety database and nonclinical requirements for registration.

The results of the Phase 2b trials of BNC210 in SAD and PTSD, along with previous results observed in earlier trials in general anxiety disorder (GAD) and panic attacks, underscores BNC210's potential in multiple, highly prevalent neuropsychiatric

indications with significant market opportunity.

Positive Allosteric Modulators (PAMs) of the $\alpha 7$ Nicotinic Acetylcholine Receptor Program with Merck & Co., Inc.

The ongoing partnership with MSD* on $\alpha 7$ PAMs for the treatment of cognitive disorders such as Alzheimer's disease (AD) and cognitive impairment associated with schizophrenia (CIAS) has generated two clinical candidates that are currently in late Phase 1 clinical development after completing several Phase 1 safety, tolerability, pharmacokinetic and biomarkers studies. The partnership has a potential value of \$500m in regulatory and clinical milestones with additional potential royalties from commercialization.

Key Corporate Highlights

- In support of the Company's transformation into a commercial-stage company, expanded the U.S.-based team with new highly experienced management appointments, positioning it to become a leading company in neuropsychiatry.
- Voluntarily delisted from the Australian Stock Exchange in August 2023 and is currently solely listed on the NASDAQ Global Market.
- Further reduced cash burn through efficient capital allocation.
- Maintained its current institutional investors' support while adding new institutional investors to its register.
- Sustained strong analyst coverage that highlights the Company's potential future value.
- The Company has no outstanding debt, convertible securities, or warrants.
- Continued strengthening BNC210 intellectual property portfolio in the U.S. and abroad.

Future Anticipated Milestones for BNC210 Clinical Program

- Bionomics continues to plan the initiation of its first Phase 3 study of BNC210 in patients with SAD.
- The Company plans to discuss a potential dose-ranging late-stage study of BNC210 in PTSD with the FDA; an update on the next steps is expected by the end of Q2'24.
- The Company is exploring the submission of a request for Breakthrough Therapy designation in PTSD in Q2'24.
- Leveraging the inbound demand, the Company is looking to secure a strategic partnership for BNC210.

"We look forward to continuing to strongly execute, in a timely and fiscally efficient manner, and keep progressing our BNC210 programs in SAD and PTSD while also aiming to establish strategic partnerships in the coming months. Following a transformational 2023 where we delivered on all anticipated milestones, I am confident 2024 will be an exciting year for Bionomics as we keep making strides towards building shareholder value through the development of new treatment options for patients in two psychiatric disorders with significant unmet needs and market potential," concluded Dr. Papapetropoulos.

* Known as MSD outside the United States and Canada

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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 $\alpha 7$ 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. 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.



Source: Bionomics Ltd