



## Bionomics Issues Shareholder Letter Highlighting Recent Achievements and Strategic Vision

Oct 7, 2024

ADELAIDE, Australia, and CAMBRIDGE, Mass., Oct. 07, 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 announced that Spyridon "Spyros" Papapetropoulos M.D., Ph.D., President and Chief Executive Officer of Bionomics, issued the following letter to Bionomics shareholders regarding recent achievements, executional efficiencies and the positive outlook for the Company's future.

Dear Fellow Bionomics Shareholders,

This year continues to be a pivotal year for Bionomics, characterized by numerous wins and essential changes that have enhanced the Company and furthered our goal of creating therapies for the countless individuals suffering from anxiety and stress disorders.

As we enter the last quarter of 2024, I would like to take a moment to highlight a few of our recent accomplishments and milestones:

- Strengthened the US-based management team and implemented necessary cost-cutting measures to ensure optimal runway for execution of our pipeline.
- Clinically, we advanced our lead program of BNC210 and initiated our first ever Phase 3 trial in social anxiety disorder (SAD) after successful regulatory interactions, expanded our IP portfolio through data-driven patent applications, extended BNC210's IP beyond 2040, and successfully communicated our scientific achievements in numerous banking, investor and scientific conferences.
- Financially, we secured funding through a private placement securities transaction and an ATM facility that allow us to complete our Phase 3 SAD study without compromising operational quality and speed of execution.

Additionally, we are in the final stages of redomiciling the Company to the U.S. and launching Neuphoria Inc, a company with new vision, strategy and CNS pipeline focus to fully leverage the strong U.S. biotechnology ecosystem, while maintaining our Australian presence and potential future tax benefits. During the ordinary course of this process, we plan to consolidate our issued shares of our trading securities and remain compliant with the NASDAQ Stock Market listing rules.

**Thanks to these efforts, we believe the company is and will be fundamentally in a much stronger position today and moving forward.**

As shareholders ourselves, we remain disappointed in Bionomics' stock performance, particularly following our Annual Report (10-K) filing on September 30, 2024. Yet, we believe that Bionomics is significantly undervalued, given our lead asset BNC210 is essentially a novel, "pipeline in a pill", small molecule with unique anxiolytic and antidepressant properties that can bring tremendous benefits to patients suffering from anxiety and stress disorders globally. Following the recent unfavorable industry developments with psychedelics in post-traumatic stress disorder (PTSD), unrelated to our product pipeline, Bionomics' BNC210 is the only promising registrational stage program with a novel mechanism of action having demonstrated the best clinical study outcomes in decades, (as announced in September 2023) with a clear path for an NDA submission, and with one successful registrational quality study already completed, requiring one additional successful Phase 3 trial for potential registration.

Of note, BNC210 also has two FDA fast track designations for SAD and PTSD programs, a sizable and favorable safety database supporting a differentiated non-sedating, non-addicting profile and positive datasets in four separate anxiety and stress-related indications. These clinical datasets and designations give us the ability to leverage regulatory privileges that can potentially accelerate review and approval. Moreover, we are also considering submitting a rebuttal in the future regarding the FDA decision to not grant a Breakthrough Designation in PTSD. It should also be noted that not being granted this designation does not in any way derail our progress or pathway in our clinical trials or intended operational success.

As we continue executing the Phase 3 program in SAD with anticipated readout in Q3 2025, we are also working diligently on exploring ways to enhance efficiencies and foster potential partnerships that will ensure our ability to drive the Phase 3 trial of BNC210 in PTSD to a successful NDA submission with a single trial. This would be a major achievement for the Company following our successful End-of-Phase 2 meeting with the FDA in June 2024. We have begun trial initiation activities, and we are on track to commence the Phase 3 trial in PTSD in the second half of 2025 or sooner, contingent upon successful financing.

Our long-standing strategic partnership with MSD (known as Merck & Co., Inc., Rahway NJ, USA in the U.S. and Canada) on the

development of  $\alpha 7$  receptor PAMs targeting cognitive dysfunction associated with Alzheimer's disease and other central nervous system conditions valued ~US \$500M is quickly advancing and is anticipated to enter Phase 2 in the near future, triggering a sizable milestone payment for the Company.

**Along with you, we believe Bionomics has significant, unrealized value that is not yet reflected in the current stock price.**

We know from experience that transformations take time, and we strongly believe that we are on the right path and are excited for what lies ahead. We will continue to work industriously and prioritize prudent financial management, operational excellence and efficiency to further position Bionomics for future success and create shareholder value.

I would like to take this opportunity to thank you for your continued support and confidence in our Company.

If you have any questions or would like more information, please do not hesitate to contact us. Thank you for your continued partnership.

Sincerely,

Spyros Papapetropoulos M.D., Ph.D.  
President & CEO  
Bionomics

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**About BNC210**

Formulated as an oral solid tablet BNC210 is a negative allosteric modulator of the  $\alpha 7$  nicotinic acetylcholine receptor under development for the treatment of social anxiety disorder (SAD) and post-traumatic stress disorder (PTSD). BNC210 has been given FDA Fast Track designation for acute treatment of SAD and other anxiety related disorders, and for treatment of PTSD and other trauma and stressor related disorders.

**About Bionomics Limited**

Bionomics (NASDAQ: BNOX) is a clinical-stage biotechnology company developing novel, potential 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 CNS 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](http://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. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to: the closing of each tranche of the Company's private placement financing, the achievement of certain milestones for the various tranches, the timely funding to the Company by each investor in the private placement, the timing, size and expectation of the closing of the private placement; and expectations regarding market conditions, the satisfaction of customary closing conditions related to the private placement and the anticipated use of proceeds therefrom; and the Company's expectation that its current cash, cash equivalents, and marketable securities will fund our operations into the third quarter of 2025. 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, uncertainties and other factors is included in Bionomics' filings with the SEC, copies of which are available from the SEC's website ([www.sec.gov](http://www.sec.gov)) and on Bionomics' website ([www.bionomics.com.au](http://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. Bionomics expressly disclaims all liability in respect to actions taken or not taken based on any or all the

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Source: Bionomics Ltd