



Bionomics' Half-Year Report

Feb 23, 2023

ADELAIDE, Australia, Feb. 23, 2023 (GLOBE NEWSWIRE) -- Bionomics Limited (ASX: BNO, NASDAQ: BNOX), today announced its FY2023 report for the half-year ended 31 December 2022. This period represented a transformational time for Bionomics in which the Company made great strides on multiple fronts, including progress on advancing the pipeline, raising capital, and implementing strategic corporate initiatives designed to create long-term shareholder value.

The Company recently completed its Phase 2 PREVAIL Study to evaluate BNC210 for the acute treatment of Social Anxiety Disorder (SAD). The PREVAIL Study, initiated in January 2022, was a randomised, double-blind, placebo-controlled, multi-center Phase 2 clinical trial with a single dose treatment conducted at 15 sites in the US and recruited approximately 150 patients with SAD. The PREVAIL Study completed recruitment, and topline data were reported on 19 December 2022. The Company announced that 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 did 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 its analysis of the PREVAIL dataset and is assessing the next steps for the development of BNC210 in SAD.

The Company continues to progress evaluation of BNC210 in patients with Post-Traumatic Stress Disorder (PTSD) in a randomised, double-blind, placebo-controlled, multi-center Phase 2b clinical trial with a 12-week treatment period recruiting approximately 200 patients. The ATTUNE study has been ongoing in the US, and new sites were recently opened for recruitment in the United Kingdom. The independent Safety Review Committee meets approximately every three months to monitor participant safety and to date, no safety concerns precluding continuation of the trial have been reported; topline results are expected in mid-2023.

Bionomics also continued to see progress in its partnership with Merck & Co (known as MSD outside the United States and Canada) to develop $\alpha 7$ receptor positive allosteric modulators (PAMs) targeting cognitive impairment in Alzheimer's disease with two compounds undergoing Phase 1 safety and biomarker clinical trials.

While the internal focus and current research and development spending are restricted to CNS programs, Bionomics continues limited activities to maximise the value of its legacy oncology programs through divestment and/or out-licensing both BNC101 and BNC105. Of the non-core legacy oncology assets, the development program established under the exclusive license agreement of BNC101 to Carina Biotech continued to advance and is projected by Carina to move into the clinic in 1H2023. There is also a Memorandum of Understanding that the Company entered into in February 2021 with EmpathBio for exploring a potential combination of BNC210 and EMP-01 (an MDMA derivative) for the treatment of PTSD.

In November 2022, the Company issued 614,026 American Depositary Shares ("ADS") in the United States at a price of US\$7.80 per ADS, raising gross proceeds of US\$5,000,000 (\$7,419,235). The offering price of US\$7.80 per ADS (\$0.0641 per ordinary share) represented a 1.63% discount to the 15-day volume weighted average price. Each ADS represents 180 fully paid Bionomics' ordinary shares and resulted in 115,384,680 fully paid shares being issued. The net proceeds raised were \$5,806,168.

In December 2022, the Company announced a critical milestone for the leadership team with the appointment of Dr. Spyridon "Spyros" Papapetropoulos starting in January 2023 as Bionomics' President, Chief Executive Officer, and Director. In conjunction with this development, it was announced that Dr. Errol De Souza, who had been serving as Bionomics' Executive Chairman since November 2018, would be stepping back from the role and, in 1 January 2023 resumed the role of Non-Executive Chairman of the Board of Directors.

The Company's cash balance as of 31 December 2022 was \$30,698,362 (30 June 2022: \$35,564,857).

FOR FURTHER INFORMATION, PLEASE CONTACT:

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About Bionomics Limited

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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 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.

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.



Source: Bionomics Ltd