Neuphoria Provides a Review of 2024 and Highlights 2025 Plans

Apr 15, 2025

- Initiation by Merck of a Phase 2 trial in Alzheimer's disease with partnered α7 nicotinic acetylcholine receptor PAM MK-1167 highlights company's pipeline diversification beyond BNC210
- US $15M milestone payment from Merck extends company's cash runway to Q3 2026
- Phase 3 AFFIRM-1 trial of BNC210 in social anxiety disorder (SAD) is progressing as planned with topline readout anticipated in Q3 2025
- A Phase 2b dose ranging study with a lower dose of BNC210 in post-traumatic stress disorder (PTSD) is planned to follow the read-out of the Phase 3 study in social anxiety disorder SAD.

BURLINGTON, Mass., April 15, 2025 (GLOBE NEWSWIRE) -- Neuphoria Therapeutics Inc. (Nasdaq: NEUP) ("Neuphoria" or the "Company"), a clinical-stage biotechnology company developing impactful treatments for neuropsychiatric disorders, today provided a review of 2024 and highlighted plans for 2025.

"2024 and the first quarter of 2025 were transformational for our pipeline; Our internal BNC210 program entered Ph3 in Social Anxiety Disorder with robust enrollment, and our partnered α7 nicotinic acetylcholine receptor positive allosteric modulator (PAM) program with Merck for the treatment of the symptoms of Alzheimer's disease dementia advanced to Phase 2," said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Neuphoria. "We are now beginning a promising 2025 as we look to deploy our resources on programs that have the highest chance of providing the greatest benefit to patients and generating the greatest value to shareholders."

Recent Highlights and 2025 Plans

Clinical Programs

- Initiated the Phase 3 AFFIRM-1 trial with 225mg BNC210 for the acute, as-needed treatment of anxiety in social anxiety disorder (SAD) in July 2024.
    - The Phase 3 AFFIRM-1 trial is progressing as planned with enrollment being on-track for topline results anticipated in Q3 2025.
    - Agreement with the U.S. Food and Drug Administration (FDA) on the design of BNC210's registrational program in social anxiety disorder (SAD) has been reached during an End-of-Phase 2 (EoP2) held in Q3 2023.
    - BNC210 has demonstrated rapid-onset, broad and meaningful anti-anxiety effects in completed clinical trials in panic attacks, generalized anxiety disorder (GAD) and social anxiety disorder (SAD) without evidence of sedation, impairments in cognition or addiction potential.
- Held a successful End-of-Phase 2 (EoP2) meeting with U.S. Food and Drug Administration (FDA) in July 2024, providing a potential registrational path for BNC210 in PTSD.
    - A Phase 2b trial of BNC210 in PTSD is being planned to help identify a second (lower) dose for BNC210 further de-risking the program before progressing to Phase III while reducing short- and mid-term capital requirements to the next program milestone.
    - Based on extensive pharmacokinetic and pharmacodynamic analysis of existing datasets, BNC210 450 mg BID (lower dose) is expected to provide clinically meaningful efficacy similar to that observed with 900mg BID in the ATTUNE Phase 2b trial while improving the overall safety and tolerability profile.
    - The Phase 2b study in PTSD is scheduled to begin in Q4 2025, following the release of topline results from the ongoing Phase 3 AFFIRM-1 trial in social anxiety disorder (SAD).
- Published the clinically meaningful improvements seen with BNC210 across several key PTSD symptoms in *NEJM Evidence* in December 2024 (https://doi.org/10.1056/evidoa2400380).
- The results of the Phase 3-enabling PREVAIL Phase 2 study of BNC210 in social anxiety disorder (SAD) published in *Psychiatry Research*, in February 2025 (https://doi.org/10.1016/j.psychres.2025.116387).
- Initiation by Merck (known as MSD outside the United States and Canada) of a Phase 2 clinical trial to evaluate the safety and efficacy of MK-1167, a partnered α7 nicotinic acetylcholine receptor positive allosteric modulator (PAM) program, for the treatment of the symptoms of Alzheimer's disease dementia (NCT06721156).

Corporate Highlights

- Successfully re-domiciled from Australia to the United States in December 2024.
- A private placement in May 2024 enabled the Company to continue executing its late-stage clinical programs.
- Received a milestone payment of AUS$1M in November 2024 from Carina Biotech for BNC101, a partnered legacy oncology program.
    - Based on the agreement with Carina, Neuphoria is eligible to receive up to approximately AUS$117 million in additional payments for certain development, regulatory and commercial milestones if Carina Biotech fully develops

and markets the new therapy.

- Received a milestone payment of US$15M in March 2025 from Merck for our α7 nicotinic acetylcholine receptor PAM partnered CNS program enabling continuing execution of our pipeline and extending company's runway to Q3 2026.
    - Under the agreement with Merck, Neuphoria is eligible to receive up to $450M in additional milestone payments for certain development and commercial milestones associated with the progress of multiple candidates plus royalties on net sales of any licensed medicines.

Dr. Papapetropoulos concluded: "We started 2025 strong and with a focus on efficiently advancing our pipeline and increasing shareholder value through leveraging capital generated through our long-term partnerships with Merck and Carina Biotech. We look forward to sharing updates across our portfolio throughout the year."

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About Neuphoria Therapeutics Inc.
Neuphoria (Nasdaq: NEUP) is a clinical-stage biotechnology company dedicated to developing therapies that address the complex needs of individuals affected by neuropsychiatric disorders. Neuphoria is advancing its lead drug candidate, BNC210, an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor, for the acute, "as needed" treatment of social anxiety disorder (SAD) and for chronic treatment of post-traumatic stress disorder (PTSD). BNC210 is a first-of-its-kind, well-tolerated, broad spectrum anti-anxiety experimental therapeutic, designed to restore neurotransmitter balance in relevant brain areas, providing rapid relief from stress and anxiety symptoms without the common pitfalls of sedation, cognitive impairment, or addiction. In addition, Neuphoria 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. Neuphoria's pipeline also includes the α7 nicotinic acetylcholine receptor next generation and the Kv3.1/3.2 preclinical programs, both in the lead optimization development stage.

Forward-Looking Statements
Neuphoria 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, plans, burn rate and expectations. Certain forward-looking statements, including (without limitation) about (1) Neuphoria's ability to develop and expand its business, successfully complete development of its current product candidates, the timing of commencement and/or completion of various clinical trials and receipt of data and current and future collaborations for the development and commercialization of its product candidates, (2) the market for drugs to treat CNS diseases and pain conditions, (3) Neuphoria's financial resources, and (4) assumptions underlying any such statements. The inclusion of forward-looking statements should not be regarded as a representation by Neuphoria that any of its plans will be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. Certain forward-looking statements involve contracts, licenses and arrangements involving third parties and their respective clinical trial and research and development projects that are out of our control, including our agreements with Merck and Carina. They may terminate or delay any or all such projects in their discretion pursuant to the terms of our agreements with them, which could result in the Company not realizing any further milestone payments or further progress on the respective product pathways. 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 SEC, including the Company's Annual Report on Form 10-K, Quarterly Report on Form 10-Q, each 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 Neuphoria 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 Neuphoria's filings with the SEC, copies of which are available from the SEC's website (www.sec.gov) and on Neuphoria's website (www.neuphoriatx.com) 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. Neuphoria expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.