Neuphoria Therapeutics Provides Update on AFFIRM-1 Phase 3 Trial Evaluating BNC210 for the Acute Treatment of Social Anxiety Disorder

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AFFIRM-1 trial did not meet primary endpoint or secondary endpoints

Company to conduct strategic review of portfolio and business operations

BURLINGTON, Mass., Oct. 20, 2025 (GLOBE NEWSWIRE) -- Neuphoria Therapeutics Inc. (Nasdaq: NEUP) ("Neuphoria" or the "Company"), a clinical-stage biotechnology company developing impactful treatments for neuropsychiatric disorders, today announced that the AFFIRM-1 Phase 3 trial of BNC210 for the acute treatment of social anxiety disorder (SAD) did not meet its primary endpoint of change from baseline to the average of the performance phase of the public speaking challenge in Subjective Units of Distress Scale (SUDS) scores. In addition, analyses of secondary endpoints did not demonstrate statistically significant differences. The safety and tolerability profile of BNC210 continued to be favorable and was consistent with previously reported studies.

"We are grateful to the AFFIRM-1 trial participants and their families, as well as the investigators and our staff, who contributed to our SAD program over the years," said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Neuphoria. "We plan to immediately take action to conserve our cash position by holding further investment in our programs and evaluating all options for Neuphoria's path forward through a strategic review, with the goal of maximizing value for shareholders."

Business Update and Outlook

Based on the results from the AFFIRM-1 trial, Neuphoria will discontinue further development of its SAD program. Given previous positive data with chronic daily dosing, Neuphoria also plans to evaluate next steps for further development of BNC210 in post-traumatic stress disorder (PTSD). The company plans to conduct a full strategic review of its operations and portfolio and to provide an update by year-end.

The Company has an ongoing partnership with Merck & Co., Inc. (Merck). MK-1167, one of two positive allosteric modulator (PAM) candidates being advanced in the strategic partnership with Merck, is currently being evaluated in a Merck-led Phase 2 trial in Alzheimer's disease. Merck is responsible for all costs of this program, and through the partnership, Neuphoria is eligible to receive up to $450 million in additional milestone payments for certain development and commercial milestones plus royalties on net sales of any licensed medicines.

As of June 30, 2025, Neuphoria's cash and cash equivalents were $14.2 million. The Company expects its current cash position to be sufficient to fund operations through the second fiscal quarter of 2027.

About AFFIRM-1
The AFFIRM-1 Phase 3 clinical trial was a multi-center, double-blind, two-arm, parallel group, placebo-controlled trial evaluating the safety and efficacy of a single, acute dose of 225 mg of BNC210 versus placebo. Participants in the trial were randomized 1:1 to receive a single dose of 225 mg BNC210 or matched placebo. One hour after dosing, participants were introduced to a public speaking challenge and had two minutes to prepare for the speech (anticipation phase) before delivering a five-minute speech in front of a small audience (performance phase). The primary endpoint of the trial was the change from baseline to the average of the performance phase of the public speaking challenge in Subjective Units of Distress Scale (SUDS) scores. Secondary endpoints included change in SUDS score from baseline to the average of the anticipation phase, changes in the Clinical Global Impression – Severity (CGI-S) scale, self-assessment with the State Trait Anxiety Inventory (STAI-State) and the Patient Global Impression – Improvement (PGI-I) scale. A follow-up visit occurred one week after the public speaking challenge.

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's lead drug candidate is BNC210, a first-of-its-kind, well-tolerated, broad spectrum anti-anxiety experimental therapeutic, designed to restore neurotransmitter balance in relevant brain areas, potentially providing rapid relief from stress and anxiety symptoms without the common pitfalls of sedation, cognitive impairment, or addiction. In addition, Neuphoria has strategic partnerships with Merck & Co., Inc. (Merck; known as MSD outside the United States and Canada) for the treatment of cognitive deficits in Alzheimer's disease and other central nervous system conditions; and with Carina Biotech, to develop a legacy oncology program. MK-1167, one of two positive allosteric modulator (PAM) candidates being advanced in the partnership with Merck, is currently being evaluated in a Merck-led Phase 2 trial in Alzheimer's disease. 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.

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