Neuphoria Therapeutics

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Neuphoria Therapeutics

QUICK REFERENCE

Neuphoria Therapeutics Inc.

NASDAQ: NEUP

www.NEUPHORIATX.com

BUSINESS SUMMARY

Neuphoria 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, BNC-210, 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). BNC-210 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.

BNC-210

BNC-210 is an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor under development for the treatment of SAD and post-traumatic stress disorder (PTSD). BNC-210 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. BNC-210 has demonstrated rapid-onset, broad and meaningful anti-anxiety effects in completed clinical trials in SAD, generalized anxiety disorder (GAD) and panic attacks without evidence of sedation, impairments in cognition or addiction potential.

CLINICAL PROGRAM HIGHLIGHTS

- The LPLV milestone has been achieved in the AFFIRM-1 Phase 3 trial evaluating BNC-210 as a first-in-class, acute, "as needed" treatment for SAD. Topline data are anticipated in early fourth quarter 2025.
- Start-up activities continue for the SYMPHONY Phase 2b/3 trial in PTSD. Neuphoria plans to initiate the clinical study in the first half of 2026.
- MK-1167, one of two positive allosteric modulator (PAM) candidates being advanced in a strategic partnership with Merck & Co, Inc., is currently being evaluated in a Merck-led Phase 2 trial in Alzheimer's disease.

CONTACT INFORMATION

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Recent Press Releases *(Headlines and Excerpts)*

Neuphoria Provides Fiscal Year-End 2025 Financial Results and Business Updates

- ***Last patient last visit (LPLV) milestone in AFFIRM-1 Phase 3 trial of BNC-210 in social anxiety disorder (SAD) achieved; topline readout anticipated in early Q4 2025***
- ***Cash runway extended through fiscal Q2 2027***

Sept. 29, 2025 -- Neuphoria Therapeutics Inc. reported its financial results for its fiscal year ended June 30, 2025, and provided recent business updates.

June 30th Fiscal Year-End 2025 Financial Results and Key Highlights

- Cash Position: Cash and cash equivalents were $14.2 million as of June 30, 2025. The Company expects its current cash position to be sufficient to fund operations through the second fiscal quarter of 2027.
- R&D Expenses: Research and development expenses were $9.0 million for the year ended June 30, 2025, compared to $9.4 million for the year ended June 30, 2024. The decrease of $0.4 million was primarily due to the timing of clinical and consulting related spend.
- G&A Expenses: General and administrative expenses were $7.8 million for the year ended June 30, 2025, compared to $8.5 million for the year ended June 30, 2024. The decrease of $0.7 million was primarily due to decreases in headcount and insurance costs.
- Net Loss: Net loss was $0.4 million, or $0.23 per basic and diluted share, for the year ended June 30, 2025, compared to a net loss of $15.5 million, or $18.62 per basic and diluted share, for the year ended June 30, 2024.

Neuphoria Therapeutics Completes Target Enrollment in Phase 3 AFFIRM-1 Trial of BNC-210 in Social Anxiety Disorder (SAD)

- ***Topline data anticipated in early Q4 2025***

Sept. 04, 2025 -- Neuphoria Therapeutics Inc. announced the achievement of target enrollment of 332 participants in the AFFIRM-1 Phase 3 trial evaluating lead candidate BNC-210 as a first-in-class, acute, "as needed", fast-acting treatment for social anxiety disorder (SAD).

"We are thrilled to reach our target enrollment in the AFFIRM-1 trial evaluating BNC-210 as a transformative therapeutic for the treatment of SAD," said Spyros Papapetropoulos, M.D., Ph.D., President and CEO of Neuphoria. "Achieving this milestone puts us on a clear path toward our first Phase 3 data for BNC-210, now expected early in the fourth quarter."

About BNC-210

BNC-210 is an oral, proprietary, selective negative allosteric modulator of the α7 nicotinic acetylcholine receptor under development for the treatment of SAD and post-traumatic stress disorder (PTSD). BNC-210 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. BNC-210 has demonstrated rapid-onset, broad and meaningful anti-anxiety effects in completed clinical trials in SAD, generalized anxiety disorder (GAD) and panic attacks without evidence of sedation, impairments in cognition or addiction potential.

About AFFIRM-1

The AFFIRM-1 Phase 3 clinical trial is 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 BNC-210 versus placebo. Participants in the trial are randomized 1:1 to receive a single dose of 225 mg BNC-210 or matched placebo. Approximately one hour after dosing, participants are introduced to a public speaking challenge and have 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 is 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 include change in SUDS score from baseline to the average of the anticipation phase, changes in the Clinical Global Impression – Severity (CGI-S) scale, and self-assessment with the State Trait Anxiety Inventory (STAI-State) and the Patient Global Impression – Improvement (PGI-I) scale. A follow-up visit occurs one week after the public speaking challenge.

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