



## **Newleos Therapeutics Debuts with \$93.5 Million Oversubscribed Series A Financing to Transform the Treatment of Neuropsychiatric Disorders through the Advancement of Novel Medicines**

- Newleos aims to develop first-in-class and best-in-class therapies to address the need for safer and more efficacious treatment options for major mental health conditions-
- Multiple clinical-stage programs licensed from Roche, ready for proof-of-concept studies in general anxiety, social anxiety, substance use disorders, and cognitive impairment-
- Founded by Longwood Fund and seasoned leaders in CNS drug development-
- Series A Financing led by Goldman Sachs Alternatives-

BOSTON – February 13, 2025 - Newleos Therapeutics, Inc., a clinical stage neuroscience company co-founded by Longwood Fund and seasoned leaders in CNS drug development, today announced the closing of an oversubscribed \$93.5 million Series A financing. The financing was led by Goldman Sachs Alternatives with participation from Novo Holdings A/S, Longwood Fund, DCVC Bio, and Arkin Bio Capital. Newleos’ clinical-stage pipeline was in-licensed from Roche and includes multiple oral small molecules targeting novel mechanisms across a broad range of indications including generalized anxiety, social anxiety, substance use disorders and cognitive impairment.

“Anxiety and substance use disorders represent some of the most prevalent neuropsychiatric indications with high unmet need, representing over 25 percent of mental illnesses in US adults and impacting over 60 million individuals,” commented David Donabedian, Ph.D., Founding CEO, Newleos and Executive Partner, Longwood Fund. “With a seasoned, founding team that has extensive company creation and CNS drug development experience, Newleos will use this capital to conduct proof-of-concept clinical trials across our programs.”

Newleos’ lead clinical program, NTX-1955 (RO7308480), is a first-in-class GABA<sub>A</sub>-γ1 selective positive allosteric modulator (PAM) designed to treat anxiety disorders with a differentiated mechanism of action without the side effects of currently available treatments. NTX-1955 was designed to specifically modulate GABAergic transmission in the anxiety brain circuit by targeting the γ1 (gamma-1) subunit-containing GABA<sub>A</sub> receptor, which is highly enriched in the amygdala. By focusing on GABA<sub>A</sub> regulation in the amygdala, NTX-1955 has the potential to



reduce anxiety while sparing other brain networks associated with safety liabilities. NTX-1955 has completed a comprehensive non-clinical package and has been in Phase 1 trials, including single and multiple ascending dose studies, drug-drug interaction and receptor occupancy studies, demonstrating that it is safe, well tolerated, brain penetrant and selective to GABA<sub>A</sub>-γ1. Newleos plans to investigate NTX-1955 in proof-of-concept clinical studies for the treatment of generalized anxiety disorder.

Newleos' additional clinical-stage assets include NTX-1472 (RO6953958), NTX-2001 (ralmitaront), and NTX-1511 (basmisanil), which target V1a, TAAR1 and GABA<sub>A</sub>-α5 receptors, respectively. NTX-1472 is a selective, brain-penetrant V1a antagonist poised to enter proof-of-concept studies targeting social anxiety disorder. A well-understood pathway, the V1a receptor is activated by arginine vasopressin (AVP), a nanopeptide structurally related to oxytocin. Preclinical studies have shown that blocking V1a reduces anxiety-like behavior in multiple animal models. NTX-2001 is a TAAR1 partial agonist, which Newleos intends to study in substance use disorders. TAAR1 activation inhibits the rewarding and reinforcing effects of drugs from different classes including psychostimulants, opioids and alcohol. NTX-1511 is a highly selective negative allosteric modulator (NAM) of the α5 (alpha-5) subunit of the GABA<sub>A</sub> receptor with the potential to address cognitive impairment in rare-neurodevelopmental indications.

The Newleos Board of Directors includes Christoph Westphal, M.D., Ph.D., Founding Executive Chairman, Newleos Therapeutics and Founding Partner, Longwood Fund; Ming Cheah, Ph.D. Vice President, within Life Sciences Investing at Goldman Sachs Alternatives; Ray Camahort, Ph.D., Partner in the Venture Investments group at Novo Holdings US; and David Donabedian, Ph.D., Executive Partner, Longwood Fund, and Founding CEO, Newleos. As part of the licensing agreement, Roche received an upfront payment and is eligible to receive success-based milestones and royalties in exchange for granting Newleos worldwide rights to the clinical stage assets.

“The Partners at Longwood Fund have long recognized that currently available treatments fall short of meeting the needs of patients with mental health conditions. A majority of anxiety patients fail to respond to first line therapy with SSRIs and SNRIs, and benzodiazepines are not recommended for long term use due to side effects such as sedation, potential for misuse and dependence, and cognitive decline,” commented Dr. Westphal. “Newleos’ portfolio of clinical stage candidates provides an exciting opportunity to advance truly differentiated medicines for some of the most prevalent indications like anxiety and substance use disorders.”

“We believe the field of neuropsychiatry is going through a period of robust innovation, with the potential to dramatically improve outcomes for patients,” commented Dr. Cheah. “We are



pleased to lead the Series A for Newleos as a differentiated opportunity to invest in an attractive portfolio of clinical-stage programs that may deliver meaningful benefit to the lives of patients with underserved neuropsychiatric disorders. We look forward to partnering with the Newleos team to advance its pipeline of novel therapeutics.”

“Novo Holdings is committed to advancing innovative solutions for neurological and psychiatric conditions, a therapeutic area that urgently needs best-in-class and novel first-in-class therapies that could meaningfully improve patient outcomes,” commented Dr. Camahort. “We believe Newleos’ pipeline has the potential to advance the treatment of neuropsychiatric diseases across multiple indications and Novo Holdings is excited to support the Newleos team on this journey to bring much needed novel medicines to patients with neuropsychiatric disorders.”

#### **About Newleos Therapeutics, Inc.**

Newleos Therapeutics is dedicated to providing a new dawn or "eos" for patients with mental health conditions by developing next generation, first- and best-in-class therapies. Over 100 million patients in the United States are affected by neuropsychiatric disorders, with anxiety and substance use disorders among the largest areas of unmet medical need. The company’s clinical-stage pipeline was licensed from Roche and includes oral small molecules targeting GABA<sub>A</sub>-γ1, V1a, TAAR1 and GABA<sub>A</sub>-α5 with broad potential in general anxiety, social anxiety, substance use disorders and cognitive impairment. Newleos was co-founded by Longwood Fund, Federico Bolognani, M.D., Ph.D., and William Martin, Ph.D., seasoned experts in company creation and CNS drug development. For more information visit [www.newleos.com](http://www.newleos.com).

#### **About Longwood Fund**

Longwood Fund is a venture capital firm dedicated to creating and investing in novel healthcare companies that develop important treatments to help patients while generating significant value for investors. The Longwood team has a long history of successfully launching and building important life science companies while providing operational leadership and strategic guidance. Collectively, the Partners at Longwood Fund have co-founded 25 companies with over 20 launched or marketed drugs and therapies, as well as over two dozen clinical stage assets, all focused on helping patients in need. Companies founded by Longwood Fund, or its principals prior to the founding of the Firm, as lead investor and CEO/CBO include Acceleron, Momenta, Alnylam, Vertex, Sirtris, TScan, Pyxis Oncology, Immunitas, Be Biopharma, Photys, Carbon Biosciences, DEM BioPharma and Solu Therapeutics. For more information, please visit [www.longwoodfund.com](http://www.longwoodfund.com).

#### **About Goldman Sachs Alternatives**

Goldman Sachs (NYSE: GS) is one of the leading investors in alternatives globally, with over \$500 billion in assets and more than 30 years of experience. The business invests in the full



spectrum of alternatives including private equity, growth equity, life sciences, private credit, real estate, infrastructure, hedge funds, and sustainability. Clients access these solutions through direct strategies, customized partnerships, and open-architecture programs. The business is driven by a focus on partnership and shared success with its clients, seeking to deliver long-term investment performance drawing on its global network and deep expertise across industries and markets. The alternative investments platform is part of Goldman Sachs Asset Management, which delivers investment and advisory services across public and private markets for the world's leading institutions, financial advisors, and individuals. Goldman Sachs has over \$3.1 trillion in assets under supervision globally as of December 31, 2024.

### **About Novo Holdings A/S**

Novo Holdings is a holding and investment company that is responsible for managing the assets and the wealth of the Novo Nordisk Foundation. The purpose of Novo Holdings is to improve people's health and the sustainability of society and the planet by generating attractive long-term returns on the assets of the Novo Nordisk Foundation.

Wholly owned by the Novo Nordisk Foundation, Novo Holdings is the controlling shareholder of Novo Nordisk A/S and Novonosis A/S (Novozymes A/S) and manages an investment portfolio with a long-term return perspective. In addition to managing a broad portfolio of equities, bonds, real estate, infrastructure and private equity assets, Novo Holdings is a world-leading life sciences investor. Through its Seed, Venture, Growth, Asia, Planetary Health Investments and Principal Investments teams, Novo Holdings invests in life science companies at all stages of development. As of year-end 2023, Novo Holdings had total assets of EUR 149 billion. [www.novoholdings.dk](http://www.novoholdings.dk).

### **Media Contact:**

Kari Watson  
617-470-8388  
[media@newleos.com](mailto:media@newleos.com)