Neurocrine Biosciences Showcases R&D Transformation Driving Innovation Across Neuroscience and Endocrinology

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Provided Update on R&D Engine Now On Track to Deliver Multiple First- and Best-in-Class Medicines, Positioning Company for Long-Term Value Creation Across Therapeutic Modalities

Reviewed Positive Data Across Late-Stage Neuropsychiatry Pipeline Including Osavampator and Direclidine; Topline Phase 3 Data from Both Programs Expected in 2027

Announced Expansion of CRF Platform as Foundation of New Class of Medicines for Metabolic Diseases, Including Obesity

SAN DIEGO, Dec. 16, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced a new chapter in its research and development strategy, designed to fuel the Company's next era for growth and deliver long-term value. Neurocrine highlighted this business strategy during its 2025 R&D Day at its headquarters in San Diego, CA.

Building on three decades of leadership in neurology, psychiatry, and endocrinology, Neurocrine is advancing a diversified pipeline of first- and best-in-class medicines across therapeutic modalities including two Phase 3 programs, osavampator for major depressive disorder and direclidine for schizophrenia. The company's clinical portfolio includes a rich pipeline of early- to mid-stage muscarinic agonists and VMAT2 inhibitors for the treatment of neuropsychiatric indications, and CRF-based therapies for metabolic diseases, including obesity. By the end of the decade, Neurocrine expects its R&D engine to deliver an approved medicine every two years.

"We are ushering in a new era for Neurocrine in which we accelerate the delivery of new medicines for patients," said Kyle W. Gano, Ph.D., Chief Executive Officer, Neurocrine Biosciences. "Today, we unveiled the full breadth of our pipeline, featuring multiple first- and best-in-class assets targeting validated biological pathways and powered by an innovative R&D engine. With more than 30 years of leadership in CRF biology, we are now introducing a platform focused on CRF2, with the goal of developing novel therapies across a range of metabolic diseases. Our efforts will begin with obesity, where we believe we can deliver superior weight loss while preserving muscle mass."

"Backed by our proven track record in drug development and commercialization, the strong foundation we built with INGREZZA in neuropsychiatry and CRENESSITY in endocrinology, and an experienced team, we are uniquely positioned to advance our pipeline and create sustained, meaningful value for patients, providers, and shareholders alike," added Dr. Gano.

Highlights from R&D Day:

Updates across mid- to late-stage assets including osavampator and muscarinic agonists, positioning Neurocrine to deliver multiple first- and best-in-class medicines this decade. This includes:

- Osavampator, a potential first in class AMPA positive allosteric modulator for the treatment of major depressive disorder. Topline data from three ongoing Phase 3 studies are expected in 2027.
- Direclidine, an M4 muscarinic agonist for the treatment of psychiatric disorders, including schizophrenia and bipolar mania. Topline data from the ongoing Phase 3 studies in schizophrenia and the Phase 2 study in bipolar mania are expected in 2027 and 2028.
- NBI-'570, a dual M1 / M4 muscarinic agonist with potential as a long acting injectable for the treatment of psychiatric disorders including schizophrenia. Topline data from the recently initiated Phase 2 study in schizophrenia is expected in 2028.

Details of Neurocrine's transformed R&D engine, designed to deliver at least four new Phase 1 and two Phase 2 programs per year by focusing on genetically or clinically validated mechanisms of action were shared during today's event. Highlighted programs include:

- NBI-'569, a dual M1 / M4 agonist for Alzheimer's psychosis, and NBI-'567, an M1 preferring agonist for Alzheimer's cognition and Lewy body dementia.
- Next-generation VMAT2 inhibitors NBI-'890 and NBI-'675, engineered for increased half-life and potency and decreased solubility, and which provide the potential for long-acting injectable administration across multiple central nervous system indications.
- A suite of differentiated assets for better quality weight loss, including NBIP-'2118, a CRF2 agonist expected to enter Phase 1 development in the first half of 2026.

Neurocrine plans to provide update on its emerging early-stage Neurology and Immunology pipeline in 2026.

An archived replay of the webcast and accompanying slides can also be accessed here and on the Neurocrine Biosciences' website under Investors.

About Neurocrine Biosciences

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neuropsychiatric, neurological, and neuroendocrine disorders. The company's diverse portfolio includes U.S. FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, classic congenital adrenal hyperplasia, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X, Facebook and YouTube. (**in collaboration with AbbVie*)

Forward-Looking Statements

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements related to: our business strategy, objectives, and future development plans; the benefits to be derived from our products and product candidates; the value our products and/or our product candidates may bring to patients; the continued success of INGREZZA; successfully launching and commercializing CRENESSITY; our financial and operating performance, including our future revenues, cash position, and profitability; our collaborative partnerships; expected future clinical and regulatory milestones; and the timing of the initiation and/or completion of our clinical, regulatory, and other development activities and those of our collaboration partners. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements include, but are not limited to, the following: risks and uncertainties associated with Neurocrine Biosciences' business and finances in general, risks and uncertainties associated with the commercialization of INGREZZA and CRENESSITY; risks related to the development of our product candidates; risks associated with our dependence on third parties for development, manufacturing, and commercialization activities for our products and product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that clinical development activities may not be initiated or completed on time or at all, or may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that the potential benefits of the agreements with our collaboration partners may never be realized; risks that our products, and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks associated with government and third-party regulatory and/or policy efforts which may, among other things, impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products; risks associated with competition from other therapies or products, including potential generic entrants for our products; our ability to manage the growth of our organization; and other risks described in our periodic reports filed with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than as required by law.

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Neurocrine Biosciences, Inc.,Tony Jewell (Media), 858-617-7578, media@neurocrine.com; Todd Tushla (Investors), 858-617-7143, ir@neurocrine.com