



Nurix Therapeutics Outlines 2025 Goals and Objectives for Advancement of Its Robust Pipeline in Cancer and Autoimmune Diseases

January 13, 2025

Initiate a suite of clinical trials in 2025 intended to support global registration of NX-5948 for the treatment of chronic lymphocytic leukemia

Expand the development of NX-5948 in additional cancer indications and inflammatory diseases

Advance our portfolio of partnered programs in inflammation and immunology, including degraders of IRAK4 and STAT6

Invest in our highly productive DEL-AI discovery engine to create and advance novel degrader-based treatments in our wholly owned and partnered portfolios

*Maintain a strong financial position, building on our estimated \$609.6 million in cash and investments at fiscal 2024 year-end**

SAN FRANCISCO, Jan. 13, 2025 (GLOBE NEWSWIRE) -- Nurix Therapeutics, Inc. (Nasdaq: NRIX), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted protein degradation medicines, the next frontier in innovative drug design aimed at improving treatment options for patients with cancer and inflammatory diseases, today outlined key objectives and anticipated milestones for 2025, which will be the subject of Nurix's corporate update at the 43rd Annual J.P. Morgan Healthcare Conference today at 3:00 p.m. PT, in San Francisco.

"Nurix had an exciting year of successful execution of our clinical trials and significant progress in several key business areas," said Arthur T. Sands, M.D., Ph.D., president and chief executive officer of Nurix. "We recently presented impressive clinical responses from our NX-5948 Phase 1a/1b clinical trial both in patients with relapsed or refractory chronic lymphocytic leukemia and in patients with Waldenstrom's macroglobulinemia. We received Fast Track Designation from the U.S. Food and Drug Administration for both of these indications as well as PRIME designation for CLL from the European Medicines Agency. Nurix is positioned to initiate a suite of late-stage clinical studies of NX-5948 in 2025, including pivotal studies in CLL. We also anticipate significant advances in our portfolio of wholly owned and partnered programs in the area of inflammation and immunology, including degraders of IRAK4 and STAT6."

"2024 was a year of significant advancement in our research and discovery organization," said Gwenn M. Hansen, Ph.D., chief scientific officer of Nurix. "We not only advanced several preclinical programs that are approaching key development milestones within our wholly owned and partnered portfolios, but we also expanded our discovery platform to include AI-powered drug discovery that leverages our early investments in E3 ligase research, DEL discovery, chemistry automation and machine learning. Nurix has developed a suite of AI tools applicable across the breadth of our technical workflows, but with a specific focus on prospective ligand discovery informed by our years of accumulated DEL know-how and screening data, which we are calling DEL-AI."

2024 Accomplishments and Business Highlights

Clinical Development Pipeline

- **Advanced NX-5948 and presented positive clinical data at oncology-focused medical meetings throughout 2024.** New positive clinical data were presented at the 66th American Society of Hematology Annual Meeting (ASH2024) in December 2024 and at the 12th International Workshop on Waldenstrom's Macroglobulinemia (IWWM-12) in October 2024, from patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (r/r CLL/SLL) and patients with Waldenstrom's macroglobulinemia (WM) treated in the Phase 1a/1b clinical trial of NX-5948. NX-5948 is an orally bioavailable, brain penetrant degrader of Bruton's tyrosine kinase (BTK). At ASH2024, Nurix reported a robust objective response rate (ORR) of 75.5% among the 49 efficacy-evaluable r/r CLL patients across all doses tested, with the majority of responses occurring at the first assessment (Week 8). With longer time on treatment, the ORR increased to 84.2% based on an exploratory efficacy analysis of patients who had at least two response assessments (Week 16). Responses and robust BTK degradation were observed across all populations regardless of prior treatment, baseline mutations including those with BTK mutations associated with treatment resistance to both covalent and non-covalent BTK inhibitors, high-risk molecular features, or central nervous system (CNS) involvement. NX-5948 was well-tolerated in all patient populations and across all doses tested from 50 to 600 mg daily. In the nine efficacy-evaluable WM patients treated with NX-5948 an ORR of 77.8% was observed with increasing depth of response over time, supporting continued development of NX-5948 for this indication. Additional information on the ongoing clinical trial can be accessed at

www.clinicaltrials.gov ([NCT05131022](https://www.clinicaltrials.gov/ct2/show/study/NCT05131022)). A webcast of Nurix's ASH2024 presentation and additional discussion on the company's programs and plans is available in the Investors section of the [Nurix website](#).

- **Successfully executed on regulatory strategy for global development of NX-5948 with U.S. FDA Fast Track and European Medicines Agency PRIME designations:** In 2024, NX-5948 received two separate Fast Track designations from the U.S. Food and Drug Administration (FDA): the first for the treatment of adult patients with r/r CLL/SLL after at least two lines of therapy, including a BTK inhibitor and a B-cell lymphoma 2 (BCL2) inhibitor, and the second for the treatment of adult patients with r/r WM after at least two lines of therapy, including a BTK inhibitor. In Europe, NX-5948 received PRIME designation for the treatment patients with r/r CLL/SLL after treatment with at least a BTK inhibitor and a BCL2 inhibitor. Regulatory clearance for clinical site initiations was received in several countries and clinical trial expansion is ongoing in France, Poland, Italy and Spain. Additional countries are anticipated to come online in 2025.
- **Re-initiated enrollment in NX-2127 Phase 1a/b trial:** Following a decision in March 2024 in which the FDA lifted a manufacturing-related, partial clinical hold on the NX-2127 clinical trial, Nurix reinitiated enrollment in a dose escalation study within the current Phase 1a/1b trial, using its new chirally controlled drug product of NX-2127, a novel orally bioavailable bifunctional molecule that degrades BTK and the cereblon neosubstrates Ikaros (IKZF1) and Aiolos (IKZF3). Nurix is focusing development on aggressive lymphomas where the combination of BTK degradation and IKZF1/3 degradation have the potential for synergy and significant therapeutic benefit. Additional information on the clinical trial can be accessed at [www.clinicaltrials.gov \(NCT04830137\)](https://www.clinicaltrials.gov/ct2/show/study/NCT04830137).
- **Advanced Phase 1a dose escalation trial of NX-1607 in monotherapy and in a combination cohort with paclitaxel in adults in a range of oncology indications.** Nurix's lead drug candidate from its E3 ligase inhibitor portfolio, NX-1607, is an orally bioavailable inhibitor of Casitas B-lineage lymphoma proto-oncogene (CBL-B) for immuno-oncology indications, including a range of solid tumor types. The company has evaluated dosing and scheduling regimens to optimize tolerability and maximize pharmacodynamic effects. Additional information on the clinical trial can be accessed at [www.clinicaltrials.gov \(NCT05107674\)](https://www.clinicaltrials.gov/ct2/show/study/NCT05107674).

Research and Discovery

- **Advanced a pipeline of wholly owned and partnered programs in inflammation and immunology:** At ACR Convergence 2024, the annual meeting of the American College of Rheumatology, Nurix presented preclinical data, including mechanism of action and activity in relevant disease models of inflammation and autoimmune diseases, from NX-5948. Nurix announced plans to initiate clinical testing of NX-5948 in autoimmune cytopenias such as warm autoimmune hemolytic anemia (wAIHA) in 2025, initially as an addition to its ongoing Phase 1b trial in patients with B-cell malignancies. At ACR Convergence 2024, positive preclinical data were also presented from Nurix's collaboration with Gilead to develop GS-6791/NX-0479, an IRAK4 degrader, that has potential applications in the treatment of rheumatoid arthritis and other inflammatory diseases. In addition, Nurix's ongoing research program with Sanofi was extended for the development of a degrader of STAT6 (signal transducer and activator of transcription 6), a key drug target in type 2 inflammation, with the goal of nominating a development candidate in the first half of 2025.
- **Expanded Nurix's portfolio of brain penetrant degraders:** At the annual meeting of the American Association for Cancer Research (AACR) in April 2024, Nurix presented the first clinical evidence of brain penetration and clinical activity in the CNS for its BTK degrader NX-5948. In addition, data from Nurix's previously undisclosed program to develop an orally available, brain penetrant pan-mutant B-RAF degrader for the treatment of mutant B-RAF driven solid tumors were presented at the 7th Annual TPD & Induced Proximity Summit. These programs, along with other scientific presentations throughout 2024, clearly demonstrate Nurix's ability to achieve brain penetrant and CNS active degraders.
- **Published the first description of BTK's clinically important scaffolding function:** Nurix scientists and clinical collaborators published a manuscript in the journal *Science* titled "*Kinase Impaired BTK Mutations Are Susceptible to Clinical Stage BTK and IKZF1/3 Degradation NX-2127*" that elucidates a previously unappreciated oncogenic scaffold function of BTK responsible for clinical resistance to enzymatic inhibitors and shows that NX-2127, a potent targeted protein degrader with differentiated activity against BTK and IKZF1/3, can overcome this resistance across a broad range of acquired mutations. The elimination of BTK's scaffolding function is a critical attribute of both NX-2127 and NX-5948, with potential clinical relevance in both B-cell malignancies and inflammation.
- **Demonstrated cellular proof of concept for its degrader antibody conjugate (DAC) platform:** Early preclinical data from Nurix's ongoing collaboration with Pfizer to develop DACs were presented at the ADC & Radiopharmaceuticals Pharma & Biotech Partnering Summit. The data from two separate DACs demonstrated cell-type selective degradation of targeted proteins by DACs and highlighted the potential advantages of this new drug class and Nurix's novel approach to DAC optimization.
- **Achieved significant milestones in collaborations with Gilead, Sanofi and Pfizer:** In April 2024, Nurix announced that Gilead elected to extend the research term of the companies' ongoing collaboration, originally established in 2019, by an additional two years, which resulted in a payment of \$15 million to Nurix. In April 2024, Nurix also announced the extension of its research term with Sanofi for its previously undisclosed STAT6 degrader program. In 2024, Nurix also

achieved its first milestone in its ongoing Pfizer collaboration and received a \$5 million payment. In total, in 2024, Nurix earned milestones and fees in these ongoing strategic collaborations totaling \$22 million through the third fiscal quarter of 2024 (August 31, 2024).

Corporate and Leadership

- **Strengthened leadership team with C-suite appointments and new Board of Directors member with drug commercialization expertise:** In 2024, Nurix announced the promotions of Paula G. O'Connor, M.D., as chief medical officer and Pasit Phiasivongsa, Ph.D., as chief technical officer of Nurix. These appointments strengthen leadership in clinical operations and CMC ahead of planned pivotal studies for NX-5948 in 2025. In addition, Anil Kapur, a senior leader in commercial operations in hematology and oncology with over 25 years of executive experience in pharmaceutical and biotech companies across both U.S. and international markets joined the Nurix board of directors.
- **Strengthened balance sheet to support development of pipeline:** Nurix ended its fiscal year with an estimated, unaudited \$609.6 million in cash and investments as of November 30, 2024.* Based on its operating plan, Nurix anticipates that the company will be able to fund its operating activities into the first half of 2027.

2025 Goals and Catalysts

- **NX-5948**
 - **Initiate pivotal studies for NX-5948:** Nurix is evaluating NX-5948 in an ongoing Phase 1b clinical trial in adults with relapsed or refractory B-cell malignancies and expects to initiate a suite of clinical trials in 2025 intended to support global registration of NX-5948 for the treatment of patients with CLL.
 - **Expand the development of NX-5948 in additional cancer indications and inflammatory diseases:** Nurix expects to complete the ongoing Phase 1b clinical trial in patients with WM and determine Phase 2 dose(s) as well as to continue to explore regulatory paths for this indication. In inflammation and immunology (I&I), Nurix plans to implement a sequenced, multi-organ system approach to evaluating NX-5948 to generate the greatest opportunity for patients and value creation, seeking first proof of concept through the study of CLL patients with secondary autoimmune-mediated hemolytic anemia with plans to explore non-malignant cytopenias, such as warm autoimmune hemolytic anemia (wAIHA), before potentially moving to dermatologic indications, such as hidradenitis suppurativa (HS), and neurologic indications, such as multiple sclerosis (MS).
- **NX-2127**
 - **Drive NX-2127 to proof-of-concept data:** Nurix is focusing development on aggressive lymphomas where the combination of BTK degradation and IKZF1/3 degradation have the potential for synergy and significant therapeutic benefit. The company plans to complete dose escalation with new chirally controlled drug product and select recommended Phase 1b dose for selected indications and expects to share additional clinical data after selection of a Phase 1b expansion dose(s) and indication(s).
- **NX-1607:**
 - **Drive NX-1607 to proof-of-concept data:** Nurix is testing both once daily (QD) and twice daily (BID) dosing of NX-1607. With additional patients in the BID dosing arms, Nurix plans to establish a Phase 1b monotherapy dose and expects to share additional clinical data after selection of a Phase 1b expansion dose(s) and indication(s).
- **Preclinical-development pipeline:**
 - **Advance IRAK4 degrader program into Phase 1:** GS-6791 (previously NX-0479) is a potent, selective, oral IRAK4 degrader. Nurix's partner Gilead exercised its option to exclusively license GS-6791 in March 2023 and is responsible for conducting IND-enabling studies and advancing this program to clinical development, which Nurix anticipates in 2025. Nurix retains its option to co-develop and co-promote in the United States, splitting U.S profits and losses evenly and receiving royalties on ex-U.S. sales.
 - **Nominate a STAT6 degrader development candidate:** Nurix anticipates nominating a STAT6 degrader development candidate in the first half of 2025. Under its collaboration with Sanofi, delivery of a development candidate data package triggers a licensing option decision for Sanofi. If licensed by Sanofi, Nurix retains its option to co-develop and co-promote in the United States, splitting U.S profits and losses evenly and receiving royalties on ex-U.S. sales.
 - **Nominate a development candidate within Nurix's wholly owned degrader pipeline:** Nurix is advancing several preclinical programs within its wholly owned pipeline. In 2025, Nurix anticipates nominating at least one development candidate to advance to IND-enabling studies.

About Nurix

Nurix Therapeutics is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of targeted protein degradation medicines, the next frontier in innovative drug design aimed at improving treatment options for patients with cancer and inflammatory diseases. Powered by a fully AI-integrated discovery engine capable of tackling any protein

class, and coupled with unparalleled ligase expertise, Nurix's dedicated team has built a formidable advantage in translating the science of targeted protein degradation into clinical advancements. Nurix aims to establish degrader-based treatments at the forefront of patient care, writing medicine's next chapter with a new script to outmatch disease. Nurix's wholly owned, clinical stage pipeline includes degraders of Bruton's tyrosine kinase (BTK), a B-cell signaling protein, and inhibitors of Casitas B-lineage lymphoma proto-oncogene B (CBL-B), an E3 ligase that regulates activation of multiple immune cell types including T cells and NK cells. Nurix also is advancing multiple potentially first-in-class or best-in-class degraders and DACs in its preclinical pipeline. Nurix's partnered drug discovery pipeline consists of preclinical stage degraders of IRAK4 and STAT6, as well as multiple additional programs under collaboration agreements with Gilead Sciences, Inc., Sanofi S.A. and Pfizer Inc., within which Nurix retains certain options for co-development, co-commercialization and profit sharing in the United States for multiple drug candidates. Nurix is headquartered in San Francisco, California. For additional information visit <http://www.nurixtx.com>.

* The estimated cash and investment amount included herein is a preliminary, unaudited estimate based upon information available to Nurix's management as of the date of this press release and is subject to the completion of financial closing procedures. The amount does not present all information necessary for a complete understanding of Nurix's financial condition as of or for the year ended November 30, 2024. Nurix's audited results as of and for the year ended November 30, 2024, will be included in Nurix's Annual Report on Form 10-K for the year ended November 30, 2024.

Forward Looking Statements

This press release contains statements that relate to future events and expectations and as such constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When or if used in this press release, the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "outlook," "plan," "predict," "should," "will," and similar expressions and their variants, as they relate to Nurix, may identify forward-looking statements. All statements that reflect Nurix's expectations, assumptions or projections about the future, other than statements of historical fact, are forward-looking statements, including, without limitation, statements regarding: Nurix's future plans, prospects and strategies, including its plans for the development of NX-5948, NX-2127 and NX-1607; Nurix's plans and expectations for its collaborations and preclinical pipeline; the tolerability, safety profile, therapeutic potential and other advantages of Nurix's drug candidates the planned timing and conduct of the clinical trials for Nurix's drug candidates; the planned timing for the provision of updates and findings from Nurix's preclinical and clinical studies; the tolerability, safety profile, therapeutic potential and other advantages of Nurix's drug candidates; the therapeutic potential of DACs; the potential benefits of Nurix's collaborations, including potential milestone and sales-related payments; the potential advantages of Nurix's drug discovery platform; Nurix's future financial or business performance; Nurix's estimated, unaudited cash and investment position as of November 30, 2024; and Nurix's ability to fund its operating activities into the first half of 2027. Forward-looking statements reflect Nurix's current beliefs, expectations and assumptions. Although Nurix believes the expectations and assumptions reflected in such forward-looking statements are reasonable, Nurix can give no assurance that they will prove to be correct. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and changes in circumstances that are difficult to predict, which could cause Nurix's actual activities and results to differ materially from those expressed in any forward-looking statement. Such risks and uncertainties include, but are not limited to: (i) risks and uncertainties related to Nurix's ability to advance its drug candidates, obtain regulatory approval of and ultimately commercialize its drug candidates; (ii) risks and uncertainties related to the timing and results of preclinical studies and clinical trials; (iii) risks and uncertainties related to Nurix's ability to fund development activities and achieve development goals; (iv) uncertainties related to the timing and receipt of payments from Nurix's collaboration partners, including milestone payments and royalties on future potential product sales; (v) the impact of macroeconomic conditions and global or regional events on Nurix's business, clinical trials, financial condition, liquidity and results of operations; (vi) risks and uncertainties related to Nurix's ability to protect intellectual property and (vii) other risks and uncertainties described under the heading "Risk Factors" in Nurix's Quarterly Report on Form 10-Q for the fiscal quarter ended August 31, 2024, and other SEC filings. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. The statements in this press release speak only as of the date of this press release, even if subsequently made available by Nurix on its website or otherwise. Nurix disclaims any intention or obligation to update publicly any forward-looking statements, whether in response to new information, future events, or otherwise, except as required by applicable law.

Contacts:

Investors

Jason Kantor, Ph.D.
Nurix Therapeutics
ir@nurixtx.com

Elizabeth Wolffe, Ph.D.
Wheelhouse Life Science Advisors
lwolffe@wheelhousesa.com

Media

Aljanae Reynolds
Wheelhouse Life Science Advisors
areynolds@wheelhousesa.com