

Nuvalent Outlines Recent Pipeline and Business Progress, Reiterates Key Anticipated Milestones, and Reports First Quarter 2025 Financial Results

Topline pivotal data expected for zidesamtinib in TKI pre-treated ROS1-positive NSCLC population in the first half of 2025 in support of anticipated first NDA submission by mid-year 2025

Initiation of ALKAZAR Phase 3 randomized, controlled trial of neladalkib for front-line ALK-positive NSCLC planned for first half of 2025

Pivotal data for neladalkib in TKI pre-treated ALK-positive NSCLC population anticipated by year-end 2025

Strengthened leadership team with key internal promotions

CAMBRIDGE, Mass., May 8, 2025 /PRNewswire/ -- [Nuvalent, Inc.](#) (Nasdaq: NUVL), a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for clinically proven kinase targets in cancer, today outlined pipeline and business progress, reiterated key anticipated milestones, and reported first quarter 2025 financial results.

"2025 is a critical year of execution for Nuvalent as we continue to transition toward becoming a fully integrated commercial-stage biopharmaceutical company," **said James Porter, Ph.D., Chief Executive Officer at Nuvalent.** "We expect multiple meaningful milestones this year, including pivotal data for TKI pre-treated patients from both of our parallel lead programs, and our first potential NDA submission for zidesamtinib for TKI pre-treated patients with ROS1-positive NSCLC."

Dr. Porter continued, "The continued progress across our portfolio is a direct reflection of the strength and dedication of our team—it is their deep expertise, operational excellence, and commitment to patients that drive our ability to execute. In

recognition of their significant contributions, we're pleased to announce the leadership promotions of Ruth Adams to Senior Vice President, Clinical Operations; Dr. Joshua Horan to Senior Vice President, Chemistry; and Jessie Lin to Senior Vice President, Corporate Strategy and Portfolio Management. With strong product candidates, a solid financial position, and an experienced team unified by an unwavering commitment to patient impact, we believe we are well-positioned to achieve our goals."

Recent Pipeline and Business Highlights

ROS1 Program

- Evaluation of zidesamtinib, the company's novel ROS1-selective inhibitor, is ongoing in the ARROS-1 Phase 1/2 trial for patients with advanced TKI-naïve and TKI pre-treated ROS1-positive non-small cell lung cancer (NSCLC) and other solid tumors. The company expects to report pivotal data for TKI pre-treated patients with advanced ROS1-positive NSCLC in the first half of 2025 in support of an anticipated New Drug Application (NDA) submission by mid-year 2025.
- A manuscript reinforcing the rational molecular design of zidesamtinib as a novel ROS1-selective inhibitor [was published](#) in *Molecular Cancer Therapeutics*, a journal of the American Association for Cancer Research (AACR), in conjunction with the presentation of [new preclinical data](#) at the AACR meeting detailing the first crystal structure of ROS1 G2032R in complex with zidesamtinib. The crystal structure further supports zidesamtinib's molecular design and provides structural insights into how the ROS1 G2032R mutation affects TKI binding. The publication additionally explores the activity of zidesamtinib and other approved or investigational ROS1 TKIs at clinically relevant concentrations against ROS1 resistance mutations, including the most commonly occurring resistance mutation, ROS1 G2032R, in preclinical mutagenesis screens and an intracranial ROS1 G2032R xenograft model. Findings presented in the manuscript show that, at clinically relevant concentrations, zidesamtinib suppressed on-target resistance in ENU mutagenesis screens simulating first-line and later-line treatment and inhibited ROS1 G2032R brain tumors more effectively than the other ROS1 TKIs evaluated.

ALK Program

- Evaluation of neladalkib, its novel ALK-selective inhibitor, is ongoing in the ALKOVE-1 Phase 1/2 trial for patients with advanced ALK-positive NSCLC and other solid tumors. The company expects to report pivotal data for TKI pre-treated patients with advanced ALK-positive NSCLC by year-end 2025.
- Nuvalent presented [new preclinical data](#) at the AACR Annual Meeting demonstrating that neladalkib suppressed resistance in ENU mutagenesis screens simulating first-line and later-line treatment.
- The company plans to initiate the ALKAZAR Phase 3 trial, its front-line development strategy for the company's ALK program, in the first half of 2025. The Phase 3 ALKAZAR trial will be a global, randomized, controlled trial designed to evaluate neladalkib versus the current standard of care for the treatment of patients with TKI-naïve ALK-positive NSCLC. Patients will be randomized 1:1 to receive neladalkib monotherapy or ALECENSA® (alectinib) monotherapy. The company will present a ["Trial in Progress" poster](#) including background and study design for ALKAZAR at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

HER2 Program

- Enrollment is ongoing in the HEROEX-1 Phase 1a/1b trial evaluating the overall safety and tolerability of NVL-330, the company's novel HER2-selective inhibitor, for pre-treated patients with HER2-altered NSCLC. Additional objectives include determination of the recommended Phase 2 dose, characterization of NVL-330's pharmacokinetic profile, and preliminary evaluation of anti-tumor activity. A ["Trial in Progress" poster](#) including background and study design for HEROEX-1 will be presented at the 2025 ASCO Annual Meeting.

Recent Leadership Promotions

- **Ruth Adams, Promoted to Senior Vice President, Clinical Operations:** Ruth joined Nuvalent in 2020, bringing more than 20 years of experience in research and development for oncology therapeutics. This promotion recognizes Ruth's continued excellence in overseeing clinical trial execution, exemplified by her leadership in the global operationalization of Nuvalent's ARROS-1, ALKOVE-1, HEROEX-1, and ALKAZAR studies.
- **Joshua Horan, Ph.D., Promoted to Senior Vice President, Chemistry:** Joshua joined the Nuvalent team in 2018, bringing more than 15 years of drug discovery experience spanning the fields of immunology, nephrology, proteopathy, and oncology. This promotion recognizes Joshua's continued excellence in overseeing Nuvalent's discovery chemistry program, which has generated three novel, potential best-in-class drug candidates and continues to advance an active discovery pipeline.
- **Jessie Lin, Promoted to Senior Vice President, Corporate Strategy & Portfolio Management:** Jessie has worked with the Nuvalent team since 2020, bringing 15 years of experience driving multidisciplinary strategic growth initiatives across the life sciences industry. This promotion recognizes Jessie's continued excellence in shaping and advancing Nuvalent's mission of becoming a fully integrated biopharmaceutical company capable of discovering, developing, and delivering *precisely* targeted therapies for patients with cancer.

Upcoming Events

- **TD Cowen 6th Annual Oncology Innovation Summit:** Management will be participating in a virtual fireside chat on Tuesday, May 27, 2025 at 4:00 p.m. ET. A live webcast will be available in the Investors section of Nuvalent's website at www.nuvalent.com, and will be archived for 30 days following the conference.

First Quarter 2025 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$1.1 billion as of March 31, 2025. Nuvalent continues to believe its existing cash, cash equivalents and marketable securities will be sufficient to fund its current operating plan into 2028.
- **R&D Expenses:** Research and development (R&D) expenses were \$74.4 million for the first quarter of 2025.
- **G&A Expenses:** General and administrative (G&A) expenses were \$20.4 million for the first quarter of 2025.
- **Net Loss:** Net loss was \$84.6 million for the first quarter of 2025.

About Nuvalent

Nuvalent, Inc. (Nasdaq: NUVL) is a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for patients with cancer, designed to overcome the limitations of existing therapies for clinically proven kinase targets. Leveraging deep expertise in chemistry and structure-based drug design, we develop innovative small molecules that have the potential to overcome resistance, minimize adverse events, address brain metastases, and drive more durable responses. Nuvalent is advancing a robust pipeline with investigational candidates for ROS1-positive, ALK-positive, and HER2-altered non-small cell lung cancer, and multiple discovery-stage research programs.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding Nuvalent's strategy, business plans, and focus; the period over which Nuvalent estimates its cash, cash equivalents and marketable securities will be sufficient to fund its future operating expenses and capital expenditure requirements; the expected timing of data announcements, clinical trial initiations and FDA product approvals; the preclinical and clinical development programs for zidesamtinib, neladalkib and NVL-330; the potential benefits and effects of Nuvalent's product development candidates; the design and enrollment of the ARROS-1, ALKAZAR, ALKOVE-1, and HEROEX-1 trials; the potential of Nuvalent's pipeline programs, including zidesamtinib, neladalkib and NVL-330; the implications of data readouts and presentations; Nuvalent's research and development programs for the treatment of cancer; and risks and uncertainties associated with drug development. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "aim," "goal," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" or the negative of these terms and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. You should not place undue reliance on these statements or the scientific data presented.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation: risks that Nuvalent may not fully enroll its clinical trials or that enrollment will take longer than expected; unexpected concerns that may arise from additional data, analysis, or results obtained during preclinical studies or clinical trials; the risk that results of earlier clinical trials may not be predictive of the results of later-stage clinical trials; the risk that data from our clinical trials may not be sufficient to support registration and that Nuvalent may be required to conduct one or more additional studies or trials prior to seeking registration of our product candidates; the occurrence of adverse safety events; risks that the FDA may not approve our potential products on the timelines we expect, or at all; risks of unexpected costs, delays, or other unexpected hurdles; risks that Nuvalent may not be able to nominate drug candidates from its discovery programs; the direct or indirect impact of public health emergencies or global geopolitical circumstances on the timing and anticipated timing and results of Nuvalent's clinical trials, strategy, and future operations; the timing and outcome of Nuvalent's planned interactions with regulatory authorities; and risks related to obtaining, maintaining, and protecting Nuvalent's intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Nuvalent's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as well as any prior and subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Nuvalent's views only as of today and should not be relied upon as representing its views as of any subsequent date. Nuvalent explicitly disclaims any obligation to update any forward-looking statements.

CONSOLIDATED STATEMENTS OF OPERATIONS **(In thousands, except share and per share amounts)** **(Unaudited)**

	Three Months Ended March 31,	
	2025	2024
Operating expenses		
	\$	\$
Research and development	74,418	38,634
General and administrative	20,394	13,954
Total operating expenses	94,812	52,588
Loss from operations	(94,812)	(52,588)
Other income (expense)		
Change in fair value of related party revenue share liability	(1,430)	—
Interest income and other income (expense), net	11,817	8,489
Total other income (expense), net	10,387	8,489
Loss before income taxes	(84,425)	(44,099)
Income tax provision	157	383
	\$	\$
Net loss	(84,582)	(44,482)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.18)	\$ (0.69)
Weighted average shares of common stock outstanding, basic and diluted	71,607,546	64,150,588

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	\$ 1,073,225	\$ 1,118,302
Working capital	\$ 1,011,519	\$ 1,078,428
Total assets	\$ 1,105,806	\$ 1,141,752
Total liabilities	\$ 94,749	\$ 71,960
Total stockholders' equity	\$ 1,011,057	\$ 1,069,792

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