Nuvalent Outlines Recent Pipeline Progress, Reiterates Key Anticipated Milestones, and Reports Fourth Quarter and Full Year 2025 Financial Results

Commercial preparations well underway to support potential U.S. launch of zidesamtinib in TKI pre-treated advanced ROS1-positive NSCLC population, pending FDA review; PDUFA target action date of September 18, 2026

NDA submission for neladalkib in TKI pre-treated advanced ALK-positive NSCLC population planned for the first half of 2026

Submission for potential label expansion of zidesamtinib in TKI-naïve advanced ROS1-positive NSCLC population planned for the second half of 2026

Strong financial position with operating runway anticipated into 2029

CAMBRIDGE, Mass., Feb. 26, 2026 /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 progress, reiterated key anticipated milestones, and reported fourth quarter and full year 2025 financial results.

"As we advance toward the culmination of our OnTarget 2026 operating plan with a first potential FDA approval targeted for later this year, our focus remains on applying the disciplined, patient-centric approach that has enabled rapid progress in discovery and development across our pipeline towards building the capabilities needed to effectively deliver new medicines to patients," **said James Porter, Ph.D., Chief Executive Officer at Nuvalent.** "We are executing against our initial registration paths for zidesamtinib and neladalkib in TKI pre-treated patients and are well underway with launch readiness efforts to ensure we have the commercial infrastructure in place to deliver these medicines to patients, if approved. In parallel, we continue to pursue label expansion opportunities for TKI-naïve patients towards our goal of bringing new therapies to all patients with ROS1-positive or ALK-positive NSCLC, and advance our earlier-stage and discovery programs. With a steady cadence of anticipated milestones across our pipeline in 2026 and a strong balance sheet, we believe we are positioned to become an enduring leader in precision oncology across the full continuum of discovery, development, and delivery, built to serve patients for years to come."

Recent Pipeline Achievements and Anticipated 2026 Milestones

ROS1 Program

- The U.S. Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for zidesamtinib for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received at least 1 prior ROS1 tyrosine kinase inhibitor (TKI), and assigned a Prescription Drug User Fee Act (PDUFA) target action date of September 18, 2026. Pending FDA review, Nuvalent anticipates U.S. commercial launch of zidesamtinib in 2026.
- Nuvalent plans to submit data to the FDA to support a potential label expansion of zidesamtinib in TKI-naïve patients with advanced ROS1-positive NSCLC in the second half of 2026.

ALK Program

- Nuvalent completed its pre-NDA meeting with the FDA and aligned on a submission strategy for neladalkib in TKI pre-treated ALK-positive NSCLC. The company plans to move forward with an NDA submission of the data for TKI pre-treated patients with advanced ALK-positive NSCLC from the ALKOVE-1 study of neladalkib in the first half of 2026.
- Enrollment is ongoing in ALKAZAR, the company's global Phase 3 randomized, controlled trial designed to evaluate neladalkib for the treatment of TKI-naïve patients with advanced ALK-positive NSCLC. Patients are randomized 1:1 to receive neladalkib or alectinib, a front-line standard of care, reflecting input from collaborating physician-scientists and alignment with global regulatory agencies. The company expects to continue to progress the ALKAZAR trial throughout 2026.

HER2 Program

- Enrollment is ongoing in the HEROEX-1 Phase 1a/1b clinical trial evaluating the overall safety and tolerability of NVL-330 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. The company expects to continue to progress the HEROEX-1 trial throughout 2026.

Discovery Research Programs

- Nuvalent continues to advance its discovery research programs and expects to disclose a new development candidate by year-end 2026.

Business Highlights

- **Completed Successful Public Offering of Common Stock Raising $500.0 Million in Gross Proceeds:** On November 20, 2025, Nuvalent closed an underwritten public offering of 4,950,496 shares of Class A common stock at a price to the public of $101.00 per share. The gross proceeds to Nuvalent from the offering were approximately $500.0 million, before deducting underwriting discounts and commissions and other offering expenses.
- **Ron Squarer Appointed to Board of Directors:** Nuvalent appointed Ron Squarer to its board of directors in December 2025. Mr. Squarer brings more than 30 years of proven leadership in oncology drug development and commercialization to the Nuvalent Board.

Upcoming Events

- **TD Cowen 46th Annual Health Care Conference in Boston:** Management will be participating in a fireside chat on Wednesday, March 4, 2026, at 9:45 a.m. ET.
- **Leerink Global Healthcare Conference 2026 in Miami:** Management will be participating in a fireside chat on Monday, March 9, 2026, at 2:20 p.m. ET.

Live webcasts of the fireside chats will be available in the Investors section of Nuvalent's website at www.nuvalent.com, and will be archived for 30 days following each conference.

Fourth Quarter and Full Year 2025 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $1.4 billion as of December 31, 2025. Nuvalent continues to believe that its existing cash, cash equivalents and marketable securities will be sufficient to fund its operations into 2029.
- **R&D Expenses:** Research and development (R&D) expenses were $67.8 million for the fourth quarter of 2025 and $307.0 million for the year ended December 31, 2025.
- **G&A Expenses:** General and administrative (G&A) expenses were $34.4 million for the fourth quarter of 2025 and $107.3 million for the year ended December 31, 2025.
- **Net Loss:** Net loss was $118.7 million for the fourth quarter of 2025 and $425.4 million for the year ended December 31, 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; Nuvalent's estimated cash runway; the expected timing of potential new product candidate announcements, clinical trial advancements, FDA submissions, product approvals and commercial launch, including the projections in our OnTarget 2026 operating plan; the clinical development programs for zidesamtinib, neladalkib and NVL-330; the potential clinical effects of Nuvalent's product development candidates; the design, timing and enrollment of Nuvalent's clinical trials, including for the ARROS-1, ALKOVE-1 and ALKAZAR trials their intended pivotal registration-directed design; the potential of Nuvalent's pipeline programs, including zidesamtinib, neladalkib and NVL-330 and expectations regarding Nuvalent's discovery pipeline; Nuvalent's potential commercialization of its product candidates, if approved; the implications of data readouts and presentations; timing and content of potential discussions with FDA; 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," "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 and 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 zidesamtinib or neladalkib; risks that Nuvalent may not achieve the goals and milestones set forth in its OnTarget 2026 operating plan; 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, including the ARROS-1, ALKOVE-1, ALKAZAR and HEROEX-1 trials; 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2025, 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 December 31,		Year Ended Decemb	
	2025	2024	2025	
Operating expenses				
Research and development	$ 67,796	$ 69,423	$ 306,970	$
General and administrative	34,432	16,876	107,337	
Total operating expenses	102,228	86,299	414,307	
Loss from operations	(102,228)	(86,299)	(414,307)	
Other income (expense)				
Change in fair value of related party revenue share liability	(27,940)	(1,340)	(55,220)	
Interest income and other income (expense), net	11,614	13,047	44,735	
Total other income (expense), net	(16,326)	11,707	(10,485)	

Loss before income taxes	(118,554)	(74,592)	(424,792)	
Income tax provision	151	171	585	
Net loss	$ (118,705)	$ (74,763)	$ (425,377)	$
Net loss per share attributable to common stockholders, basic and diluted	$ (1.58)	$ (1.05)	$ (5.85)	$
Weighted average shares of common stock outstanding, basic and diluted	75,119,584	71,156,489	72,686,749	

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	December 31,	
	2025	**2024**
Cash, cash equivalents and marketable securities	$ 1,371,952	$ 1,118,302
Working capital	$ 1,301,255	$ 1,078,428
Total assets	$ 1,412,705	$ 1,141,752
Total liabilities	$ 164,366	$ 71,960
Total stockholders' equity	$ 1,248,339	$ 1,069,792

SOURCE Nuvalent, Inc.

Investor Contact:
Chelcie Lister
Nuvalent, Inc.
clister@nuvalent.com

Media Contact:
Josie Butler
1AB
josie@1abmedia.com