# Nuvalent Highlights Recent Pipeline Progress, Reiterates Key Anticipated Milestones, and Reports Third Quarter 2025 Financial Results

## Completed rolling NDA submission for zidesamtinib in TKI pre-treated advanced ROS1-positive NSCLC

## On track to report topline pivotal data for neladalkib in TKI pre-treated advanced ALK-positive NSCLC by year-end 2025

## Strong financial position with operating runway anticipated into 2028

CAMBRIDGE, Mass., Oct. 30, 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 progress, reiterated key anticipated milestones, and reported third quarter 2025 financial results.

"The third quarter of 2025 marked the achievement of a significant milestone with the completion of our NDA submission for zidesamtinib in TKI pre-treated advanced ROS1-positive NSCLC. We look forward to working closely with the FDA throughout the review process, as well as continuing to engage with the agency on potential opportunities for line-agnostic expansion," **said Darlene Noci, A.L.M., Chief Development Officer of Nuvalent**. "We remain on track to share topline pivotal data this quarter from our ALKOVE-1 trial of neladalkib in TKI pre-treated advanced ALK-positive NSCLC, and continue to progress ALKAZAR, our global Phase 3 randomized, controlled trial of neladalkib for TKI-naïve patients with advanced ALK-positive NSCLC."

"Our commercial preparedness activities are well underway as we carry forward the momentum from these exciting development milestones and continue our efforts to transition toward becoming a fully integrated commercial-stage biopharmaceutical company," **said Alex Balcom, Chief Financial Officer of Nuvalent.** "Combined with a strong financial position with cash runway anticipated into 2028, we believe we are well positioned to achieve our goal of delivering a new and potential best-in-class option for *all* patients with ROS1 or ALK-positive NSCLC."

"We are also pleased to have recently shared the first report of preliminary clinical data demonstrating the potential for neladalkib to address medical needs for patients with ALK-positive solid tumors beyond NSCLC, and new preclinical data further demonstrating the potential for NVL-330 to offer a differentiated profile for HER2-altered NSCLC," **said James Porter, Ph.D., Chief Executive Officer of Nuvalent**. "With a portfolio anchored by complementary indications in biomarker-driven NSCLC and supported by a robust development and discovery pipeline, we continue to build towards our long-term vision of Nuvalent as a sustainable company capable of designing, developing and delivering *precisely* targeted therapies for patients with cancer."

**Recent Pipeline Achievements and Anticipated Milestones**

*ROS1 Program*

- The company has completed its rolling NDA submission for zidesamtinib in tyrosine kinase inhibitor (TKI) pre-treated patients with advanced ROS1-positive non-small cell lung cancer (NSCLC).
- Data supporting the NDA submission were presented in September as part of the Presidential Symposium at the IASLC 2025 World Conference on Lung Cancer.
- The company continues to engage with the FDA on potential opportunities for line-agnostic expansion.

*ALK Program*

- Evaluation of neladalkib is ongoing in the ALKOVE-1 Phase 1/2 trial for patients with advanced ALK-positive NSCLC and other solid tumors:
  - The company presented preliminary data from the ongoing ALKOVE-1 Phase 1/2 clinical trial of neladalkib in patients with advanced ALK-positive solid tumors outside of NSCLC during a poster presentation at the European Society for Medical Oncology (ESMO) Congress 2025. Neladalkib demonstrated encouraging preliminary activity across a diverse set of advanced ALK-positive solid tumors, and was generally well-tolerated with a preliminary overall safety profile consistent with its ALK-selective, TRK sparing design, and with previously reported data.
  - The company is on track to report topline pivotal data for TKI pre-treated patients with advanced ALK-positive NSCLC by year-end 2025.
- Enrollment is ongoing in ALKAZAR, the company's global Phase 3 randomized, controlled trial designed to evaluate neladalkib for the treatment of patients with TKI-naïve 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.

*HER2 Program*

- Nuvalent presented new preclinical data for its novel HER2-selective inhibitor, NVL-330, at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, further supporting its potentially differentiated brain-penetrant profile. Compared to several currently available and investigational HER2 TKIs in the same preclinical assays, NVL-330 demonstrated a favorable

efflux ratio and brain partitioning, metrics that are potentially positive predictors of brain exposure in humans. In preclinical models of intracranial activity, NVL-330 induced deep intracranial regression in mice. In the same models, the approved therapies T-DXd and zongertinib did not induce intracranial regression at their clinically relevant doses. Additionally, NVL-330 induced intracranial tumor regression in mice that had progressed in the CNS on zongertinib. These data add to the preclinical characterization of NVL-330 as a brain penetrant TKI that is broadly active against HER2 oncogenic alterations and selective over wild-type EGFR, and the company believes the data support its investigation in patients with advanced HER2-altered NSCLC.
- 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 2025.

**Upcoming Events**

- **Jefferies 2025 Global Healthcare Conference in London:** Management will be participating in a fireside chat on Wednesday, November 19, 2025, at 5:00 p.m. GMT. 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.

**Third Quarter 2025 Financial Results**

- **Cash Position:** Cash, cash equivalents and marketable securities were $943.1 million as of September 30, 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 $83.8 million for the third quarter of 2025.
- **G&A Expenses:** General and administrative (G&A) expenses were $28.9 million for the third quarter of 2025.
- **Net Loss:** Net loss was $122.4 million for the third 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, including potential line-agnostic 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 its clinical 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," "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 Quarterly Report on Form 10-Q for the quarter ended June 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 September 30, | | Nine Months Ended S | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | |
| Operating expenses | | | | |
| Research and development | $ 83,843 | $ 60,551 | $ 239,174 | $ |
| General and administrative | 28,853 | 15,780 | 72,905 | |
| Total operating expenses | 112,696 | 76,331 | 312,079 | |
| Loss from operations | (112,696) | (76,331) | (312,079) | |
| Other income (expense) | | | | |
| Change in fair value of related party revenue share liability | (19,810) | (16,600) | (27,280) | |
| Interest income and other income (expense), net | 10,201 | 8,626 | 33,121 | |
| Total other income (expense), net | (9,609) | (7,974) | 5,841 | |
| Loss before income taxes | (122,305) | (84,305) | (306,238) | |
| Income tax provision | 132 | 40 | 434 | |
| Net loss | $ (122,437) | $ (84,345) | $ (306,672) | $ |
| Net loss per share attributable to common stockholders, basic and diluted | $ (1.70) | $ (1.28) | $ (4.27) | $ |
| Weighted average shares of common stock outstanding, basic and diluted | 72,143,466 | 65,678,693 | 71,866,892 | |

**SELECTED BALANCE SHEET DATA**
**(In thousands)**
**(Unaudited)**

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 943,103 | $ 1,118,302 |
| Working capital | $ 867,794 | $ 1,078,428 |
| Total assets | $ 979,910 | $ 1,141,752 |
| Total liabilities | $ 134,511 | $ 71,960 |
| Total stockholders' equity | $ 845,399 | $ 1,069,792 |

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