Nuvalent Highlights Pipeline and Business Achievements, Reiterates Key Anticipated Milestones, and Reports Second Quarter 2025 Financial Results

Initiated rolling NDA submission for zidesamtinib for TKI pre-treated patients with advanced ROS1-positive NSCLC, with target completion in the third quarter of 2025

Initiated ALKAZAR Phase 3 randomized, controlled trial of neladalkib for front-line ALK-positive NSCLC

Topline pivotal data for neladalkib for TKI pre-treated patients with advanced ALK-positive NSCLC expected by year-end 2025

Preliminary data for neladalkib in patients with ALK-positive solid tumors beyond NSCLC to be presented at the ESMO Congress 2025

Jason Waters, MBA, promoted to Senior Vice President, Commercial

CAMBRIDGE, Mass., Aug. 7, 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 achievements, reiterated key anticipated milestones, and reported second quarter 2025 financial results.

"With the initiation of our rolling NDA submission for zidesamtinib in TKI pre-treated advanced ROS1-positive NSCLC and the dosing of the first patient in our ALKAZAR Phase 3 trial of neladalkib in TKI-naïve advanced ALK-positive NSCLC, 2025 has been marked by transformative milestones towards our mission to discover, develop, and deliver *precisely* targeted therapies for patients with cancer," **said Alexandra Balcom, Chief Financial Officer of Nuvalent.** "We remain focused on continuing to deliver value that is grounded in prioritizing patient impact with topline pivotal data from our ALKOVE-1 trial of neladalkib in TKI pre-treated advanced ALK-positive NSCLC expected by year-end and the first report of preliminary data for other ALK-positive solid tumors at ESMO, continued momentum in our HEROEX-1 trial of NVL-330 for HER2-altered NSCLC, and a robust discovery pipeline."

"In parallel to our continued execution against development and regulatory milestones, we are actively building the strong commercial infrastructure needed to achieve our vision of becoming a fully integrated, commercial-stage biopharmaceutical company," **said James Porter, Ph.D., Chief Executive Officer of Nuvalent.** "Today we are proud to announce the promotion of Jason Waters to Senior Vice President, Commercial, in recognition of his leadership in establishing our commercial strategy and shaping a launch-ready organization that extends from our founding values of Patient Impact, Empowerment, and Collaboration. Supported by a growing team and strong cash runway into 2028, we believe we are well-positioned to achieve our goals."

Recent Pipeline Achievements and Anticipated Milestones

ROS1 Program

- The company has initiated its rolling NDA submission for zidesamtinib, a novel ROS1-selective inhibitor, in tyrosine kinase inhibitor (TKI) pre-treated patients with advanced ROS1-positive non-small cell lung cancer (NSCLC). The FDA agreed to accept the NDA for participation in the Real-Time Oncology Review (RTOR) pilot program, which facilitates earlier submission of topline efficacy and safety results prior to the submission of the complete application, to support an earlier start to the FDA's evaluation of the application. Completion of the NDA submission is targeted for the third quarter of 2025.
- The NDA submission is based on positive pivotal data for TKI pre-treated patients with advanced ROS1-positive NSCLC enrolled in the global ARROS-1 Phase 1/2 clinical trial. These data were recently reported along with preliminary data from the ongoing Phase 2 TKI-naïve cohort of ARROS-1, in which a total of 104 patients had been enrolled as of June 16, 2025. The company continues to engage with the FDA on potential opportunities for line-agnostic expansion.

ALK Program

- Nuvalent recently announced the dosing of the first patient 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 will be randomized 1:1 to receive neladalkib monotherapy or alectinib monotherapy, a front-line standard of care, reflecting input from collaborating physician-scientists and alignment with global regulatory agencies.
- 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 expects to report pivotal data for TKI pre-treated patients with advanced ALK-positive NSCLC by year-end 2025.
    - The company will present preliminary data from the Phase 2 exploratory cohort for patients with ALK-positive solid tumors beyond NSCLC during a poster presentation at the European Society for Medical Oncology (ESMO) Congress 2025, taking place October 17-21, 2025, in Berlin, Germany. Details of the presentation are as follows:

Title: Neladalkib (NVL-655) efficacy and safety in patients with ALK-positive solid tumors in the ALKOVE-1 study
Presentation Number: 972P
Session Category: Poster Session
Session Title: Developmental Therapeutics
Presentation Date and Time: Sunday, October 19, 2025, 12:00 – 12:45 CEST
Location: Hall 25
Presenter: Benjamin J. Solomon, MBBS, Ph.D. (Peter MacCallum Cancer Centre, Melbourne, Australia)

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 2025.

Business Updates

- **Jason Waters, MBA, Promoted to Senior Vice President, Commercial:** Jason joined Nuvalent in 2024, bringing more than 20 years of experience in biopharma, and 15 years in commercial oncology focused on product launches and commercialization. Most recently, Jason served as the Head of Commercial at Mersana Therapeutics, where he led launch preparedness efforts and companion diagnostic strategy for the market entry of a novel antibody-drug conjugate. Prior to this, he held various commercial leadership roles at GSK, including Field Vice President and US Brand Lead for ZEJULA®, where he led the integration and multiple launches of the brand following the acquisition of TESARO in acquisition in 2019. At TESARO, Jason served as the Global Brand Lead for ZEJULA®, coordinating its EU launch. Earlier in his career, Jason was Senior Director, Sales Strategy at Takeda Oncology, where he contributed to the launches of subcutaneous VELCADE® and NINLARO®. He also held various sales, operational, and leadership roles at Sanofi, Aventis, and Abbott Laboratories.
- **Christy Oliger Appointed to Board of Directors:** Nuvalent announced the appointment of Christy Oliger to its board of directors. Ms. Oliger brings more than 30 years of commercial and business experience in the pharmaceutical and biotechnology industry to the Nuvalent board. Most recently, Ms. Oliger served as Senior Vice President of the Oncology Business Unit at Genentech, where she was responsible for all commercial activities in the U.S. During her 20-year tenure at Genentech, Ms. Oliger held a number of senior leadership roles in both commercial and research and development across a variety of therapeutic areas, including oncology, neurology, rare disease, respiratory, dermatology and immunology. Prior to Genentech, she held management positions at Schering-Plough.

Second Quarter 2025 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $1.0 billion as of June 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 $80.9 million for the second quarter of 2025.
- **G&A Expenses:** General and administrative (G&A) expenses were $23.7 million for the second quarter of 2025.
- **Net Loss:** Net loss was $99.7 million for the second 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, NDA submissions 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 80,913	$ 49,166	$ 155,331	$ 87,800
General and administrative	23,658	15,984	44,052	29,938
Total operating expenses	104,571	65,150	199,383	117,738
Loss from operations	(104,571)	(65,150)	(199,383)	(117,738)
Other income (expense)				
Change in fair value of related party revenue share liability	(6,040)	—	(7,470)	—
Interest income and other income (expense), net	11,103	8,154	22,920	16,643
Total other income (expense), net	5,063	8,154	15,450	16,643
Loss before income taxes	(99,508)	(56,996)	(183,933)	(101,095)
Income tax provision	145	170	302	553
Net loss	$ (99,653)	$ (57,166)	$ (184,235)	$ (101,648)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.39)	$ (0.88)	$ (2.57)	$ (1.58)
Weighted average shares of common stock outstanding, basic and diluted	71,843,774	64,605,308	71,726,313	64,377,948

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	June 30, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$1,005,598	$ 1,118,302
Working capital	$ 944,463	$ 1,078,428
Total assets	$ 1,040,543	$ 1,141,752
Total liabilities	$ 100,801	$ 71,960
Total stockholders' equity	$ 939,742	$ 1,069,792

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https://investors.nuvalent.com/2025-08-07-Nuvalent-Highlights-Pipeline-and-Business-Achievements,-Reiterates-Key-Anticipated-Milestones,-and-Reports-Second-Quarter-2025-Financial-Results