Nuvalent Highlights Recent Pipeline Progress, Reiterates Key Anticipated Milestones, and Reports First Quarter 2026 Financial Results

NDA submitted for neladalkib in TKI pre-treated advanced ALK-positive NSCLC

NDA for zidesamtinib in TKI pre-treated advanced ROS1-positive NSCLC under FDA review with PDUFA target action date of September 18, 2026

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

Strengthened leadership team with key

internal promotions

CAMBRIDGE, Mass., May 7, 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 first quarter 2026 financial results.

"The forward momentum continues at Nuvalent, with both of our parallel-lead programs advancing toward key US regulatory milestones and the opportunity to bring our first new medicine to patients this year," **said James Porter, Ph.D., Chief Executive Officer of Nuvalent**. "We recently submitted our NDA for neladalkib in TKI pre-treated ALK-positive NSCLC and are continuing to build our commercial infrastructure in preparation for a potential US launch of zidesamtinib in TKI pre-treated ROS1-positive NSCLC, if approved."

Dr. Porter continued, "Beyond these initial opportunities, we remain focused on progressing our label expansion strategies for ROS1- and ALK-positive NSCLC, as well as our earlier-stage pipeline, with the goal of driving meaningful, long-term impact in NSCLC and beyond. Through these efforts, we believe we are well positioned to realize our vision of becoming a sustainable biotechnology company capable of designing, developing and delivering *precisely* targeted therapies for patients with cancer."

Recent Pipeline Achievements and Anticipated Milestones

ROS1 Program

- The New Drug Application (NDA) for zidesamtinib, an investigational ROS1-selective inhibitor, is under review by the U.S. Food and Drug Administration (FDA) 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) with a Prescription Drug User Fee Act (PDUFA) target action date of September 18, 2026. Nuvalent continues to advance commercial preparations ahead of an anticipated U.S. commercial launch of zidesamtinib in 2026, pending FDA review.
- 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.
- Nuvalent presented new clinical and preclinical data for zidesamtinib during poster sessions at the American Association for Cancer Research (AACR) Annual Meeting 2026, including:
    - Clinical data from a subgroup of patients with advanced ROS1-positive NSCLC in the ARROS-1 clinical trial who had been previously treated with the dual TRK/ROS1 TKIs repotrectinib and/or taletrectinib. Treatment with zidesamtinib resulted in clinically meaningful activity in this heavily pre-treated subgroup, including activity in tumors with the ROS1 G2032R resistance mutation and intracranial complete responses for patients with CNS disease. These results indicate that ROS1-positive NSCLC tumors may remain ROS1-dependent beyond treatment with repotrectinib or taletrectinib.
    - Preclinical analyses supporting the potential for differentiation of the brain penetrance and intracranial ROS1 G2032R antitumor activity of zidesamtinib compared to the dual TRK/ROS1 inhibitors repotrectinib and taletrectinib. Among these three ROS1 TKIs, zidesamtinib demonstrated the highest in vitro measures of brain penetrance, most sustained intracranial efficacy in a mouse ROS1 G2032R brain tumor model, and efficacy after progressive disease on earlier-line taletrectinib treatment in a mouse ROS1 G2032R brain tumor model. Data demonstrating that switching from repotrectinib to zidesamtinib resulted in more sustained tumor suppression in the same preclinical model have been previously reported.[1]
- The company also plans to present preliminary data from the ongoing ARROS-1 Phase 1/2 clinical trial of zidesamtinib in patients with advanced ROS1-positive solid tumors outside of non-small cell lung cancer (NSCLC) during a poster session at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting from May 29 – June 2, 2026, in Chicago.

[1]Tangpeerachaikul et al. Annals of Oncology 2024; 35(2):S217.

ALK Program

- Nuvalent submitted an NDA for neladalkib, an investigational ALK-selective inhibitor, in TKI pre-treated advanced ALK-positive NSCLC to the FDA. The application is based on data in TKI pre-treated patients with advanced ALK-positive NSCLC treated with neladalkib in the global, registration-directed ALKOVE-1 Phase 1/2 clinical trial. In this population, neladalkib demonstrated encouraging overall activity, including intracranial responses, the ability to address key drivers of disease progression, and a generally well-tolerated safety profile consistent with its ALK-selective, TRK-sparing design. The company plans to present pivotal data for neladalkib in TKI pre-treated patients with advanced ALK-positive NSCLC from the ALKOVE-1 study, in addition to preliminary data for TKI-naïve patients, during an oral presentation at the 2026 ASCO Annual Meeting.
- 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. 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 make progress across its discovery research programs and expects to disclose a new development candidate by year-end 2026.

Recent Leadership Promotions

- **Benjamin Lane, Ph.D., Promoted to Chief Technology Operations Officer:** Ben joined Nuvalent in 2020, bringing more than 20 years of experience focused on the development of pre-clinical through commercial programs at both large and small biotech companies. Most recently, Ben served as Senior Director, Process Chemistry at Agios Pharmaceuticals where he led the process chemistry group and was responsible for pre-clinical to commercial drug substance development and manufacturing, including for the mitapivat program (now marketed as AQVESME™ and PYRUKYND®). Prior to Agios, Ben served in various drug development leadership roles at Infinity Pharmaceuticals and Biogen.
- **Kirsten Duncan, Pharm.D., Promoted to Vice President, Medical Affairs:** Kirsten joined Nuvalent in 2024, bringing more than 25 years of experience across biopharma, with a focus on oncology strategy and stakeholder engagement. Prior to joining Nuvalent, Kirsten spent more than five years at Pfizer, most recently as Director, Thoracic Oncology, where she led global medical affairs strategy across the lung cancer franchise. Prior to Pfizer, Kirsten served in various medical affairs leadership roles at Arivale, Percolation Communications, Duncan Communications, and OnCare.

Upcoming Events

- **TD Cowen 7th Annual Oncology Innovation Summit:** Management will be participating in a virtual fireside chat on Wednesday, May 27, 2026, at 9:30 a.m. ET.
- **2026 Jefferies Healthcare Conference in New York:** Management will be participating in a fireside chat on Thursday, June 4, 2026, at 11:40 a.m. ET.

A live webcast of each fireside chat 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 2026 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $1.3 billion as of March 31, 2026. 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 $83.6 million for the first quarter of 2026.
- **G&A Expenses:** General and administrative (G&A) expenses were $35.8 million for the first quarter of 2026.
- **Net Loss:** Net loss was $109.3 million for the first quarter of 2026.

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 initiations, data presentations, FDA submissions, product approvals and commercial launch; 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 ALKOVE-1 its 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; 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 Annual Report on Form 10-K for the fiscal year ended December 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 March 31,	
	2026	2025
Operating expenses		
Research and development	$ 83,608	$ 74,418
General and administrative	35,799	20,394
Total operating expenses	119,407	94,812
Loss from operations	(119,407)	(94,812)
Other income (expense)		
Change in fair value of related party revenue share liability	(2,570)	(1,430)
Interest income and other income (expense), net	12,866	11,817
Total other income (expense), net	10,296	10,387
Loss before income taxes	(109,111)	(84,425)
Income tax provision	168	157
Net loss	$ (109,279)	$ (84,582)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.39)	$ (1.18)
Weighted average shares of common stock outstanding, basic and diluted	78,670,371	71,607,546

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	March 31, 2026	December 31, 2025
Cash, cash equivalents and marketable securities	$ 1,287,476	$ 1,371,952
Working capital	$ 1,226,886	$ 1,301,255
Total assets	$ 1,331,148	$ 1,412,705
Total liabilities	$ 156,781	$ 164,366
Total stockholders' equity	$ 1,174,367	$ 1,248,339

SOURCE Nuvalent, Inc.

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

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

---

https://investors.nuvalent.com/2026-05-07-Nuvalent-Highlights-Recent-Pipeline-Progress,-Reiterates-Key-Anticipated-Milestones,-and-Reports-First-Quarter-2026-Financial-Results