

# Nuvalent Highlights Pipeline Progress, Reiterates Key Anticipated Milestones, and Reports First Quarter 2024 Financial Results

Updates from the ongoing Phase 1/2 ARROS-1 and ALKOVE-1 clinical trials expected at a medical meeting in the second half of 2024

Strong financial position with

# operating runway anticipated into 2027

CAMBRIDGE, Mass., May 9, 2024 /PRNewswire/ -- [Nuvalent, Inc.](#) (Nasdaq: NUVL), a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for clinically proven kinase targets in cancer, today highlighted pipeline progress, reiterated key anticipated milestones, and reported first quarter 2024 financial results.

"Guided by our OnTarget 2026 operating plan, 2024 is a year of focused execution on our path towards a potential first approval in 2026 from our pipeline of novel kinase inhibitors," said **James Porter, Ph.D., Chief Executive Officer at Nuvalent.** "We expect to share clinical updates from our parallel lead programs for ROS1-positive and ALK-positive NSCLC at a medical meeting in the second half of the year and are on-track to dose the first patient in our HER2 program this year. This is an important time for Nuvalent, and we are excited to carry this momentum forward in hopes of bringing our therapies to patients as efficiently as possible."

## Recent Pipeline Progress and Anticipated Milestones

### *ROS1 Program*

- Nuvalent presented [new preclinical data](#) at the American Association for Cancer Research (AACR) Annual Meeting demonstrating that zidesamtinib, its novel ROS1-selective inhibitor, was effective at suppressing on-target ROS1 resistance mutations in preclinical mutagenesis screens.
- The company expects to share updated data from the ARROS-1 Phase 1/2 trial at a medical meeting in the second half of 2024. Enrollment is ongoing in the global Phase 2 portion of the study.

### *ALK Program*

- Enrollment is ongoing in the global Phase 2 portion of the ALKOVE-1 trial of NVL-655 for patients with advanced ALK-positive NSCLC and other solid tumors. The Phase 2 cohorts are designed with registrational intent for TKI pre-treated patients with ALK-positive NSCLC and to enable preliminary evaluation in patients with ALK-positive NSCLC who are TKI naïve.
- The company expects to share updated data from the ALKOVE-1 trial at a medical meeting in the second half of 2024. Additionally, Nuvalent plans to outline its broader front-line development strategy for its ALK program in 2024.

### *HER2 Program*

- Nuvalent presented [new preclinical data](#) at AACR supporting the broad activity against HER2 oncogenic alterations, selectivity over wild-type EGFR, and differentiated brain-penetrant profile of its novel HER2-selective inhibitor, NVL-330.
- The company expects to initiate the Phase 1 trial for its HER2 program in 2024.

## Upcoming Events

- **TD Cowen 5th Annual Oncology Innovation Summit:** Management will be participating in a virtual fireside chat on May 29, 2024 at 9:30 am ET. A live webcast will be available in the Investors section of Nuvalent's website at [www.nuvalent.com](http://www.nuvalent.com), and will be archived for 30 days following the conference.

## First Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$691.8 million as of March 31, 2024. Nuvalent believes these existing cash, cash equivalents and marketable securities to be sufficient to fund its current operating plan into 2027.
- **R&D Expenses:** Research and development (R&D) expenses were \$38.6 million for the first quarter of 2024.
- **G&A Expenses:** General and administrative (G&A) expenses were \$14.0 million for the first quarter of 2024.
- **Net Loss:** Net loss was \$44.5 million for the first quarter of 2024.

## About OnTarget 2026

OnTarget 2026 delineates Nuvalent's 3-year operating plan towards bringing new, potential best-in-class medicines to patients with cancer. As part of this plan announced in January 2024, Nuvalent outlined the following anticipated milestones throughout 2024, leading to the company's first potential pivotal data in 2025 and first potential approved product in 2026:

- **2024: Execute on Global Registrational Strategies**

- Progress the Phase 2 portion of its ARROS-1 trial of zidesamtinib in patients with advanced ROS1-positive NSCLC with registrational intent;
- Initiate the Phase 2 portion of its ALKOVE-1 trial of NVL-655 in patients with advanced ALK-positive NSCLC with registrational intent;
- Launch the front-line development strategy for its ALK program;
- Present interim data from its ongoing ARROS-1 and ALKOVE-1 clinical trials at medical meetings; and,
- Initiate the Phase 1 trial for its HER2 program.

- **2025: First Pivotal Data**

- **2026: First Approved Product**

## **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 the projections in our OnTarget 2026 operating plan; the preclinical and clinical development programs for zidesamtinib, NVL-655 and NVL-330; the potential benefits and effects of Nuvalent's product development candidates; the design and enrollment of the ARROS-1 and ALKOVE-1 trials, including their intended pivotal registration-directed design; the potential of Nuvalent's pipeline programs, including zidesamtinib, NVL-655 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 the ARROS-1 or ALKOVE-1 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; 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 and ALKOVE-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, 2023, 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)** **(Unaudite)**

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Operating expenses		
	\$	\$
Research and development	38,634	22,125
General and administrative	13,954	8,085
Total operating expenses	52,588	30,210
Loss from operations	(52,588)	(30,210)
Other income (expense)		
Interest income and other income (expense), net	8,489	5,018
Total other income (expense), net	8,489	5,018
Loss before income taxes	(44,099)	(25,192)
Income tax provision	383	—
	\$	\$
Net loss	(44,482)	(25,192)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.69)	\$ (0.44)
Weighted average shares of common stock outstanding, basic and diluted	64,150,588	56,703,873

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

	<b>March 31, 2024</b>	<b>December 31, 2023</b>
Cash, cash equivalents and marketable securities	\$ 691,837	\$ 719,905
Working capital	\$ 666,067	\$ 694,665
Total assets	\$ 708,466	\$ 732,384
Total liabilities	\$ 33,427	\$ 31,823
Total stockholders' equity	\$ 675,039	\$ 700,561

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