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

Company plans to host a conference call in conjunction with oral presentations at ESMO on September 14, 2024, at 8:30 a.m. ET/2:30 p.m. CEST

$658.0 million in cash, cash equivalents and marketable securities expected to support operating runway into 2027

CAMBRIDGE, Mass., Aug. 8, 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 second quarter 2024 financial results.

"The focused efforts of our team have led to strong execution across our pipeline in 2024 to date, including the initiation of the Phase 2 portion of our ALKOVE-1 trial for NVL-655 with registrational intent, receipt of FDA breakthrough therapy designation for both zidesamtinib and NVL-655, and initiation of the HEROEX-1 trial for our third development program, NVL-330," **said James Porter, Ph.D., Chief Executive Officer at Nuvalent.** "We've entered the second half of 2024 with significant enrollment progress in the global Phase 2 portions of our ARROS-1 and ALKOVE-1 clinical trials, and plan to provide a status update for both trials concurrent with the presentations of updated Phase 1 dose-escalation datasets at ESMO. We also expect to outline our broader front-line development strategy for our ALK program later this year. Guided by our OnTarget 2026 operating plan and an unwavering commitment to our goal of bringing *precisely* targeted therapies to patients with cancer, we remain confident in our ability to deliver at least one pivotal dataset in 2025 towards our first potential approved product in 2026."

Recent Pipeline Progress and Anticipated Milestones

ALK Program

- Enrollment is ongoing in the Phase 2 portion of the ALKOVE-1 Phase 1/2 trial of NVL-655 for patients with advanced ALK-positive non-small cell lung cancer (NSCLC) and other solid tumors, which is designed with registrational intent. At the ESMO Congress 2024, the company plans to provide an update on the status of the global Phase 2 portion of the trial in conjunction with an oral presentation of updated Phase 1 dose-escalation data on Saturday, September 14, 2024, 9:40 – 9:50 a.m. CEST.
- The U.S. Food and Drug Administration (FDA) has granted breakthrough therapy designation (BTD) to NVL-655 for the treatment of patients with locally advanced or metastatic ALK-positive NSCLC who have been previously treated with two or more ALK tyrosine kinase inhibitors (TKIs). NVL-655 was previously granted FDA Orphan Drug Designation for the treatment of ALK-positive NSCLC.
- Nuvalent plans to outline its broader front-line development strategy for its ALK program in 2024.

ROS1 Program

- Enrollment is ongoing in the Phase 2 portion of the ARROS-1 Phase 1/2 trial of zidesamtinib for patients with advanced ROS1-positive NSCLC and other solid tumors, which is designed with registrational intent. At the ESMO Congress 2024, the company plans to provide an update on the status of the global Phase 2 portion of the trial in conjunction with an oral presentation of updated Phase 1 dose-escalation data on Saturday, September 14, 2024, 10:30 – 10:35 a.m. CEST.
- Additionally, at the ESMO Congress 2024, the company will present new preclinical data further characterizing the intracranial activity of zidesamtinib during a poster session on Sunday, September 15, 2024.

HER2 Program

- Enrollment is ongoing in the HEROEX-1 Phase 1a/1b clinical trial evaluating NVL-330 for pre-treated patients with HER2-altered NSCLC (NCT06521554). The trial will evaluate the overall safety and tolerability of NVL-330. Additional objectives include determination of the recommended Phase 2 dose (RP2D), characterization of the pharmacokinetic profile, and preliminary evaluation of anti-tumor activity.

ESMO Conference Call Information

Management will host a live webcast and conference call in conjunction with its data presentations at the ESMO Congress 2024 in Barcelona, Spain on Saturday, September 14, 2024, at 8:30 a.m. ET/2:30 p.m. CEST.

To access the call, register online here for the live webcast or dial +1 (800) 836-8184 (domestic) or +1 (646) 357-8785 (international) at least 10 minutes prior to the start time and ask to be joined to the Nuvalent call. Accompanying slides and a live video webcast will be available in the Investors section of the Nuvalent website at https://investors.nuvalent.com/events. A replay and accompanying slides will be archived on the Nuvalent website for 30 days.

Second Quarter 2024 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $658.0 million as of June 30, 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 $49.2 million for the second quarter of 2024.

- **G&A Expenses:** General and administrative (G&A) expenses were $16.0 million for the second quarter of 2024.
- **Net Loss:** Net loss was $57.2 million for the second 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 and development strategy announcements and FDA product approvals, including the projections in our OnTarget 2026 operating plan; the clinical development programs for zidesamtinib, NVL-655 and NVL-330; the potential clinical effects of Nuvalent's product development candidates; the design and enrollment of Nuvalent's clinical trials, including for ARROS-1 and ALKOVE-1 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 its clinical trials or that enrollment will take longer than expected; unexpected concerns that may arise from additional data, analysis, or results obtained during 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 ARROS-1 and ALKOVE-1 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 zidesamtinib or NVL-655 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, ALKOVE-1 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 March 31, 2024, 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	
	2024	2023	2024	
Operating expenses				
Research and development	$ 49,166	$ 25,922	$ 87,800	$
General and administrative	15,984	8,140	29,938	
Total operating expenses	65,150	34,062	117,738	
Loss from operations	(65,150)	(34,062)	(117,738)	
Other income (expense)				
Interest income and other income (expense), net	8,154	4,972	16,643	
Total other income (expense), net	8,154	4,972	16,643	
Loss before income taxes	(56,996)	(29,090)	(101,095)	
Income tax provision	170	—	553	
Net loss	$ (57,166)	$ (29,090)	$ (101,648)	$
Net loss per share attributable to common stockholders, basic and diluted	$ (0.88)	$ (0.51)	$ (1.58)	$
Weighted average shares of common stock outstanding, basic and diluted	64,605,308	56,866,991	64,377,948	

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 657,994	$ 719,905
Working capital	$ 628,066	$ 694,665
Total assets	$ 675,230	$ 732,384
Total liabilities	$ 38,192	$ 31,823
Total stockholders' equity	$ 637,038	$ 700,561

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