Nuvalent Highlights Pipeline and Business Progress and Reports First Quarter 2022 Financial Results

Two clinical-stage programs ongoing for potential best-in-class ROS1 and ALK-selective inhibitors

On-track for selection of two additional development candidates in 2022

Ended the first quarter of 2022 with $272.7 million in cash, cash equivalents, and marketable

securities to support planned operations into 2024

CAMBRIDGE, Mass., May 12, 2022 /PRNewswire/ -- Nuvalent, Inc. (Nasdaq: NUVL), a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for clinically proven kinase targets in cancer, today reported pipeline and business progress and first quarter 2022 financial results.

"At Nuvalent, we're building a fully integrated biotech company with the goal to design, develop, and deliver a portfolio of best-in-class therapies for patients with cancer. We view 2022 as a critical year of execution and we have already made meaningful progress across our pipeline. Enrollment is progressing well in the ongoing Phase 1 portion of our ARROS-1 Phase 1/2 trial of NVL-520 for advanced ROS1-positive NSCLC and other solid tumors, and following the recently announced clearance of the IND for NVL-655, we are on track for planned initiation of our ALKOVE-1 Phase 1/2 study for advanced ALK-positive NSCLC and other solid tumors in the second quarter of 2022," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "By year-end, our team has the potential to have delivered four novel development candidates since company formation, with two clinical trials underway. With an exceptional team and strong foundation in place, I am confident in our ability to bring *precisely* targeted therapies that can enable deeper and more durable responses to patients with cancer."

Upcoming Pipeline Milestones

- **ALKOVE-1 Trial of NVL-655 for Patients with ALK-positive Non-Small Cell Lung Cancer (NSCLC) Expected to Begin in Second Quarter of 2022:** Nuvalent has received confirmation from the U.S. Food and Drug Administration (FDA) that its Investigational New Drug (IND) application for NVL-655 has been cleared. The company is on track to initiate the ALKOVE-1 Phase 1/2 study of NVL-655 for patients with advanced ALK-positive NSCLC and other solid tumors, anticipated in the second quarter of 2022. NVL-655 is a novel ALK-selective inhibitor designed to address the clinical challenges of emergent treatment resistance, CNS adverse events, and brain metastases that may limit the use of currently available ALK kinase inhibitors.
- **Selection of Two Additional Development Candidates from Discovery Pipeline Targeted in 2022:** Nuvalent continues to advance its pipeline expansion efforts with multiple discovery-stage research programs. The company expects to select development candidates for its programs directed toward ALK IXDN compound resistance mutations and HER2 Exon 20 insertions in 2022.

Recent Business Highlights

- **Appointed Anna Protopapas as Chair of Board of Directors:** Nuvalent appointed Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics, as Chair of its Board of Directors in March 2022. Ms. Protopapas joined Mersana in March 2015 and has a substantial track record of executive leadership and business growth in the field of oncology. Her broad industry experience ranges from global development to commercial expertise with a focus on building companies from start-ups to leaders in their categories.
- **Presented Expanded Preclinical Profiles of NVL-520 and NVL-655 at AACR 2022** : Nuvalent presented new preclinical data supporting the potential for broad clinical utility of NVL-520 and NVL-655 across an expanded set of ROS1 and ALK fusion partners, resistance mutations, and tumor types beyond NSCLC.

Upcoming Investor Conference Presentations

- **2022 H.C. Wainwright Hybrid Global Investment Conference:** Dr. Porter will conduct an in-person corporate presentation during the 2022 H.C. Wainwright Hybrid Global Investment Conference on Wednesday May 25, 2022 at 4:00 p.m. ET. The conference is being held May 23-26, 2022, with in-person presentations and meetings in Miami, FL. A live webcast will be available in the Investors section of the company's website at www.nuvalent.com and will be archived for 30 days following the presentation.

First Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $272.7 million as of March 31, 2022. Nuvalent continues to expect the existing cash, cash equivalents, and marketable securities to be sufficient to fund its planned operations into 2024.
- **R&D Expenses:** Research and development (R&D) expenses were $12.7 million for the first quarter of 2022.
- **G&A Expenses:** General and administrative (G&A) expenses were $5.0 million for the first quarter of 2022.
- **Net Loss:** Net loss for the first quarter of 2022 was $17.5 million, or $0.36 per share.

SELECTED CONSOLIDATED STATEMENTS OF OPERATIONS DATA
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 12,693	$ 5,484
General and administrative	4,995	678
Total operating expenses	17,688	6,162
Loss from operations	(17,688)	(6,162)
Other income (expense):		
Change in fair value of preferred stock tranche rights	—	(635)
Other income (expense), net	139	12
Total other income (expense), net	139	(623)
Net loss	$ (17,549)	$ (6,785)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.36)	$ (2.20)
Weighted average shares of common stock outstanding, basic and diluted	48,284,778	3,085,009

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

	March 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 272,734	$ 68,526
Working capital	$ 266,349	$ 281,841
Total assets	$ 277,039	$ 293,824
Total liabilities	$ 8,124	$ 8,787
Total stockholders' equity	$ 268,915	$ 285,037

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 parallel lead programs in ROS1-positive and ALK-positive non-small cell lung cancer (NSCLC), along with multiple discovery-stage research programs. We routinely post information that may be important to investors on our website at www.nuvalent.com. Follow us on Twitter (@nuvalent) and LinkedIn.

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 clinical development programs for NVL-520, NVL-655, ALK IXDN compound resistance mutations and HER2 Exon 20 insertions and the timing thereof; the potential clinical effect of NVL-520 and NVL-655; the design and enrollment of the ARROS-1 study and the timing thereof; the design and initiation of the ALKOVE-1 Phase 1/2 study and the timing thereof; the potential of Nuvalent's pipeline programs, including NVL-520 and NVL-655; Nuvalent's research and development programs for the treatment of cancer; risks and uncertainties associated with drug development; and capital allocation. 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 study or it will take longer than expected; unexpected concerns that may arise from additional data, analysis, or results obtained during clinical trials; the occurrence of adverse safety events; risks of unexpected costs, delays, or other unexpected hurdles; risks that Nuvalent may not be able to nominate drug candidates from its HER2 Exon 20 and ALK IXDN programs; the direct or indirect impact of COVID-19 or other global geopolitical circumstances on the timing and anticipated timing and results of Nuvalent's clinical trials, strategy, and future operations, including the global ARROS-1 study and the planned initiation of the ALKOVE-1 Phase 1/2 study; the timing and outcome of Nuvalent's planned interactions with regulatory authorities; and obtaining, maintaining, and protecting its intellectual property. These and other risks and

uncertainties are described in greater detail in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as well as any 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.

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