Nuvalent Investors

Nuvalent Announces Business and Program Highlights and Reports Second Quarter 2021 Financial Results

IND Application for NVL-520 Cleared by US FDA; Company Expects to Initiate Phase 1/2 Clinical Trial in Second Half of 2021

$190.6 Million Upsized IPO Completed to Fund Continued Advancement of Novel Portfolio of Precisely Targeted Kinase Inhibitors

Leadership Team Further Strengthened with Appointments of Deborah Miller, Ph.D., J.D., as Chief Legal Officer and Sapna Srivastava, Ph.D., to the Board of Directors

CAMBRIDGE, Mass., Sept. 8, 2021 /PRNewswire/ -- Nuvalent, Inc., (Nasdaq: NUVL), a biopharmaceutical company focused on creating *precisely* targeted therapies for clinically proven kinase targets in cancer, today reported recent pipeline and business highlights and second quarter 2021 financial results.

"At Nuvalent, we are leveraging our team's deep expertise in chemistry and structure-based drug design to advance a novel pipeline of product candidates for patients with cancer. Our therapies are specifically designed to solve for challenges limiting the activity and durability of currently available therapies, such as kinase resistance, adverse events due to off-target activity, and metastases to the brain," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "In the first half of 2021, our team has made meaningful progress to deliver on our clear vision for advancing the field of precision oncology. We have received clearance from the FDA to proceed with the Phase 1/2 study for our ROS1-selective inhibitor NVL-520, advanced our parallel lead product candidate, the ALK-selective inhibitor NVL-655, into IND-enabling studies, and progressed multiple additional discovery-stage research programs. With the recent talented additions to our team and capital raised in our upsized IPO, we stand well positioned to fuel our upcoming transition to a clinical organization and efforts to renew hope for patients in need."

Second Quarter Highlights

- **IND Application for NVL-520 Cleared by FDA, Enabling Clinical Trial Initiation:** The U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for NVL-520, its brain-penetrant ROS1-selective inhibitor. The company is preparing to initiate the Phase 1 portion of a global, Phase 1/2 clinical trial for NVL-520 in patients with ROS1-positive NSCLC and other advanced solid tumors in the second half of 2021.

- **$190.6 Million Upsized Initial Public Offering (IPO) Successfully Completed**: In July 2021, Nuvalent sold 11,212,500 shares of common stock at a price to the public of $17.00 per share. The gross proceeds from the offering were approximately $190.6 million, before deducting underwriting discounts and commissions and other offering expenses.

- **Company Leadership Strengthened through Appointments to Management and Board:** Nuvalent recently appointed Deborah Miller, Ph.D., J.D., as Chief Legal Officer, and Sapna Srivastava, Ph.D., Chief Financial Officer of eGenesis, to its Board of Directors.

  Dr. Miller most recently served as Senior Vice President, Deputy General Counsel and Chief IP Counsel for Sumitomo Dainippon Pharma America (SDPA). Prior to that, Dr. Miller served as Deputy General Counsel and Chief IP Counsel at Sunovion Pharmaceuticals Inc., a subsidiary of SDPA. She previously held various roles at Infinity Pharmaceuticals, Inc. including Vice President, Deputy General Counsel and Chief Patent Counsel, where she built and managed the intellectual property group and supported various in-licensing, out-licensing and financing ventures. Earlier in her career, Dr. Miller was IP corporate counsel at Sepracor Inc. (currently, Sunovion Pharmaceuticals Inc.), and an associate at the law firm Nutter McClennen & Fish LLP. Dr. Miller earned her J.D. from Suffolk University Law School, Ph.D. in biological chemistry and molecular pharmacology from Harvard University, M.S. in medical sciences from Harvard Medical School and B.S. in chemistry from Swarthmore College.

  Dr. Srivastava brings over 20 years of experience as a senior executive in the biopharmaceutical industry. She has served as the Chief Financial Officer at eGenesis Bio since April 2021. Prior to eGenesis, she held similar roles as the Chief Financial and Strategy Officer at Abide Therapeutics (acquired by Lundbeck) and at Intellia Therapeutics. Before Intellia, Dr. Srivastava was a senior biotechnology analyst at Goldman Sachs, Morgan Stanley and ThinkEquity Partners, and began her career as a research associate at J.P. Morgan. Dr. Srivastava received her Ph.D. in neuroscience from the New York University School of Medicine and her B.S. in biology from St. Xavier's College at the University of Bombay.

Second Quarter 2021 Financial Results

- As of June 30, 2021, Nuvalent had cash of $138.9 million, which does not include net proceeds from its IPO, which was completed on August 2, 2021.
- Research & Development expenses for the second quarter of 2021 were $7.8 million.
- General & Administrative expenses for the second quarter of 2021 were $2.0 million.
- Net Loss for the second quarter was $9.8 million, or $3.17 per share.

About Nuvalent

Nuvalent, Inc. (Nasdaq: NUVL) is a preclinical 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 NSCLC, along with multiple discovery-stage research programs. To learn more, visit www.nuvalent.com and 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, Inc.'s ("Nuvalent," the "Company," "we," or "our") strategy, business plans and focus; the progress and timing of the preclinical and clinical development of Nuvalents' programs, including NVL-520 and NVL-655; expectations regarding the planned clinical trial initiation of NVL-520, including timing; expectations regarding Nuvalent's use of capital, expenses and other financial results during 2021 and in the future. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "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.

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 associated with: the impact of COVID-19 on countries or regions in which the Company has operations or does business, as well as on the timing and anticipated timing and results of its clinical trials, strategy and future operations, including the planned initiation of the Phase 1 portion of a global, Phase 1/2 clinical trial for NVL-520, the timing and progress of IND-enabling studies of NVL-655 and progress from the Company's discovery-stage programs; the Company's expectations regarding its management and board additions; the Company's ability to successfully demonstrate the safety and efficacy of its drug candidates; 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 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 our views as of any subsequent date. Nuvalent explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 7,826	$ 3,657	$ 13,310	$ 6,983
General and administrative	2,024	349	2,702	668
Total operating expenses	9,850	4,006	16,012	7,651
Loss from operations	(9,850)	(4,006)	(16,012)	(7,651)
Other income (expense):				
Change in fair value of preferred stock tranche rights	—	(4,542)	(635)	4,471
Other income (expense), net	12	(9)	24	(18)
Total other income (expense), net	12	(4,551)	(611)	4,453
Net loss and comprehensive loss	$ (9,838)	$ (8,557)	$ (16,623)	$ (3,198)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.17)	$ (2.82)	$ (5.37)	$ (1.20)
Weighted average shares of common stock outstanding, basic and diluted	3,106,152	3,037,974	3,095,639	2,675,827

SELECTED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	June 30,	December 31,

	2021	2020
Cash	$ 138,919	$ 10,332
Working capital	$ 133,452	$ 6,266
Total assets	$ 143,502	$ 10,646
Total liabilities	$ 5,829	$ 6,615
Total stockholders' deficit	$ (47,740)	$ (31,323)

SOURCE Nuvalent, Inc.

For further information: Investor Contact, Chelcie Lister, THRUST Strategic Communications, chelcie@thrustsc.com; Media Contact, Sarah Ellinwood, Ph.D., Verge Scientific Communications, sellinwood@vergescientific.com

---