# Nuvalent Reports Pipeline Progress and Third Quarter 2021 Financial Results

# ARROS-1 Clinical Trial of NVL-520 for the Treatment of Patients with Advanced ROS1-positive NSCLC and Other Solid Tumors is Open for Enrollment

# Company On-track for Initiation of Clinical Trial of NVL-655 for the Treatment of Patients with Advanced ALK-positive NSCLC and Other Cancers in First Half of 2022

CAMBRIDGE, Mass., Nov. 10, 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 progress and third quarter 2021 financial results.

"Throughout the third quarter of 2021, we continued to progress our novel portfolio of precisely targeted therapies for patients with cancer. Notably, our first clinical trial of NVL-520, the 'ARROS-1' study, is now open for enrollment of patients with advanced ROS1-positive NSCLC and other solid tumors," said James Porter, Ph.D., Chief Executive Officer at Nuvalent. "We anticipate a robust set of upcoming operational milestones, including the dosing of the first patient in our ARROS-1 study in 2021, the advancement of our parallel lead program NVL-655 into clinical development for ALK-positive cancers, and the expansion of our portfolio with additional internally developed product candidates. With a dedicated, expert team and a strong balance sheet in place, we believe we are well-positioned to achieve the milestones ahead."

**Recent Program Highlights**

- **ARROS-1 Phase 1/2 Clinical Trial of NVL-520 Open for Enrollment:**
  Nuvalent has activated multiple U.S. sites to begin enrollment in its ARROS-1 clinical trial, a Phase 1/2, multicenter, open-label, dose-escalation and expansion study evaluating NVL-520 as an oral monotherapy in patients with advanced ROS1-positive non-small cell lung cancer (NSCLC) and other solid tumors. NVL-520 is a novel ROS1-selective inhibitor designed to address the clinical challenges of emergent treatment resistance, central nervous system (CNS)-related adverse events, and brain metastases that may limit the use of currently available ROS1 tyrosine kinase inhibitors (TKIs). The

Phase 2 portion of the ARROS-1 study is designed to support potential registration of NVL-520 in both ROS1-positive patients with NSCLC who are kinase inhibitor-naïve and who have been previously treated with ROS1 kinase inhibitors. Clinical site expansion in the US and EU is ongoing.

- **Preclinical Data Supporting Lead Programs for ROS1-Positive and ALK-Positive NSCLC Presented at 2021 AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference:** Nuvalent presented new preclinical data at the 2021 AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference further demonstrating that NVL-520 and NVL-655, its parallel lead product candidates, were active against both wild-type and various known resistance variants of ROS1 or ALK, respectively; were brain-penetrant with the potential to address brain metastases; and selectively inhibited their respective targets compared to the structurally related tropomyosin receptor kinase B (TRKB), thereby minimizing the potential for off-target TRKB-related CNS adverse events. The ARROS-1 Phase 1/2 clinical trial of NVL-520 is open for enrollment, and Nuvalent plans to initiate a Phase 1/2 clinical trial of NVL-655 in advanced ALK-positive NSCLC and other cancers during the first half of 2022.

**Upcoming Investor Conference Presentations**

- **33rd Annual Virtual Piper Healthcare Conference:** Dr. Porter will participate in a pre-recorded fireside chat during the 33rd Annual Virtual Piper Healthcare Conference, being held November 30 – December 2, 2021. The fireside chat will be available to registered participants beginning on November 22, 2021, and the webcast will be available in the investor section of the company's website at www.nuvalent.com for 30 days following the presentation.

**Third Quarter 2021 Financial Results**

- **Cash Position:** Cash, cash equivalents and marketable securities were $302.4 million as of September 30, 2021, including net proceeds from the initial public offering completed on August 2, 2021, compared to $10.3 million as of December 31, 2020.
- **Research & Development (R&D) expenses**: R&D expenses were $9.1 million for the third quarter of 2021, compared to $3.7 million for the third quarter of 2020.
- **General & Administrative (G&A) expenses**: G&A expenses were $3.4 million for the third quarter of 2021, compared to $0.3 million for the third quarter of 2020.
- **Net Loss:** Net loss for the third quarter of 2021 was $12.4 million, or $0.39 per share, compared to $4.8 million, or $1.57 for the third quarter of 2020.

**About Nuvalent**

Nuvalent, Inc. (Nasdaq: NUVL) is a 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.

**Customary Note Regarding 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; potential of, and expectations for, our lead programs and other product candidates in our pipeline; capital allocation; the progress and timing of the preclinical and clinical development of Nuvalent's programs, including NVL-520 and NVL-655; the potential clinical effect of NVL-520 and NVL-655; 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," "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 associated with: the impact of COVID-19 on countries or regions in which Nuvalent 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 global Phase 1/2 clinical trial for NVL-520 and the planned initiation of a Phase 1/2 clinical trial for NVL-655; Nuvalent's expectations regarding the preclinical data for NVL-520 and NVL-655 presented at the AACR-NCI-EORTC Molecular Targets Conference, including the potential therapeutic benefit of its lead product candidates; 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; 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 September 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 its views as of any subsequent date. Nuvalent explicitly disclaims any obligation to update any forward-looking statements.

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 302,429 | $ 10,332 |
| Working capital | $ 298,297 | $ 6,266 |
| Total assets | $ 307,973 | $ 10,646 |
| Total liabilities | $ 6,842 | $ 6,615 |
| Total stockholders' equity (deficit) | $ 301,131 | $ (31,323) |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Research and development | $ 9,055 | $ 3,721 | $ 22,365 | $ 10,704 |
| General and administrative | 3,372 | 319 | 6,074 | 987 |
| Total operating expenses | 12,427 | 4,040 | 28,439 | 11,691 |
| Loss from operations | (12,427) | (4,040) | (28,439) | (11,691) |
| Other income (expense): | | | | |
| Change in fair value of preferred Stock tranche rights | — | (724) | (635) | 3,747 |
| Other income (expense), net | 1 | (14) | 25 | (32) |
| Total other income (expense), net | 1 | (738) | (610) | 3,715 |
| Net loss | $ (12,426) | $ (4,778) | $ (29,049) | $ (7,976) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.39) | $ (1.57) | $ (2.26) | $ (2.85) |
| Weighted average shares of common stock outstanding, basic and diluted | 32,066,089 | 3,042,398 | 12,858,574 | 2,798,910 |

SOURCE Nuvalent, Inc.

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https://investors.nuvalent.com/2021-11-10-Nuvalent-Reports-Pipeline-Progress-and-Third-Quarter-2021-Financial-Results