# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934**

**Date of Report (date of earliest event reported): May 9, 2022**

# Neoleukin Therapeutics, Inc.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-36327** | **98-0542593** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

**188 East Blaine Street, Suite 450**
**Seattle, Washington 98102**
**(Address of principal executive offices) (Zip Code)**

**Registrant's telephone number, including area code (866) 245-0312**

**N/A**
**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| **Common Stock, $0.000001 par value** | **NLTX** | **The Nasdaq Global Market** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02 Results of Operations and Financial Condition**

On May 9, 2022, Neoleukin Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the three months ended March 31, 2022. The full text of the press release announcing such results is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this current report on Form 8-K and in Exhibit 99.1 attached hereto is being furnished, but shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and is not incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| Number | Description |
|---|---|
| 99.1 | Press Release of Neoleukin Therapeutics, Inc. dated May 9, 2022 |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL) |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 9, 2022

**Neoleukin Therapeutics, Inc.**
By: /s/ Jonathan Drachman
Name: Jonathan Drachman
Title: President and Chief Executive Officer

# Neoleukin Therapeutics Announces First Quarter 2022 Financial Results and Corporate Update

**SEATTLE, Washington, May 9, 2022** – Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design *de novo* protein therapeutics, today announced financial results for the quarter ending March 31, 2022 and provided a corporate update.

“During the first quarter of 2022 our dedicated team at Neoleukin has been focused on execution of our NL-201 Phase 1 clinical trial, evaluating multiple schedules during dose escalation in patients with relapsed and refractory solid tumors," said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. "We anticipate reporting interim data from this trial during the second half of 2022; we also expect to initiate testing of NL-201 in combination with pembrolizumab around mid-year. Our scientists continue preclinical evaluation of NL-201 in novel regimens and additional indications as well as advancing our *de novo* protein technology and early-stage research programs.”

**NL-201 Update**

Neoleukin is conducting a clinical trial of intravenous NL-201 in patients with advanced solid tumors. It is currently enrolling patients at sites in Australia, the United States, and Canada, evaluating two different schedules and multiple dose levels in order to determine a recommended Phase 2 dose and schedule. Neoleukin anticipates disclosing interim data during the second half of 2022.

In January, Neoleukin announced a clinical trial collaboration and supply agreement with Merck (known as MSD outside the United States and Canada) to evaluate NL-201 plus pembrolizumab as part of Neoleukin's ongoing Phase 1 trial in patients with advanced solid tumors. This additional arm of the ongoing clinical trial is expected to begin enrollment mid-year 2022.

In April 2022, Neoleukin announced the presentation of preclinical data at the American Association for Cancer Research (AACR) Annual Meeting, highlighting the potential for NL-201 to treat non-Hodgkin lymphoma as well as synergistic antitumor activity when NL-201 is combined with radiation therapy, including significant inhibition of tumor growth and increased survival in preclinical models.

Based on encouraging preclinical activity, Neoleukin announced plans to initiate a separate clinical trial to evaluate NL-201 in patients with hematologic malignancies. The timing for enrolling patients in this trial will be determined based on data we receive from our ongoing solid tumor Phase 1 trial relating to safety and optimal dosing schedules.

**Executive Appointment**

In March 2022, Neoleukin announced the appointment of Donna M. Cochener as General Counsel, Senior Vice President, Legal. Ms. Cochener joins Neoleukin after serving as Senior Vice President, Deputy General Counsel at HomeStreet, Inc., the parent company of HomeStreet Bank. Prior to her position with HomeStreet, Ms. Cochener was a partner at Davis Wright Tremaine, LLP in Seattle, and worked as an associate at the Seattle offices of Heller Ehrman, LLP, Riddell Williams, P.S. and Perkins Coie, LLP.

**Summary of Financial Results**

**Cash Position:** Cash and cash equivalents totaled $128.1 million as of March 31, 2022, compared to $142.5 million as of December 31, 2021.

Based upon current internal infrastructure and pipeline initiatives, Neoleukin believes it has sufficient cash to fund operations through 2023.

**R&D Expenses:** Research and development expenses for the quarter ended March 31, 2022 increased to $10.7 million from $9.7 million for the quarter ended March 31, 2021. The increase was primarily due to increased clinical trial expenses related to our lead product candidate, NL-201, and costs incurred in connection with the advancement of other Neoleukin technologies. The increase was partially offset by higher costs incurred during the three months ended March 31, 2021 in connection with the build-out of our headquarters and laboratory space in Seattle, Washington, as well as development costs associated with our NL-CVX1 program which was suspended in June 2021.

**G&A Expenses:** General and administrative expenses for the quarter ended March 31, 2022 decreased to $4.7 million from $5.2 million for the quarter ended March 31, 2021. The decrease was primarily attributable to decreases in personnel-related and facility-related costs.

**Net Loss:** Net loss for the quarter ended March 31, 2022 was $15.4 million compared to a net loss of $14.9 million for the quarter ended March 31, 2021.

**About NL-201**

NL-201 is a de novo agonist of the IL-2 and IL-15 receptors, designed to expand cancer-fighting CD8 T cells and natural killer (NK) cells without any bias toward cells expressing the alpha receptor subunit (CD25). Previously presented preclinical data has demonstrated the ability of NL-201 to stimulate and expand CD8+ and NK cells at low doses with minimal impact on immunosuppressive regulatory T cells. Furthermore, NL-201 has demonstrated both monotherapy and combination activity across a wide range of preclinical syngeneic tumor models.

**About Neoleukin Therapeutics, Inc.**

Neoleukin is a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. Neoleukin uses sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. Neoleukin's lead product candidate, NL-201, is a combined IL-2 and IL-15 agonist designed to improve tolerability and activity by eliminating the alpha receptor binding interface. For more information, please visit the Neoleukin website: www.neoleukin.com.

**Safe Harbor / Forward-Looking Statements**

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the therapeutic properties and potential of the company's *de novo* protein design technology, the results and timing of the clinical trial for NL-201, expectations regarding cash forecasts, and planned clinical and development activities and timelines. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties, including risks and uncertainties related to the company's cash forecasts, the company's ability to advance its product candidates, the receipt and timing of potential regulatory submissions, designations, approvals and commercialization of product candidates, the timing and results of preclinical and clinical trials, changes to laws or regulations, market conditions, geopolitical events, and further impacts of COVID-19, that could cause actual results to differ materially from what Neoleukin expects. Further information on potential risk factors that could affect Neoleukin's business and its financial results are detailed under the heading "Risk Factors" included in Neoleukin's Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K filed from time to time with the Securities and Exchange Commission (SEC). Neoleukin undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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**NEOLEUKIN THERAPEUTICS, INC.**

**Condensed Balance Sheet Data**

(In thousands of U.S. dollars)

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 128,057 | $ 142,467 |
| Other current assets | 2,308 | 1,522 |
| Non-current assets | 18,761 | 19,274 |
| **Total assets** | $ 149,126 | $ 163,263 |
| **Liabilities** | | |
| Current liabilities | $ 7,596 | $ 8,636 |
| Non-current liabilities | 11,437 | 11,763 |
| Total liabilities | 19,033 | 20,399 |
| Stockholders' equity | 130,093 | 142,864 |
| **Total liabilities and stockholders' equity** | $ 149,126 | $ 163,263 |

**NEOLEUKIN THERAPEUTICS, INC.**

**Condensed Statements of Operations**

(In thousands of U.S. dollars, except per share and share amounts)

| | Quarter ended March 31, 2022 | Quarter ended March 31, 2021 |
|---|---|---|
| **Operating expenses** | | |
| Research and development | $ 10,701 | $ 9,707 |
| General and administrative | 4,664 | 5,241 |
| Total operating expenses | 15,365 | 14,948 |
| Other income, net | 14 | (2) |
| **Net loss** | $ (15,351) | $ (14,950) |
| Net loss per common stock – basic and diluted | $ (0.28) | $ (0.27) |
| Basic and diluted weighted average common shares outstanding | 55,143,537 | 54,944,421 |