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): November 4, 2021

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 November 4, 2021, Neoleukin Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the quarter ended September 30, 2021. 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 November 4, 2021
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: November 4, 2021

Neoleukin Therapeutics, Inc.
By: /s/ Robert Ho
Name: Robert Ho
Title: Chief Financial Officer

Neoleukin Therapeutics Announces Third Quarter 2021 Financial Results and Corporate Update

– NL-201 Phase 1 solid tumor trial interim data anticipated in 2022 –

– Upcoming presentations at ACR, SITC, and ASH to highlight preclinical data –

– Planning to initiate a Phase 1 trial in hematologic malignancies with NL-201 in 2022 –

SEATTLE, Washington, November 4, 2021 – Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design *de novo* protein therapeutics, today announced financial results and a corporate update for the third quarter ended September 30, 2021.

“During the third quarter, we made progress with our NL-201 phase 1 clinical trial, initiating multiple additional sites in the United States, Australia, and Canada; we look forward to providing interim data in 2022,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “In addition, we and our collaborators continue to generate preclinical data, demonstrating the potential for NL-201 in additional indications and novel regimens. Based on these data, we plan to initiate a second NL-201 clinical trial in patients with hematology malignancies next year.”

“Furthermore, our presentation next week at the American College of Rheumatology Annual Meeting will highlight a *de novo* IL-2/IL-15 inhibitor we have developed that could have applications in inflammatory and autoimmune disorders."

Recent Updates

NL-201

NL-201 is a *de novo* protein therapeutic candidate, designed to mimic the therapeutic activity of natural cytokines IL-2 and IL-15, while potentially reducing the toxicities associated with high-dose IL-2. NL-201 is currently in a phase 1 clinical trial for patients with relapsed and refractory solid tumors. A second trial for patients with hematologic malignancies is expected to begin next year.

Executive Appointment

In September, Neoleukin announced the appointment of Bill Arthur, Ph.D., as Vice President and Head of Research. Dr. Arthur joins Neoleukin after a decade at Seagen Inc., where he served most recently as Senior Director & Head of Cancer Biology. Prior to Seagen, Dr. Arthur worked at Merck & Co. and Rosetta Inpharmatics.

Scientific Conference Presentations

In September, an oral presentation at IDWeek by Neoleukin scientists and collaborators demonstrated the potential of NL-CVX1 to prevent or treat SAR-CoV-2 related disease, including new variants of concern.

At the upcoming American College of Rheumatology Annual Meeting (taking place virtually November 5-9, 2021), Neoleukin will have an oral presentation, titled "*Development of a Computationally Designed, Hyperstable Dual Inhibitor of the IL-2 and IL-15 Receptors: A Novel Therapeutic Candidate for Inflammatory Conditions*" (Monday, Nov. 8 at 2 p.m.). The abstract highlights development of a potent and hyperstable protein that blocks signaling by endogenous IL-2 and IL-15.

Neoleukin and collaborators will present four abstracts at SITC 2021:

> Title: *NL-201 Induces Inflammation in a 'Cold' Tumor Microenvironment through Upregulation of MHC-I, Expansion of the TCR Repertoire, and Potent Antitumor Activity when Combined with PD-1 Inhibition*
>
> Poster/Abstract Number: 716,
> Date/Time: Saturday, November 13, 7 a.m. to 8:30 p.m., ET
>
> Title: *Intratumoral Administration of NL-201, an Alpha-Independent IL-2/15 Receptor Agonist, Inhibits the Growth of Both Injected and Uninjected Tumors in Preclinical Models*
>
> Poster/Abstract Number: 898,
> Date/Time: Saturday, November 13, 7 a.m. to 8:30 p.m., ET
>
> Title: *A First-in-Human Phase 1 Study of NL-201 in Patients with Relapsed or Refractory Cancer* (*Trials in Progress*)
>
> Poster/Abstract Number: 509,
> Date/Time: Friday, November 12, 7 a.m. to 8:30 p.m. ET
>
> Title: *ICT01, an Anti-BTN3A Monoclonal Antibody, and NL-201, an Alpha-Independent IL-2/IL-15 Agonist, Combine to Elicit a Potent Anti-Tumor Response by Synergistically Stimulating Vγ9Vδ2 T Cell Activation and Proliferation*
>
> Poster/Abstract Number: 563
> Date/Time: Friday, November 12, 7 a.m. to 8:30 p.m. ET

Two abstracts have been submitted regarding NL-201 for the upcoming 63rd American Society of Hematology Annual Meeting (ASH 2021) taking place virtually and in person December 11-14, 2021, and one will be presented as a poster:

> Title: *The IL-2/IL-15 Mimetic NL-201 Prevents Myeloma Relapse after ASCT by Expanding Highly Cytolytic T Cells in the Bone Marrow that are Resistant to Exhaustion*
>
> Abstract number: 1609

Title: *NL-201, a De Novo Agonist of IL-2 and IL-15 Receptors, Demonstrates Synergistic Antitumor Activity with Anti-PD-1 Checkpoint Inhibitor Therapy in a Preclinical Non-Hodgkin Lymphoma Model*

Abstract number: 4560

To be published in the November supplemental issue of *Blood.*

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled $154.9 million as of September 30, 2021, compared to $192.6 million as of December 31, 2020.

Based upon current internal infrastructure and pipeline initiatives, Neoleukin believes it has sufficient cash to fund operations into the second half of 2023.

R&D Expenses: Research and development expenses for the third quarter of 2021 increased to $9.9 million from $6.2 million for the third quarter of 2020. The increase was primarily due to increased expenses incurred from clinical trial activities related to Neoleukin's lead product candidate, NL-201, personnel-related costs, and in connection with the advancement of other Neoleukin technologies.

G&A Expenses: General and administrative expenses for the third quarter of 2021 increased to $5.6 million from $3.9 million for the third quarter of 2020. The increase in general and administrative expenses was primarily due to increases in personnel-related costs and professional service fees as Neoleukin continues to grow its operations.

Gain on Sale of Aquinox Canada: The gain in the third quarter of 2020 relates to the sale of Aquinox Canada, a wholly owned subsidiary of Neoleukin. The gain of $7.8 million recognized was the total consideration of $8.2 million, less transaction costs of $0.4 million.

Net Loss: Net loss for the third quarter of 2021 was $15.4 million compared to a net loss of $2.2 million in the third quarter of 2020.

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 of the clinical trial for NL-201, expectations regarding cash forecasts, 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, the timing of announcements and updates relating to the company's clinical trials and related data market conditions 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" in documents the company files from time to time with the Securities and Exchange Commission (SEC), and other reports as filed with the 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 consolidated balance sheet data

(In thousands of U.S. dollars)

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 154,924	$ 192,556
Other current assets	1,574	1,966
Non-current assets	19,436	15,997
Total assets	$ 175,934	$ 210,519
Liabilities		
Current liabilities	$ 8,996	$ 7,889
Non-current liabilities	12,072	11,414
Total liabilities	21,068	19,303
Stockholders' equity	154,866	191,216
Total liabilities and stockholders' equity	$ 175,934	$ 210,519

NEOLEUKIN THERAPEUTICS, INC.

Condensed consolidated statements of operations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating loss				
Research and development	$ 9,896	$ 6,216	$ 29,402	$ 16,557
General and administrative	5,556	3,860	16,122	12,359
Gain on sale of Aquinox Canada	—	(7,826)	—	(7,826)
Total operating loss	15,452	2,250	45,524	21,090
Other income (loss), net	6	1	(1)	453
Net loss	$ (15,446)	$ (2,249)	$ (45,525)	$ (20,637)
Net loss per common stock – basic and diluted	$ (0.28)	$ (0.04)	$ (0.83)	$ (0.41)
Basic and diluted weighted average common shares outstanding	55,087,777	54,121,676	55,020,059	50,896,014