
**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): August 12, 2020

Neoleukin Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36327
(Commission File Number)

98-0542593
(IRS Employer
Identification No.)

360 - 1616 Eastlake Avenue E,
Seattle, Washington 98102
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (206) 732-2133

NA
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.000001	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.

Item 2.02 Results of Operations and Financial Condition

On August 12, 2020, Neoleukin Therapeutics, Inc. (the “Company”) issued a press release announcing financial results for the quarter ended June 30, 2020. 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 the press release attached as Exhibit 99.1 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

<u>Number</u>	<u>Description</u>
99.1	Press Release of Neoleukin Therapeutics, Inc. dated August 12, 2020

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.

Neoleukin Therapeutics, Inc.

By: /s/ Robert Ho
Name: Robert Ho
Title: Chief Financial Officer

Date: August 12, 2020



Neoleukin Therapeutics Announces Second Quarter 2020 Financial Results & Provides Corporate Update

- *NL-201 IND submission anticipated during fourth quarter of 2020* -
- *Recent financing raises \$71.4M in net proceeds to enable broad NL-201 clinical plan and product pipeline development into 2023* -
- *Company to host Conference Call Today, August 12, 2020 at 1:30 p.m. Pacific / 4:30 p.m. Eastern* -

SEATTLE, Washington, August 12, 2020 – 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 second quarter ending June 30, 2020 and a midyear corporate update.

“All of the preclinical activities for NL-201 are substantially complete, and we are excited to be moving towards our first clinical trial in patients with advanced solid tumors,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “To our knowledge, this will be the first fully *de novo* protein to enter clinical testing and has the potential to improve outcomes for patients with a wide variety of cancers. Additionally, our research group continues to advance future pipeline programs and to broaden the *de novo* protein design platform, some of which was highlighted during the recent AACR-II Conference.”

Recent Updates

NL-201 Development

In June, Neoleukin announced the presentation of preclinical data on its lead immunotherapy candidate NL-201, an IL-2 and IL-15 agonist, and applications of its *de novo* protein design platform at the American Association for Cancer Research (AACR) Virtual Annual Meeting II.

Key findings include the ability of NL-201 to potently stimulate and expand key cancer-killing cells and induce robust and durable antitumor activity across many tumor types as well as encouraging immunogenicity data in non-human primates. New data highlights the ability of NL-201 to stimulate and expand CD8+ and NK cells at very low doses with minimal impact on immunosuppressive regulatory T cells. Additionally, low incidence of immunogenicity was observed following five weekly doses of NL-201 in non-human primates.

Neoleukin remains focused on its efforts to support an Investigational New Drug (IND) Application for its lead therapeutic, NL-201, anticipated during the fourth quarter of 2020, and is working with key vendors to finalize all activities and study reports. At this time, Neoleukin does not expect a delay due to COVID-19 but acknowledges the potential exists for this timing to be impacted.

Other Applications of De Novo Protein Design Presented at AACR Virtual Meeting

Research presented highlights a conditional activation approach – *de novo* split technology – demonstrating that *de novo* proteins can be divided into two inactive pieces that regain the ability to bind receptors when co-located in the tumor microenvironment. This split approach to conditional activation may increase the therapeutic index and offers the potential to create next-generation *de novo* therapeutics.

Additional research demonstrated that NL-201 and targeted variants may improve outcomes when combined with CAR-T cells in vivo in lymphoma and solid tumor models.

De Novo Protein Design for Coronavirus

In the past several months, Neoleukin scientists developed NL-CVX1, a fully *de novo* ACE2 decoy that binds to the SARS-CoV2 spike protein and neutralizes viral infection of mammalian cells in vitro. This protein is highly stable, was designed to be resilient to viral mutation, and has the potential for local administration to treat and/or prevent infection. The early results of this discovery research were recently posted on the public access website bioRxiv.org.

Board Appointment

In June, Neoleukin announced the appointment of Erin Lavelle to the Company's Board of Directors. Ms. Lavelle has more than 20 years of strategic and operational leadership experience in the biopharmaceutical industry. Ms. Lavelle started her career in Merrill Lynch's Investment Banking group, spent 15 years at Amgen, and most recently served as Chief Operating Officer for Alder Biopharmaceuticals, Inc.

Follow-On Offering

In July, Neoleukin closed a public offering of approximately 3.2 million shares of common stock and pre-funded warrants to purchase 1.7 million shares of common stock with an exercise price of \$0.000001. The aggregate net proceeds received by the Company from the offering, after deducting offering fees and expenses, were \$71.4 million. This is a subsequent event to the quarter. As such, Neoleukin's cash balance as of June 30, 2020 does not include these proceeds.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled \$129.6 million as of June 30, 2020 compared to \$143.1 million as of December 31, 2019. The decrease in cash was primarily the result of cash used in operations as well as expenditures on property and equipment, offset partially by proceeds from the exercise of options.

Based upon our current operating plan, and following the completion of the July follow-on offering, Neoleukin believes that its cash-on-hand will be sufficient to fund operations into 2023.

R&D Expenses: Research and development expenses for the second quarter of 2020 increased to \$4.8 million from (\$2.0) million for the second quarter of 2019. This increase was primarily due to IND-enabling activities related to Neoleukin's lead product candidate, NL-201, and advancement of other Neoleukin technologies, compared to a credit in expenses during Q2 2019 as a result of the suspension of all research and development activities from the former Aquinox operations in June 2018, as well as reductions to accrued research and development expenses given final costs were less than contracted.

G&A Expenses: General and administrative expenses for the second quarter of 2020 increased to \$4.9 million from \$2.4 million for the second quarter of 2019. The increase is primarily due to investments in G&A after the merger, completed in August 2019, compared to lower personnel and overhead costs as a result of Aquinox's restructuring in the prior year.

Net Loss: Net loss for the second quarter of 2020 was \$9.7 million compared to a net loss of \$0.0 million in the second quarter of 2019 primarily due to increased costs related to Neoleukin's lead candidate, NL-201, and other Neoleukin technologies in 2020, as well as the reductions to accrued research and development expenses during the second quarter of 2019.

Conference Call Information

Neoleukin will host a conference call today to provide a second quarter corporate update and review financials. Details are as follows:

Date: August 12, 2020

Time: 1:30 p.m. Pacific / 4:30 p.m. Eastern

Toll-free: (866) 357-7878

International: (315) 625-3088

Conference ID: 5862564

Webcast URL: <http://investor.neoleukin.com/events>

The archived audio webcast with slides will be available on the Investor Relations section of the Neoleukin website approximately two hours after the event and will be available for replay for at least 30 days after the event.

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, planned development activities and timelines, use and adequacy of cash reserves and the potential benefits of the company's product candidates and platform. 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. Examples of such forward-looking statements include but are not limited to statements regarding the therapeutic properties and potential of the company's *de novo* protein design technology and statements regarding the impact of COVID-19 on the company's ongoing and planned clinical trials. 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.

Contacts:

Media

Julie Rathbun
206-769-9219
jrathbun@neoleukin.com

Investors

Solebury Trout
Brian Korb
646-378-2923
bkorb@troutgroup.com

NEOLEUKIN THERAPEUTICS INC.
Condensed consolidated balance sheet data
(Unaudited)
(In thousands of U.S. dollars)

	<u>JUNE 30,</u> <u>2020</u>	<u>DECEMBER 31,</u> <u>2019</u>
Assets		
Cash and cash equivalents	\$ 129,596	\$ 143,093
Other current assets	1,401	503
Other non-current assets	14,327	3,427
Total assets	<u>\$ 145,324</u>	<u>\$ 147,023</u>
Liabilities		
Current liabilities	\$ 6,320	\$ 4,743
Non-current liabilities	10,305	593
Total liabilities	<u>16,625</u>	<u>5,336</u>
Stockholders' equity	<u>128,699</u>	<u>141,687</u>
Total liabilities and stockholders' equity	<u>\$ 145,324</u>	<u>\$ 147,023</u>

NEOLEUKIN THERAPEUTICS, INC.

Condensed consolidated statements of operations

(Unaudited)

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

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30,		JUNE 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	\$ 4,843	\$ (1,995)	\$ 10,341	\$ (1,891)
General and administrative	4,926	2,423	8,499	4,978
Total operating expenses	<u>9,769</u>	<u>428</u>	<u>18,840</u>	<u>3,087</u>
Other income, net	23	427	452	878
Net loss	<u>\$ (9,746)</u>	<u>\$ (1)</u>	<u>\$ (18,388)</u>	<u>\$ (2,209)</u>
Net loss per common stock – basic and diluted	\$ (0.20)	\$ —	\$ (0.37)	\$ (0.09)
Basic and diluted weighted average number of common stock outstanding	49,392,533	23,537,368	49,280,492	23,537,368