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 12, 2019**

NEON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38551**	**46-3915846**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

40 Erie St., Suite 110
Cambridge, MA 02139
(Address of principal executive offices, including zip code)

(617) 337-4701
(Registrant's telephone number, including area code)

Not Applicable
(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:

☐ 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	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	NTGN	The Nasdaq Global Select 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 November 12, 2019, Neon Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "**Exchange Act**") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on November 12, 2019, furnished herewith

SIGNATURES

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

Neon Therapeutics, Inc.

Date: November 12, 2019

By: /s/ Yasir B. Al-Wakeel

Yasir B. Al-Wakeel, B.M., B.Ch.

Chief Financial Officer

Exhibit 99.1

Neon Therapeutics Reports Third Quarter 2019 Financial Results and Recent Highlights

Recent Progress Achieved Across RECON® Bioinformatics Platform and Lead Neoantigen-Targeted Immunotherapy Programs

Cambridge, Mass. - November 12, 2019 - Neon Therapeutics, Inc. (Nasdaq: NTGN), a clinical-stage immuno-oncology company developing neoantigen-based therapeutics, today reported financial results for the third quarter ended September 30, 2019 and provided a business update.

"We continue to make important progress in advancing our leadership in the field of neoantigen-targeted therapies and are pleased to have recently presented updates across our personalized cancer vaccine and adoptive T cell therapy programs at the SITC Annual Meeting. In the remaining months of 2019, we look to continue building on our leadership position by completing our process development work that will enable our planned Clinical Trial Application in Europe for Phase 1 development of our neoantigen-targeted T cell therapy candidate, NEO-PTC-01," said Hugh O'Dowd, Neon's Chief Executive Officer.

Recent Highlights

- **RECON Bioinformatics Platform:** Neon scientists published in the scientific journal *Immunity* a breakthrough process for predicting which neoantigens will be presented by MHC class II molecules in the tumor microenvironment.
  - Predicting the relevant cancer-specific antigens is a crucial precursor to developing immunotherapies that effectively train T cells to traffic to the tumor and destroy malignant cells. In the paper, titled "Defining HLA-II ligand processing and binding rules with mass spectrometry enhances cancer epitope prediction," Neon's proprietary mono-allelic profiling technology called MAPTAC™ facilitated the development of convolutional neural network-based predictors.
  - These algorithms achieved up to a 61-fold improvement in predicting MHC class II peptides compared to publicly available tools.
  - This MHC class II technology will be integrated into Neon's RECON bioinformatics platform and is expected to improve the efficacy of immunotherapies developed by Neon by predicting recruitment of CD4+ T cells, which are believed to be important in controlling tumor growth.
- **NEO-PV-01:** Neon presented updated results at the SITC Annual Meeting from the ongoing, multicenter Phase 1b NT-001 clinical trial evaluating NEO-PV-01, Neon's personal neoantigen vaccine candidate, in combination with OPDIVO® (nivolumab) in patients with advanced or metastatic melanoma, smoking-associated non-small cell lung cancer (NSCLC) and bladder cancer.
  - Across all three distinct tumor types, results demonstrated prolonged and consistent improvements in progression-free survival (PFS) and overall survival (OS) that compare favorably to that observed with checkpoint inhibitor monotherapy, based on historical benchmark data.
  - Further, neoantigen-specific immune responses and epitope spread to RECON-predicted targets were associated with longer PFS, and major pathological responses post-administration of NEO-PV-01 in melanoma patients were also associated with longer PFS.
  - The safety data for NT-001 were consistent with the safety profile for OPDIVO monotherapy. These updated results come from 82 patients who received at least one dose of OPDIVO in the Phase 1b NT-001 trial.
- **NEO-PTC-01:** Neon presented at the SITC Annual Meeting an update on preclinical and process development work for NEO-PTC-01, its personal neoantigen-targeted T cell therapy candidate consisting of multiple T cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor.

- NEO-PTC-01 leverages Neon's RECON bioinformatics platform to individually select a set of neoantigen targets for each patient, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T cells *ex vivo.* Neon believes that this approach will allow NEO-PTC-01, a non-engineered product that leverages peripheral blood mononuclear cells (PBMCs) as starting material, to specifically target each patient's individual tumor with T cells that can drive a robust and persistent anti-tumor response.
- In the SITC update, Neon demonstrated that it can reproducibly generate a potent T cell product from PBMCs of melanoma patients, as well as at therapeutic scale using a healthy donor sample. This process development work showed that NEO-PTC-01 induced multiple $CD8^+$ and $CD4^+$ T cell responses from both the memory and the naïve T cell compartments.
- Neon is focusing the initial clinical development of NEO-PTC-01 in patients with solid tumorsthat are refractory to checkpoint inhibitors. Neon expects to file a clinical trial application, or CTA, in Europe by the end of 2019 to evaluate NEO-PTC-01 in the solid tumor setting.

Expected Near-Term Milestones

- NEO-PTC-01: Planned European CTA filing to evaluate NEO-PTC-01 in a refractory solid tumor setting (2H 2019).
- NEO-PTC-01: Planned Phase 1 initiation in a refractory solid tumor setting (1H 2020).
- NEO-PV-01: Planned clinical results and correlative immune data, including 12-month follow-up, from NT-002 Phase 1b trial in first-line metastatic NSCLC (Q3 2020).

Third Quarter 2019 Financial Results and Financial Guidance:

- R&D Expenses: Research and development expenses were $14.1 million for the third quarter of 2019, compared to $14.4 million for the same period last year. The decrease was primarily due to a reduction in clinical development and manufacturing costs, partially offset by an increase in personnel-related costs and costs related to the preparation for the planned CTA filing in Europe for Phase 1 development of NEO-PTC-01.
- G&A Expenses**:** General and administrative expenses were $5.1 million for the third quarter of 2019, compared to $4.6 million for the same period last year. The increase was primarily due to personnel-related costs and costs associated with being a public company.
- Net Loss: Net loss was $19.0 million for the third quarter of 2019, compared to $18.4 million for the same period last year.
- Cash Position: As of September 30, 2019, cash, cash equivalents and marketable securities were $44.3 million, as compared to cash, cash equivalents and marketable securities of $103.3 million as of December 31, 2018.
- Financial Guidance: Based on its current operating plan, Neon expects that its existing cash and cash equivalents will enable the Company to fund its operating expenses and capital expenditure requirements into June 2020.

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About Neon Therapeutics

Neon Therapeutics is a clinical-stage immuno-oncology company and a leader in the field of neoantigen-targeted therapies, dedicated to transforming the treatment of cancer by directing the immune system towards neoantigens. Neon is using its neoantigen platform to develop both vaccine and T cell therapies, including NEO-PV-01, a clinical-stage neoantigen vaccine for the treatment of metastatic melanoma, non-small cell lung cancer, and bladder cancer; NEO-PTC-01, a neoantigen T cell therapy for the treatment of solid tumors; and NEO-SV-01, a neoantigen vaccine for the treatment of a subset of hormone receptor-positive (HR+) breast cancer.

For more information, please visit neontherapeutics.com.

Forward-Looking Statements

This press release contains "forward-looking statements" of Neon Therapeutics, Inc. within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, express or implied statements regarding our ability to obtain and maintain regulatory approval of our product candidates; the potential timing and advancement of our clinical trials; the potential timing and manner of data readouts from our ongoing and planned clinical trials; the design and potential efficacy of our therapeutic approaches; financial plans and projections; and our ability to replicate results achieved in our preclinical studies or clinical trials in any future studies or trials. Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: uncertainties related to the initiation, timing and conduct of studies and other development requirements for our product candidates; the risk that any one or more of our product candidates will not be successfully developed and commercialized; the risk that the results of preclinical studies and clinical trials may not be predictive of future results in connection with future studies or trials; the risk that Neon's collaborations will not continue or will not be successful; risks related to our ability to protect and maintain our intellectual property position; risks related to our capital requirements and use of capital; and risks related to the ability of our licensors to protect and maintain their intellectual property position. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Neon's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Neon's most recent Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Neon's other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Neon undertakes no duty to update this information unless required by law.

Selected Consolidated Balance Sheet Data (Unaudited)
(amounts in thousands)

	September 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 44,278	$ 103,311
Working capital [1]	$ 36,215	$ 92,737
Total assets	$ 62,317	$ 114,088
Total stockholders' equity	$ 45,334	$ 101,249

(1) Working capital is defined as current assets less current liabilities.

Consolidated Statements of Operations (Unaudited)
(amounts in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 14,120	$ 14,441	$ 47,027	$ 42,403
General and administrative	5,134	4,612	16,122	12,524
Total operating expenses	19,254	19,053	63,149	54,927
Loss from operations	(19,254)	(19,053)	(63,149)	(54,927)
Other income (expense), net				
Interest income	278	672	1,252	1,136
Other expense	(4)	(10)	(39)	(20)
Total other income, net	274	662	1,213	1,116
Net loss	(18,980)	(18,391)	(61,936)	(53,811)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(6,371)
Net loss attributable to common stockholders	$ (18,980)	$ (18,391)	$ (61,936)	$ (60,182)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.68)	$ (0.67)	$ (2.23)	$ (5.55)
Weighted average common shares outstanding, basic and diluted	27,935	27,358	27,792	10,834

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