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 13, 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))

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. ☒

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

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2019, Neon Therapeutics, Inc., issued a press release announcing its financial results for the quarter ended March 31, 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 May 13, 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: May 13, 2019

By: /s/ Yasir B. Al-Wakeel

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

Chief Financial Officer

Exhibit 99.1

Neon Therapeutics Reports First Quarter 2019 Financial Results and Provides Clinical Update

Advancing a class-leading position in neoantigen-based therapies with ongoing progress across its multiple clinical-stage programs, pre-clinical pipeline and bioinformatics engine

Expect to report in July top-line clinical results, including 12-month follow-up, from NT-001 trial of personal neoantigen vaccine NEO-PV-01 in metastatic melanoma, non-small cell lung and bladder cancers

Completed enrollment in NT-002 trial of NEO-PV-01, in combination with standard of care, in first-line metastatic non-small cell lung cancer, with data expected in 2020

Continued pipeline progress with near-term expected submissions of clinical trial applications for personal T cell therapy program, NEO-PTC-01 and off-the-shelf neoantigen vaccine, NEO-SV-01

Cambridge, Mass. — **May 13, 2019** — Neon Therapeutics, Inc. (Nasdaq: NTGN), a clinical-stage immuno-oncology company developing neoantigen-based therapeutics, today reported financial results for the first quarter ended March 31, 2019 and provided a business update.

"The field of cancer immunotherapy has advanced considerably in recent years, but there remains a significant need for new approaches that could extend the benefits of immunotherapy and lead to improved patient outcomes. Neoantigen-based therapies hold the promise to transform the treatment of cancer and we are proud of our leadership in pursuing these untapped targets," said Hugh O'Dowd, Neon's Chief Executive Officer. "We continue to make important progress across the Company, including our efforts to establish RECON® as the best-in-class neoantigen bioinformatic prediction engine with our machine learning and proteomics expertise. We intend to further strengthen our position as a class-leader in neoantigen selection by continuing to leverage proprietary immunogenicity data from our ongoing clinical studies. We remain excited about numerous upcoming clinical milestones, including the top-line results from our NT-001 study of NEO-PV-01, which we expect to be the first clinical dataset ever reported with 12-month follow-up for a personal neoantigen vaccine in metastatic melanoma, non-small cell lung and bladder cancers."

Pipeline Updates

Neon is developing neoantigen-targeting therapies across multiple treatment modalities, including vaccines, adoptive T cell therapies and TCR-based T cell therapies to bring benefit to a broad set of patients across tumor types and stages of disease. This approach requires effectively identifying and selecting the optimal neoantigen targets for the unique mutational fingerprint of each individual patient's tumor. Neon is pioneering a proprietary neoantigen platform to identify and harness the most therapeutically relevant neoantigens, including through its RECON bioinformatic neoantigen prediction engine, deep capabilities in peptide chemistry and manufacturing, and NEO-STIM™ T cell biology and immune-monitoring expertise.

Neon is using two distinct neoantigen therapeutic approaches across this platform: personal therapies that target individualized mutations (NEON / ONE), and off-the-shelf precision therapies (NEON / SELECT) that target shared mutations present in sub-populations of cancer patients.

"Neon is pursuing novel therapeutic approaches at the frontiers of immuno-oncology. We designed our R&D strategy to enable us to determine how our neoantigen-targeted platform and product candidates could improve patient outcomes beyond the limitations of current standard of care treatment. Our near-term R&D strategy is focused on leveraging Phase 1b clinical trials to determine the optimal patient selection, rational combinations and trial designs to inform subsequent Phase 2 and later stage clinical trials," said Richard Gaynor, M.D., Neon's President of Research and Development.

NEON / ONE is Neon's personal medicine approach to neoantigen-targeted therapies that are tailored for the individual profile of each patient's tumor. Neon's initial clinical strategy has focused on solid tumor indications where checkpoint inhibitors have been approved, either in combination or in refractory settings.

- **NEO-PV-01: Personal Neoantigen Vaccine**
  - NEO-PV-01: Neon is evaluating its lead product candidate, a personal neoantigen vaccine, in a variety of treatment settings in Phase 1b development to determine the optimal late-stage clinical trials.
  - NT-001 Trial: Neon's ongoing Phase 1b open-label clinical trial is evaluating a combination of NEO-PV-01 with OPDIVO® (nivolumab) in patients with metastatic melanoma, non-small cell lung cancer (NSCLC) or bladder cancer.
    - Neon recently presented updated data from NT-001 at the American Association for Cancer Research (AACR) Annual Meeting, describing the immune and pathologic markers associated with study subjects remaining progression-free at nine months. The analysis both confirmed the mechanism of action of NEO-PV-01 and highlighted new data on the association between histology and epitope spread in patients who had not progressed at nine months in the melanoma cohort. In addition, multiple molecular markers were determined to correlate with lack of clinical progression, which may prove useful for patient selection in late-stage clinical trials.
    - Neon expects to report top-line clinical results, including 12-month follow-up, from NT-001 in July 2019. The results are expected to include data from an intention-to-treat (ITT) analysis from 82 enrolled patients, including median progression-free survival (PFS) and objective response rates (ORR), safety and baseline patient characteristics in each of the three tumor cohorts.
  - NT-002 Trial: Neon recently completed enrollment in NT-002, its Phase 1b clinical trial evaluating NEO-PV-01 in combination with the current standard of care, KEYTRUDA® (pembrolizumab) and chemotherapy, in first-line patients with untreated advanced or metastatic NSCLC. This trial is evaluating the safety, tolerability and efficacy of NEO-PV-01 in the metastatic setting. Neon expects to report immune monitoring and clinical outcome data from this trial by the end of Q3 2020.
  - NT-003 Trial: This Phase 1b clinical trial of NEO-PV-01 in metastatic melanoma combinations is currently enrolling. NT-003 will evaluate NEO-PV-01 and OPDIVO in combination with other agents, including Apexigen's CD40 agonist (APX005M) or a CTLA-4 antagonist, to further enhance any NEO-PV-01-induced neoantigen immune response and improve clinical outcomes. This trial will also evaluate alternative NEO-PV-01 dosing schedules. Neon plans to announce immune monitoring data from this study in 2H 2020.
  - NT-004 Trial: Neon is planning to explore NEO-PV-01 in a monotherapy approach in an earlier disease setting in this Phase 1b trial.

- **NEO-PTC-01: Personal Neoantigen T cell Therapy**
  - NEO-PTC-01: Neon's personal adoptive T cell therapy consists of multiple T cell populations targeting neoantigens that are predicted to be the most therapeutically relevant from each patient's tumor. NEO-PTC-01 uses T cells from the periphery of each patient that are then primed, activated and expanded to generate a therapy that specifically targets that patient's personal neoantigens, with the potential to drive a robust and persistent anti-tumor response.
  - CTA Filing: Building on success to date in generating both memory and de novo immune responses, Neon is completing process development, which supports its plan to file a Clinical Trial Application (CTA) in Europe in the second half of 2019 to evaluate NEO-PTC-01 in refractory solid tumor settings. This work is being performed in collaboration with the Netherlands Cancer Institute (NKI), a leading academic research and treatment center with expertise in T cell biology and treatments.

NEON / SELECT is Neon's off-the-shelf precision approach to neoantigen-targeted therapies that seek to target prevalent neoantigens that are shared across subsets of patients or tumor types.

- **NEO-SV-01: Breast Neoantigen Vaccine**
  - NEO-SV-01: Neon is planning to develop its off-the-shelf neoantigen vaccine for the treatment of a genetically-defined subset of hormone receptor-positive (HR+) breast cancer, potentially across disease stages in combination with hormonal, chemotherapy or targeted therapies.
  - IND Filing: Following the completion of target validation and preclinical product development work, Neon expects to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration for a Phase 1b clinical trial of NEO-SV-01 in Q2 2019.

- **TCR-based T cell Therapies**
  - TCRs: Neon continues to advance its precision T cell approach and has assembled libraries of high-quality T-cell receptors (TCRs) against various shared neoantigens. Neon is leveraging its proprietary NEO-STIM

induction protocol to rapidly generate T cells specific to these targets where multiple TCRs can be sequenced and characterized.

Expected Milestones

Clinical Trial Results:

- NEO-PV-01: Top-line clinical results, including 12-month follow-up, from NT-001 Phase 1b trial in metastatic melanoma, NSCLC and bladder cancers (July 2019)
- NEO-PV-01: Clinical results and correlative immune data from NT-001 Phase 1b trial planned for presentation at a medical congress (2H 2019)
- NEO-PV-01: Clinical results and correlative immune data, including 12-month follow-up, from NT-002 Phase 1b trial in first-line metastatic NSCLC (Q3 2020)
- NEO-PV-01: Immune data from NT-003 Phase 1b trial in metastatic melanoma combinations (2H 2020)

Clinical Trial Applications/Initiations:

- NEO-SV-01: U.S. IND filing to evaluate NEO-SV-01 in a genetically defined subset of HR+ breast cancer (Q2 2019)
- NEO-PTC-01: European CTA filing to evaluate NEO-PTC-01 in a refractory solid tumor setting (2H 2019)

First Quarter 2019 Financial Results and Financial Guidance:

- R&D Expenses: Research and development expenses were $16.2 million for the first quarter of 2019, compared to $13.2 million for the same period last year. The increase was primarily due to costs related to research and development of NEO-PV-01, NEO-PTC-01 and NEO-SV-01, as well as investments in R&D headcount to support the advancement of Neon's pipeline.
- G&A Expenses: General and administrative expenses were $5.4 million for the first quarter of 2019, compared to $3.6 million for the same period last year. The increase was primarily due to personnel-related expenses, professional fees to support expanding operations and costs associated with being a public company.
- Net Loss: Net loss attributable to common stockholders was $21.0 million for the first quarter of 2019, compared to $19.7 million for the same period last year.
- Cash Position: As of March 31, 2019, cash, cash equivalents and marketable securities were $81.3 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, cash equivalents and marketable securities will enable the Company to fund its anticipated operating expenses and capital expenditure requirements into at least Q2 2020.

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 **www.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 preclinical studies and 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; the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials; our

ability to replicate results achieved in our preclinical studies or clinical trials in any future studies or trials; regulatory developments in the United States and foreign countries; our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; and our expectations regarding our uses of capital, expenses, future accumulated deficit and other financial results. 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 will 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; 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 Annual Report on Form 10-K, 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)

	March 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 81,264	$ 103,311
Working capital [1]	$ 72,154	$ 92,737
Total assets	$ 101,040	$ 114,088
Total stockholders' equity	$ 82,071	$ 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 March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 16,172	$ 13,158
General and administrative	5,408	3,599
Total operating expenses	21,580	16,757
Loss from operations	(21,580)	(16,757)
Other income (expense), net		
Interest income	556	247
Other expense	—	(10)
Total other income, net	556	237
Net loss	(21,024)	(16,520)
Accretion of redeemable convertible preferred stock to redemption value	—	(3,186)
Net loss attributable to common stockholders	$ (21,024)	$ (19,706)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.76)	$ (9.47)
Weighted average common shares outstanding, basic and diluted	27,651	2,081

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