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 6, 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 August 6, 2019, Neon Therapeutics, Inc., issued a press release announcing its financial results for the quarter ended June 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 August 6, 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: August 6, 2019

By: /s/ Yasir B. Al-Wakeel

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

Chief Financial Officer

Exhibit 99.1

Neon Therapeutics Reports Second Quarter 2019 Financial Results

Planning to present more detailed data from NT-001 clinical trial evaluating NEO-PV-01 in advanced or metastatic melanoma, non-small cell lung and bladder cancers at an upcoming medical society meeting

Announces U.S. Food & Drug Administration (FDA) clearance of Neon's Investigational New Drug (IND) application for off-the-shelf candidate, NEO-SV-01, for a genetically-defined subset of hormone receptor-positive breast cancer

Planning to file a Clinical Trial Application (CTA) in Europe in the second half of 2019 to evaluate personal neoantigen T cell therapy candidate, NEO-PTC-01, in refractory solid tumor settings

Cambridge, Mass. - August 6, 2019 - Neon Therapeutics, Inc. (Nasdaq: NTGN), a clinical-stage immuno-oncology company developing neoantigen-based therapeutics, today reported financial results for the second quarter ended June 30, 2019 and provided a business update.

"We continue to make important progress across Neon's programs as we continue to advance our leadership in the field of neoantigen-bases therapies. In recent months, we made important steps forward, including the release of the top-line data from our NT-001 trial of NEO-PV-01 that demonstrated consistent prolongation of progression-free survival across all three tumor types compared with historical checkpoint inhibitor monotherapy studies. We are also proud that the FDA recently cleared the IND for our off-the-shelf neoantigen vaccine candidate, NEO-SV-01," said Hugh O'Dowd, Neon's Chief Executive Officer. "In the months ahead, we look forward to presenting detailed data from our NT-001 trial at a fall medical society meeting, including potential immune correlates and biomarker-selection strategies that could guide Phase 2 development, and also to completing process development work that will enable our planned CTA filing in Europe for our personal neoantigen T cell therapy candidate, NEO-PTC-01."

Pipeline Updates

Neon is developing neoantigen-targeting therapies across multiple treatment modalities, including both personal and precision vaccine and T cell therapy candidates.

- **NEO-PV-01:** Neon's investigational personal neoantigen vaccine, NEO-PV-01, is custom-designed and manufactured based on the unique mutational fingerprint of each individual patient. NEO-PV-01 is being studied in multiple ongoing Phase 1b clinical trials.
  - NT-001 Trial: Neon's ongoing, multicenter Phase 1b clinical is evaluating a combination of NEO-PV-01 with OPDIVO® (nivolumab) in patients with metastatic melanoma, smoking-associated non-small cell lung cancer (NSCLC) or bladder cancer.
    - In July, Neon announced top-line results from 82 patients in the NT-001 trial, with at least 12-month median follow-up in each of the three cohorts.
    - Across all three distinct tumor types, the results demonstrated prolonged and consistent improvements in progression-free survival (PFS) that compare favorably to those observed with checkpoint inhibitor monotherapy, based on historical benchmark data. At 13.4-month median follow-up in 34 patients with metastatic melanoma, the median PFS had not yet been reached; in 27 patients with metastatic NSCLC, median PFS was 5.6 months; and in 21 patients with metastatic bladder cancer, median PFS was 5.6 months.
    - No serious adverse events were observed that were related to the NEO-PV-01/OPDIVO combination. Low grade adverse events attributable to the NEO-PV-01/OPDIVO combination included injection site reactions, fatigue and influenza-like illness.
    - These top-line data, which come from the 82 patients in the Intention-to-Treat population who received at least one dose of OPDIVO in the Phase 1b NT-001 trial, support further development of NEO-PV-01, including randomized Phase 2 trials of NEO-PV-01 in metastatic disease settings.

        - Neon plans to present more detailed data from its NT-001 clinical trial at an upcoming medical society meeting.
    - NT-002 Trial: In April, Neon 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 the second half of 2020.

- **NEO-PTC-01:** Neon's personal adoptive T cell therapy candidate 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 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.

- **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 Clearance: Neon today announced that the U.S. Food & Drug Administration (FDA) has cleared Neon's IND application for NEO-SV-01.

Expected Milestones

- 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-PTC-01: Planned European CTA filing to evaluate NEO-PTC-01 in a refractory solid tumor setting (2H 2019)
- 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)
- NEO-PTC-01: Planned Phase 1 initiation in a refractory solid tumor setting (Q2 or Q3 2020)
- NEO-PV-01: Planned immune data from NT-003 Phase 1b trial in metastatic melanoma combinations (2H 2020)
- NEO-PV-01: Planned Phase 2 initiation of randomized clinical trial in first-line metastatic melanoma (2020)

Second Quarter 2019 Financial Results and Financial Guidance:

- R&D Expenses: Research and development expenses were $16.7 million for the second quarter of 2019, compared to $14.8 million for the same period last year. The increase was primarily due to costs related to continued 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 $5.6 million for the second quarter of 2019, compared to $4.3 million for the same period last year. The increase was primarily due to personnel-related costs, expenses associated with intellectual property protection and costs associated with being a public company.
- Net Loss: Net loss was $21.9 million for the second quarter of 2019, compared to $18.9 million for the same period last year.
- Cash Position: As of June 30, 2019, cash, cash equivalents and marketable securities were $61.0 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 June 2020.

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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-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)

	June 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 60,999	$ 103,311
Working capital [1]	$ 52,722	$ 92,737
Total assets	$ 79,682	$ 114,088
Total stockholders' equity	$ 62,206	$ 101,249

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 16,735	$ 14,804	$ 32,907	$ 27,962
General and administrative	5,580	4,313	10,988	7,912
Total operating expenses	22,315	19,117	43,895	35,874
Loss from operations	(22,315)	(19,117)	(43,895)	(35,874)
Other income (expense), net				
Interest income	418	218	974	464
Other expense	(35)	—	(35)	(10)
Total other income, net	383	218	939	454
Net loss	(21,932)	(18,899)	(42,956)	(35,420)
Accretion of redeemable convertible preferred stock to redemption value	—	(3,185)	—	(6,371)
Net loss attributable to common stockholders	$ (21,932)	$ (22,084)	$ (42,956)	$ (41,791)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.79)	$ (7.84)	$ (1.55)	$ (17.05)
Weighted average common shares outstanding, basic and diluted	27,787	2,816	27,720	2,450

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