Neon Therapeutics Logo

Neon Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Business Update

March 11, 2019

CAMBRIDGE, Mass., March 11, 2019 (GLOBE NEWSWIRE) -- Neon Therapeutics, Inc. (Nasdaq: NTGN), a clinical-stage immuno-oncology company developing neoantigen-based therapeutics, today reported financial results for the fourth quarter and full-year ended December 31, 2018 and provided a business update.

“2018 was a transformative year for Neon, highlighted by significant advances in applying our insights into neoantigen biology not only to our vaccine product candidates but also to our emerging cellular therapies. Our initial public offering in June provided us with capital to advance these important programs, which have the potential to truly change the paradigm for immunotherapy by enabling more targeted treatment,” said Hugh O’Dowd, Neon’s Chief Executive Officer. “As we move into 2019, we are excited about the opportunities ahead to share data from our ongoing clinical trials of our personal neoantigen vaccine NEO-PV-01. We are also making progress to advance our personal T cell therapy program, NEO-PTC-01, into the clinic. We have adjusted timelines to enable the release of more mature data from our NT-002 study and to complete the scale-up process for our NEO-PTC-01 program.”

“With regard to NEO-PV-01, we have been closely tracking multiple metrics of patients’ immune response following dosing with the vaccine, and we are looking forward to presenting a correlative analysis from our NT-001 trial with data from more than a dozen patients at the American Association for Cancer Research (AACR) Annual Meeting. Later this year, we will present the more mature 52-week data set, which will include additional patients followed for a full year, a time frame that allows us to further evaluate not only their immune responses but also clinical outcomes, including progression free-survival,” said Richard Gaynor, M.D., Neon’s President of Research and Development.

“We have also made important developments in our NEO-PTC-01 program, including the evaluation of additional patient sample materials, which builds upon data presented at the Society for Immunotherapy of Cancer’s 33rd Annual Meeting last year. The additional evaluation of both melanoma and non-small cell lung cancer patient materials confirm that NEO-STIM™, our proprietary ex vivo co-culture process using peripheral blood mononuclear cells, can reliably and reproducibly generate multiple enriched neoantigen-specific T cell populations. These findings, now replicated across multiple patient samples, support the feasibility of advancing this program into the clinic.

“Finally, we have meaningfully advanced the science behind our precision medicine approaches, which target mutations shared across patient populations known as shared neoantigens. We are leveraging our NEO-STIM induction protocol to rapidly generate T cells specific to these targets where multiple T cell receptors, or TCRs, can be sequenced and characterized. Importantly, since we can derive these TCRs from the natural repertoire of healthy donors, our TCRs show cytotoxic functionality and strong specificity for mutant targets without engineering or modification. Due to our focused efforts in this area, we now have libraries of these high-quality TCRs,” concluded Dr. Gaynor.

Fourth Quarter Business Highlights

- In April 2019, Neon will present data relating to both its personal neoantigen vaccine, NEO-PV-01, and its personal neoantigen T cell therapy, NEO-PTC-01, at the AACR Annual Meeting taking place in Atlanta, GA. Data from the NEO-PV-01 program will include a correlative analysis from the melanoma cohort in NT-001, a clinical trial exploring the feasibility, safety, efficacy and immunogenicity of NEO-PV-01 dosed in combination with nivolumab in patients with advanced or metastatic melanoma, non-small cell lung cancer and bladder cancer. In addition, data from the NEO-PTC-01 program will include a detailed analysis of immune responses induced against patient-specific neoantigens using its ex vivo induction protocol, NEO-STIM.

- In December 2018, Neon announced that patient dosing had commenced in NT-003, a Phase 1b combination trial of NEO-PV-01 in metastatic melanoma. This Phase 1b trial is evaluating NEO-PV-01 and nivolumab in combination with other agents, including Apexigen's APX005M, an investigational CD40 agonist, or in combination with ipilimumab, to enhance vaccine-induced neoantigen immune responses.

- In November 2018, the Company presented results related to its personal T cell product, NEO-PTC-01, at SITC. Data from two melanoma patients were presented that showed that NEO-STIM can prime, activate and expand neoantigen-specific $CD8^+$ and $CD4^+$ T cell responses from peripheral blood mononuclear cells. Responses were shown to be mutant-specific, polyfunctional and capable of killing antigen expressing tumor targets. Since this presentation, Neon has obtained data from additional samples from cancer patients.

- In November 2018, Neon was named one of the top places to work in Massachusetts by *The Boston Globe*, an honor awarded based on employee feedback. The Top Places to Work awards recognize the most admired workplaces in the state as voted on by the employees of those companies. The annual survey, now in its eleventh year, measures employee opinions about their company’s direction, management, culture, pay and benefits and engagement with employees, among other factors.

Pipeline Overview and Upcoming Milestones

NEO-PV-01

- NT-001: Phase 1b Clinical Trial of NEO-PV-01 in the Metastatic Setting
  - Neon will present updated correlative data from its NT-001 trial at the AACR Annual Meeting.
  - Full 52-week data, including clinical outcomes, will be presented later in the first half of 2019.

- NT-002: Phase 1b Clinical Trial of NEO-PV-01 in Metastatic Non-Small Cell Lung Cancer
  - Neon now expects to report immune and clinical data over the course of 2020.

- NT-003: Phase 1b Clinical Trial of NEO-PV-01 in Metastatic Melanoma Combinations
  - Neon expects to report immune monitoring data in the first half of 2020.

- NT-004: Phase 1b Clinical Trial of NEO-PV-01 in Earlier Disease Setting
  - Planning ongoing.

NEO-PTC-01

- Neon will present a detailed analysis of immune responses induced against patient-specific neoantigens using its ex vivo induction protocol, NEO-STIM, at the AACR Annual Meeting.

- Building on our success to date in generating both memory and *de novo* immune responses, Neon is in the process of completing large scale process development, which supports its plan to file a Clinical Trial Application in Europe in the second half of 2019 for the first clinical trial of this cell therapy.

- This work is being performed in collaboration with the Netherlands Cancer Institute (NKI), an academic research and treatment center with leading expertise in T cell biology and treatments.

NEO-SV-01

- Phase 1 Clinical Trial in Subset of ER+ Breast Cancer: Following the completion of target validation and preclinical product development work, Neon expects to submit an Investigational New Drug application to the U.S. Food and Drug Administration in the first half of 2019.

Fourth Quarter and Full Year 2018 Financial Results:

- **Cash Position:** As of December 31, 2018, cash, cash equivalents and marketable securities were $103.3 million, as compared to cash, cash equivalents and marketable securities of $79.7 million as of December 31, 2017.

- **R&D Expenses:** R&D expenses were $18.0 million for the fourth quarter of 2018 and $60.4 million for the year ended December 31, 2018, as compared to $10.9 million for the fourth quarter of 2017 and $37.2 million for the year ended December 31, 2017. The increase for both fourth quarter and full year 2018 was primarily driven by increased costs related to the advancement of NEO-PV-01, as well as higher personnel costs.

- **G&A Expenses:** G&A expenses were $5.8 million for the fourth quarter of 2018 and $18.3 million for the year ended December 31, 2018, as compared to $3.7 million for the fourth quarter of 2017 and $10.9 million for the year ended December 31, 2017. The increase for both fourth quarter and full year 2018 was primarily driven by increased costs of being a public company, including professional fees and personnel costs, as well as other general and administrative costs to support Neon's overall growth.

- **Net Loss Attributable to Common Stockholders:** Net loss was $23.1 million for the fourth quarter of 2018 and $83.3 million for the year ended December 31, 2018, or a net loss per basic and diluted share of $(0.84) and $(5.54), respectively, as compared to a net loss of $17.4 million for the fourth quarter of 2017 and $57.9 million for the year ended December 31, 2017, or a net loss per basic and diluted share of $(8.93) and $(34.32), respectively.

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 the second quarter of 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 estrogen-receptor-positive 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 and related regulatory submissions; the potential timing 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 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)

	December 31, 2018	December 31, 2017
Cash, cash equivalents and marketable securities	$ 103,311	$ 79,725
Working capital [(1)]	$ 92,737	$ 72,539
Total assets	$ 114,088	$ 90,493
Redeemable convertible preferred stock & contingently redeemable restricted common stock	$ —	$ 175,250
Total stockholders' equity (deficit)	$ 101,249	$ (93,572)

(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 December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 18,022	$ 10,921	$ 60,425	$ 37,195
General and administrative	5,752	3,712	18,276	10,892
Total operating expenses	23,774	14,633	78,701	48,087
Loss from operations	(23,774)	(14,633)	(78,701)	(48,087)
Other income (expense), net				
Interest income	656	175	1,792	569
Other expense	(5)	(18)	(25)	(18)
Total other income, net	651	157	1,767	551
Net loss	(23,123)	(14,476)	(76,934)	(47,536)
Accretion of redeemable convertible preferred stock to redemption value	—	(2,887)	(6,371)	(10,396)
Net loss attributable to common stockholders	$ (23,123)	$ (17,363)	$ (83,305)	$ (57,932)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.84)	$ (8.93)	$ (5.54)	$ (34.32)
Weighted average common shares outstanding, basic and diluted	27,507	1,944	15,036	1,688

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