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): April 3, 2018

ELEVEN BIOTHERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36296**	**26-2025616**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

245 First Street, Suite 1800 **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 444-8550

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. ☒

Item 8.01 – Other Events.

On April 3, 2018, Eleven Biotherapeutics, Inc. (the "Company") issued a press release announcing that preliminary efficacy and safety data from the Company's ongoing Phase 3 VISTA trial of Vicinium™ in patients with non-muscle invasive bladder cancer who have been previously treated with bacillus Calmette-Guérin have been selected for presentation during a plenary session at the American Urological Association Annual Meeting. The plenary session is currently scheduled for May 21, 2018 at 11:00 a.m. PT.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated April 3, 2018, issued by Eleven Biotherapeutics, Inc.

SIGNATURE

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.

Date: April 5, 2018

Eleven Biotherapeutics, Inc.

By: /s/ Richard F. Fitzgerald

Richard F. Fitzgerald

Chief Financial Officer, Secretary and Treasurer

Preliminary Data from Phase 3 VISTA Trial in Bladder Cancer to be Presented in a Plenary Session at American Urological Association Annual Meeting

Eleven Biotherapeutics to Host Conference Call in Conjunction with Data Presentation in May

CAMBRIDGE, Mass., April 3, 2018 – Eleven Biotherapeutics, Inc. (NASDAQ: EBIO), a late-stage clinical company developing next-generation antibody-drug conjugate (ADC) therapies for the treatment of cancer, today announced that preliminary efficacy and safety data from its ongoing Phase 3 VISTA trial of Vicinium™ in patients with non-muscle invasive bladder cancer (NMIBC) who have been previously treated with bacillus Calmette-Guérin (BCG) have been selected for presentation during a plenary session currently scheduled for Monday, May 21, 2018 at 11:00 a.m. PT at the American Urological Association Annual Meeting taking place in San Francisco. Vicinium is a fusion protein, designed to be a next-generation ADC, that targets the epithelial cell adhesion molecule (EpCAM) antigens on the surface of bladder cancer cells to deliver a potent cytotoxin into those cells.

Data, as reported in the abstract published online today, are from a subgroup of the first 75 evaluable carcinoma in situ patients. Within these patients, preliminary findings show that greater than 95 percent expressed EpCAM on the surface of tumor cells, the target of Vicinium. Efficacy data as measured by complete response rates at three-months will be reported during the plenary session. Vicinium has been well-tolerated. Treatment-related adverse events (AEs) were reported in 46 percent of patients, the majority of which were Grade 1 or 2. The most common of these were dysuria (12%), UTI or pollakiuria (10%) and hematuria (7%), which are often associated with catheter-delivered treatments into the bladder and bladder cancer itself. As of the December 2017 data cut off, three treatment-related serious AEs were reported, including renal failure (CTCAE Grade 5) with cholestatic hepatitis (Grade 4) in one patient and acute kidney injury (Grade 3) in a second patient who recovered.

In March 2018, recruitment was completed in the VISTA trial, a single-arm registration study designed in accordance with U.S. Food and Drug Administration's final guidance for developing treatments for BCG-unresponsive NMIBC.

"When treatment with today's standard of care, BCG, is no longer an option, the next treatment option is typically removal of the patient's bladder, a challenging, life-altering procedure that many patients elect not to undergo," said Stephen Hurly, president and chief executive officer of Eleven Biotherapeutics. "Vicinium has demonstrated that it is a well-tolerated and active agent in patients with BCG unresponsive NMIBC in studies to-date. We are excited to be presenting the first preliminary data from our Phase 3 VISTA trial of Vicinium for patients with NMIBC at this year's AUA meeting. During our plenary presentation, we will share initial efficacy findings and data supporting the favorable safety we have observed so far with Vicinium. We believe

Vicinium holds tremendous potential as a treatment for bladder cancer, and we look forward to sharing these and additional data later in the year."

The company plans to host a conference call in conjunction with the data presentation, with details to follow.

About the VISTA Clinical Trial
The VISTA trial is an open-label, multicenter, single-arm Phase 3 clinical trial evaluating the efficacy and tolerability of Vicinium™ in patients with high-risk non-muscle invasive bladder cancer (NMIBC) that is carcinoma in situ (CIS, cancer found on the inner lining of the bladder that has not spread into muscle or other tissue) or papillary (cancer that has grown from the bladder lining out into the bladder but has not spread into muscle or other tissue), who have been previously treated with bacillus Calmette-Guérin (BCG). The primary endpoint of the trial is the complete response rate in patients with CIS with or without papillary disease and durability of that response. Patients in the study receive locally administered Vicinium twice a week for six weeks, followed by once-weekly treatment for another six weeks, then treatment every other week for up to two years. Topline data assessing responses and durability of responses at three-months on treatment are expected in mid-2018, with 12-month data anticipated in mid-2019.

About Vicinium™
Vicinium™, Eleven Biotherapeutics' lead product candidate, is a next-generation antibody-drug conjugate developed using the company's proprietary Targeted Protein Therapeutics platform. Vicinium is comprised of a recombinant fusion protein that targets epithelial cell adhesion molecule (EpCAM) antigens on the surface of tumor cells to deliver a potent protein payload, *Pseudomonas* Exotoxin A (ETA). Vicinium is constructed with a stable, genetically engineered linker to ensure the payload remains attached until it is internalized by the cancer cell, which is believed to decrease the risk of toxicity to healthy tissues, thereby improving its safety. In prior clinical studies conducted by Eleven Biotherapeutics, EpCAM has been shown to be overexpressed in non-muscle invasive bladder cancer (NMIBC) cells with minimal to no EpCAM expression observed on normal bladder cells. Eleven Biotherapeutics is currently conducting the Phase 3 VISTA trial, designed to support the registration of Vicinium for the treatment of NMIBC in patients who have previously received two courses of bacillus Calmette-Guérin (BCG) and whose disease is now BCG-unresponsive. Topline, three-month data from the trial are expected in mid-2018. Additionally, Eleven Biotherapeutics believes that Vicinium's cancer cell-killing properties promote an anti-tumor immune response that may potentially combine well with immuno-oncology drugs, such as checkpoint inhibitors. The activity of Vicinium in BCG-unresponsive NMIBC is also being explored at the US National Cancer Institute in combination with AstraZeneca's immune checkpoint inhibitor durvalumab.
About Eleven Biotherapeutics
Eleven Biotherapeutics, Inc. is a late-stage clinical company advancing next-generation antibody-drug conjugate therapies for the treatment of cancer based on the company's Targeted Protein Therapeutics platform. The company's lead program, Vicinium™, is currently in a Phase 3 registration trial for the treatment of non-muscle invasive bladder cancer, with topline data expected in mid-2018. Vicinium incorporates a tumor-targeting antibody fragment and a protein

cytotoxic payload into a single protein molecule designed to selectively and effectively kill cancer cells while sparing healthy cells. For more information, please visit the company's website at www.elevenbio.com.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and conduct of clinical trials, our ability to successfully develop our product candidates and complete our planned clinical programs, our ability to obtain marketing approvals for our product candidates, expectations regarding our ongoing clinical trials, availability and timing of data from clinical trials, whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical studies will be indicative of the results of future studies, the adequacy of any clinical models, expectations regarding regulatory approvals and other factors discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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