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 2, 2018**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36193	**26-1469215**
(Commission File No.)	(IRS Employer Identification No.)

955 Chesterbrook Boulevard, Suite 110
Chesterbrook, PA 19087
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(610) 354-8840**

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 November 2, 2018, the Company issued a press release announcing that the U.S. Food and Drug Administration has issued a complete response letter with respect to the Company's New Drug Application for oliceridine. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press Release dated November 2, 2018

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated November 2, 2018

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.

TREVENA, INC.

Date: November 2, 2018

By: /s/ John M. Limongelli
John M. Limongelli
Sr. Vice President, General Counsel & Chief Administrative Officer

Exhibit 99.1

Trevena Receives Complete Response Letter for Oliceridine from FDA

— Company to host conference call and webcast on November 5th —

CHESTERBROOK, PA, November 2, 2018 — Trevena, Inc. (NASDAQ: TRVN) today announced the Company has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for oliceridine.

"While we are disappointed with FDA's decision, we continue to believe in the strength of the data and the ultimate approvability of oliceridine," said Carrie L. Bourdow, President and Chief Executive Officer. "We plan to schedule a follow-up meeting with FDA as soon as possible with the goal of bringing this important medicine to clinicians and hospital patients."

Consistent with the discussion at the recent Advisory Committee meeting, FDA has requested additional clinical data on QT prolongation and indicated that the submitted safety database is not of adequate size for the proposed dosing. FDA also requested certain additional nonclinical data and validation reports.

"Developing a novel chemical entity is complex, and we believe the data we have to support oliceridine advances the pharmacology of acute pain therapeutics," said Mark A. Demitrack, M.D., SVP and Chief Medical Officer. "We were encouraged by the discussion at the Advisory Committee meeting and look forward to continuing a productive dialogue with FDA."

A conference call and webcast will be held on November 5th at 8:00 AM ET. To join the call, please dial in at (855) 465-0180 (conference ID: 5489646).

To join a live audio webcast of the call, please visit the Investor Presentation section of the Company's website (conference ID: 5489646). Following the conclusion of the call, the webcast will be available for replay for 30 days.

About Oliceridine

Oliceridine is a G-protein biased mu-opioid receptor (MOR) ligand in development for the management of moderate to severe acute pain in hospitals or other controlled clinical settings where intravenous (IV) therapy is warranted. It is a new chemical entity with a novel mechanism of action that enables more selective targeting of newly discovered pathways with the potential for fewer side effects. Oliceridine is an investigational product and has not been approved by the FDA or any other regulatory agency. If approved, the Company has requested that oliceridine be classified as a Schedule II controlled substance.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of new and innovative treatment options for patients in pain. The Company has discovered three novel and differentiated drug candidates using its proprietary platform, including intravenous (IV) oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the treatment of acute migraine, and TRV734 for pain and/or management of opioid dependence. In its preclinical programs, Trevena is evaluating a set of novel S1P modulators that may offer a new, non-narcotic approach to managing chronic pain.

Cautionary note on forward looking statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of its therapeutic candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "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 status, timing, costs, results and interpretation of the Company's clinical trials or any future trials, including with respect to the strength of data and the ultimate approvability of oliceridine the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including plans for an timing of future meetings with FDA; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties related to the Company's intellectual property; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates; and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments may 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, it specifically disclaims any obligation to do so, except as may be required by law.

Contacts

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