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): **October 11, 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 October 11, 2018, Trevena, Inc. (the "Company") issued a press release announcing the outcome of the meeting of the U.S. Food and Drug Administration Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) to review and discuss the Company's lead investigational product, 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 October 11, 2018

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated October 11, 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: October 12, 2018

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

Exhibit 99.1

Trevena Announces Oliceridine FDA Advisory Committee Meeting Outcome

CHESTERBROOK, PA, October 11, 2018 — Trevena, Inc. (NASDAQ: TRVN), today announced the outcome of the meeting of the U.S. Food and Drug Administration (FDA) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) to review and discuss oliceridine. At the meeting, the Advisory Committee voted 8 against, and 7 in favor of, the approval of oliceridine for the management of moderate to severe acute pain in adult patients for whom an intravenous (IV) opioid is warranted.

"We continue to believe that the totality of evidence presented and discussed today supports the utility of oliceridine as a new analgesic option for the management of moderate to severe acute pain for patients in hospitals or other controlled clinical settings," said Carrie L. Bourdow, President and Chief Executive Officer. "Trevena is committed to working closely with the FDA as they complete their review of the NDA for oliceridine."

The Advisory Committee reviewed data from oliceridine's full clinical development program with a focus on the Phase 3 APOLLO 1 and APOLLO 2 efficacy studies, as well as the Phase 3 ATHENA open-label safety study that was intended to emulate real world use of oliceridine in a broad spectrum of surgical and medical acute pain conditions. In controlled clinical trials, oliceridine demonstrated efficacy compared to placebo along with a safety and tolerability profile consistent with the class.

Trevena's New Drug Application (NDA) submission for oliceridine was accepted for review by the FDA on January 2, 2018 with a Prescription Drug User Fee Act (PDUFA) target date for completion of review by the FDA of November 2, 2018. The FDA is not bound by the Advisory Committee's recommendations but takes its advice into consideration when making its decision.

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 and 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 results of the Company’s controlled clinical trials versus placebo and suggest that oliceridine may be effective and generally well-tolerated for patients with acute pain who require the use of IV opioids; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including with respect to the oliceridine NDA and the impact, if any, of the Advisory Committee recommendation on the FDA’s decision regarding the NDA; 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.

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