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): **January 28, 2019**

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 2.02. Results of Operations and Financial Condition.

The information under this caption and contained in the press release attached hereto as Exhibit 99.1 is furnished by Trevena, Inc. (the "Company") in accordance with Securities Exchange Commission Release No. 33-8216. This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date of this Current Report, except as shall be expressly set forth by specific reference in such a filing.

On January 28, 2019, the Company issued a press release that included the Company's preliminary estimate of cash, cash equivalents, and marketable securities as of December 31, 2018 of approximately $61.5 million. In March 2019, the Company expects to issue a press release with full financial results for the fourth quarter and full year ended December 31, 2018 and file with the U.S. Securities and Exchange Commission its Annual Report on Form 10-K for the fiscal year ended December 31, 2018. Based on its current estimates, the Company believes that its cash, cash equivalents, and marketable securities as of December 31, 2018 will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2020.

Cautionary Note on Forward Looking Statements

Any statements in Item 2.02 of this Current Report on Form 8-K regarding future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations (including the sufficiency of its cash, cash equivalents, and marketable securities to fund operations to a future date), 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: uncertainties related to the Company's intellectual property; the status, timing, costs, results and interpretation of the Company's clinical trials; the uncertainties inherent in conducting clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials results will be indicative of the results of future trials; expectations for regulatory approvals; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and whether cash, cash equivalents, and marketable securities as of December 31, 2018 will be sufficient to fund operating expenses and capital expenditure requirements into the second quarter of 2020; 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 Current Report on Form 8-K 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.

Item 8.01. Other Events

On January 28, 2019, the Company issued a press release announcing the receipt of the official Type A meeting minutes from the U.S. Food and Drug Administration (FDA) regarding the Complete Response Letter (CRL) received for the oliceridine New Drug Application (NDA). 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 January 28, 2019

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: January 28, 2019

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

Exhibit 99.1

Trevena Announces Receipt of Type A Meeting Minutes and Provides Regulatory Update for Oliceridine

— Company announces initial path forward on oliceridine NDA —

— Company to host conference call on Monday, January 28 at 8:30 a.m. ET —

CHESTERBROOK, PA, January 28, 2019 — Trevena, Inc. (NASDAQ: TRVN) today announced the receipt of the official Type A meeting minutes from the U.S. Food and Drug Administration (FDA) regarding the Complete Response Letter (CRL) received for the oliceridine New Drug Application (NDA).

FDA has agreed that the Company's current safety database will support labeling at a maximum daily dose of 27 mg.

FDA also has agreed that the Company can conduct a study in healthy volunteers to collect the requested QT interval data and that the study should include placebo- and positive-control arms. The Company intends to submit a detailed protocol and analysis plan to FDA shortly and, following receipt of FDA feedback, anticipates initiating this study in the first half of this year. The Company is not required to provide any additional efficacy data to resubmit the oliceridine NDA.

"We are encouraged by the productive discussion with FDA, which we believe has provided a path to resubmit the oliceridine NDA," said Carrie L. Bourdow, President and Chief Executive Officer. "We remain committed to our mission of ensuring access to safe and effective treatment options for hospital patients who require an IV opioid to manage their moderate to severe acute pain."

To address other items in the CRL, FDA has indicated that the Company should include supporting nonclinical data related to the characterization of the 9662 metabolite and the remaining product validation reports when the oliceridine NDA is resubmitted.

The Company also announced that it expects cash, cash equivalents, and marketable securities as of December 31, 2018 to be approximately $61.5 million, which the Company anticipates will be sufficient to fund operating expenses and capital expenditure requirements into the second quarter of 2020. In March 2019, the Company expects to announce full financial results for the fourth quarter and full year ended December 31, 2018.

Conference Call and Webcast

A conference call and webcast will be held on January 28, 2019 at 8:30 a.m. ET. To join the call, please dial in at (855) 465-0180 (conference ID: 3882155).

To join a live audio webcast of the call, please visit the Investor Presentation section of the Company's website. 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 three novel and differentiated investigational drug candidates, including 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 receptor modulators that may offer a new, non-opioid 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 any future clinical study of oliceridine; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including the Company's assessment of the discussions with FDA, whether there is a path to resubmit the oliceridine NDA, and the timing of any FDA review of the protocol for a future oliceridine study; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and whether cash, cash equivalents, and marketable securities as of December 31, 2018 will be sufficient to fund operating expenses and capital expenditure requirements into the second quarter of 2020; 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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