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): **March 5, 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 8.01. Other Events.

In February 2016, based on the preliminary evidence from Trevena's (the "Company") Phase 2 clinical studies of oliceridine, the U.S. Food and Drug Administration ("FDA") granted Breakthrough Therapy designation to oliceridine for the management of moderate to severe acute pain. Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious or life-threatening conditions and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. If granted, FDA regularly reviews the Breakthrough Therapy designation for a product candidate to ensure that any additional clinical evidence continues to support this designation. In March 2019, based on its review of data from the Company's Phase 3 studies of oliceridine, the FDA informed Trevena that under the conditions studied, these data were not sufficient to support the continuation of FDA's previously granted Breakthrough Therapy designation.

As announced in late January 2019, the Company received the Type A meeting minutes from FDA addressing the items identified in FDA's complete response letter (the "CRL") related to the oliceridine new drug application. In those minutes, FDA agreed that the Company's current safety database will support labeling at a maximum daily dose of 27 mg and indicated that the Company can conduct a study in healthy volunteers to collect the additional QT interval data requested in the CRL. Recently, the Company submitted a detailed protocol and analysis plan for this study to the FDA, and the Company continues to anticipate that it will initiate this study in the first half of 2019, following the receipt of feedback from the FDA. The Company does not expect the absence of Breakthrough Therapy designation to impact the timing of FDA's review of the oliceridine new drug application following resubmission.

Cautionary Note on Forward Looking Statements

Any statements in Item 8.01 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, 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, including with respect to the timing of the initiation of the healthy volunteer study; 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 interactions and approvals; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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.

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: March 7, 2019

By: /s/ John P. Hamill
John P. Hamill
Vice President, Finance