

**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 26, 2020**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36193
(Commission
File No.)

26-1469215
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	TRVN	The Nasdaq Stock Market LLC

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 March 26, 2020, Trevena, Inc. (the “Company”) announced that due to the global COVID-19 pandemic, enrollment has been paused in the proof-of-concept clinical trials for TRV250 (treatment of acute migraine) and TRV734 (opioid use disorder). The Company is withdrawing its previous guidance with respect to timing of top line data and will issue further information regarding these clinical trials as it becomes available. The Company also announced the U.S. Food and Drug Administration’s (the “FDA”) review of the resubmission of its NDA for oliceridine is ongoing and that the Company expects the FDA’s Prescription Drug User Fee Act goal date for the completion of the FDA’s review of the NDA to remain August 7, 2020.

The Company is also supplementing and updating the risk factors in its prior filings with the Securities and Exchange Commission (the “SEC”), including those discussed under the heading “Item 1A. Risk Factors,” in the Company’s most recent Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 12, 2020:

Our business could be adversely affected by the effects of health epidemics and pandemics, including the recent COVID-19 outbreak, in regions where we or third parties on which we rely have significant concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters in Pennsylvania and at our clinical trial sites, as well as the business or operations of our CROs or other third parties with whom we conduct business.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations and could cause significant disruption in the operations of CROs upon whom we rely. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the United States and several European countries. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Further, the President of the United States declared the COVID-19 pandemic a national emergency. The Governor of Pennsylvania declared a state of emergency related to the spread of COVID-19, and issued orders directing all individuals in seven counties, including where our headquarters is located, to “stay at home” except to perform certain essential activities. The orders took effect on March 23, 2020 and will continue until at least April 6, 2020. We have implemented work-from-home policies for all employees. The effects of the Pennsylvania orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. For instance, enrollment has been paused in our proof-of-concept clinical trials for TRV250 (treatment of acute migraine) and TRV734 (opioid use disorder). Also, some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Forward-Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans and prospects for the Company, including statements about the Company’s strategy, future operations, clinical development and trials of its 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 global COVID-19 pandemic; the status, timing, costs, results and interpretation of the Company’s clinical trials or any future trials of any of the Company’s product candidates; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including the Company’s assessment of the discussions with FDA and the timing of FDA’s decision on the oliceridine NDA; available funding; and other factors discussed in the Risk Factors set forth in the Company’s Annual Report on Form 10-K filed with the SEC and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this report 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 26, 2020

By: /s/ Barry Shin
Barry Shin
Chief Financial Officer
