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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **February 7, 2020**

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**TREVENA, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of incorporation)

**001-36193**  
(Commission  
File No.)

**26-1469215**  
(IRS Employer  
Identification No.)

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**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.)

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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**  
Common Stock, \$0.001 par value

**Trading Symbol(s)**  
TRVN

**Name of each exchange on which registered**  
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. ☐

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**Item 8.01**      **Other Events.**

On February 10, 2020, Trevena, Inc. (the “Company”) issued a press release announcing that it has resubmitted the New Drug Application for IV oliceridine to the U.S. Food and Drug Administration. 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

<u>Number</u>	<u>Description</u>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release dated February 10, 2020</u></a>

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EXHIBIT INDEX

Exhibit  
Number  
[99.1](#)

Description  
[Press Release dated February 10, 2020](#)



**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: February 10, 2020

By: /s/ Barry Shin

Barry Shin

Sr. Vice President, Chief Financial Officer

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## Trevena Resubmits New Drug Application for Oliceridine

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*Oliceridine is a new chemical entity intended for the management of moderate-to-severe acute pain*  
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CHESTERBROOK, Pa., February 10, 2020 (GLOBE NEWSWIRE) --**Trevena, Inc. (Nasdaq: TRVN)**, a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with central nervous system (CNS) disorders, today announced that it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for IV oliceridine, the Company's lead investigational product for the management of moderate-to-severe acute pain. The Company anticipates a six-month review period by FDA.

The NDA for oliceridine was resubmitted based on the outcome and final minutes of a Type A meeting with FDA, which was conducted to obtain clarity on their Complete Response Letter (CRL). The resubmission package included data from the multi-dose healthy volunteer QT study, nonclinical data that confirmed levels of an inactive metabolite, and drug product validation reports. The resubmission package also specified a maximum daily dose of 27 mg, as previously acknowledged by FDA in the Type A meeting minutes. No efficacy data or additional comparative data versus IV morphine were requested as part of the CRL.

"The resubmission of the oliceridine NDA represents a significant milestone for the program and an important achievement for the company. I am thankful for the team's commitment and diligent work to bring us to this exciting point," said Carrie Bourdow, President and Chief Executive Officer of Trevena. "We appreciate FDA's guidance through the resubmission process and look forward to continuing to work closely with the Agency as they review our application."

### About Oliceridine

Oliceridine is a G protein-selective mu-opioid receptor agonist in development for the management of moderate-to-severe acute pain in hospitals or other controlled clinical settings where intravenous 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 FDA or any other regulatory agency. If approved, the Company expects that oliceridine will be classified as a Schedule II controlled substance.

### About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with CNS disorders. The Company has four novel and differentiated investigational drug candidates, including IV oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the acute treatment of migraine, and TRV734 for maintenance treatment of opioid use disorder. The Company has also identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid approach to treating a variety of CNS disorders.

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## **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 and trials 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 of any of the Company's investigational drug 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, FDA's acknowledgement of the submitted NDA for oliceridine and the timing of FDA's decision on the oliceridine NDA; available funding ; 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.

## **For more information, please contact:**

### **Investor Contact:**

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### **Company Contact:**

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