# 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): **May 7, 2020**

# 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))

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 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 May 7, 2020, the Company issued a press release announcing its financial results for the quarter ended March 31, 2020. 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.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated May 7, 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: May 7, 2020

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

**Exhibit 99.1**

**Trevena Reports First Quarter 2020 Results**

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***FDA review of oliceridine NDA ongoing; PDUFA date August 7, 2020***

***IND filing for novel S1P modulator (TRV045) in 1H 2021; ongoing collaboration with NIH to evaluate for epilepsy and pain***

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*Company to host conference call today, May 7, 2020, at 8:00 a.m. ET*

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CHESTERBROOK, Pa., [May 7], 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 reported its financial results for the first quarter ended March 31, 2020, and provided an overview of its recent operational highlights.

"In the first quarter, we reached a significant milestone for the oliceridine program, with our resubmission and FDA's acceptance of the NDA. I am very pleased with FDA's engagement in the review process, and we look forward to receiving their decision in August," said Carrie Bourdow, President and Chief Executive Officer of Trevena, Inc.

**First Quarter 2020 and Recent Corporate Highlights:**

- **Resubmitted NDA for oliceridine, with FDA review ongoing.** In March 2020, the Company announced that the U.S. Food and Drug Administration (FDA) had set a Prescription Drug User Fee Act (PDUFA) goal date of August 7, 2020 for oliceridine, and the Agency considered the resubmitted New Drug Application (NDA) to be a complete response to their 2018 action letter.

  FDA's review of the NDA resubmission is ongoing, and the Company continues to expect a decision from the Agency by August 7.

- **Further expanded body of peer-reviewed literature.** The Company recently announced the publication of a comprehensive review of the nonclinical and clinical data for oliceridine. The monograph provides an overview of the data the Company has published over the past 18 months, including head-to-head data versus IV morphine in hard- and soft-tissue surgical models and safety / tolerability data in high-risk patients from an open-label, "real world" safety study. These high-risk patients – elderly, obese, renally impaired and / or co-morbid – make up the initial target market for oliceridine.

- **Initiated collaboration with NIH to evaluate TRV045 for epilepsy and non-addictive treatment for pain.** In March 2020, the Company announced it had entered into a collaboration with NIH to evaluate the potential of TRV045, the lead candidate for its novel S1P receptor modulator program, as a treatment for epilepsy. NIH has initiated the first round of assays for TRV045 within its Epilepsy Treatment Screening Program.

The Company today announced that NIH is also investigating TRV045 as a potential non-addictive treatment for various acute and chronic pain conditions, including inflammatory and neuropathic pain, within its Preclinical Screening Platform for Pain.

- **Advanced IND-enabling activities for TRV045.** The Company today announced it plans to file an Investigational New Drug (IND) application for TRV045 in 1H 2021. IND-enabling activities are currently ongoing.

**Financial Results for First Quarter 2020**

For the first quarter of 2020, the Company reported a net loss attributable to common stockholders of $5.7 million, or $0.06 per share, compared to $5.2 million, or $0.06 per share, for the first quarter of 2019. This increase in net loss is primarily due to higher research and development expenses associated with the TRV250 acute migraine proof-of-concept study and activities to support the NDA resubmission for oliceridine.

Cash and cash equivalents were $28.1 million at March 31, 2020, which the Company believes to be sufficient to fund the Company's operating expenses and capital expenditure requirements into the first quarter of 2021.

**Conference Call and Webcast Information**

The Company will host a conference call and webcast with the investment community on May 7, 2020, at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and Chief Executive Officer, Robert Yoder, Chief Business Officer, Mark Demitrack, M.D., Chief Medical Officer, and Barry Shin, Chief Financial Officer.

| | |
|---|---|
| **Title:** | Trevena First Quarter 2020 Conference Call and Webcast |
| **Date:** | Thursday, May 7, 2020 |
| **Time:** | 8:00 a.m. ET |
| **Conference Call Details:** | Toll-Free: 855-465-0180<br>International: 484-756-4313<br>Conference ID: 5469527 |
| **Webcast:** | https://www.trevena.com/investors/events-presentations/ir-calendar |

**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.

**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, the timing of FDA's decision on the oliceridine NDA; available funding ; uncertainties related to the Company's intellectual property; uncertainties related to the ongoing COVID-19 pandemic, 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:**

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**TREVENA, INC.**
**Condensed Statements of Operations**
**(Unaudited, in thousands except share and per share data)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Revenue | $ - | $ - |
| Operating expenses: | | |
| General and administrative | 3,632 | 3,060 |
| Research and development | 2,191 | 2,154 |
| Total operating expenses | 5,823 | 5,214 |
| Loss from operations | (5,823) | (5,214) |
| Other income | 98 | 45 |
| Loss before income tax expense | (5,725) | (5,169) |
| Income tax expense | - | - |
| Net loss | $ (5,725) | $ (5,169) |
| Per share information: | | |
| Net loss per share of common stock, basic and diluted | $ (0.06) | $ (0.06) |
| Weighted average shares outstanding, basic and diluted | 96,332,324 | 88,897,292 |

**TREVENA, INC.**
**Condensed Balance Sheets**
**(Unaudited, in thousands)**

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 28,090 | $ 32,305 |
| Marketable securities | - | 3,500 |
| Prepaid expenses and other current assets | 1,666 | 1,683 |
| Total current assets | 29,756 | 37,488 |
| Restricted cash | 1,310 | 1,309 |
| Property and equipment, net | 2,577 | 2,705 |
| Right-of-use lease assets | 5,389 | 5,472 |
| Other assets | 18 | 20.00 |
| Total assets | $ 39,050 | $ 46,994 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 698 | $ 1,047 |
| Accrued expenses and other current liabilities | 1,277 | 2,403 |
| Current portion of loans payable, net | - | 5,037 |
| Current portion of lease liabilities | 642 | 620 |
| Total current liabilities | 2,617 | 9,107 |
| Leases, net of current portion | 7,636 | 7,804 |
| Warrant liability | 2 | 5 |
| Total liabilities | 10,255 | 16,916 |
| | | |
| Common stock | 99 | 94 |
| Additional paid-in capital | 447,566 | 443,129 |
| Accumulated deficit | (418,870) | (413,145) |
| Total stockholders' equity | 28,795 | 30,078 |
| Total liabilities and stockholders' equity | $ 39,050 | $ 46,994 |