# 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 13, 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 March 13, 2019, the Company issued a press release announcing its financial results for the quarter and full year ended December 31, 2018. 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 March 13, 2019 |

EXHIBIT INDEX

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release dated March 13, 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: March 13, 2018

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

**Exhibit 99.1**

**Trevena Reports Fourth Quarter and Full Year 2018 Results**

**— Company announces submission of oliceridine healthy volunteer study protocol and analysis plan to FDA —**
**— Successful fundraising extends cash runway into 3Q 2020 —**

—

*Company to host conference call today, March 13, 2019 at 8:00 am ET*

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**CHESTERBROOK, PA, March 13, 2019 — Trevena, Inc. (NASDAQ: TRVN)**, a biopharmaceutical company focused on the development and commercialization of innovative treatment options that target and treat diseases affecting the central nervous system, or CNS, today reported its financial results for the fourth quarter and full year ended December 31, 2018, and provided an overview of its 2018 and 2019 year-to-date operational highlights.

"Following our successful Type A meeting with FDA, we have continued to rapidly move the oliceridine program forward," said Carrie L. Bourdow, President and Chief Executive Officer. "We have submitted the protocol for the previously announced healthy volunteer study of oliceridine and anticipate commencing this study in the first half of 2019. In addition, we have achieved meaningful milestones with our early-stage pipeline assets and, in 2019, expect to continue the development of these assets to build long-term stockholder value."

**2018 and recent corporate highlights:**

- **Gained clarity on path forward to address CRL.** In January 2019, the Company announced receipt of the Type A meeting minutes from FDA related to the oliceridine complete response letter (CRL). 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 as part of the CRL. The Company has submitted a detailed protocol and analysis plan for this study to FDA and anticipates study initiation in first half of 2019, following receipt of feedback from FDA.

- **Announced publication of APOLLO 1 Phase 3 results for oliceridine.** The Company announced the publication of the Phase 3 results in *The Journal of Pain Research* on the effects of oliceridine versus IV morphine for the management of moderate-to-severe acute pain following bunionectomy.

- **Completed successful capital raise.** In January 2019, the Company completed a $10 million registered direct offering of common stock that yielded $9.2 million of net proceeds and enabled the Company to extend its cash runway into the third quarter of 2020.

- **Continued progress with pipeline assets**. In 2018, the Company completed a Phase 1 trial for TRV250, a potential new mechanism of action for the treatment of acute migraine and commenced a partnership with the National Institute on Drug Abuse (NIDA) for TRV734 in the management of opioid use disorder. In its S1P receptor program, the Company is today announcing its identification of a lead candidate for this program, designated as TRV045. This candidate holds promise as a new mechanism of action for a novel, non-opioid treatment of chronic pain and other CNS conditions.

- **Strengthened the Board of Directors**. Effective October 1, 2018, Scott Braunstein, M.D., was appointed to the Board of Directors bringing over twenty-five years of industry experience to the Trevena Board.

- **Executed two ex-US licensing agreements.** In the second quarter of 2018, the Company entered into exclusive licensing agreements for the development and commercialization of oliceridine in South Korea with PharmBio Korea Inc. and in China with Jiangsu Nhwa Pharmaceutical Co. Ltd.

**Financial Results for Fourth Quarter and Full Year 2018**

For the fourth quarter of 2018, the Company reported a net loss attributable to common stockholders of $8.0 million, or $0.10 per share, compared to $14.7 million, or $0.24 per share, for the fourth quarter of 2017. For the full year ended December 31, 2018, net loss attributable to common stockholders was $30.8 million, or $0.42 per share, compared to $71.9 million, or $1.21 per share, for the year ended December 31, 2017. This decrease is primarily due to the recognition in 2018 of collaboration revenue associated with the licensing agreements for oliceridine, and to substantially lower research and development expenses.

Cash, cash equivalents, and marketable securities were $61.5 million at December 31, 2018. On January 29, 2018, the Company completed a registered direct offering of 10.0 million shares of common stock, which yielded net proceeds to the Company of approximately $9.2 million. The Company believes that its cash and cash equivalents and marketable securities as of December 31, 2018, together with interest thereon, and the approximately $9.2 million of net proceeds from the registered direct offering, to be sufficient to fund the Company's operating expenses and capital expenditure requirements into the third quarter of 2020.

**Conference Call and Webcast Information**

The Company will host a conference call and webcast with the investment community on Wednesday, March 13th at 8:00 a.m. Eastern Time featuring remarks by Carrie L. Bourdow, President and CEO, Mark A. Demitrack, M.D., SVP and Chief Medical Officer, and John P. Hamill, VP, Finance.

**Live Call:** Toll-Free: (855) 465-0180
International: (484) 756-4313

**Webcast:** investors.trevena.com

**Replay:** Toll-Free: (855) 859-2056
International: (404) 537-3406
Conference ID: 3496246
(Available approximately one hour after the completion of the live call until 11:59 p.m. ET on March 27, 2019)

**About Trevena**

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative treatment options that target and treat diseases affecting the central nervous system, or CNS. 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 the management of pain and/or management of opioid dependence. In its preclinical programs, we have identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid approach to managing chronic pain.

**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 third 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.

**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 December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Revenue | $ 232 | $ — | $ 5,732 | $ — |
| Operating expenses: | | | | |
| General and administrative | 4,073 | 5,143 | 18,979 | 19,639 |
| Research and development | 2,747 | 7,198 | 15,824 | 48,974 |
| Restructuring charges | 1,363 | 1,774 | 1,427 | 1,774 |
| Total operating expenses | 8,183 | 14,115 | 36,230 | 70,387 |
| Loss from operations | (7,951) | (14,115) | (30,498) | (70,387) |
| Other income (expense) | (25) | (605) | 459 | (1,478) |
| Loss before income tax expense | (7,976) | (14,720) | (30,039) | (71,865) |
| Foreign income tax expense | — | — | (745) | — |
| Net loss | $ (7,976) | $ (14,720) | $ (30,784) | $ (71,865) |
| | | | | |
| Per share information: | | | | |
| Net loss per share of common stock, basic and diluted | $ (0.10) | $ (0.24) | $ (0.42) | $ (1.21) |
| Weighted average shares outstanding, basic and diluted | 82,323,393 | 62,290,002 | 73,558,548 | 59,436,649 |

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

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 32,892 | $ 16,557 |
| Marketable securities | 28,590 | 49,543 |
| Prepaid expenses and other current assets | 607 | 1,393 |
| Total current assets | 62,089 | 67,493 |
| Restricted cash | 1,303 | 1,413 |
| Property and equipment, net | 3,387 | 3,805 |
| Intangible asset, net | — | 11 |
| Total assets | $ 66,779 | $ 72,722 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,416 | $ 1,424 |
| Accrued expenses and other current liabilities | 3,305 | 4,303 |
| Current portion of loans payable, net | 12,562 | 12,425 |
| Deferred rent | 207 | 61 |
| Total current liabilities | 17,490 | 18,213 |
| Loans payable, net | 4,811 | 15,725 |
| Capital leases, net of current portion | 20 | 31 |
| Deferred rent, net of current portion | 2,931 | 3,006 |
| Warrant liability | 1 | 10 |
| Other long term liabilities | — | 1,104 |
| Total liabilities | 25,253 | 38,089 |
| | | |
| Common stock | 82 | 62 |
| Additional paid-in capital | 429,727 | 392,103 |
| Accumulated deficit | (388,274) | (357,490) |
| Accumulated other comprehensive income (loss) | (9) | (42) |
| Total stockholders' equity | 41,526 | 34,633 |
| Total liabilities and stockholders' equity | $ 66,779 | $ 72,722 |