
**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 10, 2019**

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))

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.

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

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 10, 2019, the Company issued a press release announcing its financial results for the quarter ended March 31, 2019, and receipt of comments from the U.S. Food and Drug Administration regarding the Company's proposed protocol and statistical analysis plan for the oliceridine healthy volunteer study. 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>
99.1	Press Release dated May 10, 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: May 10, 2019

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

Trevena Reports First Quarter 2019 Results
— Company announces receipt of FDA feedback on healthy volunteer study protocol and analysis plan for oliceridine —
— Study on track to initiate by end of June —

—
Company to host conference call Monday, May 13, 2019 at 8:00 a.m. ET
—

CHESTERBROOK, PA, May 10, 2019 — **Trevena, Inc. (Nasdaq: TRVN)**, a biopharmaceutical company focused on the development and commercialization of novel medicines for patients affected by Central Nervous System (CNS) conditions, today announced receipt of comments from the U.S. Food and Drug Administration (FDA) on the proposed healthy volunteer study protocol, and reported its financial results for the quarter ended March 31, 2019.

“We are very pleased with the feedback from FDA, which provides us with the necessary information to move forward and initiate the healthy volunteer study by the end of June,” said Carrie Bourdow, President and Chief Executive Officer. “This marks a critical step on the path towards resubmission of the new drug application for oliceridine, and I am proud of our team for their considerable efforts in preparing for this important upcoming work.”

First Quarter and Recent Corporate Highlights:

- **Received feedback from FDA on key design elements for the healthy volunteer study.** The FDA confirmed that the study can be conducted in healthy volunteers over a 24-hour period. The study will be performed at a single site as a three-period crossover design that includes oliceridine, placebo, and moxifloxacin as a positive control.

The Company plans to submit data on approximately 60 participants. Among this study population, a minimum of 20 participants will receive a cumulative dose of 27 mg of oliceridine, the proposed maximum daily dose, through the 24-hour study period.

The study remains on track to initiate by the end of June. The Company will provide additional details on a conference call scheduled for Monday, May 13th at 8:00 a.m. Eastern Time.

- **Completed successful capital raise.** In January, the Company completed a \$10 million registered direct offering of common stock that yielded \$9.2 million of net proceeds.

Financial Results for First Quarter 2019

For the first quarter of 2019, the Company reported a net loss attributable to common stockholders of \$5.2 million, or \$0.06 per share, compared to \$9.0 million, or \$0.14 per share, for the first quarter of 2018. This decrease is primarily due to lower personnel related costs associated with the 2018 restructuring and reduction in force, and lower research and development expenses.

Cash, cash equivalents, and marketable securities were \$60.1 million at March 31, 2019. The Company believes its cash, cash equivalents, and marketable securities as of March 31, 2019, together with interest thereon, 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 Monday, May 13th at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and CEO, and Mark Demitrack, SVP and Chief Medical Officer.

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: 7698684
(Available approximately one hour after the completion of the live call until 11:59 p.m. ET on May 22, 2019)

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients affected by Central Nervous System (CNS) conditions. 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 use disorder. In its preclinical programs, the Company has identified TRV045, a novel SIP 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 March 31, 2019 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:

Investor Contact:

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Company Contact:

Bob Yoder, SVP and Chief Business Officer
Trevena, Inc.
Phone: 610-354-8840

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

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
Revenue	\$ —	\$ —
Operating expenses:		
General and administrative	3,060	5,072
Research and development	2,154	4,598
Restructuring charges	—	23
Total operating expenses	<u>5,214</u>	<u>9,693</u>
Loss from operations	(5,214)	(9,693)
Other income (expense)	45	672
Loss before income tax expense	(5,169)	(9,021)
Foreign income tax expense	—	—
Net loss	<u>\$ (5,169)</u>	<u>\$ (9,021)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding, basic and diluted	<u>88,897,292</u>	<u>64,562,236</u>

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,261	\$ 32,892
Marketable securities	39,802	28,590
Prepaid expenses and other current assets	1,581	607
Total current assets	61,644	62,089
Restricted cash	1,305	1,303
Property and equipment, net	3,238	3,387
Right-of-use lease assets	5,702	—
Total assets	\$ 71,889	\$ 66,779
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 358	\$ 1,416
Accrued expenses and other current liabilities	1,956	3,305
Current portion of loans payable, net	14,330	12,562
Current portion of lease liabilities	563	—
Deferred rent	—	207
Total current liabilities	17,207	17,490
Loans payable, net	—	4,811
Leases, net of current portion	8,281	20
Deferred rent, net of current portion	—	2,931
Warrant liability	14	1
Total liabilities	25,502	25,253
Common stock	92	82
Additional paid-in capital	439,735	429,727
Accumulated deficit	(393,443)	(388,274)
Accumulated other comprehensive income (loss)	3	(9)
Total stockholders' equity	46,387	41,526
Total liabilities and stockholders' equity	\$ 71,889	\$ 66,779