

**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): **August 7, 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))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 August 7, 2019, the Company issued a press release announcing its financial results for the quarter ended June 30, 2019, and also provided updates regarding the status of the ongoing healthy volunteer QT study, other pipeline developments and general corporate matters. 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 August 7, 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: August 7, 2019

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

Trevena Reports Second Quarter 2019 Results

— Enrollment for healthy volunteer QT study ongoing, topline data on schedule for Q4 2019 readout —

— Company remains on track to resubmit NDA for oliceridine in Q1 2020 —

— Cash runway as of June 30, 2019 continues to sufficiently fund operations into Q3 2020 —

Company to host conference call today, August 7, 2019 at 8:00 a.m. ET

CHESTERBROOK, PA, August 7, 2019 — **Trevena, Inc. (Nasdaq: TRVN)**, a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with Central Nervous System (CNS) conditions, today reported its financial results for the second quarter ended June 30, 2019, and provided an overview of its recent operational highlights.

“We made substantive progress in the second quarter on the key activities to support resubmission of the NDA for oliceridine and advancement of our pipeline,” said Carrie Bourdow, President and Chief Executive Officer. “Subject enrollment in our healthy volunteer study for oliceridine is progressing well, and we remain focused on delivering topline data next quarter. We’re also excited to continue development efforts for our other pipeline assets, including the acute migraine study for TRV250, which is slated to start next quarter.”

Second Quarter and Recent Corporate Highlights:

- **Strengthened leadership team.** The Company recently announced the appointment of Barry Shin as Senior Vice President and Chief Financial Officer. Mr. Shin brings over 17 years of investment banking and corporate advisory experience focused in the biopharmaceuticals sector, including in the Healthcare Investment Banking groups of Mizuho Securities, Guggenheim Securities, and Piper Jaffray.
 - **Initiated healthy volunteer QT interval study for oliceridine.** In June, the Company announced initiation of its single-site, three-period crossover, healthy volunteer study for oliceridine. The primary objective of the study is to collect the additional QT interval data requested by the U.S. Food and Drug Administration (FDA) for the resubmission of the NDA for oliceridine.

Study enrollment is on track to support topline data readout in the fourth quarter of 2019. As of today, over half of study subjects have begun dosing, with more than 20 subjects receiving the maximum daily dose of 27 mg of oliceridine, a key FDA requirement of the study design. The Company continues to expect to resubmit the NDA for oliceridine as early as possible in the first quarter of 2020.
 - **Advanced acute migraine proof-of-concept study protocol for TRV250.** This double-blind, placebo-controlled clinical study will enroll approximately 120 migraineurs in a validated
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nitroglycerin (NTG) provocation migraine model. Migraineurs will receive a 20 mg subcutaneous dose of TRV250 or placebo. Target engagement will be determined by the reduction in the number of subjects who experience a sustained NTG-induced headache. The Company continues to expect to initiate this study in the fourth quarter of 2019.

Submitted four oliceridine abstracts, all of which were accepted for presentation at the 2019 Annual Meeting of the American Society of Anesthesiologists (ASA). The Company today announced that all abstracts submitted to the 2019 ASA meeting have been accepted for presentation, including one that will be featured in the Best of Clinical Science session. The meeting will take place October 19-23, 2019, at the Orange County Convention Center in Orlando, Florida. The presentations will feature data highlighting the safety profile of oliceridine compared to IV morphine.

Presentation details:

1. Improved safety of opioid analgesic Oliceridine compared to Morphine assessed by utility function analysis (oral presentation, Best of Abstracts: Clinical Science featured session)
 - Saturday, October 19, 2019 from 1:00 p.m. — 3:00 p.m. EST
 - Sunday, October 20, 2019 from 8:00 a.m. — 9:30 a.m. EST
2. Low Incidence Of Opioid-induced Respiratory Depression Observed With Oliceridine Regardless Of Age Or Body Mass Index (e-poster, abstract #2228)
 - Sunday, October 20, 2019 from 1:30 p.m. — 2:00 p.m. EST
3. Lower Incidence Of Postoperative Opioid-induced Respiratory Depression With Oliceridine Compared To Morphine: A Retrospective Analysis (e-poster, abstract #2232)
 - Sunday, October 20, 2019 from 2:00 p.m. — 2.30 p.m. EST
4. Oliceridine (TRV130) Demonstrates Less Opioid-induced Respiratory Depression Than Morphine (M) As Measured By The Average Cumulative Duration Of Dosing Interruption In Patients Being Treated For Acute Post-surgical Pain (e-poster, abstract #3069)
 - Monday, October 21, 2019 from 10:00 a.m. — 10:30 a.m. EST

All abstracts will be made available on <https://www.asahq.org/annualmeeting/education/sessions>.

Published clinical data for oliceridine. In June, the Company announced the publication of pivotal Phase 3 results in the journal Pain Practice on the effects of oliceridine for the management of moderate to severe acute pain following soft tissue surgery.

Financial Results for Second Quarter 2019

For the second quarter of 2019, the Company reported a net loss attributable to common stockholders of \$4.7 million, or \$0.05 per share, compared to \$9.3 million, or \$0.13 per share, for the second quarter of 2018. This decrease is primarily due to a decrease in expenditures resulting from the 2018 restructuring and reduction in force and associated cost-saving initiatives.

Cash, cash equivalents, and marketable securities were \$54.0 million as of June 30, 2019. The Company believes its cash, cash equivalents, and marketable securities as of June 30, 2019, together with interest thereon, to be sufficient to fund the Company's operating expenses, debt service, and capital expenditure requirements for at least twelve months following the date of this filing, 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, August 7, 2019 at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and CEO, Barry Shin, SVP and Chief Financial Officer, 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: 3799758
(Available approximately one hour after the completion of the live call until 11:59 p.m. ET on August 14, 2019)

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with Central Nervous System conditions. 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 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, and whether there is a path to resubmit the oliceridine NDA; 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 June 30, 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:

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenue	\$ —	\$ 2,500	\$ —	\$ 2,500
Operating expenses:				
General and administrative	3,311	5,926	6,371	10,998
Research and development	2,722	5,128	4,876	9,726
Restructuring charges	—	41	—	64
Impairment of property and equipment	108	—	108	—
Total operating expenses	<u>6,141</u>	<u>11,095</u>	<u>11,355</u>	<u>20,788</u>
Loss from operations	(6,141)	(8,595)	(11,355)	(18,288)
Other income	1,450	36	1,495	708
Loss before income tax expense	(4,691)	(8,559)	(9,860)	(17,580)
Foreign income tax expense	—	(745)	—	(745)
Net loss	<u>\$ (4,691)</u>	<u>\$ (9,304)</u>	<u>\$ (9,860)</u>	<u>\$ (18,325)</u>
Per share information:				
Net loss per share of common stock, basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.13)</u>	<u>\$ (0.11)</u>	<u>\$ (0.27)</u>
Weighted average shares outstanding, basic and diluted	<u>92,414,644</u>	<u>69,664,994</u>	<u>90,665,684</u>	<u>67,127,711</u>

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,826	\$ 32,892
Marketable securities	30,140	28,590
Prepaid expenses and other current assets	1,301	607
Total current assets	55,267	62,089
Restricted cash	1,306	1,303
Property and equipment, net	2,982	3,387
Right-of-use lease assets	5,629	—
Total assets	<u>\$ 65,184</u>	<u>\$ 66,779</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 403	\$ 1,416
Accrued expenses and other current liabilities	2,416	3,295
Current portion of loans payable, net	11,258	12,562
Current portion of lease liabilities	581	10
Deferred rent	—	207
Total current liabilities	14,658	17,490
Loans payable, net	—	4,811
Leases, net of current portion	8,127	20
Deferred rent, net of current portion	—	2,931
Warrant liability	7	1
Total liabilities	22,792	25,253
Common stock	92	82
Additional paid-in capital	440,424	429,727
Accumulated deficit	(398,134)	(388,274)
Accumulated other comprehensive income (loss)	10	(9)
Total stockholders' equity	42,392	41,526
Total liabilities and stockholders' equity	<u>\$ 65,184</u>	<u>\$ 66,779</u>