
**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 3, 2018**

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 200
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 May 3, 2018, the Company issued a press release announcing its financial results for the quarter ended March 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

<u>Number</u>	<u>Description</u>
99.1	Press Release dated May 3, 2018

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated May 3, 2018

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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 3, 2018

By: /s/ Roberto Cuca
Roberto Cuca
Sr. Vice President and Chief Financial Officer

Trevena Reports First Quarter 2018 Financial Results

— *First license agreements for ex-US development and commercialization of oliceridine add potential revenue streams* —

— *Oliceridine NDA on track for potential approval in November* —

CHESTERBROOK, PA, May 3, 2018 — Trevena, Inc. (NASDAQ: TRVN) today announced financial results for the quarter ended March 31, 2018 and provided an update on its pipeline of differentiated new chemical entities, including its lead asset, oliceridine, currently under review by the U.S. Food and Drug Administration (FDA) for potential approval this year.

“In 2018, we have made important progress in Trevena’s evolution,” said Maxine Gowen, Ph.D., president and chief executive officer. “We have initiated a smooth and constructive transition in preparation for Carrie Bourdow to assume the CEO position later this year. We also have begun to broaden the potential revenue from oliceridine by completing our first ex-US licensing agreements. We continue to have an ongoing productive dialogue with the FDA as they review our oliceridine NDA, and look forward to an advisory committee meeting later this year and potential approval in November.”

First quarter and recent corporate highlights

- **New Drug Application (NDA) for oliceridine submitted and accepted.** In January 2018, the Company announced that the FDA has accepted the Company’s NDA for oliceridine, an investigational product for the management of moderate to severe acute pain. Oliceridine is the first G protein biased ligand of the mu receptor, and was designed to provide IV opioid pain relief with fewer associated adverse effects. The FDA has informed the Company that it intends to convene an advisory committee meeting to discuss the oliceridine NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of oliceridine in the first quarter of 2019, following DEA scheduling.
 - **Licensed oliceridine for development and commercialization in two ex-US territories.** In April, the Company and privately held Phambio Korea Inc. announced that they have entered into an exclusive license agreement for the development and commercialization of oliceridine in South Korea. In May, the Company and Jiangsu Nwha Pharmaceutical Co. Ltd. announced that they have entered an exclusive license agreement for the development and commercialization of oliceridine in China. Under these agreements, Trevena will receive a total of \$5.5 million in upfront payments, and is eligible for further regulatory and commercial milestones and royalties. The Company remains in active discussions for licensing oliceridine in additional territories.
 - **Carrie Bourdow selected as next CEO.** In April, the Company announced that President and Chief Executive Officer, Maxine Gowen, Ph.D., will retire on October 1, 2018 and will continue to serve on the Trevena Board of Directors. The Board of Directors has selected Carrie L. Bourdow, who
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currently serves as Trevena's Executive Vice President and Chief Operating Officer, to be the Company's next President and Chief Executive Officer, effective October 1, 2018.

- **Early pipeline advancing.** In March, the Company announced that its early pipeline programs continued to progress. The Company has completed dosing in its Phase 1 study of TRV250 for treatment of acute migraine, which had been extended following positive interim results for the initially planned doses demonstrating dose-proportional exposure after subcutaneous administration and adequate oral bioavailability to support further clinical development. The Company expects to release data in the coming months. In addition, the Company is evaluating a set of novel S1P modulators that may offer a new non-narcotic approach to managing chronic pain. The Company continues to expect complete characterization of the lead compounds in 2018 to determine if any merit IND-enabling studies to support Phase 1 clinical trials.

Financial results

For the first quarter of 2018, Trevena reported a net loss attributable to common stockholders of \$9.0 million, or \$0.14 per share, compared with a net loss attributable to common stockholders for the first quarter of 2017 of \$20.7 million, or \$0.36 per share. Research and development expenses were \$4.6 million in the first quarter of 2018 compared to \$16.1 million for the same period in 2017; general and administrative expenses were \$5.1 million, compared to \$4.9 million for the first quarter of 2017. Cash, cash equivalents, and marketable securities were \$61.6 million as of March 31, 2018. The Company expects this amount, together with interest thereon and proceeds from oliceridine ex-U.S. licensing activities, to be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from today's date.

For additional details, please see the Company's Form 10-Q, which will be filed with the SEC today.

Conference Call and Webcast

Date: May 3, 2018
Time: 8:00 a.m. EDT
Telephone Access: (855) 465-0180
International: (484) 756-4313
Webcast: <http://investors.trevena.com/index.cfm>
Conference ID: 1350009

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on providing better, safer therapies to patients in pain. The Company has leveraged breakthrough science to discover and develop its investigational product, oliceridine injection, for the management of moderate-to-severe acute pain. Oliceridine has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, and is

intended to provide healthcare providers an innovative new option for patients who require an intravenous opioid. The Company also has an early stage pipeline of new chemical entities targeting novel mechanisms of action, including TRV250 for acute migraine, neuropathic pain, and other indications.

Cautionary note on 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 whether the positive interim data from the Phase I study of TRV250 will be seen in the final study results and will support further clinical development, whether the final data for TRV250 Phase I study will be released in the coming months, whether the Company's novel set of S1P modulators may offer a new, non-narcotic approach to managing chronic pain, and whether the Company will complete characterization of the S1P lead compounds in 2018; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including whether the Company's ongoing dialogue with the FDA with respect to the oliceridine NDA is or will remain productive; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, including whether the Company's cash, cash equivalents, and marketable securities, together with interest thereon and proceeds from oliceridine ex-U.S. licensing activities, will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from today's date; 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.

Contacts

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

	<u>Three Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>
Revenue	\$ —	\$ —
Operating expenses:		
General and administrative	5,072	4,879
Research and development	4,598	16,096
Restructuring charges	23	—
Total operating expenses	<u>9,693</u>	<u>20,975</u>
Loss from operations	(9,693)	(20,975)
Other income	672	261
Net loss	<u>\$ (9,021)</u>	<u>\$ (20,714)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.36)</u>
Weighted average shares outstanding, basic and diluted	<u>64,562,236</u>	<u>56,894,672</u>

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

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,146	\$ 16,557
Marketable securities	43,445	49,543
Prepaid expenses and other current assets	1,847	1,393
Total current assets	63,438	67,493
Restricted cash	1,413	1,413
Property and equipment, net	3,779	3,805
Intangible asset, net	11	11
Total assets	<u>\$ 68,641</u>	<u>\$ 72,722</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,387	\$ 1,424
Accrued expenses and other current liabilities	1,519	4,303
Current portion of loans payable, net	12,460	12,425
Deferred rent	63	61
Total current liabilities	15,429	18,213
Loans payable, net	12,595	15,725
Capital leases, net of current portion	28	31
Deferred rent, net of current portion	2,992	3,006
Warrant liability	10	10
Other long term liabilities	1,270	1,104
Total liabilities	32,324	38,089
Common stock	68	62
Additional paid-in capital	402,806	392,103
Accumulated deficit	(366,511)	(357,490)
Accumulated other comprehensive income (loss)	(46)	(42)
Total stockholders' equity	36,317	34,633
Total liabilities and stockholders' equity	<u>\$ 68,641</u>	<u>\$ 72,722</u>