
**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 5, 2016**

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.)

**1018 West 8th Avenue, Suite A
King of Prussia, PA 19406**
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(610) 354-8840**

(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))
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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 5, 2016, the Company issued a press release announcing its financial results for the quarter ended March 31, 2016. 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 May 5, 2016

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 5, 2016

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

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EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated May 5, 2016

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Trevena Reports First Quarter 2016 Financial Results and Provides Corporate Update

- Results of BLAST-AHF study of TRV027 in acute heart failure expected this month -
- Oliceridine pivotal Phase 3 efficacy studies expected to begin this quarter -

KING OF PRUSSIA, Pa., May 5, 2016 - Trevena, Inc. (NASDAQ: TRVN), a clinical stage pharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors (GPCRs), today announced financial results for the quarter ended March 31, 2016 and provided an update regarding its ongoing clinical programs.

“The first quarter set the stage for a critical year in Trevena’s evolution,” said Maxine Gowen, Ph.D., chief executive officer. “We had a successful End-of-Phase 2 discussion of oliceridine with the FDA, and look forward to completing our ongoing Phase 3 program aimed at both approval and differentiation of oliceridine for moderate to severe acute pain. In addition, we completed enrollment of the BLAST-AHF Phase 2b Study of TRV027 for acute heart failure and expect to present topline data later this month.”

First Quarter and Recent Highlights

- **Received Breakthrough Therapy Designation for oliceridine.** In February, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to the company’s lead product candidate, intravenous oliceridine (TRV130), for the management of moderate-to-severe acute pain. Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious conditions, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. The company believes this is the first Breakthrough Therapy designation for a pain therapy.
- **Conducted a successful End-of-Phase 2 meeting for oliceridine with the FDA and announced details of the Phase 3 clinical program.** Earlier this week, the company announced that it had reached agreement with the FDA on key elements of the Phase 3 program to support a New Drug Application (NDA) for oliceridine. The company also provided additional details of the Phase 3 clinical program, which will include two 375-patient, randomized, double-blind, placebo- and active-controlled, pivotal efficacy trials: the APOLLO-1 study, which will evaluate pain for 48 hours following bunionectomy; and the APOLLO-2 study, which will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the management of their post-operative pain, with approximately 75 patients enrolled per study arm. The primary endpoint for both APOLLO studies will be a responder analysis comparing active treatment arms to placebo. Secondary endpoints in both APOLLO

studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.

In January, the company initiated the Phase 3 clinical program with the enrollment of patients in the open label ATHENA study, which is evaluating the safety and tolerability of oliceridine in patients with moderate-to-severe acute pain caused by medical conditions or surgery. Patients will be treated with oliceridine on an as-needed basis via IV bolus, PCA administration, or both, as determined by the investigator.

The company expects to start the APOLLO studies in the second quarter of this year, and to report top-line data from these studies in the first quarter of 2017. The company continues to expect to file an NDA in the second half of 2017.

- **Completed enrollment of the BLAST-AHF study.** In April, the company announced that results from its BLAST-AHF Phase 2b study of TRV027 in acute heart failure (AHF) will be presented at Heart Failure 2016, the annual congress of the Heart Failure Association of the European Society of Cardiology, in Florence, Italy. Results of the trial will be presented in a late-breaking trials session scheduled for 2:15-3:45pm CEST on Saturday May 21. The company expects to host a webcast to review the study results following the presentation.

Financial Results

Net loss attributable to common stockholders for the quarter ended March 31, 2016 was \$17.8 million, or \$0.35 per share, compared to \$12.9 million, or \$0.33 per share for the quarter ended March 31, 2015. Research and development expenses were \$15.8 million in the first quarter of 2016 compared to \$10.6 million for the same period in 2015, due to increased clinical trial expenses; general and administrative expenses were \$3.9 million, compared to \$3.1 million for the first quarter of 2015.

Cash, cash equivalents, and marketable securities totaled \$163.5 million as of March 31, 2016, which Trevena expects will be sufficient to fund its operations into 2018.

About Trevena

Trevena, Inc. is a clinical stage biopharmaceutical company that discovers, develops and intends to commercialize therapeutics that use a novel approach to target G protein coupled receptors, or GPCRs. Trevena is developing four biased ligand product candidates it has identified from its proprietary product platform— oliceridine (TRV130) to treat moderate to severe acute pain intravenously (Phase 3), TRV027 to treat acute heart failure (Phase 2b), TRV734 to treat moderate-to-severe acute and chronic pain orally (Phase 1), and TRV250 for acute migraine and other CNS disorders (preclinical).

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, including with respect to the expected announcement of the BLAST-AHF Phase 2b study of TRV027; the uncertainties inherent in conducting clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials will be indicative of the results of future trials, including with respect to earlier studies with oliceridine and expectations for the Phase 3 program; expectations for regulatory approvals; availability of funding sufficient for the company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the viability or commercial potential of the company’s therapeutic candidates; the inherent uncertainties associated with intellectual property; 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.

Contact:

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TREVENA, INC.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenue	\$ 1,875,000	\$ 625,000
Operating expenses:		
General and administrative	3,917,750	3,089,622
Research and development	15,753,087	10,598,993
Total operating expenses	19,670,837	13,688,615
Loss from operations	(17,795,837)	(13,063,615)
Other income	16,858	133,970
Net loss	<u>\$ (17,778,979)</u>	<u>\$ (12,929,645)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (0.35)</u>	<u>\$ (0.33)</u>
Weighted average shares outstanding, basic and diluted	<u>51,350,365</u>	<u>39,251,184</u>

TREVENA, INC.
Condensed Balance Sheets

	March 31, 2016	December 31, 2015
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 34,452,266	\$ 46,773,566
Marketable securities	129,016,409	125,864,447
Prepaid expenses and other current assets	2,486,566	1,892,217
Total current assets	165,955,241	174,530,230
Property and equipment, net	823,515	696,280
Intangible asset, net	14,375	14,844
Restricted cash	112,620	112,620
Total assets	<u>\$ 166,905,751</u>	<u>\$ 175,353,974</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,980,488	\$ 6,749,625
Accrued expenses and other current liabilities	3,636,896	3,029,782
Deferred revenue	1,875,000	3,750,000
Deferred rent	45,996	43,907
Total current liabilities	9,538,380	13,573,314
Loans payable, net	18,219,788	18,185,898
Capital leases, net of current portion	14,312	7,942
Deferred rent, net of current portion	226,918	238,917
Warrant liability	111,751	153,238
Other long term liabilities	167,575	63,200
Total liabilities	28,278,724	32,222,509
Common stock	52,171	50,802
Additional paid-in capital	338,821,662	325,784,484
Accumulated deficit	(200,276,944)	(182,497,965)
Accumulated other comprehensive income (loss)	30,138	(205,856)
Total stockholders' equity	138,627,027	143,131,465
Total liabilities and stockholders' equity	<u>\$ 166,905,751</u>	<u>\$ 175,353,974</u>