
**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 9, 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 March 9, 2016, the Company issued a press release announcing its financial results for the quarter and full year ended December 31, 2015. 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 March 9, 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: March 9, 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 March 9, 2016

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Trevena Reports Full Year 2015 Financial Results

- Achieved significant clinical and regulatory milestones in CNS and AHF programs -
- Net loss for the year of \$50.5 million, or \$1.15 per share -
- Company to host conference call at 7:30 AM EST today -

KING OF PRUSSIA, Pa., March 9, 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 fourth quarter and full year ended December 31, 2015 and provided an update regarding its ongoing clinical programs.

"In 2015, we made remarkable progress in building the company and advancing our pipeline," said Maxine Gowen, Ph.D., chief executive officer. "Our Phase 2b data for intravenous oliceridine in moderate-to-severe post-operative pain demonstrated impressive results compared to morphine and concluded a Phase 2 program that supported a Breakthrough Therapy designation from the FDA. We also added key personnel and expertise to the company and are well positioned to advance oliceridine through Phase 3, an NDA filing, and towards commercial launch. In addition, we significantly progressed the ongoing TRV027 Phase 2 study and our earlier programs, and strengthened our balance sheet to enable furtherance of these important programs."

2015 and Recent Corporate Highlights

CNS Programs (oliceridine, TRV734, and TRV250)

Announced positive results from Phase 2b study of oliceridine (TRV130). In August, the company announced positive data from its randomized, double-blind, placebo- and active-controlled Phase 2b trial of oliceridine in moderate to severe acute pain after abdominoplasty surgery. The study achieved its primary endpoint of statistically greater pain reduction than placebo over 24 hours. In addition, in pre-specified secondary measures, oliceridine demonstrated significantly reduced nausea, vomiting, and hypoventilation events with similar levels of analgesia compared to morphine.

Initiated the Phase 3 program for oliceridine. In January 2016, the company announced the launch of the oliceridine Phase 3 clinical program with the enrollment of patients in the open-label Phase 3 ATHENA-1 study. This study will evaluate the safety and tolerability of oliceridine in patients with acute moderate-to-severe pain in a variety of surgical and medical settings.

Received Breakthrough Therapy designation for oliceridine. In February 2016, the company announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to the Company's lead product candidate, intravenous oliceridine, for the

management of moderate-to-severe acute pain. Based on publicly available information, the company believes that this is the first and only Breakthrough Therapy designation granted to a product candidate for the treatment of 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.

Presented oliceridine Phase 2 data in peer-reviewed forums. In September, complete results from the company's Phase 2 bunionectomy study of oliceridine were published in the leading journal *PAIN*. In addition, in September, the company highlighted data from this study, as well as data from its other CNS programs, at PAINWeek®, the National Conference on Pain for Frontline Practitioners.

Reported positive phase 1 data for TRV734. In September and February 2015, Trevena reported data from two Phase 1 studies of TRV734, an orally administered clinical compound expected to be used for first-line treatment of moderate to severe acute and chronic pain. Results showed pharmacokinetics, safety, tolerability, and CNS activity supporting further study in Phase 2. The company has now completed the Phase 1 program for TRV734, and intends to continue to focus its efforts on securing a worldwide development and commercialization partner for this compound.

Advanced TRV250, a G protein biased ligand targeting the delta receptor, into preclinical development. TRV250 is a potential first-in-class treatment for acute intermittent migraine that also may have utility in a range of other central nervous system indications. There are no approved drugs selectively targeting the delta receptor. The company currently expects to submit an investigational new drug application for TRV250 to the FDA in the second half of 2016.

Presented TRV250 preclinical data. In May and June, Trevena presented the preclinical pharmacology of TRV250 in a late-breaking oral session at the International Headache Society meeting in Valencia, Spain, and in a poster at the American Headache Society 57th annual meeting in Washington, D.C., respectively.

Acute Heart Failure Program (TRV027)

Expanded TRV027 Phase 2b BLAST-AHF trial and completed enrollment. Early last year, the company conducted a planned interim analysis evaluating data from approximately 250 patients. Upon reviewing the data, the data safety monitoring board and the BLAST-AHF Steering Committee recommended that future enrollment be weighted to the most promising dose of 5 mg/hr. The company announced in March 2015 that remaining enrollment will be weighted 2:1:2:1 for placebo, 1 mg/hr, 5 mg/hr, and 25 mg/hr, respectively, and that target enrollment in the study had been increased from 500 patients to 620 patients. Allergan plc, which holds an exclusive option to license TRV027, made a \$10 million payment to Trevena to fully fund the external and internal costs of increasing the study sample size. Enrollment in the BLAST-AHF study has now concluded. Following scheduled 30 day measures and data

collection and database lock, the company expects to release top line data in the second quarter of 2016.

Published the TRV027 Phase 2b BLAST-AHF trial design. In February 2015, the company announced the publication of the trial design for its ongoing Phase 2b study of TRV027 in acute heart failure in the *Journal of the American College of Cardiology: Heart Failure*.

Received key U.S. and EU patents for TRV027. In August, the company announced that the U.S. Patent and Trademark Office granted Trevena U.S. Patent No. 8,796,204, a new patent covering methods of use for TRV027 for the treatment of cardiovascular disorders, including acute heart failure. The patent is expected to provide coverage for TRV027 until at least 2029, strengthening the protection provided by the previously issued composition of matter patent which is expected to extend until at least 2031. In December, the company announced that the European Patent Office has granted European Patent EP2376101B1, "Beta-Arrestin Effectors and Compositions and Methods of Use Thereof," which covers the composition of matter for TRV027 and uses thereof.

Corporate Developments

Strengthened corporate management team. Trevena added two new executives to the management team. In May, the company appointed Carrie Bourdow as chief commercial officer and, in July, Yacoub Habib Ph.D. was appointed senior vice president, business development and corporate planning.

Hosted first Investor and Analyst Day. Leading external researchers and Trevena management discussed the Phase 3 and commercial plans for oliceridine and the rationale for and design of the ongoing Phase 2b study of TRV027 during an Investor and Analyst Day in October.

Financial Results

For the fourth quarter of 2015, Trevena reported a net loss attributable to common stockholders of \$15.5 million, or \$0.30 per share, compared with a net loss attributable to common stockholders for the fourth quarter of 2014 of \$13.3 million, or \$0.45 per share.

For the year ended December 31, 2015, the company incurred a net loss attributable to common stockholders of \$50.5 million, or \$1.15 per share, compared with a net loss attributable to common stockholders of \$49.7 million, or \$2.02 per share, for the comparable period in 2014.

Cash, cash equivalents and marketable securities were \$172.6 million as of December 31, 2015, which the company expects to fund operations into 2018, including completion of oliceridine Phase 3 studies, NDA filing in the second half of 2017, and commercial launch preparations, as well as funding the continued progress of Trevena's pipeline.

Conference Call

Trevena will host a conference call today to discuss its financial and operational results for the year ended December 31, 2015:

Date:	Wednesday, March 9, 2016
Time:	7:30 a.m. (EDT)
Call-in Numbers:	(855) 465-0180 (U.S. and Canada)
International:	(484) 756-4313
Participant Passcode:	63684856

The conference call also will be broadcast live via the company's website by visiting the "Investors" section of <http://www.trevenainc.com>. A replay of the call will be available for two weeks starting shortly after the end of the call and can be accessed on the company's website.

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. Using its proprietary product platform, Trevena has identified four biased ligand product candidates — oliceridine (TRV130) to manage moderate to severe acute pain intravenously (Phase 3), TRV027 to treat acute heart failure (Phase 2b), TRV734 to manage 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 pre-clinical work and clinical trials, including whether the Company will be able to submit an IND for TRV250 in the second half of 2016, whether top-line data for TRV027 will be released in the second quarter of 2016, and whether the Company is well positioned to advance oliceridine through Phase 3, an NDA filing and towards commercial launch; 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 for TRV130 and TRV734; expectations for regulatory approvals; availability of funding sufficient for the company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, including whether the Company has sufficient cash to fund its operations into 2018; other matters that could affect the availability or commercial potential of the company's therapeutic candidates; the inherent uncertainties associated with intellectual property, including whether and for how long the composition of matter and methods of use patent for TRV027 will

protect the product; 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.

Investor and Media Contact:

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Jonathan Violin, Ph.D.
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	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Revenue	\$ 1,875,000	\$ —	\$ 6,250,000	\$ —
Operating expenses:				
General and administrative	3,820,010	2,369,762	12,797,010	9,403,254
Research and development	13,549,556	10,875,552	44,074,157	40,546,666
Total operating expenses	17,369,566	13,245,314	56,871,167	49,949,920
Loss from operations	(15,494,566)	(13,245,314)	(50,621,167)	(49,949,920)
Other income (loss)	30,305	(51,594)	92,927	249,045
Net loss	(15,464,261)	(13,296,908)	(50,528,240)	(49,700,875)
Accretion of redeemable convertible preferred stock	—	—	—	(28,521)
Net loss attributable to common stockholders	\$ (15,464,261)	\$ (13,296,908)	\$ (50,528,240)	\$ (49,729,396)
Per share information:				
Net loss per share of common stock, basic and diluted	\$ (0.30)	\$ (0.45)	\$ (1.15)	\$ (2.02)
Weighted average shares outstanding, basic and diluted	50,770,359	29,460,497	43,794,276	24,655,603

TREVENA, INC.
Condensed Balance Sheets
(Unaudited)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 46,773,566	\$ 36,205,559
Marketable securities	125,864,447	70,698,640
Prepaid expenses and other current assets	1,892,217	669,155
Total current assets	174,530,230	107,573,354
Property and equipment, net	696,280	553,294
Intangible asset, net	14,844	—
Restricted cash	112,620	112,410
Total assets	\$ 175,353,974	\$ 108,239,058
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,749,625	\$ 4,342,480
Accrued expenses and other current liabilities	3,029,782	2,578,269
Deferred revenue	3,750,000	—
Deferred rent	43,907	38,359
Total current liabilities	13,573,314	6,959,108
Loan payable, net	18,185,898	1,692,884
Capital lease, net of current portion	7,942	10,677
Deferred rent, net of current portion	238,917	281,885
Warrant liability	153,238	82,851
Other long term liabilities	63,200	8,025
Total liabilities	32,222,509	9,035,430
Common stock	50,802	39,241
Additional paid-in capital	325,784,484	231,152,894
Accumulated deficit	(182,497,965)	(131,969,725)
Accumulated other comprehensive loss	(205,856)	(18,782)
Total stockholders' equity	143,131,465	99,203,628
Total liabilities and stockholders' equity	\$ 175,353,974	\$ 108,239,058