

**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): **November 3, 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))

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 November 3, 2016, the Company issued a press release announcing its financial results for the quarter ended September 30, 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

<u>Number</u>	<u>Description</u>
99.1	Press Release dated November 3, 2016

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: November 3, 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 November 3, 2016

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Trevena Reports Third Quarter 2016 Financial Results and Provides Corporate Update

- *Oliceridine Phase 3 pivotal efficacy trials progressing on schedule for top-line data in 1Q17* -

KING OF PRUSSIA, PA. Trevena, Inc. (NASDAQ: TRVN) today announced financial results for the quarter ended September 30, 2016 and provided an update regarding its ongoing clinical programs.

“This quarter saw important progress for our company, with continued execution of our Phase 3 program for oliceridine. We had extensive engagement with the medical community to discuss the challenges of acute pain management in the hospital and how oliceridine may provide an important treatment option to patients and physicians,” said Maxine Gowen, Ph.D., chief executive officer. “We look forward to sharing top-line data from both Phase 3 APOLLO pivotal efficacy studies in the first quarter of 2017, and filing an NDA in the second half of next year.”

Third Quarter and Recent Highlights

- **APOLLO-1 and APOLLO-2 Phase 3 efficacy trials of oliceridine remain on track for first quarter 2017 top-line data release.** The APOLLO-1 trial includes patients suffering moderate to severe pain after undergoing bunionectomy, while the APOLLO-2 trial includes patients suffering moderate to severe pain after undergoing abdominoplasty; both are 375-patient, multicenter, randomized, double-blind, placebo- and active-controlled studies. Patients are randomized to receive placebo, morphine, or one of three oliceridine regimens, all dosed as needed via patient-controlled analgesia (PCA) device for the management of their post-operative pain, with approximately 75 patients per study arm. The primary objective of both trials is to evaluate the analgesic efficacy of oliceridine versus placebo. Secondary endpoints compare the efficacy, safety, and tolerability of oliceridine to morphine.
- **Patient enrollment remains on track in the ATHENA multi-procedure safety study of oliceridine to support NDA filing in 2H 2017.** This trial complements the APOLLO studies and aims to evaluate the safety and tolerability of oliceridine in patients with moderate to severe acute pain caused by a broad range of medical conditions or surgeries. Patients are treated on an as-needed basis via IV bolus, PCA administration, or both, as determined by the investigator.
- **Continued engagement at pain medicine conferences.** The company gave or sponsored presentations at numerous medical conferences, including meetings of the American Society for Pain Management Nursing, American College of Surgeons, and American Society of Anesthesiologists (ASA). Two abstracts were selected for oral podium presentations at the ASA meeting.
- **Hosted an investor webcast featuring presentations on acute pain management by leading clinicians.** In October, the company webcast a symposium in which leading clinicians provided their perspectives on the unmet needs associated with current injectable analgesics and how

oliceridine may fit into the current treatment landscape for acute moderate to severe pain. A webcast replay is available at <http://investors.trevena.com/events.cfm>.

- **TRV250 program on track for IND submission this year.** TRV250 is a potential first-in-class medicine in preclinical development for the treatment of episodic migraine. It was designed to use a novel non-narcotic approach to treating migraine by selectively targeting the delta receptor. There are no approved drugs selectively targeting this receptor. The company continues to expect to submit an investigational new drug application for TRV250 to the FDA by the end of 2016.

Financial Results

Net loss attributable to common stockholders for the quarter ended September 30, 2016 was \$29.9 million, or \$0.57 per share, compared to \$10.6 million, or \$0.24 per share for the quarter ended September 30, 2015. General and administrative expenses were \$4.1 million in the third quarter of 2016, compared to \$2.8 million for the third quarter of 2015. Research and development expenses were \$25.5 million in the third quarter of 2016 compared to \$9.7 million for the same period in 2015, with the increase primarily due to expenses associated with the oliceridine Phase 3 program. The Company expects that research and development expenses will be higher in the fourth quarter of 2016 than in the third quarter before decreasing in 2017 as ongoing Phase 3 trials are completed.

Cash, cash equivalents, and marketable securities totaled \$119.6 million as of September 30, 2016, which Trevena continues to expect will be sufficient to fund its operations into 2018.

About Trevena

Trevena, Inc. is a biopharmaceutical company developing innovative therapies based on breakthrough science to benefit patients and healthcare providers confronting serious medical needs. The company has discovered four novel and differentiated drug candidates including oliceridine (TRV130), an FDA-designated Breakthrough Therapy currently in Phase 3 development for intravenous management of moderate-to-severe acute pain. Trevena has also discovered TRV250, in preclinical development for the treatment of migraine, as well as TRV734 for pain and TRV027 for acute heart failure. The Company also has an early stage portfolio of drug discovery programs.

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 the expected timing of the release of top-line data from the APOLLO studies and the timing of the NDA filing for oliceridine; the uncertainties inherent in conducting clinical trials, including whether the Phase 3 studies will support the approval of oliceridine and any potential differentiation of oliceridine from conventional opioids; 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; expectations for regulatory approvals, including for oliceridine; availability of funding sufficient for the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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.

Investor contact:

Trevena, Inc.
Jonathan Violin, Ph.D.
Sr. Director, Investor Relations
(610) 354-8840 x231
jviolin@trevenainc.com

Media Contact:

Trevena, Inc.
Public Relations
PR@trevena.com

TREVENA, INC.
Condensed Statements of Operations
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenue	\$ —	\$ 1,875,000	\$ 3,750,000	\$ 4,375,000
Operating expenses:				
General and administrative	4,078,349	2,780,115	11,692,781	8,977,000
Research and development	<u>25,548,532</u>	<u>9,650,138</u>	<u>58,504,964</u>	<u>30,524,601</u>
Total operating expenses	<u>29,626,881</u>	<u>12,430,253</u>	<u>70,197,745</u>	<u>39,501,601</u>
Loss from operations	(29,626,881)	(10,555,253)	(66,447,745)	(35,126,601)
Other income (expense)	<u>(271,775)</u>	<u>(60,230)</u>	<u>(446,208)</u>	<u>62,622</u>
Net loss	<u>\$ (29,898,656)</u>	<u>\$ (10,615,483)</u>	<u>\$ (66,893,953)</u>	<u>\$ (35,063,979)</u>
Per share information:				
Net loss per share of common stock, basic and diluted	<u>\$ (0.57)</u>	<u>\$ (0.24)</u>	<u>\$ (1.29)</u>	<u>\$ (0.85)</u>
Weighted average shares outstanding, basic and diluted	<u>52,205,156</u>	<u>44,214,428</u>	<u>51,911,107</u>	<u>41,443,362</u>

TREVENA, INC.
Condensed Balance Sheets

	<u>30-Sep-16</u>	<u>December 31, 2015</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,228,034	\$ 46,773,566
Marketable securities	94,386,006	125,864,447
Prepaid expenses and other current assets	<u>1,644,792</u>	<u>1,892,217</u>
Total current assets	121,258,832	174,530,230
Property and equipment, net	745,292	696,280
Intangible asset, net	13,438	14,844
Restricted cash	<u>112,620</u>	<u>112,620</u>
Total assets	<u>\$ 122,130,182</u>	<u>\$ 175,353,974</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,903,250	\$ 6,749,625
Accrued expenses and other current liabilities	3,530,702	3,029,782
Current portion of loans payable, net	4,635,046	—
Deferred revenue	—	3,750,000
Deferred rent	<u>50,175</u>	<u>43,907</u>
Total current liabilities	15,119,173	13,573,314
Loans payable, net	13,644,787	18,185,898
Capital leases, net of current portion	12,022	7,942
Deferred rent, net of current portion	200,666	238,917
Warrant liability	90,561	153,238
Other long term liabilities	<u>373,488</u>	<u>63,200</u>
Total liabilities	29,440,697	32,222,509
Common stock	52,243	50,802
Additional paid-in capital	341,973,243	325,784,484
Accumulated deficit	(249,391,918)	(182,497,965)
Accumulated other comprehensive income (loss)	55,917	(205,856)
Total stockholders' equity	<u>92,689,485</u>	<u>143,131,465</u>

Total liabilities and stockholders' equity

\$ 122,130,182

\$ 175,353,974
