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 8, 2017**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36193	**26-1469215**
(Commission File No.)	(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 March 8, 2017, the Company issued a press release announcing its financial results for the quarter and full year ended December 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 March 8, 2017

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 8, 2017

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated March 8, 2017

Trevena Reports Full Year 2016 Earnings

— Two positive Phase 3 pivotal efficacy studies of OLINVO™ (oliceridine injection) completed —

— OLINVO program on track for NDA submission in fourth quarter of 2017 —

— Company to host conference call at 8:00 am EST today, to include additional data from recently completed Phase 3 APOLLO trials —

Trevena, Inc. (NASDAQ: TRVN) today announced financial results for the fourth quarter and full year ended December 31, 2016 and provided an update on its ongoing clinical programs, including additional data from the recently completed Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of OLINVO in moderate-to-severe acute pain.

"The recent successful completion of the pivotal efficacy studies for OLINVO puts us in a strong position to bring this innovative analgesic to physicians and patients in need of a new option for managing moderate-to-severe acute pain in the hospital," said Maxine Gowen, Ph.D., chief executive officer. "We believe the data from these studies highlight the potential for OLINVO to reduce the burden of opioid-related adverse effects, particularly for those patients who are at elevated risk for serious consequences from post-operative nausea and vomiting or opioid-induced respiratory depression."

2016 and recent corporate highlights

- **Obtained Breakthrough Therapy Designation for OLINVO.** In February 2016, the Company announced that the U.S. Food and Drug Administration (FDA) had awarded OLINVO Breakthrough Therapy status, a designation granted to new therapies intended to treat serious conditions and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over currently available therapies.

- **Successful End-of-Phase 2 meeting with FDA.** In May 2016, the Company announced that it had reached general agreement with the FDA on key elements of the Phase 3 OLINVO program to support a New Drug Application (NDA), including that the APOLLO-1 and APOLLO-2 pivotal efficacy trials in bunionectomy and abdominoplasty included appropriate patient populations to support an indication for moderate-to-severe acute pain.

- **In February 2017, announced positive top-line results from two Phase 3 pivotal efficacy studies of OLINVO in moderate-to-severe acute pain.**OLINVO demonstrated fast onset and strong opioid efficacy in hard tissue and soft tissue pain models, supporting the Company's planned NDA submission and a potential indication for the management of moderate-to-severe acute pain. Numerous measures of respiratory safety and gastrointestinal tolerability all showed trends of meaningful improvements for OLINVO compared to a commonly used IV morphine regimen.

- **Initiated Phase 3 ATHENA open label safety study of OLINVO.** In January 2016, the Company announced the launch of the OLINVO Phase 3 clinical program with the enrollment of patients in the open label Phase 3 ATHENA study. This study is evaluating the safety and tolerability of OLINVO in

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patients with acute moderate-to-severe pain in a variety of surgical settings. As of February 15, 2017, more than 400 patients have been treated with OLINVO, with no apparent off-target or unexpected drug-related adverse effects to date. The Company remains on track to submit an NDA for OLINVO in the fourth quarter of 2017.

- **Completed clinical pharmacology and pharmacokinetics studies suggesting that OLINVO may offer potentially safer dosing in hard-to-treat patients.**In February 2017, the Company announced the completion of a number of additional studies of OLINVO.
  - A renal impairment study found no evidence of altered pharmacokinetics or accumulation in patients with renal failure, both of which occur with morphine and hydromorphone.
  - Preclinical and clinical studies have found no evidence of active metabolites, which for other opioids can cause variable and delayed adverse events.

- **Continued engagement with academic and medical communities.** The Company presented peer-reviewed data from its Phase 2 studies of OLINVO at a number of academic and medical conferences, including the 41st Annual Regional Anesthesiology and Acute Pain Medicine Meeting, the 35th Annual Scientific Meeting of the American Pain Society, and the 2016 Annual Meeting of the American Society of Anesthesiologists.

- **Completed preclinical development of TRV250 for migraine.** The Company announced today that it expects to initiate first-time-in-human studies of TRV250 for the treatment of migraine in the second quarter of this year. TRV250 is a G protein biased ligand targeting the δ-receptor with potential for a first-in-class, non-narcotic mechanism for the treatment of migraine. TRV250 also may have utility in a range of other central nervous system indications. Because TRV250 selectively targets the δ-receptor, the Company believes it will not have the addiction liability or other adverse effects associated with compounds targeting the mu-opioid receptor.

Financial results

For the fourth quarter of 2016, Trevena reported a net loss attributable to common stockholders of $36.1 million, or $0.67 per share, compared with a net loss attributable to common stockholders for the fourth quarter of 2015 of $15.5 million, or $0.30 per share.

For the year ended December 31, 2016, the Company incurred a net loss attributable to common stockholders of $103.0 million, or $1.97 per share, compared with a net loss attributable to common stockholders of $50.5 million, or $1.15 per share, for the comparable period in 2015.

Cash, cash equivalents, and marketable securities were $110.6 million as of December 31, 2016. The Company expects that expenses will decrease in 2017 compared to 2016, primarily attributable to lower R&D expense following the recent completion of the Phase 3 APOLLO trials. As such, the Company expects currently available cash, cash equivalents, and marketable securities to fund operations into the second quarter of 2018, which should be sufficient to complete the OLINVO Phase 3 ATHEHA study,

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submit the NDA in 4Q 2017, continue OLINVO commercial launch preparations, complete the TRV250 first-time-in-human study, and continue the progression of Trevena's pipeline.

Conference call and webcast

Date: March 8, 2017

Time: 8:00 a.m. EST

Telephone Access: (855) 465-0180

International: (484) 756-4313

Conference ID: 81728820

To access the live audio webcast of the presentation, please visit the Investor section of the Company's website. The webcast will be available for replay for 30 days.

About OLINVO™ (oliceridine injection)

OLINVO™ (oliceridine injection), Trevena's lead product candidate, is a next generation IV analgesic in Phase 3 development for the management of moderate-to-severe acute pain in the hospital and similar settings and has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA). OLINVO was specifically designed to improve conventional opioid pharmacology to deliver the pain-reducing potential of an opioid but with fewer associated adverse effects. In Phase 2 and Phase 3 clinical trials, OLINVO provided rapid and powerful analgesic efficacy while demonstrating a wider therapeutic window compared to morphine, suggesting it may be highly effective and well-tolerated for patients in need of strong analgesia. OLINVO is an investigational product and has not been approved by the FDA or any other regulatory agency. The Company expects OLINVO to be a Schedule II controlled substance.

About Trevena

Trevena, Inc. is a biopharmaceutical company developing innovative therapies based on breakthrough science to benefit patients and healthcare providers confronting serious medical conditions. The Company has discovered four novel and differentiated drug candidates, including OLINVO™ (oliceridine injection). Trevena also has discovered TRV250, in preclinical development for the treatment of migraine, and TRV734 for pain. The Company maintains 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 interpretation of the top-line results from the APOLLO trials, whether such results put the Company in a strong position to file the OLINVO NDA and bring this product to market, whether OLINVO will provide safer dosing for hard-to-treat patients or reduce the burden of opioid-related adverse effects, whether TRV250 may have utility in other central nervous system indications and not have the addiction liability or other adverse effects seen with mu-opioid receptors, and the expected timing of the NDA submission for oliceridine; the uncertainties inherent in conducting clinical trials, including whether top-line results from the APOLLO trials will be consistent with the full results of the trials, once available, or adverse events seen to date in the ATHENA safety study will be consistent with any future adverse events; expectations for regulatory approvals, including whether the Phase 3 data will support FDA approval of oliceridine for the management of moderate-to-severe pain; 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, including whether physicians, patients, and payers will conclude that the oliceridine development program has shown consistent differentiation from morphine across multiple clinical trials; 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

Trevena, Inc.

Investors:

Jonathan Violin, Ph.D.
Sr. Director, Investor Relations
610-354-8840 x231
jviolin@trevena.com

or

Media:

Public Relations
PR@trevena.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Collaboration revenue	$ —	$ 1,875	$ 3,750	$ 6,250

Operating expenses:				
General and administrative	4,384	3,820	16,077	12,797
Research and development	31,451	13,549	89,956	44,074
Total operating expenses	35,835	17,369	106,033	56,871
Loss from operations	(35,835)	(15,494)	(102,283)	(50,621)
Other income (expense)	(265)	30	(711)	93
Net loss	$ (36,100)	$ (15,464)	$ (102,994)	$ (50,528)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.67)	$ (0.30)	$ (1.97)	$ (1.15)
Weighted average shares outstanding, basic and diluted	53,850	50,770	52,399	43,794

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

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 24,266	$ 46,774
Marketable securities	86,335	125,864
Prepaid expenses and other current assets	1,788	1,893
Total current assets	112,389	174,531
Property and equipment, net	1,059	696
Intangible asset, net	13	15
Restricted cash	1,193	112
Total assets	$ 114,654	$ 175,354
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 8,749	$ 6,750
Accrued expenses and other current liabilities	8,208	3,030
Current portion of loans payable, net	5,039	—
Deferred revenue	—	3,750
Deferred rent	52	44
Total current liabilities	22,048	13,574
Loans payable, net	13,270	18,186
Capital leases, net of current portion	18	8
Deferred rent, net of current portion	187	239
Warrant liability	75	153
Other long term liabilities	475	63
Total liabilities	36,073	32,223
Common stock	56	51
Additional paid-in capital	364,148	325,784
Accumulated deficit	(285,625)	(182,498)
Accumulated other comprehensive income (loss)	2	(206)
Total stockholders' equity	78,581	143,131
Total liabilities and stockholders' equity	$ 114,654	$ 175,354