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 7, 2018**

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.)

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 March 7, 2018, the Company issued a press release announcing its financial results for the quarter and full year ended December 31, 2017. 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 7, 2018

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated March 7, 2018

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 7, 2018

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

Exhibit 99.1

Trevena Reports Full Year 2017 Earnings

— OLINVO™ (oliceridine) Injection New Drug Application submitted and accepted for review by FDA, with PDUFA date of November 2, 2018 —

— Company to host conference call at 8:00 am EST today —

Trevena, Inc. (NASDAQ: TRVN) today announced financial results for the fourth quarter and full year ended December 31, 2017 and provided an update on its pipeline of differentiated new chemical entities, including its lead asset OLINVO™ (oliceridine) Injection, currently under review by the U.S. Food and Drug Administration (FDA) for potential approval this year.

"2017 marked important progress for Trevena as we completed our Phase 3 program and NDA submission for OLINVO and prepared to support commercial launch," said Maxine Gowen, Ph.D., chief executive officer. "We look forward to potential approval of OLINVO later this year, as well as advancement of our earlier R&D programs. We remain committed to bringing patients innovative medicines for safer and more successful pain management."

2017 and recent corporate highlights

- **New Drug Application (NDA) for OLINVO submitted and accepted.** In January 2018, the Company announced that the FDA has accepted the Company's NDA for OLINVO. OLINVO is an investigational product for the management of moderate to severe acute pain. It is the first G protein biased ligand of the mu receptor 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 OLINVO NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of OLINVO in the first quarter of 2019 following DEA scheduling.

- **Announced top line data from the successful Phase 3 open label ATHENA safety study.** In November, the Company announced top-line results from 768 patients administered OLINVO to manage medical or postoperative pain in the ATHENA study, which was designed to model real-world use including multimodal analgesia regimens incorporating OLINVO. Data highlight the potential effectiveness and utility of OLINVO in treating patients who require an IV opioid to manage acute pain. Patients at elevated risk of opioid-related adverse events were well represented in the study; more than 30% of patients were 65 years or older, and more than 50% of patients were obese, with body mass index (BMI) >30 kg/m^2. Only 4% of patients discontinued for lack of efficacy, and 2% of patients discontinued for adverse events. Adverse event rates associated with OLINVO administered by patient controlled analgesia (PCA) and as-needed clinician-administered bolus dosing were similar, supporting potential use of OLINVO in both administration paradigms.

- **Completed dosing in a Phase 1 study of TRV250 for acute migraine.** TRV250 is under investigation as a potential new mechanism of action for the treatment of acute migraine. The first-time-in-human Phase 1 trial was a single ascending dose study of safety, tolerability, and pharmacokinetics of subcutaneous TRV250 in healthy volunteers, and included a separate cohort who received a single oral dose of TRV250. In November, the Company announced positive interim results for the initially planned doses, which demonstrated dose-proportional exposure after subcutaneous administration and adequate oral bioavailability to support further clinical development. Following this interim readout, the Company extended the trial to study additional subcutaneous doses. Dosing is now complete, having reached a top subcutaneous dose of 30 mg. The Company expects to release data in the coming months.

- **Discovered novel S1P modulators, a new non-narcotic approach to managing chronic pain.** In July, the Company disclosed a new preclinical lead optimization program targeting S1P receptors. The Company's compounds are all new chemical entities, expected to be non-addictive, and use a new mechanism of action that in preclinical models avoids the immune suppression associated with approved and investigational S1P receptor targeted drugs. These molecules have demonstrated activity in preclinical models of chemotherapy-induced peripheral neuropathy, neuropathic pain, and inflammatory pain. The Company expects to complete characterization of the lead compounds in 2018 to determine if any merit IND-enabling studies to support Phase 1 clinical trials.

- **Continued engagement with academic and medical communities.** The Company continues to present OLINVO clinical data and analyses of unmet needs in acute pain in peer-reviewed journals and at medical meetings, including:

  - The costs and prevalence of opioid-induced respiratory depression and postoperative nausea and vomiting at PainWeek, the Academy of Managed Care Pharmacy Nexus meeting, and the Annual Pain & Migraine Therapeutics Summit;

  - Efficacy and safety of OLINVO versus morphine in hard tissue and soft tissue pain models from the Phase 3 APOLLO study at the American Society of Anesthesiology Annual Meeting;

  - Efficacy and safety of OLINVO versus morphine in soft tissue pain model from the Phase 2b study in the Journal of Pain Research;

  - Characterization of the pharmacokinetic/pharmacodynamics relationship for OLINVO published in the Journal of Clinical Pharmacology, describing how the fast onset and lack of active metabolites enables a tight coupling between dosing and effect;

  - A series of basic research studies from Trevena and from independent research groups supporting OLINVO's novel mechanism of action and new hypotheses for clinical benefits of molecules like OLINVO;

  - An upcoming presentation of ATHENA data for colorectal surgery patients at the American Society of Colorectal Surgeons meeting in May 2018; and

  - An upcoming oral presentation of APOLLO results at the American Academy of Orthopaedic Surgeons in March 2018.

Financial results

For the fourth quarter of 2017, Trevena reported a net loss attributable to common stockholders of $14.7 million, or $0.24 per share, compared with a net loss attributable to common stockholders for the fourth quarter of 2016 of $36.1 million, or $0.67 per share.

For the year ended December 31, 2017, the Company incurred a net loss attributable to common stockholders of $71.9 million, or $1.21 per share, compared with a net loss attributable to common stockholders of $103.0 million, or $1.97 per share, for the comparable period in 2016. This reduction in 2017 expenses compared to 2016 was largely attributable to substantially reduced R&D expenses following the completion of the OLINVO Phase 3 program and the cessation of early stage research in the fourth quarter of 2017.

Cash, cash equivalents, and marketable securities were $66.1 million as of December 31, 2017. The Company expects that expenses will decrease in 2018 compared to 2017,

primarily attributable to lower R&D expense following the completion in 2017 of the OLINVO Phase 3 program. As such, the Company expects currently available cash, cash equivalents, and marketable securities, together with interest thereon, to be sufficient to fund operations into the second quarter of 2019.

Conference call and webcast

Date: March 7, 2018

Time: 8:00 a.m. EST

Telephone Access: (855) 465-0180

International: (484) 756-4313

Conference ID: 7843918

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 focused on providing better, safer therapies to patients in pain. The Company has leveraged breakthrough science to discover and develop its investigational product OLINVO™ (oliceridine) Injection for the management of moderate-to-severe acute pain. OLINVO 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, including the interpretation of the top-line results from the ATHENA open label safety study, whether such results highlight the potential effectiveness and utility of OLINVO in treating patients who require an IV opioid to manage acute pain, whether OLINVO will provide safer dosing for hard-to-treat patients or reduce the burden of opioid-related adverse effects, whether the Phase 1 study results from TRV250 will be available in the coming months and whether such results will support further clinical development; the uncertainties inherent in conducting clinical trials; expectations for regulatory approvals, including whether OLINVO NDA will be approved by FDA on the November 2, 2018 PDUFA date and the timing for any subsequent DEA scheduling; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, including whether the Company's currently available cash, cash equivalents, and marketable securities, together with interest thereon, to be sufficient to fund operations until at least the second quarter of 2019; 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

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Collaboration revenue	$ —	$ —	$ —	$ 3,750
Operating expenses:				
General and administrative	5,143	4,384	19,639	16,077
Research and development	7,198	31,451	48,974	89,956
Restructuring charges	1,774	—	1,774	—
Total operating expenses	14,115	35,835	70,387	106,033
Loss from operations	(14,115)	(35,835)	(70,387)	(102,283)
Other income (expense)	(605)	(265)	(1,478)	(711)
Net loss	$ (14,720)	$ (36,100)	$ (71,865)	$ (102,994)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.24)	$ (0.67)	$ (1.21)	$ (1.97)
Weighted average shares outstanding, basic and diluted	62,290,002	53,850,166	59,436,649	52,398,521

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

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 16,557	$ 24,266
Marketable securities	49,543	86,335
Prepaid expenses and other current assets	1,393	1,788
Total current assets	67,493	112,389
Restricted cash	1,413	1,193
Property and equipment, net	3,805	1,059
Intangible asset, net	11	13
Total assets	$ 72,722	$ 114,654
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,424	$ 8,749
Accrued expenses and other current liabilities	4,303	8,208
Current portion of loans payable, net	12,425	5,039
Deferred rent	61	52
Total current liabilities	18,213	22,048
Loans payable, net	15,725	13,270
Capital leases, net of current portion	31	18
Deferred rent, net of current portion	3,006	187
Warrant liability	10	75
Other long term liabilities	1,104	475
Total liabilities	38,089	36,073
Common stock	62	56
Additional paid-in capital	392,103	364,148
Accumulated deficit	(357,490)	(285,625)
Accumulated other comprehensive income (loss)	(42)	2
Total stockholders' equity	34,633	78,581
Total liabilities and stockholders' equity	$ 72,722	$ 114,654