TREVENA INC

FORM 8-K
(Current report filing)

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Address	955 CHESTERBROOK BOULEVARD SUITE 200 CHESTERBROOK, PA, 19087
Telephone	6103548840
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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 7, 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.)

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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**

1018 West 8th Avenue, Suite A,
King of Prussia, PA 19406
(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 November 7, 2017, the Company issued a press release announcing its financial results for the quarter ended September 30, 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 November 7, 2017

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated November 7, 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: November 7, 2017

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

Exhibit 99.1

Trevena Reports Third Quarter 2017 Financial Results and Announces New Positive Clinical Trial Data

— New ATHENA data show OLINVO effectiveness with promising safety/tolerability in key target procedures —

— Positive interim data for Phase 1 study of investigational migraine treatment TRV250 leads to study expansion —

CHESTERBROOK, PA, November 7, 2017 — Trevena, Inc. (NASDAQ: TRVN) today announced financial results for the quarter ended September 30, 2017, and announced positive new data from both its OLINVO ™ (oliceridine injection) and TRV250 programs.

"The recent submission of the OLINVO NDA capped a transformative period for our Company," said Maxine Gowen, Ph.D., chief executive officer. "We are now focused on preparing for the approval and commercialization of OLINVO, while continuing to advance our development pipeline following our recent strategic decision to halt our discovery research efforts. To this end, new results continue to highlight the potential value of OLINVO for patients in a real world setting who require IV opioids but are at risk of opioid-related adverse events. Positive interim Phase 1 data for TRV250 bode well for future clinical development of this exciting potential migraine therapy."

Third quarter and recent corporate highlights

- **OLINVO New Drug Application submitted.** The Company recently submitted its New Drug Application (NDA) for OLINVO to the U.S. Food and Drug Administration (FDA). OLINVO is the first G protein biased ligand of the mu opioid receptor, a new class of opioid receptor modulator, and the first pain program to receive Breakthrough Therapy designation from the FDA. The submission includes data showing that intravenous OLINVO demonstrated analgesic efficacy in all three dosing regimens tested in the two Phase 3 APOLLO pivotal efficacy studies. These trials were designed to support an indication for the management of moderate-to-severe acute pain in adult patients for whom an intravenous opioid is warranted. The filing also includes safety and tolerability data for over 1,100 patients administered OLINVO across Phase 2 and Phase 3 studies, including the ATHENA open label safety study. Additional pharmacokinetic data, clinical pharmacology data, and results from five randomized controlled trials with head to head comparisons to morphine, support potential differentiation of OLINVO.

- **New data from Phase 3 ATHENA open label safety study** . In July, the Company announced top-line results from the first 418 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 for all 768 patients administered OLINVO are now final, and highlight the effectiveness and utility of OLINVO in treating patients who require an IV opioid to manage pain. Across the ATHENA study:

- The most common procedures were orthopedic, colorectal, gynecologic, and general surgeries. Patients at elevated risk of opioid-related adverse events were well represented; 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 2% of patients discontinued for adverse events, and 4% of patients discontinued for lack of efficacy. The most common adverse events were nausea, constipation, and vomiting, with prevalence lower than in the APOLLO studies. Adverse event rates associated with OLINVO administered by patient controlled analgesia (PCA) and as-needed bolus dosing were similar, supporting potential use of OLINVO in both administration paradigms.

- **Hosted an Analyst Day featuring four leading experts in acute pain management in the hospital.** In July, the Company hosted an Analyst Day where it outlined its commercial strategy for OLINVO, including plans to focus on patients who require IV opioids and are at greater risk of opioid-related adverse effects (ORAEs). These patients comprise approximately 7 to 9 million annual hospital inpatients in the United States. Among other data presented, investigator-reported observations from the ATHENA study included a retrospective chart review at one site that found that colorectal surgery patients who received OLINVO showed return of bowel function 28 hours faster than similar patients treated with conventional opioids (p=0.0001 vs. historical control at the same site).

- **Continued publication and medical conference presentation of OLINVO data.** The Company has continued to present OLINVO clinical data and analyses of unmet needs in acute pain in peer-reviewed journals and at medical meetings. OLINVO has also been featured in independent peer-reviewed publications. Select presentations and publications included:

  - **Peer-reviewed publication of full Phase 2b results,** by Singla et al: https://www.dovepress.com/getfile.php?fileID=38764

  - **Prevalence and costs of opioid-related adverse events** presented at PainWeek and the American Society of Anesthesiologist annual meetings

  - **Unmet needs and potential new options in acute pain management,** by Gan et al: https://www.dovepress.com/getfile.php?fileID=38563

  - **Structural basis for the novel OLINVO mechanism of action,** by Kappor et al: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5595830/pdf/41598_2017_Article_11483.pdf

- **Joined a Department of Health and Human Services Secretarial Round Table on Opioids** , held October 5, 2017 in Washington, D.C. The round table invited industry leaders, including Dr. Gowen, to discuss novel drugs and delivery systems that have the potential to improve pain management or reduce opioid addiction. At the meeting, Dr. Gowen emphasized that because IV opioids will remain necessary for millions of hospital patients, there is an urgent need for new options that may offer improved safety while helping to avoid unnecessarily prolonged exposure to opioids.

- **Positive interim results of Phase 1 study of TRV250 for acute migraine.** TRV250 is under investigation as a potential new mechanism of action for the acute treatment of migraine. The ongoing first-time-in-human Phase 1 trial is a single ascending dose study of safety, tolerability, and pharmacokinetics of both subcutaneous and oral TRV250 in healthy volunteers. The Company has completed dosing of the initially planned cohorts.

    - In the doses studied to date, TRV250 demonstrated dose-proportional exposure after s.c. administration. TRV250 was well tolerated at all doses tested. Because no dose-limiting adverse events were identified in the initial cohorts of healthy subjects, the company has expanded the study to evaluate higher doses to support future Phase 2 planning.

    - Preliminary data from oral administration of TRV250 to healthy volunteers suggest TRV250 has adequate oral bioavailability to support further clinical development.

- **Discovery of 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.

Financial results

For the third quarter of 2017, Trevena reported a net loss attributable to common stockholders of $16.0 million, or $0.27 per share, compared with a net loss attributable to common stockholders for the third quarter of 2016 of $29.9 million, or $0.57 per share. Research and development expenses were $10.2 million in the third quarter of 2017 compared to $25.5 million for the same period in 2016; general and administrative expenses were $5.2 million, compared to $4.1 million for the third quarter of 2016.Cash, cash equivalents, and marketable securities were $76.6 million as of September 30, 2017, which the Company expects to be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from today's date.

For additional details, please see the Company's Form 10-Q, which will be filed with the SEC today.

Conference Call and Webcast

Date: November 7, 2017
Time: 8:00 a.m. EST
Telephone Access: (855) 465-0180
International: (484) 756-4313
Webcast: http://investors.trevena.com/index.cfm
Conference ID: 9796968

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 was designed to provide healthcare providers an innovative new option for patients who would otherwise require conventional intravenous opioids. The Company has an early stage pipeline of new chemical entities targeting novel mechanisms of action, including 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 or any future trials, including whether the positive interim data from the Phase 1 study of TRV250 bode well for the future clinical development of this therapy; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals; 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 the ATHENA data highlights the potential value of OLINVO for patients who require IV opioids but are at risk of opioid-related adverse events; 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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TREVENA, INC.
Condensed Statements of Operations
(Unaudited, in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Collaboration revenue	$ —	$ —	$ —	$ 3,750
Operating expenses:				
General and administrative	5,232	4,078	14,496	11,693
Research and development	10,181	25,549	41,776	58,505
Total operating expenses	15,413	29,627	56,272	70,198
Loss from operations	(15,413)	(29,627)	(56,272)	(66,448)
Other income (expense)	(586)	(272)	(873)	(446)
Net loss	$ (15,999)	$ (29,899)	$ (57,145)	$ (66,894)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.27)	$ (0.57)	$ (0.98)	$ (1.29)
Weighted average shares outstanding, basic and diluted	60,113,327	52,205,156	58,475,079	51,911,017

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

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 18,068	$ 24,266
Marketable securities	58,505	86,335
Prepaid expenses and other current assets	2,111	1,788
Total current assets	78,684	112,389
Property and equipment, net	4,132	1,059
Restricted cash	1,413	1,193
Intangible asset, net	12	13
Total assets	$ 84,241	$ 114,654
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,783	$ 8,749
Accrued expenses and other current liabilities	3,868	8,208
Current portion of loans payable, net	10,283	5,039
Deferred rent	58	52
Total current liabilities	15,992	22,048
Loans payable, net	17,783	13,270
Capital leases, net of current portion	34	18
Deferred rent, net of current portion	2,675	187
Warrant liability	22	75
Other long term liabilities	925	475
Total liabilities	37,431	36,073
Common stock	62	56
Additional paid-in capital	389,539	364,148
Accumulated deficit	(342,770)	(285,625)
Accumulated other comprehensive income (loss)	(21)	2
Total stockholders' equity	46,810	78,581
Total liabilities and stockholders' equity	$ 84,241	$ 114,654