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TREVENA INC

FORM 8-K
(Current report filing)

Filed 01/05/18 for the Period Ending 01/02/18

Address	955 CHESTERBROOK BOULEVARD SUITE 200 CHESTERBROOK, PA, 19087
Telephone	6103548840
CIK	0001429560
Symbol	TRVN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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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): **January 2, 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.)

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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**

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 8.01 Other Events .

On January 2, 2018, Trevena, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for OLINVO™ (oliceridine) Injection. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference. On January 5, 2018, the FDA indicated to the Company that (1) the Prescription Drug User Fee Act review date for the OLINVO NDA is November 2, 2018, and (2) it plans to hold an advisory committee meeting to discuss the NDA.

Item 9.01. Financial Statements and Exhibits .

(d) Exhibits

Number	Description
99.1	Press Release dated January 2, 2018

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated January 2, 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: January 5, 2018

By: /s/ John M. Limongelli
John M. Limongelli
Sr. Vice President, General Counsel & Chief Administrative Officer

Exhibit 99.1

Trevena Announces FDA Acceptance for Review of New Drug Application for OLINVO (oliceridine) Injection

January 2, 2018 — Trevena, Inc. (NASDAQ:TRVN) today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for OLINVO™ (oliceridine) Injection. The Company expects that the PDUFA date for the NDA will be in the fourth quarter of 2018. 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 NDA file acceptance represents another major step in our progress towards delivering OLINVO to patients and healthcare providers in need of new options for managing moderate to severe acute pain in the hospital setting," said Maxine Gowen, Ph.D., chief executive officer. "We look forward to working with the FDA as they evaluate the OLINVO application."

About OLINVO™ (oliceridine) Injection

OLINVO is a next generation IV analgesic for the management of moderate-to-severe acute pain in the hospital and similar settings and has been granted Breakthrough Therapy designation by the FDA. OLINVO was specifically designed to deliver the pain relief of a conventional IV opioid, with fewer associated adverse effects via its biased ligand mechanism of action. 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 for the management of moderate-to-severe acute pain. 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; the uncertainties inherent in conducting clinical trials; expectations for regulatory approvals, including with respect to the OLINVO NDA and the timing of the PDUFA date; 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 OLINVO will be a new option for managing moderate to severe acute pain in the hospital setting; 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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