TREVENA INC
Form 8-K
May 02, 2016

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 8-K

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d)**

**of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **May 2, 2016**

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# TREVENA, INC.

(Exact name of registrant as specified in its charter)

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**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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 7.01** **Regulation FD.**

On May 2, 2016, Trevena, Inc. ( Trevena or the Company ) announced that it will host a conference call and webcast at 5:30 pm EDT on May 2, 2016 (the Event ) to discuss the results of its recently completed End-of-Phase 2 ( EoP2 ) meeting with the U.S. Food and Drug Administration ( FDA ) with respect to the Company s product candidate oliceridine (TRV130). To access the live webcast of the Event, please visit the Investors section of the Company s website at www.trevenainc.com. Following the conclusion, an archive of the Event will be available on the Company s website until June 1, 2016.

The Company will utilize a slide presentation during the Event, a copy of which is furnished hereto as Exhibit 99.2.

The information set forth in this Item 7.01 and furnished hereto as Exhibit 99.2 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act ), and is not incorporated by reference into any of the Company s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

*Cautionary Note on Forward Looking Statements*

Any statements in Item 7.01 of this Current Report on Form 8-K, including within Exhibit 99.2 hereto, regarding 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, cons 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: uncertainties related to the Company s intellectual property; the status, timing, costs, results and interpretation of the Company s clinical trials, including whether oliceridine will prove to be a differentiated analgesic for patients and caregivers seeking alternatives to conventional opioids; the uncertainties inherent in conducting clinical trials, including the timing around the initiation of the pivotal efficacy studies in the Phase 3 program, the release of top-line data and the potential filing of an NDA; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials, including the Phase 2 oliceridine studies and any post-hoc analysis of such trial results, will be indicative of the results of future trials; expectations for regulatory approvals, including the Company s assessment of the results of the End-of-Phase 2 meeting with FDA and whether the Company ultimately will achieve regulatory approval for oliceridine; availability of funding sufficient for the Company s foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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 Current Report on Form 8-K, including Exhibit 99.2 hereto, 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.

**Item 8.01** **Other Events**.

On May 2, 2016, the Company issued a press release announcing completion of the EoP2 meeting with FDA and outlining the Company s plans for the Phase 3 program for oliceridine. A copy of the press release is furnished herewith as Exhibits 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01.** **Financial Statements and Exhibits.**

(d) Exhibits

| Number | Description |
|---|---|
| 99.1 | Press Release dated May 2, 2016 |
| 99.2* | Slides presentation for the Trevena, Inc. May 2, 2016 conference call and webcast |

* Exhibit 99.2 is furnished as part of this Current Report on Form 8-K.

**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: May 2, 2016

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

EXHIBIT INDEX

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