

TREVENA INC
Form 8-K
November 17, 2014

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 17, 2014**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

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001-36193
(Commission
File No.)

26-1469215
(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))
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Item 7.01

Regulation FD.

In connection with the press release dated November 17, 2014 described in Item 8.01 below, Trevena, Inc. (the "Company") will hold a conference call and webcast on November 17, 2014. Details regarding accessing the conference call and webcast are contained in the press release under the heading "Conference Call and Webcast." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The information contained in the press release furnished as Exhibit 99.1 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.

Item 8.01

Other Events.

On November 17, 2014, the Company issued a press release with respect to its Phase 2a/b study of TRV130 in acute postoperative pain. In the release, the Company announced positive top-line data from its randomized, double-blind, placebo- and active-controlled Phase 2a/b trial of TRV130 in moderate to severe postoperative acute pain. At doses of 2 mg and 3 mg TRV130 administered every 3 hours, the study achieved its primary endpoint of statistically greater pain reduction than placebo over 48 hours, successfully demonstrating proof of concept for TRV130. The trial was designed with key secondary endpoints to evaluate the differentiation of TRV130 from morphine at a standard reference dose of 4 mg every 4 hours. Over the 48 hour study period, TRV130 3 mg every 3 hours showed statistically superior analgesic efficacy compared to morphine. Additionally, the 2 mg and 3 mg doses of TRV130 demonstrated statistically superior analgesic efficacy to 4 mg morphine in the first 3 hours of dosing, when study pain was most severe. For these doses, patients also reported maximum pain relief during the first dosing period that was statistically superior compared to morphine. Notably, in this study TRV130 at 2 mg and 3 mg demonstrated similar tolerability to morphine 4 mg over 48 hours. TRV130 and morphine were both associated with opioid-related adverse events, including dizziness, headache, somnolence, nausea, vomiting, flushing, and itching.

Item 9.01.

Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press release dated November 17, 2014

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 17, 2014

By:

/s/ John M. Limongelli
John M. Limongelli
Sr. Vice President, General Counsel & Corporate
Secretary

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated November 17, 2014.