TREVENA INC
Form 8-K
August 31, 2015

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): **August 31, 2015**

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.)

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.**

In connection with its press release dated August 31, 2015, Trevena, Inc. (the Company) will hold a conference call and webcast on August 31, 2015. 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 August 31, 2015, the Company announced results from its randomized, double-blind, placebo- and active-controlled Phase 2b trial of TRV130 in moderate to severe postoperative pain after abdominoplasty surgery. The trial achieved its primary endpoint of statistically greater pain reduction than placebo over 24 hours. In addition, TRV130 was superior to morphine in pre-specified secondary measures, exhibiting significantly reduced nausea, vomiting, and hypoventilation events. In the trial, two regimens of TRV130 were tested: the first consisted of a 1.5 mg intravenous loading dose with 0.1 mg self-administered on-demand doses as often as every 6 minutes (together referred to here as TRV130 0.1 mg) using a patient controlled analgesia (PCA) device; the second consisted of a 1.5 mg loading dose with 0.35 mg on-demand doses (together referred to here as TRV130 0.35 mg) using a PCA device. A commonly used morphine PCA regimen was also tested, consisting of a 4 mg loading dose with 1 mg on-demand doses. Placebo was administered as a loading dose and on-demand doses that were volume-matched to the active regimens. Specifically, the Company reported the following results:

Efficacy

- TRV130 demonstrated statistically significant pain reduction compared to placebo and comparable efficacy to morphine. The TRV130 0.1 mg regimen reduced average pain scores (LS mean change in time-weighted average over 24 hours) by 2.3 points ($p<0.0001$ vs. placebo). The TRV130 0.35 mg regimen reduced average pain scores by 2.1 points ($p=0.0003$ vs. placebo), similar to morphine, which reduced average pain scores by 2.1 points ($p=0.0001$ vs. placebo).

- TRV130 provided rapid reduction in average pain scores, consistent with the previous Phase 2 trial where TRV130 showed more rapid onset of meaningful pain relief than morphine.

- Rescue analgesic use was similar for both TRV130 and morphine, and less than half the rate of rescue analgesic use for placebo. The proportion of patients using rescue analgesic was 64% with placebo, 31% with TRV130 0.1 mg, 21% with TRV130 0.35 mg, and 25% with morphine (post hoc $p<0.0005$ for all three active arms vs. placebo).

Safety and tolerability

- In this study, the TRV130 groups had a significantly lower prevalence (percentage of patients) of hypoventilation events (a measure of respiratory safety), nausea, and vomiting than the morphine group (post hoc $p<0.05$ for both TRV130 regimens vs. morphine).

	Placebo	TRV130 0.1 mg	TRV130 0.35 mg	Morphine
Hypoventilation	10%	15%	31%	53%
Vomiting	8%	15%	15%	42%
Nausea	18%	41%	46%	72%

- Adverse events associated with TRV130 were largely opioid-related; the most frequently reported events were nausea, vomiting, hypoventilation and headache. Opioid-related AEs were generally less frequent in the TRV130 groups compared to morphine. No drug-related serious adverse events were reported in the study.

Total TRV130 use in the study was similar for the two TRV130 regimens with mean cumulative doses of 7.6 mg and 5.4 mg for the TRV130 0.1 mg and TRV130 0.35 mg regimens, respectively. The mean cumulative dose of morphine was 26.3 mg.

The Phase 2b study was a randomized, double-blind, placebo- and active-controlled, multiple dose, adaptive study in 200 patients undergoing abdominoplasty surgery at a single center in the United States. At baseline, patients had a mean baseline pain score on the numerical pain rating scale (NPRS) of 7.7 out of 10, which is considered severe pain. Pain intensity was measured using validated numeric rating scales at multiple time points up to 24 hours

All study arms used a flexible dose, PCA administration regimen intended to optimize treatment and reflect the as-needed dosing most commonly used with post-operative opioid analgesics. All regimens were blinded and volume-matched, and consisted of intravenous loading doses followed by patient-controlled intravenous doses with a 6 minute lockout period after every on-demand dose. Patients were assigned randomly to post-operative regimens of TRV130, placebo, or morphine, in a 2:1:2 ratio respectively, beginning when post-operative pain became moderate or severe in intensity and continuing for 24 hours thereafter.

Rescue analgesics were available as necessary for patients whose pain was not adequately treated by TRV130, morphine, or placebo; first line rescue was oral ibuprofen and second line rescue was oral oxycodone. A standard methodology was used to avoid including effects of rescue analgesics on pain intensity measures: an unscheduled pain intensity assessment was made before rescue analgesic dosing, and this value was used instead of the scheduled pain intensity values until the end of the study.

In this trial, respiratory safety was measured as hypoventilation events, defined as clinically apparent and persistently decreased respiratory rate, respiratory effort or oxygen saturation. In practice, such events can result in interruption of opioid analgesic administration or, if unrecognized and if additional opioids are administered, to more serious consequences.

A pre-specified interim analysis was conducted after enrollment of 100 patients to evaluate opportunities for studying additional regimens of TRV130, after which the on-demand dose of TRV130 was increased to 0.35 mg for the remaining portion of the study.

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

(d) Exhibits

Number	**Description**
99.1	Press release dated August 31, 2015

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: August 31, 2015	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 August 31, 2015.