TREVENA INC
Form 8-K
February 21, 2017

# 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): **February 21, 2017**

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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.**

In connection with its press release dated February 21, 2017, Trevena, Inc. (the Company ) will hold a conference call and webcast on February 21, 2017. 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 February 21, 2017, the Company announced positive top-line results from its Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of oliceridine in moderate-to-severe acute pain following bunionectomy and abdominoplasty, respectively. In both studies, all dose regimens achieved their primary endpoint of statistically greater analgesic efficacy than placebo, as measured by responder rate.

The APOLLO-1 and APOLLO-2 studies were both Phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine. APOLLO-1 and APOLLO-2 evaluated oliceridine s efficacy in patients for 48 hours following bunionectomy and 24 hours following abdominoplasty, respectively. During the study period, a loading dose of placebo, morphine (4 mg), or oliceridine (1.5 mg) was administered first, and then patients used a PCA button to dose themselves as often as every 6 minutes with the same study drug: 1 mg morphine or 0.1 mg, 0.35 mg, or 0.5 mg oliceridine. If PCA dosing was inadequate to control pain, patients could request supplemental study medication (0.75 mg oliceridine or 2 mg morphine, no more than once an hour). If the study medication regimen did not adequately manage pain, patients could opt for an NSAID rescue analgesic. Placebo loading, demand, and supplemental doses were volume-matched.

All endpoints were the same in both studies. Efficacy was measured by a responder analysis, which defined a responder as a patient who experienced at least a 30% reduction in their sum of pain intensity difference (SPID) at the end of the treatment period without either early discontinuation (for lack of efficacy or safety/tolerability) or use of rescue medication. Non-inferiority to morphine and superiority to morphine were key secondary endpoints. Respiratory safety events were defined as clinically relevant worsening of respiratory status (e.g., oxygen saturation, respiratory rate, or sedation). The product of the frequency and conditional duration of these events was reported as respiratory safety burden, a key secondary endpoint. Additional measures of respiratory safety included prevalence of oxygen saturation less than 90% and prevalence of supplemental oxygen use. Measures of gastrointestinal tolerability included use of rescue antiemetics, vomiting, and spontaneously reported nausea.

**Results of APOLLO-1 (bunionectomy)**

- All three oliceridine regimens (0.1 mg, 0.35 mg, and 0.5 mg on-demand doses) achieved the primary endpoint with statistically superior responder rates compared to placebo at 48 hours ($p<0.0001$, adjusted for multiplicity).

- The 0.35 mg and 0.5 mg oliceridine dose regimens demonstrated efficacy comparable to morphine at 48 hours based on responder rate (both doses $p<0.005$ for non-inferiority to morphine). Both doses were also comparable to morphine for rates of rescue analgesic use.

- Following the 1.5 mg initial loading dose, all oliceridine regimens demonstrated rapid onset with statistically significant efficacy by 5 minutes ($p<0.05$).

- Oliceridine exhibited a dose-related trend of improved respiratory safety burden in all three oliceridine dose regimens ($p<0.05$ for the 0.1 mg regimen vs. morphine). Consistent with this, in all dose regimens oliceridine showed dose-related trends of reduced prevalence of oxygen desaturation ($O_2<90\%$) and lower prevalence of supplemental oxygen use ($p<0.05$ for the 0.1 mg regimen vs. morphine for both measures).

- Oliceridine exhibited a dose-related trend of less antiemetic use compared to morphine ($p<0.05$ for all oliceridine regimens vs. morphine). Consistent with this, oliceridine showed dose related trends of lower prevalence of nausea and vomiting in all three oliceridine regimens ($p<0.05$ for the 0.1 mg regimen vs. morphine).

**Results of APOLLO-2 (abdominoplasty)**

- All three oliceridine dose regimens achieved the primary endpoint with statistically superior responder rates compared to placebo (adjusted $p<0.05$ for the 0.1 mg regimen; adjusted $p<0.001$ for the 0.35 mg and 0.5 mg regimens).

- The 0.35 mg and 0.5 mg oliceridine dose regimens demonstrated efficacy comparable to morphine at 24 hours based on responder rate ($p<0.05$ for non-inferiority of the 0.35 mg regimen vs. morphine). Both doses were also comparable to morphine for rates of rescue analgesic use.

- Following the 1.5 mg initial loading dose, all oliceridine regimens demonstrated rapid onset with statistically significant efficacy by 5 to 15 minutes ($p<0.05$).

- Oliceridine showed a dose-related trend of improved respiratory safety burden in all three oliceridine dose regimens ($p<0.05$ for the 0.1 mg regimen vs. morphine). Consistent with this, for all dose regimens oliceridine showed dose-related trends of reduced prevalence of oxygen desaturation ($O_2<90\%$) and lower prevalence of supplemental oxygen use ($p<0.05$ for the 0.1 mg regimen vs. morphine for both measures).

- Oliceridine showed a dose-related trend of less antiemetic use than morphine for all three oliceridine regimens ($p<0.05$ for the 0.1 mg oliceridine regimen vs. morphine). Consistent with this, oliceridine showed dose-related trends of lower prevalence of nausea and vomiting ($p<0.05$ for the 0.1 mg regimen vs. morphine for both nausea and vomiting; $p<0.05$ for the 0.35 mg regimen vs. morphine for vomiting).

In both studies, oliceridine was generally well-tolerated. The most common drug-related adverse events were nausea, vomiting, headache, and dizziness.

Where specific p values are included under Results of APOLLO-1 (bunionectomy) and Results of APOLLO-2 (abdominoplasty) above, statistical significance was reached on the cited measure for the cited dose and statistical significance was not achieved for any dose not so cited.

Separately, the Company also announced that patient enrollment for its Phase 3 ATHENA multi-procedure safety study remains on track, with over 400 patients treated with oliceridine and no apparent off-target or unexpected adverse effects, in each case as of February 15, 2017. In addition, a recently completed renal impairment study suggests that no dose adjustment will be required in renally impaired patients, and a metabolism study showed no evidence of active metabolites. All additional clinical, non-clinical, and manufacturing activities remain on track to support an NDA submission in the fourth quarter of 2017.

The Company also announced that the U.S. Food & Drug Administration has conditionally accepted OLINVO as the proprietary brand name for oliceridine.

**Risks Related to the Reported Results of Oliceridine**

***The reported results of oliceridine are based on top-line data and may ultimately differ from actual results once additional data are received and fully evaluated.***

The reported results of oliceridine that we have publicly disclosed, and that are discussed herein, consist of top-line data. Top-line data are based on a preliminary analysis of currently-available efficacy and safety data, and therefore the reported results, findings and conclusions related to oliceridine are subject to change following a comprehensive review of the more extensive data that we expect to receive related to oliceridine. Top-line data are based on important assumptions, estimations, calculations, and information currently available to us, and we have not received or had an opportunity to fully and carefully evaluate all of the data related to oliceridine. As a result, the top-line results of oliceridine that we have reported may differ from future results, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of oliceridine, the approvability or commercialization of oliceridine, and our business in general. If the top-line data that we have reported related to oliceridine differ from actual results, our ability to obtain approval for, and commercialize, our products may be harmed, which could harm our business, financial condition, operating results or prospects.

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

(d) Exhibits

| Number | Description |
|---|---|
| 99.1 | Press release dated February 21, 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: February 21, 2017

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

EXHIBIT INDEX

| Exhibit Number | Description |
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| 99.1 | Press release dated February 21, 2017. |