TREVENA INC
Form 8-K
October 28, 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): **October 28, 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.**

On October 28, 2015, Trevena, Inc. (Trevena or the Company) will be hosting analysts and investors in New York City from 12:00 p.m. EDT to approximately 3:00 p.m. EDT. The analyst and investor event (the Event) will focus on the Company s clinical programs, including its most advanced assets, TRV130 and TRV027. Highlights from the meeting will include the following:

- The USAN-approved generic name for TRV130 is oliceridine.
- At its end of phase 2 meeting with the U.S. Food and Drug Administration (FDA), Trevena expects to present the following outline for the TRV130 Phase 3 program:
- Conducting two pivotal studies (in bunionectomy and abdominoplasty surgeries) with a total of approximately 300 600 patients to support a broad acute pain indication;
- Including placebo and morphine in both pivotal studies; and
- Conducting a multi-procedure safety study with approximately 600 900 patients.
- Trevena also may conduct additional clinical studies to support labeling and/or publication, with patient enrollment reallocated from the multi-procedure safety study.
- Preliminary estimated timelines for the Company s Phase 3 program for TRV130 are as follows:
- 1Q 2016: Conduct end-of-phase 2 meeting with FDA; initiate multi-procedure safety study;
- 2Q 2016: Initiate pivotal Phase 3 studies;
- 1Q 2017: Top-line data from pivotal Phase 3 studies; and
- 2H 2017: File the new drug application (NDA) for TRV130.
- 446 patients have been enrolled in the BLAST-AHF Phase 2b trial of TRV027 in acute heart failure as of October 21, 2015. Trevena remains on track to report top-line data for this study in 2Q 2016.
- The Data Safety Monitoring Board has reviewed the BLAST-AHF Phase 2b data one time since the interim analysis conducted in 1Q 2015 and did not identify any safety concerns.

The Event will be webcast live and, following the Event, an archive will be available on the Company s website until November 30, 2015. To access the live webcast of the Event, please visit the Investors section of the Company s website at www.trevenainc.com.

The information set forth in this Item 7.01 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 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, s potential, will, would, could, should, continue, and similar expressions, constitute forward-looking statements within the meaning of The 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, including the Company s expectations for the types of studies, numbers of patients and timelines for initiation and completion of the TRV130 Phase 3 program and the filing of the NDA for TRV130 and the timing of the completio; the uncertainties inherent in conducting clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials will be indicative of the results of future trials, including with respect to whether the results of the previous clinical studies of TRV130 will be consistent with the results obtained in any future Phase 3 studies; expectations for regulatory approvals; availability of funding sufficient for the Company s foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the viability or commercial potential of the Company s therapeutic candidates; the inherent uncertainties associated with intellectual property; 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.

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: October 28, 2015

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