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 11, 2018**

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.)

955 Chesterbrook Boulevard, Suite 110
Chesterbrook, PA 19087
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(610) 354-8840**

Not applicable
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 **Regulation FD**.

Trevena, Inc. (the "Company" or the "Sponsor") is providing the following information to clarify and further expand upon the interactions between Trevena and the U.S. Food and Drug Administration ("FDA") with respect to the primary endpoint for the two pivotal Phase 3 studies, APOLLO-1 and APOLLO-2, conducted by the Company with respect to oliceridine.

Prior to the Company's End-of-Phase 2 meeting, the Division of Anesthesia, Analgesia, and Addiction Products (the "Division"), Center for Drug Evaluation and Research of FDA indicated to the Company that it did not agree with the proposed primary efficacy endpoint for the APOLLO-1 and APOLLO-2 studies. Following this, the Company submitted additional analyses to, and had further discussions with, the Division. In the meeting minutes dated April 28, 2016 from the End-of-Phase 2 meeting between the Division and the Company, the Division indicated the following to the Company:

> "Regarding the relevance of the proposed primary endpoint, the Sponsor plans to include multiple secondary endpoints in their analyses to reflect appropriate endpoints of clinical importance. They have tried patient global assessments, but these have limitations in the acute setting. The Division stated that while a 30% improvement in summed pain intensity difference (SPID) is acceptable statistically, the clinical relevance of a 30% improvement in this setting using this measure is not clear.

Interpretability of SPIDs can be challenging because the value is dependent on the formula for calculating the SPID and has no obvious meaning. Further, the SPID may be different for the two treatment groups, but the difference can reflect only an early or late effect. The Division stated that a 30% decrease in pain has typically been used as a marker to determine a clinically-meaningful difference in chronic pain settings. **The Division has no objection to use of a responder rate as an endpoint, however, the Sponsor must incorporate those patients who discontinue into the analysis as non-responders**." (emphasis added)

In its analysis of the primary endpoint of the APOLLO-1 and APOLLO-2 studies of oliceridine, the Company treated any patient who discontinued for any reason as non-responders, as requested by the Division.

The information contained 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.

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 11, 2018

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