

TREVENA INC
Form 8-K
January 05, 2018

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): **January 2, 2018**

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.)

955 Chesterbrook Boulevard, Suite 200

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 X

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. X

Item 8.01 **Other Events.**

On January 2, 2018, Trevena, Inc. (the Company) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for OLINVO (oliceridine) Injection. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference. On January 5, 2018, the FDA indicated to the Company that (1) the Prescription Drug User Fee Act review date for the OLINVO NDA is November 2, 2018, and (2) it plans to hold an advisory committee meeting to discuss the NDA.

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

(d) Exhibits

| Number | Description |
|---------------|-------------------------------------|
| 99.1 | Press Release dated January 2, 2018 |

EXHIBIT INDEX

| Exhibit Number | Description |
|---------------------------|--|
| 99.1 | <u>Press Release dated January 2, 2018</u> |

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: January 5, 2018

By:

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