TREVENA INC
Form 8-K
February 23, 2016

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): **February 22, 2016**

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 8.01 **Other Events.**

On February 22, 2016, Trevena, Inc. (the Company) announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to the Company s lead product candidate, intravenous oliceridine (TRV130), for the management of moderate-to-severe acute pain. Oliceridine is now in Phase 3 development and the ATHENA-1 safety and tolerability study is ongoing, with pivotal studies expected to begin in the second quarter of 2016.

Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious conditions, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. For oliceridine, the designation request included the full study results of both of the Company s recent Phase 2 studies. Breakthrough Therapy designation provides all the benefits of the Fast Track program, as well as more intensive FDA guidance on preparing an efficient drug development program and eligibility for rolling review and priority review.

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 23, 2016	By:	/s/ John M. Limongelli John M. Limongelli Sr. Vice President, General Counsel & Corporate Secretary