

TREVENA INC
Form 8-K
March 10, 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): **March 5, 2015**

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

26-1469215
(IRS Employer

File No.)

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:

- 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))
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Item 1.01. Entry into a Material Definitive Agreement.

On March 5, 2015, Trevena, Inc. (the Company) entered into a letter agreement (the Agreement) with Actavis plc (Actavis), the indirect parent company of Forest Laboratories Holdings Limited (Forest), related to the Option Agreement between the Company and Forest dated as of May 3, 2013. Under the Agreement, the Company and Actavis agreed with respect the Company's ongoing Phase 2b study of TRV027 in patients with acute heart failure (the Study) to, among other things, increase target enrollment in the Study from 500 patients to 620 patients and to weight remaining enrollment in the Study 2:1:2:1 for placebo, 1 mg/hr of TRV027, 5 mg/hr of TRV027 and 25 mg/hr of TRV027, respectively. In exchange for these changes to the Study, Actavis agreed to pay to the Company the sum of ten million dollars (\$10,000,000) within five business days following March 5, 2015.

The descriptions of the Agreement contained herein does not purport to be complete and is qualified in its entirety by reference to the Agreement, attached hereto as Exhibit 10.1 and incorporated herein by reference.

Item 8.01 Other Events.

Based on a review of the safety and efficacy data from 254 study patients enrolled in the Study to date, the Company announced on March 9, 2015 that it has agreed with Actavis to weight future enrollment in the Study toward the most promising dose and to increase target enrollment in the Study from 500 patients to 620 patients. Actavis, which holds an exclusive option to license TRV027, will fully fund this expansion of the Study via a \$10.0 million payment to the Company.

The purpose of the planned interim analysis was to qualitatively and quantitatively evaluate safety and efficacy data to determine how best to allocate future patients in the Study to generate the most robust data. Upon reviewing the data from the interim analysis, the data safety monitoring board (DSMB) and the BLAST-AHF Steering Committee (the Steering Committee) recommended that future enrollment in the Study be weighted to the most promising dose of 5 mg/hr. Remaining enrollment in the Study will be weighted 2:1:2:1 for placebo, 1 mg/hr, 5 mg/hr, and 25 mg/hr, respectively. In addition, the DSMB and Steering Committee determined that patients with lower baseline systolic blood pressure could safely enroll in the Study; inclusion criteria have been modified accordingly. As a result of the increased target enrollment, the Company now expects to release top-line data from the Study in the first half of 2016.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| Number | Description |
|--------|---|
| 10.1 | Letter Agreement dated March 5, 2015 between Trevena, Inc. and Actavis plc. |

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: March 10, 2015

By:

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

EXHIBIT INDEX

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