## 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) 001-36193 26-1469215 (Commission (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:

Ш	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))

#### 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.

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## **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

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## EXHIBIT INDEX

Exhibit Number Description

10.1 Letter Agreement dated March 5, 2015 between Trevena, Inc. and Actavis plc.

#### [ACTAVIS LETTERHEAD]

#### VIA E-MAIL AND OVERNIGHT DELIVERY

March 5, 2015

Maxine Gowen, Ph.D.
President and Chief Executive Officer
Trevena, Inc.
1018 West 8th Avenue, Suite A
King of Prussia, PA 19460

RE: Option Agreement between Trevena, Inc. ("Trevena") and Forest Laboratories Holdings Limited, an indirect, wholly-owned subsidiary of Actavis plc ("Actavis"), dated as of May 3, 2013 (the "Agreement")

Dear Max,

This letter agreement (the "Letter"), effective as of the date set forth above, is in reference to the Agreement and sets forth our mutual understanding with respect to the continuation of the Development Program following the recent completion of the Interim Analysis. All capitalized terms used in this Letter that are not otherwise defined herein shall have the meanings given to them in the Agreement.

- 1. Protocol Amendment. Trevena shall conduct the Trevena Study in accordance with the amended protocol set forth on Schedule 1 attached hereto (the "Amended Protocol"). Trevena shall submit the Amended Protocol to the FDA, other applicable Regulatory Authorities and applicable Institutional Review Boards (IRBs), and shall not amend or modify the Amended Protocol without the prior written consent of Actavis; provided, however, that Actavis' consent shall not be required with respect to any amendment to the Amended Protocol that, if Trevena is the current holder of the IND with respect to the Trevena Study, is explicitly (i) required in writing by the EMA or FDA or (ii) recommended in writing by the DSMB to address a safety concern with respect to the Lead Product (but, for clarity, not to address a concern regarding efficacy of the Lead Product).
- 2. <u>Development Plan Analyses</u>. Pursuant to Section 2.3.2 of the Agreement, set forth on <u>Schedule 2</u> attached hereto are certain clarifications agreed by the Parties with respect to the Development Plan Analyses.
- 3. PRA Testing. Schedule 3 attached hereto sets forth the understanding of the parties with respect to PRA Testing (as defined therein).
- 4. <u>Consideration</u>. In consideration of the foregoing, Actavis hereby agrees to remit to Trevena the sum of Ten Million U.S. Dollars (US\$10,000,000), payable, within 5 business days following the execution of this Letter and the receipt by Actavis of written wire transfer instructions from Trevena, by wire transfer in immediately available funds to such bank account as Trevena shall designate in such wire transfer instructions.

The Agreement shall remain in full force and effect and is hereby ratified and confirmed except that each reference to the "Agreement" or words of like import in the Agreement will mean and be a reference to the Agreement as amended by this Letter.

This Letter constitutes the legal, valid and binding obligation of the Parties and is enforceable against each of the Parties in accordance with its terms. This Letter, together with the Agreement and the schedules and exhibits thereto, constitutes the entire agreement between the Parties hereto pertaining to the subject matter hereof and supersedes all prior agreements, understandings, negotiations and discussions, whether oral or written, of the Parties pertaining to the subject matter hereof. No modification of this Letter will be binding on the Parties unless and until the modification is set forth in writing, specifically referencing this Letter and signed by the Parties. This Letter and all controversies arising from or relating to the performance under this Letter shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Letter to the substantive law of another jurisdiction.

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Please sign two copies of this Letter where indicated below to confirm Trevena's agreement to this Letter and return one copy to the attention of Kira M. Schwartz, Vice President, Associate General Counsel, M&A, Licensing & Alliance Management, Actavis plc, 400 Interpace Parkway, Parsippany, NJ 07054. This Letter may be executed in one or more counterparts, each of which, when executed, shall be deemed to be an original and together shall constitute one and the same document. Further, this Letter may be executed by facsimile or electronic signatures, which signatures shall have the same force and effect as original signatures.

Sincerely,

ACTAVIS PLC

/s/ A. Robert D. Bailey
Name: A. Robert D. Bailey
Title: Chief Legal Officer

#### ACKNOWLEDGED AND AGREED:

TREVENA, INC.

/s/ Maxine Gowen

Name: Maxine Gowen, Ph.D.

Title: President and Chief Executive Officer

/s/ A. Robert D. Bailey Name: A. Robert D. Bailey Title: Vice President

Encl.: Schedule 1, Schedule 2, Schedule 3