

TREVENA INC

FORM 8-K (Current report filing)

Filed 10/13/17 for the Period Ending 10/11/17

Address	955 CHESTERBROOK BOULEVARD SUITE 200 CHESTERBROOK, PA, 19087
Telephone	6103548840
CIK	0001429560
Symbol	TRVN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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, 2017**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

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

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 2.02. Results of Operations and Financial Condition .

The information under this caption and contained in the press release attached hereto as Exhibit 99.1 is furnished by Trevena, Inc. (the “Company”) in accordance with Securities Exchange Commission Release No. 33-8216. This information shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date of this Current Report, except as shall be expressly set forth by specific reference in such a filing.

On October 11, 2017, the Company issued a press release announcing its cash and cash equivalents and marketable securities balance as of September 30, 2017. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

Item 2.05 Costs Associated with Exit or Disposal Activities .

On October 11, 2017, management of the Registrant, upon the approval of the Board of Directors of the Company, announced a restructuring and reduction in force (the “Restructuring”) of approximately 30% of its workforce, or 21 employees, as well as other cost saving initiatives intended to lower the Registrant’s annualized net operating cash burn. The Restructuring has been completed as of October 13, 2017.

The Registrant has determined that the total costs related to the Restructuring are estimated to be up to approximately \$2.0 million, of which approximately \$1.7 million will result in future cash outlays primarily related to severance costs and related expenses. The remaining costs are expected to be non-cash charges associated with the write-off of laboratory equipment, among other things. The Registrant expects to record these charges in the fourth quarter of 2017.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers .

(b) In connection with the Restructuring, Michael W. Lark, Ph.D., the Company’s Senior Vice President, Research and Chief Scientific Officer, will depart from the Registrant, effective as of December 15, 2017.

Item 8.01 Other Events .

On October 11, 2017, the Company issued a press release announcing the Restructuring. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits .

(d) Exhibits

<u>Number</u>	<u>Description</u>
99.1	Press Release dated October 11, 2017

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated October 11, 2017

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 13, 2017

By: /s/ Roberto Cuca
Roberto Cuca
Sr. Vice President and Chief Financial Officer

Trevena Announces Restructuring to Focus Resources on Commercial Strategy

— Initiative streamlines operations to focus on approval and commercial launch of OLINVO™ (oliceridine injection) and significantly reduces operating expenses —

— New Drug Application for OLINVO remains on track for submission in October —

CHESTERBROOK, PA, October 11 - Trevena, Inc. (NASDAQ: TRVN) today announced an update to its strategy to focus its resources on the potential approval and commercialization of OLINVO™ (oliceridine injection) in the United States. With this strategic re-positioning, the Company is halting its investment in early stage research. The Company intends to complete the ongoing Phase 1 trial of TRV250 for acute migraine, after which it will assess options for further development of this asset, as well as for its series of novel S1P modulators for neuropathic pain.

As part of this plan, the Company is reducing its workforce by approximately 30 percent, or 21 full time employees, predominantly from its research team. As part of this, chief scientific officer Michael Lark, Ph.D., will depart the Company in mid-December. The Company estimates this reduction in force, along with other cost savings initiatives, will reduce cash expected to be used in operating activities over the next three calendar years by approximately \$40 million. The Company also expects to incur a charge in the fourth quarter of 2017 of approximately \$2.0 million related to the reduction, of which approximately \$1.7 million is a cash charge relating primarily to severance costs and related expenses.

“After a thorough review of our portfolio, we have decided to reduce our capital needs and focus our resources on the future approval and commercialization of OLINVO, which we believe will be an important new option for physicians and patients. As part of this plan we made the very difficult, yet necessary, decision to reduce our work force,” said Maxine Gowen, Ph.D., chief executive officer. “I would like to extend my sincere gratitude to the talented and dedicated individuals affected by this plan for their many contributions to the organization. I would also like to thank Michael for his tremendous leadership of our R&D activities since he joined Trevena at its founding. Finally, I want to thank our remaining employees for their continued commitment to our long-term success as we move forward to the approval and commercial launch of OLINVO.”

The Company also announced that the New Drug Application for OLINVO remains on track for submission to the U.S. Food and Drug Administration this month. In addition, the Company continues to expect to report data later this year from the ongoing Phase 1 study of TRV250. Additionally, the Company expects to report cash, cash equivalents and marketable securities as of September 30, 2017 of approximately \$76.7 million, which the Company expects will be sufficient to support operations into the fourth quarter of 2018.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on providing better, safer therapies to patients in pain. The Company has leveraged breakthrough science to discover and develop its investigational

product OLINVO™ (oliceridine injection) for the management of moderate-to-severe acute pain. OLINVO has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration and was designed to provide healthcare providers an innovative new option for patients who would otherwise require conventional intravenous opioids. The Company has an early stage pipeline of new chemical entities targeting novel mechanisms of action, including for acute migraine, neuropathic pain, and other indications.

Cautionary note on forward looking statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of its therapeutic candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the status, timing, costs, results and interpretation of the Company's clinical trials, and the expected timing of the NDA submission for OLINVO; the uncertainties inherent in conducting clinical trials; expectations for regulatory approvals; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, including the impact of the restructuring on operating activities over the next three years and whether the Company's cash, cash equivalents and marketable securities at September 30, 2017 will be sufficient to support operations into the fourth quarter of 2018; uncertainties related to the Company's intellectual property; the ability of the Company to advance its programs; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates, including whether OLINVO will be an important new option for physicians and patients; and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

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