# 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): **August 3, 2017**

# 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.) |

**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**

**1018 West 8th Avenue, Suite A,**
**King of Prussia, PA 19406**
(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 August 3, 2017, the Company issued a press release announcing its financial results for the quarter ended June 30, 2017. 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

| Number | Description |
|---|---|
| 99.1 | Press Release dated August 3, 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: August 3, 2017

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



EXHIBIT INDEX

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated August 3, 2017 |

**Trevena Reports Second Quarter 2017 Financial Results and Provides Corporate Update**

*— OLINVO program on track for NDA submission in September/October 2017 —*

*— First-time-in-human study of TRV250 for acute treatment of migraine remains on track; results expected in 2H 2017 —*

**August 3, 2017** — Trevena, Inc. (NASDAQ: TRVN) today announced financial results for the quarter ended June 30, 2017 and provided an update on its pipeline of investigational products.

"The second quarter saw continued progress towards our goal of delivering an innovative new option for patients who are at risk of adverse events associated with IV opioids like morphine," said Maxine Gowen, Ph.D., chief executive officer. "We have now completed our Phase 3 clinical development for OLINVO and successfully completed our pre-NDA meetings with the FDA. In addition, we have refined our commercial strategy to lay the groundwork for a successful commercial launch. With the comparative data from our successful APOLLO pivotal efficacy studies, as well as data and investigator observations from more real-word use in the ATHENA open label study, we believe the value of OLINVO will resonate with potential prescribers who want to improve the care of hospital patients suffering severe pain."

**Second quarter and recent corporate highlights**

- **OLINVO™ (oliceridine injection) program remains on track for a new drug application (NDA) submission in September/October 2017.** In July 2017, the Company announced that enrollment in the ATHENA open-label safety study was complete to support the NDA file, with 772 patients treated with OLINVO across more than 40 sites. In addition, the Company successfully completed a chemistry, manufacturing, and controls (CMC) Type B pre-NDA meeting and a preclinical and clinical Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA). All pre-NDA activities remain on track to support an NDA submission to the FDA in September/October of 2017.

- **Hosted an Analyst Day featuring four leading experts in acute pain management in the hospital.** In July, the Company hosted an Analyst Day where it provided an update on its clinical portfolio, including new data and commercial strategy for the OLINVO program:

  - The Company outlined its commercial strategy for OLINVO, including its plans to initially focus on patients who require IV opioids and are at greater risk of opioid-related adverse effects (ORAEs). Specifically, the Company expects to target medical education and post-approval promotion to eight physician specialties with 80 select procedures and diagnoses where pain is most severe and/or prolonged, and where procedure, comorbidity, or demographic factors place patients at elevated risk of ORAEs. These patients comprise approximately 7 to 9 million annual hospital inpatients in the United States.

  - New analyses of the Premier Perspective® Hospital Database quantified the clinical and economic burden of illness associated with ORAEs in the 80 procedures and diagnoses where the Company will initially focus its commercialization efforts. These analyses showed that

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patients undergoing these procedures require substantial doses of IV opioids despite multimodal analgesia, and that the prevalence and costs associated with ORAEs are significant.

  - Topline data from the ATHENA open-label safety study highlighted the successful use of OLINVO, including in the procedures and patient populations the Company will focus on at commercial launch. The most frequent procedures were orthopedic, gynecologic, colorectal, general, and plastic surgeries. OLINVO was administered by titration in post-anesthesia recovery rooms, as-needed by bolus injection, and by patient-controlled analgesia. Patients at risk of ORAEs were common, including patients over 65 years old and obese patients. Discontinuation rates were less than 5% for lack of efficacy or for adverse effects.

  - Investigator-reported observations from the ATHENA study included a retrospective chart review at one site that found that colorectal surgery patients who received OLINVO showed return of bowel function 28 hours faster than similar patients at the same site treated with conventional opioids prior to the ATHENA study (p=0.0001 vs. historical control).

- **Continued publication and medical conference presentation of OLINVO data.** The Company presented data from the APOLLO-1 and APOLLO-2 Phase 3 pivotal efficacy studies of OLINVO at several medical conferences, including the 42nd Annual Regional Anesthesiology and Acute Pain Medicine Meeting (ASRA), the 36th Annual Scientific Meeting of the American Pain Society (APS), and the 32nd Annual Meeting of the Society for Ambulatory Anesthesia (SAMBA). In addition, the Company published original nonclinical research in the Journal of Pharmacology and Experimental Therapeutics, showing that the OLINVO mechanism of action may avoid triggering the opioid-induced hyperalgesia (OIH) associated with conventional opioids. Published research has shown that OIH may prolong and exacerbate pain in patients treated with conventional opioids.

- **First-time-in-human study of TRV250 currently ongoing.** TRV250 is under investigation as a potential new mechanism of action for the acute treatment of migraine. The study is a single ascending dose trial in healthy volunteers and is evaluating the safety, tolerability, and pharmacokinetics of subcutaneous and oral TRV250. The Company continues to expect results in the second half of 2017.

- **Disclosed new S1P receptor modulation program.** In July, the Company disclosed a new preclinical lead optimization program targeting S1P receptors with a novel mechanism that has demonstrated activity in preclinical models of chemotherapy-induced peripheral neuropathy, neuropathic pain, and inflammatory pain. The Company's compounds are all new chemical entities, expected to be non-addictive, and use a new mechanism of action that in preclinical models avoids the immune suppression associated with approved and investigational S1P receptor targeted drugs.

- **Attended National Institutes of Health meeting on the development of novel, improved pain medications.** In June, Trevena participated in an NIH summit entitled "Cutting Edge Science Meeting Series to End the Opioid Crisis: Development of Safe, Effective, Non-Addictive Pain Treatments". The event brought together scientists, government officials, and leading industry representatives to discuss new approaches to pain management that have the potential to reduce risks to patients and

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communities who have suffered from the opioid crisis while still providing treatment options for patients in serious pain.

**Financial results**

For the second quarter of 2017, Trevena reported a net loss attributable to common stockholders of $20.4 million, or $0.35 per share, compared with a net loss attributable to common stockholders for the second quarter of 2016 of $19.2 million, or $0.37 per share. Research and development expenses were $15.5 million in the second quarter of

2017 compared to $17.2 million for the same period in 2016; general and administrative expenses were $4.4 million, compared to $3.7 million for the second quarter of 2016.

Cash, cash equivalents, and marketable securities were $84.2 million as of June 30, 2017, which the Company expects will fund operations into the third quarter of 2018, including submitting the NDA to the FDA in September or October of 2017, advancing TRV250 through a first-time-in-human study, and the continued progression of the Company's pipeline.

**About Trevena**

Trevena, Inc. is a biopharmaceutical company developing innovative therapies based on breakthrough science to benefit patients and healthcare providers confronting serious medical conditions. The Company's lead program is OLINVO™ (oliceridine injection), which has successfully completed three successful Phase 3 trials for the management of moderate-to-severe acute pain. Trevena has discovered four novel and differentiated drug candidates, including OLINVO. Trevena also has discovered TRV250, in early clinical development for the treatment of acute migraine. The Company maintains an early stage portfolio of drug discovery programs.

**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 or any future trials, including the interpretation of the topline results from the APOLLO and ATHENA trials, whether the existing clinical data is sufficient to support the Company's NDA to FDA, and whether results of the TRV250 first-time-in-human study will be available in the second half of 2017; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including whether the pre-NDA meetings with FDA were successful and whether the Company will submit the OLINVO NDA in September or October of 2017; availability of funding sufficient for the

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Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties related to the Company's intellectual property; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates, including the plans for the initial focus of the Company's commercial strategy, whether the Company has laid the groundwork for a successful commercial launch of OLINVO, and whether the value of OLINVO will resonate with potential prescribers; 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.

**Contacts**

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**TREVENA, INC.**
**Condensed Statements of Operations**
**(Unaudited, in thousands except share and per share data)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Collaboration revenue | $ — | $ 1,875 | $ — | $ 3,750 |
| Operating expenses: | | | | |
| General and administrative | 4,385 | 3,697 | 9,264 | 7,615 |
| Research and development | 15,499 | 17,203 | 31,595 | 32,956 |
| Total operating expenses | 19,884 | 20,900 | 40,859 | 40,571 |
| Loss from operations | (19,884) | (19,025) | (40,859) | (36,821) |
| Other income (expense) | (548) | (191) | (287) | (174) |
| Net loss | $ (20,432) | $ (19,216) | $ (41,146) | $ (36,995) |
| Per share information: | | | | |
| Net loss per share of common stock, basic and diluted | $ (0.35) | $ (0.37) | $ (0.71) | $ (0.71) |
| Weighted average shares outstanding, basic and diluted | 58,381,868 | 52,174,569 | 57,642,379 | 51,762,467 |

**TREVENA, INC.**
**Condensed Balance Sheets**
**(Unaudited, in thousands)**

| | June 30, 2017 | December 31, 2016 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 14,037 | $ 24,266 |
| Marketable securities | 70,163 | 86,335 |
| Prepaid expenses and other current assets | 3,462 | 1,788 |
| Total current assets | 87,662 | 112,389 |
| Property and equipment, net | 2,921 | 1,059 |
| Restricted cash | 1,413 | 1,193 |
| Intangible asset, net | 12 | 13 |
| Total assets | $ 92,008 | $ 114,654 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,290 | $ 8,749 |
| Accrued expenses and other current liabilities | 2,822 | 8,208 |
| Current portion of loans payable, net | 7,093 | 5,039 |
| Deferred rent | 56 | 52 |
| Total current liabilities | 12,261 | 22,048 |
| Loans payable, net | 20,895 | 13,270 |
| Capital leases, net of current portion | 15 | 18 |
| Deferred rent, net of current portion | 2,465 | 187 |
| Warrant liability | 19 | 75 |
| Other long term liabilities | 747 | 475 |
| Total liabilities | 36,402 | 36,073 |
| | | |
| Common stock | 59 | 56 |
| Additional paid-in capital | 382,375 | 364,148 |
| Accumulated deficit | (326,771 ) | (285,625 ) |
| Accumulated other comprehensive income (loss) | (57 ) | 2 |
| Total stockholders' equity | 55,606 | 78,581 |
| Total liabilities and stockholders' equity | $ 92,008 | $ 114,654 |