
**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 4, 2016**

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.)

**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 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 4, 2016, the Company issued a press release announcing its financial results for the quarter ended June 30, 2016. 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 August 4, 2016 |

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 4, 2016

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

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EXHIBIT INDEX

| Exhibit Number | Description |
|---------------------------|------------------------------------|
| 99.1 | Press Release dated August 4, 2016 |

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Trevena Reports Second Quarter 2016 Financial Results and Provides Corporate Update

- Oliceridine Phase 3 pivotal efficacy trials enrolling on schedule for top-line data in 1Q17 -

KING OF PRUSSIA, PA. Trevena, Inc. (NASDAQ: TRVN), a clinical stage pharmaceutical company focused on the discovery and development of biased ligands targeting G protein coupled receptors (GPCRs), today announced financial results for the quarter ended June 30, 2016 and provided an update regarding its ongoing clinical programs.

“This quarter marked an important milestone for the company’s oliceridine program with the initiation of our two Phase 3 pivotal efficacy trials,” said Maxine Gowen, Ph.D., chief executive officer. “Following our successful End-of-Phase-2 and Breakthrough Therapy designation meeting with the FDA in the first quarter, we were able to rapidly initiate the pivotal efficacy trials, which are enrolling well.”

Second Quarter and Recent Highlights

- **Enrolled first patients in APOLLO-1 and APOLLO-2 Phase 3 trials of oliceridine.** In June, the company announced the enrollment of the first patients in the APOLLO-1 and APOLLO-2 pivotal Phase 3 efficacy studies. APOLLO-1 is studying patients suffering moderate to severe pain for 48 hours after undergoing bunionectomy, while APOLLO-2 is studying patients suffering moderate to severe pain for 24 hours after undergoing abdominoplasty; both are 375-patient, multicenter, randomized, double-blind, placebo- and active-controlled studies. Patients are randomized to receive placebo, morphine, or one of three oliceridine regimens, all dosed as needed via patient-controlled analgesia (PCA) device for the management of their post-operative pain, with approximately 75 patients per study arm. The primary objective of both trials is to evaluate the analgesic efficacy of oliceridine versus placebo. Secondary endpoints compare the efficacy, safety, and tolerability of oliceridine to morphine. The company continues to expect to release top-line data in the first quarter of 2017 and to file an NDA in the second half of 2017.
- **Continued progress in the ATHENA multi-procedure safety study.** This trial, which initiated in the first quarter, complements the APOLLO studies and aims to evaluate the safety and tolerability of oliceridine in patients with moderate to severe acute pain caused by a broad range of medical conditions or surgeries. Patients are treated on an as-needed basis via IV bolus, PCA administration, or both, as determined by the investigator.
- **Continued engagement at pain medicine conferences.** During the quarter, the company made a total of 16 presentations at five different medical conferences, including the American Pain Society and American Society of Regional Anesthesia and Pain Medicine annual meetings. New analyses of the company’s Phase 2 oliceridine data were presented, including:
 - Responder rate analysis of the Phase 2b primary endpoint, which was used to design the primary analysis of the Phase 3 APOLLO studies.

- A pharmacokinetic/pharmacodynamic model of oliceridine analgesia, including simulations of dosing regimens used to inform dosing in the Phase 3 APOLLO studies.

At the Society for Ambulatory Anesthesia (SAMBA) 31st Annual Meeting, the company was awarded a First Place in Excellence and Innovation Award for its presentation of data from the oliceridine Phase 2 program. Further presentations of oliceridine data at additional pain medicine conferences are expected in the second half of 2016, including at the American Society of Anesthesiology 2016 annual meeting in October.

- **Results from TRV027 Phase 2b trial.** In May, the company announced that TRV027 did not achieve primary or secondary endpoints in the Phase 2b BLAST-AHF trial in acute heart failure. In August 2016, Allergan, Plc (NYSE: AGN) notified the company that it does not intend to exercise its exclusive option to license TRV027.

Financial Results

Net loss attributable to common stockholders for the quarter ended June 30, 2016 was \$19.2 million, or \$0.37 per share, compared to \$11.5 million, or \$0.28 per share for the quarter ended June 30, 2015. Research and development expenses were \$17.2 million in the second quarter of 2016 compared to \$10.3 million for the same period in 2015, primarily due to increased clinical trial expenses associated with the oliceridine Phase 3 program. For the remainder of 2016, the company anticipates that research and development expenses will increase as compared to the first half of 2016, primarily as a result of the initiation of the APOLLO efficacy studies in June and the expected acceleration of the ATHENA safety study recruitment. General and administrative expenses were \$3.7 million, compared to \$3.1 million for the second quarter of 2015.

Cash, cash equivalents, and marketable securities totaled \$144.5 million as of June 30, 2016, which Trevena expects will be sufficient to fund its operations into 2018.

About Trevena

Trevena, Inc. is a clinical stage biopharmaceutical company that discovers, develops, and intends to commercialize therapeutics that use a novel approach to target G protein coupled receptors, or GPCRs. Oliceridine (TRV130), Trevena’s lead product candidate, is the first pain program granted Breakthrough Therapy designation by the U.S. Food & Drug Administration and is in Phase 3 development for intravenous treatment of moderate to severe post-operative acute pain. In Phase 2b, intravenous oliceridine demonstrated rapid and powerful analgesic efficacy with reduced frequency of opioid-related adverse events including nausea, vomiting, and hypoventilation compared to intravenous morphine, thus offering a promising safety and tolerability profile compared to conventional opioid analgesics while providing powerful pain relief to patients.

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, including the expected timing of the release of top-line data from the APOLLO studies and the timing of the NDA filing for oliceridine; the uncertainties inherent in conducting clinical trials, including whether the Phase 3 studies will support the approval of oliceridine and any potential differentiation of oliceridine from conventional opioids; whether interim results from a clinical trial will be predictive of the final results of the trial or results of early clinical trials will be indicative of the results of future trials; expectations for regulatory approvals, including for oliceridine; availability of funding sufficient for the 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; 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.

Contact:

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TREVENA, INC.
Condensed Statements of Operations
(Unaudited)

| | <u>Three Months Ended June 30,</u> | | <u>Six Months Ended June 30,</u> | |
|--|------------------------------------|------------------------|----------------------------------|------------------------|
| | <u>2016</u> | <u>2015</u> | <u>2016</u> | <u>2015</u> |
| Revenue | \$ 1,875,000 | \$ 1,875,000 | \$ 3,750,000 | \$ 2,500,000 |
| Operating expenses: | | | | |
| General and administrative | 3,696,682 | 3,107,263 | 7,614,432 | 6,196,885 |
| Research and development | 17,203,345 | 10,275,470 | 32,956,432 | 20,874,463 |
| Total operating expenses | <u>20,900,027</u> | <u>13,382,733</u> | <u>40,570,864</u> | <u>27,071,348</u> |
| Loss from operations | (19,025,027) | (11,507,733) | (36,820,864) | (24,571,348) |
| Other income (expense) | (191,291) | (11,118) | (174,433) | 122,852 |
| Net loss | <u>\$ (19,216,318)</u> | <u>\$ (11,518,851)</u> | <u>\$ (36,995,297)</u> | <u>\$ (24,448,496)</u> |
| Per share information: | | | | |
| Net loss per share of common stock, basic and diluted | \$ (0.37) | \$ (0.28) | \$ (0.71) | \$ (0.61) |
| Weighted average shares outstanding, basic and diluted | <u>52,174,569</u> | <u>40,809,931</u> | <u>51,762,467</u> | <u>40,034,864</u> |

TREVENA, INC.
Condensed Balance Sheets

| | <u>June 30, 2016</u> | <u>December 31, 2015</u> |
|--|-----------------------|--------------------------|
| | <u>(Unaudited)</u> | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 36,802,778 | \$ 46,773,566 |
| Marketable securities | 107,707,828 | 125,864,447 |
| Prepaid expenses and other current assets | 3,129,866 | 1,892,217 |
| Total current assets | <u>147,640,472</u> | <u>174,530,230</u> |
| Property and equipment, net | 807,353 | 696,280 |
| Intangible asset, net | 13,906 | 14,844 |
| Restricted cash | 112,620 | 112,620 |
| Total assets | <u>\$ 148,574,351</u> | <u>\$ 175,353,974</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 4,925,372 | \$ 6,749,625 |
| Accrued expenses and other current liabilities | 3,785,223 | 3,029,782 |
| Deferred revenue | — | 3,750,000 |
| Deferred rent | 48,086 | 43,907 |
| Total current liabilities | <u>8,758,681</u> | <u>13,573,314</u> |
| Loans payable, net | 18,249,810 | 18,185,898 |
| Capital leases, net of current portion | 13,176 | 7,942 |
| Deferred rent, net of current portion | 214,679 | 238,917 |
| Warrant liability | 83,517 | 153,238 |
| Other long term liabilities | 270,532 | 63,200 |
| Total liabilities | <u>27,590,395</u> | <u>32,222,509</u> |
| Common stock | 52,178 | 50,802 |
| Additional paid-in capital | 340,349,923 | 325,784,484 |
| Accumulated deficit | (219,493,262) | (182,497,965) |
| Accumulated other comprehensive income | 75,117 | (205,856) |
| Total stockholders' equity | <u>120,983,956</u> | <u>143,131,465</u> |
| Total liabilities and stockholders' equity | <u>\$ 148,574,351</u> | <u>\$ 175,353,974</u> |