
**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 11, 2015**

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 11, 2015, the Company issued a press release announcing its financial results for the quarter ended June 30, 2015. 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.

- (a) Financial Statements of Business Acquired: Not applicable
- (b) Pro Forma Financial Information: Not applicable
- (c) Exhibits

Number	Description
99.1	Press Release dated August 11, 2015

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 11, 2015

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

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EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated August 11, 2015

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Trevena Reports Second Quarter 2015 Financial Results and Provides a Corporate Update

- Enrollment complete for Phase 2b trial of TRV130 in postoperative pain following soft tissue surgery; data expected in September -
- TRV027 AHF Phase 2b trial on track to report top-line data in the second quarter of 2016 -

KING OF PRUSSIA, Pa., August 11, 2015 - 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, 2015 and provided an update regarding its ongoing clinical programs.

"Trevena has finished the first half of 2015 in a strong position to advance our maturing pipeline of differentiated biased ligands," said Maxine Gowen, Ph.D., chief executive officer. "Today we announced the completion of enrollment in the Phase 2b soft tissue surgery study for TRV130 in postoperative pain, which puts us on track to report data in September of this year and initiate our Phase 3 program in the first quarter of 2016. We also continued to progress our ongoing Phase 2b BLAST-AHF trial for TRV027 in acute heart failure and our Phase 1 program for oral TRV734, and highlighted the preclinical data from our TRV250 migraine program at key scientific meetings. We look forward to continuing this momentum through the second half of 2015 as we build value across our entire portfolio."

Second Quarter and Recent Highlights

CNS Programs (TRV130, TRV734, and TRV250)

- **Completed enrollment for the Phase 2b study of TRV130 for acute postoperative pain following soft tissue surgery.** The company announced today that it has completed planned enrollment of 200 patients in its Phase 2b study of intravenous TRV130 in postoperative abdominoplasty pain. The company expects to report key results in September 2015 on the efficacy, safety, and tolerability of TRV130 versus placebo and versus morphine. The primary endpoint of this study is the time-weighted average change from baseline in the numeric pain rating scale scores over the 24-hour assessment interval for TRV130 compared to placebo with pre-specified secondary comparisons to morphine.

This study utilized a flexible dose, intravenous patient-controlled analgesia (PCA) administration regimen intended to reflect the dose titration typically used for post-operative opioid analgesics. Two hundred abdominoplasty patients with pain scores ≥ 5 out of 10 were assigned randomly following surgery to a regimen of TRV130, placebo, or morphine, in a 2:1:2 ratio, respectively. TRV130, placebo, and morphine were

administered as initial loading doses, followed by on-demand doses administered no more often than every 6 minutes. TRV130 was given as a 1.5 mg loading dose followed by 0.1 mg on-demand doses. Morphine was administered as a typical regimen consisting of a 4 mg loading dose, followed by patient-administered doses of 1.0 mg with a 6 minute lockout period following each dose. A pre-specified interim analysis was conducted after enrollment of 100 patients to evaluate opportunities for studying additional regimens of TRV130, after which the on-demand dose of TRV130 was increased to 0.35 mg for the remaining portion of the study. The TRV130 loading dose, placebo regimen, and morphine regimens were not altered.

TRV130 was designed to optimize mu-opioid receptor pharmacology to deliver an improved analgesic profile compared to currently used opioid analgesics. In completed Phase 1 and Phase 2 clinical trials, TRV130 demonstrated superior analgesic activity and the potential for less respiratory depression than i.v. morphine.

- **Granted key composition of matter patent in the U.S. for TRV734.** In June 2015, the Company announced that the U.S. Patent and Trademark Office (USPTO) had granted U.S. Patent No. 9,044,469, "Opioid Receptor Ligands and Methods of Using and Making Same." The patent covers TRV734, compositions comprising TRV734, and methods of using TRV734, and is expected to provide patent coverage for TRV734 until at least 2032. Trevena is currently testing TRV734 for the treatment of acute and chronic moderate-to-severe pain in Phase 1 clinical trials.
- **Presented preclinical data for TRV250.** Trevena presented the preclinical pharmacology of TRV250, its oral G protein biased ligand targeting the delta receptor, in a late-breaking oral session at the International Headache Society meeting in Valencia, Spain, May 14-17, 2015, and in a poster at the American Headache Society 57th annual meeting in Washington D.C. on June 20, 2015. Trevena initially is developing TRV250 to treat episodic migraine with a potential first-in-class mechanism. There are 12 million migraine patients treated in the U.S., of which up to 3 million treatment-refractory patients cannot take or do not benefit from triptan drugs, the current standard of care for episodic migraine. Molecules targeting the delta receptor, like TRV250, have not been associated with the addiction liability of mu opioid drugs like morphine or oxycodone. TRV250 also may have utility in a range of other CNS indications. Trevena anticipates filing an IND in 2016.

Acute Heart Failure Program (TRV027)

- **BLAST-AHF trial is on track for top-line data in the second quarter of 2016.** The Company continues to advance its Phase 2b TRV027 BLAST-AHF trial, which is now targeted to enroll 620 patients after Actavis plc (now Allergan plc) fully funded an expansion from the initial target of 500 patients following an interim analysis in March. Based on enrollment rates following the interim analysis, Trevena has refined its expectations for top-line data release from the first half to the second quarter of 2016.

Corporate Developments

- **Strengthened corporate management team.** Trevena added two new executives to the management team. In May, the Company appointed Carrie Bourdow as chief commercial officer and, in July, Yacoub Habib was appointed senior vice president, business development and corporate planning.

Financial Results

Net loss attributable to common stockholders for the quarter ended June 30, 2015 was \$11.5 million, or \$0.28 per share, compared to \$11.5 million, or \$0.44 per share for the quarter ended June 30, 2014. Research and development expenses were \$10.3 million in the second quarter of 2015 compared to \$9.0 million for the same period in 2014; general and administrative expenses were \$3.1 million, compared to \$2.5 million for the second quarter of 2014. Cash, cash equivalents, and marketable securities totaled \$106.4 million as of June 30, 2015. Trevena expects that its existing cash and cash equivalents will be sufficient to fund operations through the end of 2016.

In April 2015, the Company entered into a \$40.0 million at the market ("ATM") sales facility with Cowen and Company, LLC acting as our sales agent. In May 2015, the Company sold 2.7 million shares of common stock under the ATM facility, generating net proceeds of \$16.2 million.

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. Using its proprietary product platform, Trevena is developing four biased ligand product candidates it has identified — TRV027 to treat acute heart failure (Phase 2b), TRV130 to treat moderate to severe acute pain intravenously (Phase 2b), TRV734 to treat moderate-to-severe acute and chronic pain orally (Phase 1), and TRV250 for treatment-refractory migraine and other CNS disorders (preclinical).

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 with respect to the timing of the release of data for the Phase 2 trial of TRV130 and the timing and status of the BLAST-AHF study of TRV027; the uncertainties inherent in conducting clinical trials; 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, including with respect to earlier studies with TRV130; expectations for regulatory approvals; availability of funding sufficient for the company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the viability or commercial potential of the company's therapeutic candidates; the inherent uncertainties associated with intellectual property; 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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TREVENA, INC. Condensed Statements of Operations (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Collaboration revenue	\$ 1,875,000	\$ —	\$ 2,500,000	\$ —
Operating expenses:				
General and administrative	3,107,263	2,475,820	6,196,885	4,496,685
Research and development	10,275,470	9,031,037	20,874,463	16,664,546
Total operating expenses	13,382,733	11,506,857	27,071,348	21,161,231
Loss from operations	(11,507,733)	(11,506,857)	(24,571,348)	(21,161,231)
Other income (expense)	(11,118)	11,176	122,852	292,136
Net loss	(11,518,851)	(11,495,681)	(24,448,496)	(20,869,095)
Accretion of redeemable convertible preferred stock	—	—	—	(28,521)
Net loss attributable to common stockholders	\$ (11,518,851)	\$ (11,495,681)	\$ (24,448,496)	\$ (20,897,616)
Per share information:				
Net loss per share of common stock, basic and diluted	\$ (0.28)	\$ (0.44)	\$ (0.61)	\$ (0.98)
Weighted average shares outstanding, basic and diluted	40,809,931	26,327,895	40,034,864	21,343,803

TREVENA, INC. Condensed Balance Sheets

	June 30, 2015 (Unaudited)	December 31, 2014 As Adjusted
Assets		
Current assets:		
Cash and cash equivalents	\$ 43,665,766	\$ 36,205,559
Marketable securities	62,716,174	70,698,640
Prepaid expenses and other current assets	883,165	669,155

Total current assets	107,265,105	107,573,354
Property and equipment, net	609,344	553,294
Restricted cash	112,410	112,410
Total assets	<u>\$ 107,986,859</u>	<u>\$ 108,239,058</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,061,369	\$ 4,342,480
Accrued expenses and other current liabilities	1,569,315	2,578,269
Deferred revenue	7,500,000	—
Deferred rent	42,074	38,359
Total current liabilities	<u>13,172,758</u>	<u>6,959,108</u>
Loan payable, net	1,748,667	1,692,884
Capital lease, net of current portion	9,332	10,677
Deferred rent, net of current portion	260,622	281,885
Warrant liability	85,916	82,851
Other long term liabilities	29,791	8,025
Total liabilities	<u>15,307,086</u>	<u>9,035,430</u>
Common stock		
Common stock	42,060	39,241
Additional paid-in capital	249,045,832	231,152,894
Accumulated deficit	(156,418,221)	(131,969,725)
Accumulated other comprehensive income (loss)	10,102	(18,782)
Total stockholders' equity	<u>92,679,773</u>	<u>99,203,628</u>
Total liabilities and stockholders' equity	<u>\$ 107,986,859</u>	<u>\$ 108,239,058</u>