# 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 18, 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))

# Item 2.02. <u>Results of Operations and Financial Condition</u>.

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 March 18, 2015, the Company issued a press release announcing its financial results for the quarter and full year ended December 31, 2014. 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) <u>Financial Statements of Business Acquired:</u> Not applicable
- (b) <u>Pro Forma Financial Information</u>: Not applicable
- (c) <u>Exhibits</u>

Number

Description

2

# **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 18, 2015	By: <u>/s/ Roberto Cuca</u> Roberto Cuca Sr. Vice President, Chief Financial Officer
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	EXHIBIT INDEX
Exhibit Number	Description
99.1 Press Re	lease dated March 18, 2015
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#### **Trevena Reports Full Year 2014 Financial Results**

On Track to Report Phase 2 Data for TRV130 in Soft-Tissue Surgery Patients in Mid-2015 Phase 2b BLAST-AHF Trial of TRV027 in Acute Heart Failure Expanded Company to Host Conference Call at 8:30 AM EDT Today -

KING OF PRUSSIA, PA, March 18, 2015 — Trevena, Inc. (NASDAQ: TRVN), a clinical stage biopharmaceutical company focused on the discovery and development of G protein coupled receptor (GPCR) biased ligands, today announced financial results for the fourth quarter and year ended December 31, 2014.

"In 2014, Trevena made outstanding progress across all areas of our business and we are now well positioned to advance our clinical pipeline this year as we look to initiate the Company's first Phase 3 study in 2016," said Maxine Gowen, Ph.D., chief executive officer. "The results of our Phase 2a/b study of TRV130 in postoperative pain support its potential to provide more powerful pain relief than may be achievable with currently used opioids, with an encouraging safety and tolerability profile. We are on track to complete our ongoing Phase 2b soft-tissue surgery trial and are continuing to plan for the Phase 3 program. For TRV027, we launched a large-scale, well-designed Phase 2b study in acute heart failure at the beginning of 2014. We have completed the pre-specified interim analysis and recently announced additional funding of \$10 million from Actavis to expand the number of patients in this study. Finally, we rapidly advanced oral TRV734 through two Phase 1 studies, and recently added a preclinical delta receptor compound, TRV250, to our pipeline."

### **Recent Corporate Highlights**

## CNS Programs (TRV130, TRV734, and TRV250)

- Announced positive results from a phase 2a/b study of TRV130 in acute postoperative pain following bunionectomy surgery. In November 2014, the Company announced positive top-line data from its randomized, double-blind, placebo- and active-controlled Phase 2a/b trial of TRV130 in moderate-to-severe acute postoperative pain. Over the 48 hour study period, 3 mg TRV130 every 3 hours showed statistically superior analgesic efficacy compared to 4 mg morphine every four hours. Additionally, in the first 3 hours of dosing, when pain was most severe, the 2 mg and 3 mg doses of TRV130 demonstrated statistically superior analgesic efficacy compared to 4 mg morphine. At these doses, trends in respiratory depression favored TRV130 versus morphine. Overall tolerability of 2 mg TRV130 was similar to morphine and at lower TRV130 doses, there was a trend toward improved tolerability.
- Initiated a phase 2b study of TRV130 for acute postoperative pain following soft tissue surgery. In January 2015, Trevena initiated a 200-patient Phase 2b clinical trial of TRV130 for acute postoperative pain in patients following abdominoplasty surgery. This study uses patient-controlled analgesia to allow patients to optimally treat their pain. The Company expects to report top-line results from this trial in mid-2015.
- Reported positive phase 1 data for TRV734. In February 2015, Trevena reported data from a Phase 1 multiple ascending dose trial of TRV734 showing pharmacokinetics, safety, tolerability, and CNS activity consistent with that found in a previous Phase 1 study and supporting further study in Phase 2. The recently completed Phase 1 study used an experimental pain model in

which TRV734 showed effectiveness similar to immediate-release oxycodone with trends in Bowel Function Index that favored TRV734 versus oxycodone. Selected a delta receptor candidate, TRV250, for preclinical development.During the fourth quarter of 2014, Trevena identified a new product candidate, TRV250, an oral delta receptor biased ligand with promise as a therapy for treatment refractory migraine. TRV250 may also have utility in a range of other CNS indications, and targets a receptor that is not associated with the addiction liability of mu opioid drugs like morphine or oxycodone.

# Acute Heart Failure Program (TRV027)

- **Completed pre-specified interim analysis of TRV027 BLAST-AHF trial and expanded study** Based on a review of the safety and efficacy data from 254 study patients, the data safety monitoring board and the BLAST-AHF Steering Committee recommended that future enrollment be weighted to the most promising dose of 5 mg/hr. Based on these recommendations, Trevena and Actavis are increasing target enrollment in the study from 500 patients to 620 patients to provide additional dose ranging data. Actavis, which holds an exclusive option to license TRV027, has paid Trevena \$10.0 million to fully fund the study expansion. As a result of the increased target enrollment, Trevena now expects to release top-line data in the first half of 2016.
- Published the TRV027 phase 2b BLAST-AHF trial design. In February 2015, the Company announced the publication of the trial design for its ongoing Phase 2b study of TRV027 in acute heart failure (AHF) in the Journal of the American College of Cardiology: Heart Failure.

# **Corporate Developments**

- Increased financial resources. In December 2014, the Company raised net proceeds of \$47.7 million in an underwritten public offering of common stock and in March 2015 the Company received \$10 million from Actavis to fully fund the expansion of the TRV027 study.
- Appointed Anne Phillips to the board of directors. In December 2014, Trevena appointed Anne M. Phillips, M.D., senior vice president of clinical, medical and regulatory affairs at Novo Nordisk Inc., to the board of directors.
- Appointed David Soergel as chief medical officer. In March 2015, David Soergel, M.D., senior vice president, clinical, also was appointed as the Company's chief medical officer.

#### **Financial Results**

For the fourth quarter of 2014, Trevena reported a net loss attributable to common stockholders of \$13.3 million, or \$0.45 per share, compared with a net loss attributable to common stockholders for the fourth quarter of 2013 of \$7.0 million, or \$7.48 per share.

For the year ended December 31, 2014, the Company incurred a net loss attributable to common stockholders of \$49.7 million, or \$2.02 per share, compared with a net loss attributable to common stockholders of \$23.6 million, or \$29.71 per share, for the comparable period in 2013.

Cash, cash equivalents and marketable securities were \$106.9 million as of December 31, 2014.

The increase in net loss attributable to common stockholders for the year ended December 31, 2014, compared to the net loss attributable to common stockholders for the same period in 2013, was primarily due to higher clinical research expenses in 2014 associated with the Company's advancement into a Phase

## **Conference Call Information**

Trevena will host a conference call today, March 18<sup>th</sup> at 8:30 a.m. Eastern Daylight Savings Time. The call can be accessed by dialing (855) 465-0180 (U.S. and Canada) or (484) 756-4313 (international), and entering passcode 98326456. To access the live audio webcast, or the subsequent archived recording, visit the "Investors" section at trevenainc.com. The webcast will be recorded and will be available for replay on the company's website for 30 days. A replay of the call will be available for 30 days and can be accessed by dialing (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international), and entering passcode 98326456.

### 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 (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," "wull," "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 when top-line Phase 2 data will be reported for TRV027 and TRV130; the uncertainties inherent in conducting clinical trials, including whether (i) the interim results from the TRV027 Phase 2 will be consistent with the final results of early clinical trials will be indicative of the results of future trials, including whether (i) the interim results from the TRV027 Phase 2 will be consistent with the final results from the study, (ii) the results from and trends seen in the Phase 2a/b bunionectomy study of TRV130 will be consistent with the results from the study, (iii) the Phase 1 data for TRV734 support further study in Phase 2; expectations for regulatory approvals; availability of funding sufficient for 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 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

# **Investor Contacts**

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#### TREVENA, INC. Condensed Statements of Operations

	Year En	Year Ended December 31,		
	2014		2013	
	(Unaudited)			
Revenue	\$	- \$	134,980	
Operating expenses:				
General and administrative	9,403,25	4	4,718,047	
Research and development	40,546,66	6	18,762,219	
Total operating expenses	49,949,92	0	23,480,266	
Loss from operations	(49,949,92	0)	(23,345,286)	
Other income	249,04	5	93,851	
Net loss	(49,700,87	5)	(23,251,435)	
Accretion of redeemable convertible preferred stock	(28,52	1)	(333,710)	
Net loss attributable to common stockholders	\$ (49,729,39	6) \$	(23,585,145)	
Per share information:				
Net loss per share of common stock, basic and diluted	\$ (2.0	2) \$	(29.71)	
Weighted average shares outstanding, basic and diluted	24,655,60	3	793,806	

# TREVENA, INC.

# **Condensed Balance Sheets**

		December 31, 2014 (Unaudited)		December 31, 2013	
Assets					
Current assets:					
Cash and cash equivalents	\$	36,205,559	\$	37,965,198	
Marketable securities		70,698,640		_	
Prepaid expenses and other current assets		669,155		3,957,044	
Total current assets		107,573,354		41,922,242	
Property and equipment, net		553,294		343,059	
Restricted cash		112,410		112,000	
Other assets		98,401		15,625	
Total assets	\$	108,337,459	\$	42,392,926	
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)					
Current liabilities:					
Accounts payable	\$	4,342,480	\$	545,053	
Accrued expenses and other current liabilities		2,578,269		2,158,792	
Deferred rent		38,359		33,114	
Total current liabilities		6,959,108		2,736,959	
Loan payable, net of debt discount		1,791,285			
Capital lease, net of current portion		10,677		_	
Deferred rent, net of current portion		281,885		313,919	
Warrant liability		82,851		350,519	
Other long term liabilities		8,025			
Total liabilities		9,133,831		3,401,397	
Redeemable convertible preferred stock		—		120,562,138	
Common stock		39,241		958	
Additional paid-in capital		231,152,894		697,283	
Accumulated deficit		(131,969,725)		(82,268,850)	
Accumulated other comprehensive loss		(18,782)			
Total stockholders' equity (deficit)		99,203,628		(81,570,609)	
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$	108,337,459	\$	42,392,926	