# 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): May 9, 2014

## **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)

D 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. Results of Operations and Financial Condition.

On May 9, 2014, Trevena, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2013. The text of the press release is included as Exhibit 99.1 to this Current Report on Form 8-K. Pursuant to the rules and regulations of the Securities and Exchange Commission, such exhibits and the information set forth therein and herein are deemed to be furnished and shall not be deemed to be filed.

## Item 9.01. Financial Statements and Exhibits.

(d) Exhibits			
Exhibit Number		Exhibit Description	
99.1	Press release dated May 9, 2014.		
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#### 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.

By: /s/ Roberto Cuca Roberto Cuca Chief Financial Officer



## **Trevena Reports First Quarter 2014 Financial Results**

-Announces Clinical Progress with TRV130 and TRV734 Programs -Company to Host Conference Call at 11:00 AM Eastern Time-

KING OF PRUSSIA, PA, May 9, 2014 — Trevena, Inc. (NASDAQ: TRVN), a clinical stage pharmaceutical company focused on the discovery and development of G protein coupled receptor (GPCR) biased ligands, today announced financial results for the quarter ended March 31, 2014.

"We have had a strong start to 2014, reflecting continued investment in our novel pipeline of biased ligands targeting validated GPCRs," stated Maxine Gowen, Ph.D., chief executive officer of Trevena. "Since the beginning of the year, we have advanced each of our clinical candidates into a new stage of development, initiating a Phase 2b trial for TRV027 in acute heart failure, initiating a Phase 2 trial for TRV130 for the treatment of moderate to severe postoperative pain, successfully completing the first part of a multiple ascending dose study of TRV130, and successfully completing dosing in our first clinical study of TRV734 for acute and chronic pain. Each of these candidates has the potential to offer a superior therapeutic profile compared to current treatment options, and we look forward to learning more about their clinical utility as these programs progress."

The Company also announced today the successful completion of the first part of arandomized, double-blind, placebo-controlled multiple ascending dose study of TRV130, which Trevena is developing as a first-line intravenous treatment for patients experiencing moderate to severe acute pain. This study evaluated the maximum tolerated dose and pharmacokinetics of TRV130 when multiple doses were given, and is an important step in furthering the development of TRV130. This study also measured pharmacodynamic effects of TRV130, including pupil constriction and cold pain test analgesia. The results of this trial were consistent with earlier studies, showing reproducible pharmacokinetics and pharmacodynamic effects of TRV130. Safety and tolerability of TRV130 were also consistent with earlier trials, and no unexpected adverse effects were observed. The second part of the study, which tests the effects of subjects' metabolic capacity on TRV130 potential duration of action, is in progress.

"The encouraging results from the TRV130 multiple ascending dose trial were consistent with our expectations, demonstrating reproducible pharmacokinetics and analgesia, and an encouraging tolerability profile, upon repeat dosing," stated David Soergel, M.D., senior vice president of clinical development at Trevena. "These results are an important step in progressing TRV130 into Phase 2 studies, which we have now initiated."

In addition, Trevena reported the completion of dosing in its first Phase 1 trial TRV734, a novel drug candidate in development as an orally administered treatment for moderate to severe acute and chronic pain. The objectives of this trial were to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of single ascending doses of TRV734 in healthy subjects. Top-line data for this trial are expected mid-year.

#### Other Recent Corporate and Clinical Highlights

CNS programs

**Initiated Phase 2a/b Trial for TRV130 in Acute Postoperative Pain.** In May, Trevena initiated a Phase 2a/b trial of TRV130, which is in development as a first-line intravenous treatment for patients experiencing moderate to severe acute pain where intravenous administration is preferred. The study is a 400-patient, multicenter, randomized, double-blind, placebo- and active-controlled, multiple dose, adaptive trial that is designed to evaluate TRV130's efficacy and tolerability in the management of postoperative pain following bunionectomy surgery, using the gold-standard morphine as a benchmark. Top-line data from the trial are expected in the first quarter of 2015.

Presented Phase 1b Data for TRV130 at American Society of Pain Meeting. In May, Trevena presented results of its Phase 1b trial of TRV130 at the American Pain Society Annual Meeting. In the study, TRV130 was generally well tolerated and produced greater analgesia compared to morphine, with less reduction in respiratory drive, less vomiting, and less severe nausea in healthy subjects.

#### Acute heart failure program

Initiated Phase 2b BLAST Trial for TRV027 in Acute Heart Failure (AHF). In January, the Company reported dosing of the first patient in a randomized, double-blind, standard of care controlled, Phase 2b trial of TRV027 in AHF. The primary objective of this 500-patient trial is to evaluate the effects of three dose levels of TRV027, 1.0 mg/hr, 5.0 mg/hr and 25 mg/hr, on a composite of clinically important outcomes: mortality, worsening heart failure, hospital readmission rate, dyspnea, and length of hospital stay. Results from the study are expected in the second half of 2015. Trevena has granted Forest Laboratories an exclusive option to license TRV027 under the companies' May 2013 Option and Licensing Agreements.

#### Corporate update

Appointed Robert Prachar as SVP, Commercial and Corporate Strategy. In April, Trevena appointed Robert Prachar to the newly created position of Senior Vice President, Commercial and Corporate Strategy. Mr. Prachar, who had served as a full-time consultant for the Company since August 2013, brings over 20 years of commercial leadership experience in the life sciences industry to Trevena.

### **Financial Results**

Cash and cash equivalents totaled \$91.3 million as of March 31, 2014, compared to \$38.0 million as of December 31, 2013. The increase reflects the net proceeds of \$59.6 million received from the Company's initial public offering in January 2014, offset by operating expenses. Trevena expects that its existing cash and cash equivalents will be sufficient to fund operations through the end of 2015.

Research and development expenses were \$7.6 million in the first quarter of 2014 versus \$2.1 million in the first quarter of 2013. The increase was primarily driven by clinical research expenses for TRV130, expenses associated with the Phase 2b study for TRV027, and expenses associated with the progression of TRV734 from preclinical to clinical studies.

General and administrative expenses were \$2.0 million for the quarter ended March 31, 2014, as compared to \$0.8 million in the prior year. The increase is primarily the result of headcount and salary costs, increased compensation expense associated with stock options granted and increased insurance, professional fees and other operating costs as a result of becoming a public company. Net loss attributable to common shareholders for the quarter ended March 31, 2014 was \$9.4 million, or \$0.59 per

\$28,521 and \$79,161 for the accretion of preferred stock in 2014 and 2013, respectively.

#### **Conference Call and Webcast**

Trevena will host a conference call today, Friday, May 9, 2014, at 11:00 a.m. Eastern Time to discuss corporate updates and financial results for the first quarter ended March 31, 2014. The call can be accessed by dialing (855) 465-0180 (U.S. and Canada) or (484) 756-4313 (international), and entering passcode 36961657. To access a live audio webcast of the presentation, please visit the "Investors" section at trevenainc.com. The webcast will be recorded and available for replay on the company's website for two weeks.

## About TRV027

TRV027 is an investigational peptide drug in Phase 2b trials for the treatment of heart failure (AHF). It targets the Angiotensin II type 1 receptor, a key driver of AHF, with an innovative "biased ligand" mechanism which simultaneously vasodilates while increasing cardiac performance. This profile has the potential to become an important new therapy for AHF patients.

## About TRV130

TRV130 is in investigational small molecule drug in Phase 2 trials for the treatment of pain via intravenous administration. It binds and activates the mu opioid receptor with a biased ligand mechanism unlike other opioid drugs, and is intended to provide increased pain relief with fewer adverse effects than currently used opioid analgesics.

#### About TRV734

TRV734 is an oral follow-on to TRV130, in Phase 1 for the treatment of acute and chronic pain. It has a preclinical profile highly similar to TRV130, and is intended to provide the benefits of TRV130 in an oral form.

#### 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 has identified and advanced three differentiated biased ligand product candidates into the clinic — TRV027 to treat acute heart failure, TRV130 to treat moderate to severe acute pain intravenously, and TRV734 to treat moderate to severe acute and chronic pain orally. Trevena also plans to advance additional product candidates in its portfolio, including a preclinical program focused on central nervous system 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, its future operations, clinical development of its therapeutic candidates, potential therapeutic utility for its product candidates, market opportunities for its product candidates, its plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "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: availability and timing of data from ongoing clinical trials, the uncertainties inherent in the initiation of future relinical 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 requirements, other matters that could affect the availability or commercial potential of the Company's therapeutic candidates and unforeseeable operating expenses and capital expenditure requirements, other matters that could affect the availability or commercial potential of the Company's therapeutic candidates and bere factors discussed in the "Risk Factors" section of the Company makes with the Securities and Exchange Commission from time to time. In addition, the forward-looking statements included in this press release represent the Company suicipates 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, the Company specifically disclaims any obligation to do so. These forward-looking statements should no

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#### Trevena Inc. Statement of Operations

	Three Month	Three Months Ended March 31,		
	2013	2014		
Revenue:				
Grant revenue	\$ 41,20	I \$ —		
Collaboration revenue	-	- —		
Total revenue	41,20	ī <u> </u>		
Operating expenses:				
General and administrative	761,43	7 2,020,865		
Research and development	2,115,06	5 7,633,509		
Total operating expenses	2,876,50	3 9,654,374		

Loss from operations	(2,835,302)		(9,654,374)
Other income (expense):			
Change in fair value of warrant liability	10,255		98,922
Miscellaneous income	_		176,015
Interest income	—		6,023
Interest expense	(58,241)		_
Total other income (expense)	(47,986)		280,960
Net loss and comprehensive loss	(2,883,288)		(9,373,414)
Accretion of redeemable convertible preferred stock	(79,161)		(28,521)
Net loss attributable to common stockholders	\$ (2,962,449)	\$	(9,401,935)
Per share information:		_	
Net loss per share of common stock, basic and diluted	\$ (4.30)	\$	(0.59)
Weighted average shares outstanding, basic and diluted	689,266		16,023,497

## Trevena Inc. Balance Sheet Information

		December 31, 2013		March 31, 2014	
Assets					
Current assets:					
Cash and cash equivalents	\$	37,965,198	\$	91,344,666	
Prepaid expenses and other current assets		1,957,765		3,395,364	
Offering costs		1,999,279		<u> </u>	
Total current assets		41,922,242		94,740,030	
Property and equipment, net		343,059		257,864	
Restricted cash		112,000		112,000	
Other assets		15,625		45,300	
Total assets	\$	42,392,926	\$	95,155,194	
Liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity					
Current liabilities:					
Accounts payable	\$	545,053	\$	3,084,016	
Accrued expenses and other current liabilities		2,158,792		1,775,505	
Deferred rent		33,114		34,707	
Total current liabilities		2,736,959		4,894,228	
Deferred rent, net of current portion		313,919		307,374	
Warrant liability		350,519		106,341	
Total liabilities		3,401,397		5,307,943	
Commitments and contingencies		, ,		, ,	
Redeemable convertible preferred stock:					
Series A convertible preferred stock, \$0.001 par value; 25,074,999 and 0 shares authorized, 25,074,999 and 0 shares					
issued and outstanding at December 31, 2013 and March 31, 2014 respectively, (liquidation preference of					
\$25,074,999 at December 31, 2013)		25,024,373		_	
Series B convertible preferred stock, \$0.001 par value; 35,500,000 and 0 shares authorized, 30,800,000 and 0 shares					
issued and outstanding at December 31, 2013 and March 31, 2014, respectively (liquidation preference of					
\$30,800,000 at December 31, 2013)					
		30,778,700		_	
Series B 1 convertible preferred stock, \$0.001 par value; 6,000,000 and 0 shares authorized, 4,750,000 and 0 shares					
issued and outstanding at December 31, 2013 and 2014, respectively (liquidation preference of \$4,200,000 at					
December 31, 2013)		4,823,079		_	
Series C convertible preferred stock, \$0.001 par value; 37,000,000 and 0 shares authorized, 36,764,704 and 0 shares					
issued and outstanding at December 31, 2013 and March 31, 2014, respectively (liquidation preference of					
\$59,999,997 at December 31, 2013)		59,935,986		_	
Total redeemable convertible preferred stock		120,562,138		_	
Stockholders' (deficit) equity:					
Common stock—\$0.001 par value; 132,000,000 shares authorized, 957,756 and 26,232,941 shares issued and					
outstanding at December 31, 2013 and March 31, 2014, respectively		958		26,233	
Additional paid-in capital		697,283		181,463,282	
Deficit accumulated during the development stage		(82,268,850)		(91,642,264)	
Total stockholders' (deficit) equity		(81,570,609)		89,847,251	
Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity	\$	42,392,926	\$	95,155,194	
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