

# Trevena Reports Third Quarter 2014 Financial Results and Provides a Corporate Update

*- Top-line data from Phase 2a/b trial of TRV130 in postoperative pain expected within a few weeks -*

*- TRV027 AHF Phase 2b trial enrollment progressing as planned -*

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)-- 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 quarter ended September 30, 2014 and provided an update regarding its ongoing clinical programs.

“I am pleased with the strong progress we continued to make during recent months in advancing our clinical pipeline and developing our business,” said Maxine Gowen, Ph.D., chief executive officer. “We completed enrollment in our first Phase 2 trial of TRV130 and expect to report top-line results in the next few weeks. We also secured key intellectual property protection for both TRV130 and TRV027, advanced important clinical studies of TRV027 and TRV734 and strengthened our board with three new members. We are poised to deliver significant milestones over the next several quarters and advance our pipeline of new product candidates for underserved markets.”

## Third Quarter and Recent Highlights

### ***CNS Programs (TRV130 and TRV734)***

- **Completed enrollment of Phase 2a/b trial of i.v. TRV130 in acute postoperative pain.** In October Trevena announced that its Phase 2a/b trial of TRV130, which is in development as a first-line intravenous treatment for patients experiencing moderate to severe acute pain, had completed enrollment early, having met all study objectives upon a pre-specified interim analysis. The study is a multicenter, randomized, double-blind, placebo-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 current standard of care – morphine – as a benchmark. Top-line data from this trial are now expected within a few weeks; the Company will host a conference call to discuss the results.
- **Announced details of a previously planned second Phase 2 trial of i.v. TRV130.** The Company today announced details of its next Phase 2 study of TRV130 to evaluate flexible, as-needed, dosing. In this study, TRV130, morphine or placebo will be administered as an initial loading dose followed by delivery of on-demand doses via a patient controlled analgesia (PCA) device to patients who have undergone uncomplicated, elective abdominoplasty surgery. Approximately 200 patients will be

enrolled in the trial, with approximately 40 receiving placebo, 80 receiving TRV130 and 80 receiving morphine. The primary endpoint of the trial will be the efficacy of TRV130 compared to placebo over 24 hours, which may serve as a registration endpoint in phase 3 development. The study remains on track for initiation this quarter, and will complement the bunionectomy study in informing Phase 3 development plans.

- **Grant of key U.S. patent for TRV130.** In September, the Company announced its receipt of U.S. Patent No. 8,835,488, covering TRV130, compositions comprising TRV130, and methods of using TRV130. The patent is expected to provide coverage for TRV130 in the United States until at least 2032.
- **Completed enrollment of a Phase 1 multiple ascending dose study of oral TRV734 for acute and chronic pain.** In August, the Company initiated a study to evaluate the safety, tolerability, pharmacodynamics and pharmacokinetics of TRV734 given as a single dose and as multiple ascending doses in healthy volunteers. The aim of this study is to support Phase 2 development. Enrollment is now complete and data are expected early in the first quarter of 2015.

### ***Acute Heart Failure Program (TRV027)***

- **Phase 2b BLAST-AHF trial enrollment progressing as planned.** The Biased Ligand at the Angiotensin Receptor Study in Acute Heart Failure (BLAST-AHF) trial has enrolled over 200 patients as of October 31 towards the objective of 500 patients. More than 65 sites in 12 countries are now open and recruiting, and patient enrollment is expected to conclude in the third quarter of 2015. Since the initiation of this trial, the Data Safety Monitoring Board has reviewed safety data from BLAST-AHF on two separate occasions and has recommended that the trial continue administering all three doses under investigation. The Company anticipates top-line data from this study will be available in the fourth quarter of 2015.
- **Grant of key U.S. method of use patent for TRV027.** In August, the Company announced its receipt of U.S. Patent No. 8,796,204, a new patent covering methods of use for TRV027 including for the treatment of acute heart failure. The patent is expected to provide coverage for TRV027 in the United States until at least 2029, strengthening the protection provided by the previously issued U.S. composition of matter patent that is expected to extend until at least 2031.

### ***Corporate Developments***

- **Term loan credit facility.** In September, Trevena entered into a senior secured term loan credit facility that provides meaningful financing flexibility and the opportunity to draw up to \$35.0 million of funding. At the closing, the Company drew \$2.0 million from the facility and it has the option to draw the remaining \$33.0 million in funds in two equal tranches upon positive clinical data in the Company's ongoing TRV130 and TRV027 studies, respectively.
- **Board of Directors.** During the quarter, Adam M. Koppel M.D., Ph.D., SVP and Chief Strategy Officer at Biogen Idec, Julie H. McHugh, former president of Centocor and chief operating officer at Endo Health Solutions, and Barbara Yanni, former chief licensing officer at Merck & Co., joined Trevena's Board of Directors.

## **Financial Results**

Net loss attributable to common stockholders for the quarter ended September 30, 2014 was \$15.5 million, or \$0.59 per share. Research and development expenses were \$13.0 million in the third quarter of 2014; general and administrative expenses were \$2.5 million. Cash and cash equivalents totaled \$72.2 million as of September 30, 2014. Trevena expects that its existing cash and cash equivalents will be sufficient to fund operations through the end of 2015.

## **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 is advancing 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, 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 ongoing and planned Phase 2 trials 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; 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 availability or commercial potential of the company's therapeutic candidates; the inherent uncertainties associated with intellectual property, including whether and for how long the patents for TRV130 and TRV027 will protect these products; 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.

**TREVENA, INC.**  
**Condensed Statements of Operations (Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue	\$ -	\$ -	\$ -	\$ 134,980
Operating expenses:				
General and administrative	2,536,807	1,210,875	7,033,492	2,843,587
Research and development	13,006,568	6,629,932	29,671,114	12,239,679
Total operating expenses	15,543,375	7,840,807	36,704,606	15,083,266
Loss from operations	(15,543,375)	(7,840,807)	(36,704,606)	(14,948,286)
Other income (expense)	8,503	(941,171)	300,639	(1,397,454)
Net loss and comprehensive loss	(15,534,872)	(8,781,978)	(36,403,967)	(16,345,740)
Accretion of redeemable convertible preferred stock	-	(85,562)	(28,521)	(248,149)
Net loss attributable to common stockholders	<u>\$(15,534,872)</u>	<u>\$(8,867,540)</u>	<u>\$(36,432,488)</u>	<u>\$(16,593,889)</u>
Per share information:				
Net loss per share of common stock, basic and diluted	<u>(\$0.59)</u>	<u>(\$11.18)</u>	<u>(\$1.58)</u>	<u>(\$22.23)</u>
Weighted average shares outstanding, basic and diluted	<u>26,366,300</u>	<u>793,268</u>	<u>23,036,366</u>	<u>746,587</u>

**TREVENA, INC.**  
**Condensed Balance Sheets**

	September 30, 2014 (Unaudited)	December 31, 2013
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 72,224,557	\$ 37,965,198
Prepaid expenses and other current assets	924,338	3,957,044
Total current assets	73,148,895	41,922,242
Property and equipment, net	593,967	343,059
Restricted cash	112,000	112,000
Other assets	101,501	15,625
Total assets	<u>\$ 73,956,363</u>	<u>\$ 42,392,926</u>

**Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)**

## Current liabilities:

Accounts payable	\$ 3,890,901	\$ 545,053
Accrued expenses and other current liabilities	3,595,717	2,158,792
Deferred rent	36,615	33,114
Total current liabilities	7,523,233	2,736,959
Loan payable, net of debt discount	1,774,012	-
Capital lease, net of current portion	11,333	-
Deferred rent, net of current portion	292,253	313,919
Warrant liability	95,741	350,519
Total liabilities	9,696,572	3,401,397
Redeemable convertible preferred stock	-	120,562,138
Common stock and additional paid-in capital	182,932,608	698,241
Accumulated deficit	(118,672,817)	(82,268,850)
Total stockholders' equity (deficit)	64,259,791	(81,570,609)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 73,956,363	\$ 42,392,926

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