

# Trevena Reports First Quarter 2019 Results

— Company announces receipt of FDA feedback on healthy volunteer study protocol and analysis plan for oliceridine —

- Study on track to initiate by end of June -

Company to host conference call Monday, May 13, 2019 at 8:00 a.m. ET

CHESTERBROOK, Pa., May 10, 2019 (GLOBE NEWSWIRE) -- **Trevena, Inc. (Nasdaq: TRVN)**, a biopharmaceutical company focused on the development and commercialization of novel medicines for patients affected by Central Nervous System (CNS) conditions, today announced receipt of comments from the U.S Food and Drug Administration (FDA) on the proposed healthy volunteer study protocol, and reported its financial results for the quarter ended March 31, 2019.

"We are very pleased with the feedback from FDA, which provides us with the necessary information to move forward and initiate the healthy volunteer study by the end of June," said Carrie Bourdow, President and Chief Executive Officer. "This marks a critical step on the path towards resubmission of the new drug application for oliceridine, and I am proud of our team for their considerable efforts in preparing for this important upcoming work."

### First Quarter and Recent Corporate Highlights:

 Received feedback from FDA on key design elements for the healthy volunteer study. The FDA confirmed that the study can be conducted in healthy volunteers over a 24-hour period. The study will be performed at a single site as a three-period crossover design that includes oliceridine, placebo, and moxifloxacin as a positive control.

The Company plans to submit data on approximately 60 participants. Among this study population, a minimum of 20 participants will receive a cumulative dose of 27 mg of oliceridine, the proposed maximum daily dose, through the 24-hour study period.

The study remains on track to initiate by the end of June. The Company will provide additional details on a conference call scheduled for Monday, May 13<sup>th</sup> at 8:00 a.m. Eastern Time.

Completed successful capital raise. In January, the Company completed a \$10 million registered direct offering of common stock that yielded \$9.2 million of net proceeds.

For the first quarter of 2019, the Company reported a net loss attributable to common stockholders of \$5.2 million, or \$0.06 per share, compared to \$9.0 million, or \$0.14 per share, for the first quarter of 2018. This decrease is primarily due to lower personnel related costs associated with the 2018 restructuring and reduction in force, and lower research and development expenses.

Cash, cash equivalents, and marketable securities were \$60.1 million at March 31, 2019. The Company believes its cash, cash equivalents, and marketable securities as of March 31, 2019, together with interest thereon, to be sufficient to fund the Company's operating expenses and capital expenditure requirements into the third quarter of 2020.

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

The Company will host a conference call and webcast with the investment community on Monday, May 13<sup>th</sup> at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and CEO, and Mark Demitrack, SVP and Chief Medical Officer.

**Live Call:** Toll-Free: (855) 465-0180

International: (484) 756-4313

Webcast: investors.trevena.com

**Replay:** Toll-Free: (855) 859-2056

International: (404) 537-3406 Conference ID: 7698684

(Available approximately one hour after the completion of the

live call until 11:59 p.m. ET on May 22, 2019)

#### **About Trevena**

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of novel medicines for patients affected by Central Nervous System (CNS) conditions. The Company has three novel and differentiated investigational drug candidates, including IV oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the treatment of acute migraine, and TRV734 for the management of pain and/or management of opioid use disorder. In its preclinical programs, the Company has identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid approach to managing chronic pain.

### **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 or any future trials, including with respect to any future clinical study of oliceridine; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including the Company's assessment of

the discussions with FDA, whether there is a path to resubmit the oliceridine NDA, and the timing of any FDA review of the protocol for a future oliceridine study; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and whether cash, cash equivalents, and marketable securities as of March 31, 2019 will be sufficient to fund operating expenses and capital expenditure requirements into the third quarter of 2020; 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.

## For more information, please contact:

#### **Investor Contact:**

Valter Pinto / Allison Soss KCSA Strategic Communications Phone: 212-896-1254 / 212-896-1267

Email: IR@trevena.com

# **Company Contact:**

Bob Yoder, SVP and Chief Business Officer

Trevena. Inc.

Phone: 610-354-8840

# TREVENA, INC. Condensed Statements of Operations (Unaudited, in thousands except share and per share data)

	Three Months Ended March 31,				
		2019	_	2018	
Revenue	\$	-	\$	-	
Operating expenses:					
General and administrative		3,060		5,072	
Research and development		2,154		4,598	
Restructuring charges		-		23	
Total operating expenses		5,214		9,693	
Loss from operations		(5,214)		(9,693)	
Other income (expense)		45		672	

Loss before income tax expense	(5,169)	(9,021)
Foreign income tax expense	 	 
Net loss	\$ (5,169)	\$ (9,021)
Per share information:		
Net loss per share of common stock, basic		
and diluted	 (\$0.06)	 (\$0.14)
Weighted average shares outstanding, basic and diluted	88,897,292	64,562,236

# TREVENA, INC. Condensed Balance Sheets (Unaudited, in thousands)

		March 31, 2019	Dece	mber 31, 2018
Assets				
Current assets:				
Cash and cash equivalents	\$	20,261	\$	32,892
Marketable securities		39,802		28,590
Prepaid expenses and other current assets		1,581		607
Total current assets		61,644		62,089
Restricted cash		1,305		1,303
Property and equipment, net		3,238		3,387
Right-of-use lease assets		5,702		-
Total assets	\$	71,889	\$	66,779
Liabilities and stockholders' equity  Current liabilities:	\$	358	\$	1,416
Accounts payable Accrued expenses and other current liabilities	φ	1,956	Φ	3,305
Current portion of loans payable, net		14,330		12,562
Current portion of lease liabilities		563		12,002
Deferred rent		-		207
Total current liabilities		17,207		17,490
Loans payable, net		-		4,811
Leases, net of current portion		8,281		20
Deferred rent, net of current portion		-		2,931
Warrant liability		14		, 1
Total liabilities		25,502		25,253
Common stock		92		82
Additional paid-in capital		439,735		429,727
Accumulated deficit		(393,443)		(388,274)

Accumulated other comprehensive income (loss)

Total stockholders' equity

Total liabilities and stockholders' equity

3		(9)
46,387	-	41,526
\$ 71,889	\$	66,779



Source: Trevena Inc.