

# Trevena Reports First Quarter 2018 Financial Results

 First license agreements for ex-US development and commercialization of oliceridine add potential revenue streams –

Oliceridine NDA on track for potential approval in November –

CHESTERBROOK, Pa., May 03, 2018 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced financial results for the quarter ended March 31, 2018 and provided an update on its pipeline of differentiated new chemical entities, including its lead asset, oliceridine, currently under review by the U.S. Food and Drug Administration (FDA) for potential approval this year.

"In 2018, we have made important progress in Trevena's evolution," said Maxine Gowen, Ph.D., president and chief executive officer. "We have initiated a smooth and constructive transition in preparation for Carrie Bourdow to assume the CEO position later this year. We also have begun to broaden the potential revenue from oliceridine by completing our first ex-US licensing agreements. We continue to have an ongoing productive dialogue with the FDA as they review our oliceridine NDA, and look forward to an advisory committee meeting later this year and potential approval in November."

# First quarter and recent corporate highlights

- New Drug Application (NDA) for oliceridine submitted and accepted. In January 2018, the Company announced that the FDA has accepted the Company's NDA for oliceridine, an investigational product for the management of moderate to severe acute pain. Oliceridine is the first G protein biased ligand of the mu receptor, and was designed to provide IV opioid pain relief with fewer associated adverse effects. The FDA has informed the Company that it intends to convene an advisory committee meeting to discuss the oliceridine NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of oliceridine in the first quarter of 2019, following DEA scheduling.
- Licensed oliceridine for development and commercialization in two ex-US territories. In April, the Company and privately held Pharmbio Korea Inc. announced that they have entered into an exclusive license agreement for the development and commercialization of oliceridine in South Korea. In May, the Company and Jiangsu Nhwa Pharmaceutical Co. Ltd. announced that they have entered an exclusive license agreement for the development and commercialization of oliceridine in China. Under these agreements, Trevena will receive a total of \$5.5 million in upfront payments, and is eligible for further regulatory and commercial milestones and royalties. The Company remains in active discussions for licensing oliceridine in additional territories.

- Carrie Bourdow selected as next CEO. In April, the Company announced that
  President and Chief Executive Officer, Maxine Gowen, Ph.D., will retire on October 1,
  2018 and will continue to serve on the Trevena Board of Directors. The Board of
  Directors has selected Carrie L. Bourdow, who currently serves as Trevena's
  Executive Vice President and Chief Operating Officer, to be the Company's next
  President and Chief Executive Officer, effective October 1, 2018.
- Early pipeline advancing. In March, the Company announced that its early pipeline programs continued to progress. The Company has completed dosing in its Phase 1 study of TRV250 for treatment of acute migraine, which had been extended following positive interim results for the initially planned doses demonstrating dose-proportional exposure after subcutaneous administration and adequate oral bioavailability to support further clinical development. The Company expects to release data in the coming months. In addition, the Company is evaluating a set of novel S1P modulators that may offer a new non-narcotic approach to managing chronic pain. The Company continues to expect complete characterization of the lead compounds in 2018 to determine if any merit IND-enabling studies to support Phase 1 clinical trials.

## Financial results

For the first quarter of 2018, Trevena reported a net loss attributable to common stockholders of \$9.0 million, or \$0.14 per share, compared with a net loss attributable to common stockholders for the first quarter of 2017 of \$20.7 million, or \$0.36 per share. Research and development expenses were \$4.6 million in the first quarter of 2018 compared to \$16.1 million for the same period in 2017; general and administrative expenses were \$5.1 million, compared to \$4.9 million for the first quarter of 2017. Cash, cash equivalents, and marketable securities were \$61.6 million as of March 31, 2018. The Company expects this amount, together with interest thereon and proceeds from oliceridine ex-U.S. licensing activities, to be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from today's date.

For additional details, please see the Company's Form 10-Q, which will be filed with the SEC today.

## **Conference Call and Webcast**

Date: May 3, 2018 Time: 8:00 a.m. EDT

Telephone Access: (855) 465-0180

International: (484) 756-4313

Webcast: http://investors.trevena.com/index.cfm

Conference ID: 1350009

# **About Trevena**

Trevena, Inc. is a biopharmaceutical company focused on providing better, safer therapies to patients in pain. The Company has leveraged breakthrough science to discover and develop its investigational product, oliceridine injection, for the management of moderate-to-severe acute pain. Oliceridine has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration, and is intended to provide healthcare providers an

innovative new option for patients who require an intravenous opioid. The Company also has an early stage pipeline of new chemical entities targeting novel mechanisms of action, including TRV250 for acute migraine, neuropathic pain, and other 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 or any future trials, including whether the positive interim data from the Phase 1 study of TRV250 will be seen in the final study results and will support further clinical development, whether the final data for TRV250 Phase 1 study will be released in the coming months, whether the Company's novel set of S1P modulators may offer a new, non-narcotic approach to managing chronic pain, and whether the Company will complete characterization of the S1P lead compounds in 2018; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including whether the Company's ongoing dialogue with the FDA with respect to the oliceridine NDA is or will remain productive; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, including whether the Company's cash, cash equivalents, and marketable securities, together with interest thereon and proceeds from oliceridine ex-U.S. licensing activities, will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from today's date; 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 forwardlooking 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.

# **Contacts**

Trevena, Inc.

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TREVENA, INC.

Condensed Statements of Operations
(Unaudited, in thousands except share and per share data)

	Three Months Ended March 31,				
20′		2018		2017	
Revenue	\$	-	\$	-	
Operating expenses:					
General and administrative		5,072		4,879	
Research and development		4,598		16,096	
Restructuring charges		23		-	
Total operating expenses		9,693		20,975	
Loss from operations		(9,693)		(20,975)	
Other income		672		261	
Net loss	\$	(9,021)	\$	(20,714)	
Per share information:					
Net loss per share of common stock, basic and diluted	\$	(0.14)	\$	(0.36)	
Weighted average shares outstanding, basic and diluted	64	4,562,236		56,894,672	

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

	March 31, 2018		December 31, 2017	
Assets				
Current assets:				
Cash and cash equivalents	\$	18,146	\$	16,557
Marketable securities		43,445		49,543
Prepaid expenses and other current assets		1,847		1,393
Total current assets		63,438		67,493
Restricted cash		1,413		1,413
Property and equipment, net		3,779		3,805

Intangible asset, net		11	11
Total assets	\$	68,641	\$ 72,722
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	\$	1,387	\$ 1,424
Accrued expenses and other current liabilities		1,519	4,303
Current portion of loans payable, net		12,460	12,425
Deferred rent		63	61
Total current liabilities		15,429	 18,213
Loans payable, net		12,595	15,725
Capital leases, net of current portion		28	31
Deferred rent, net of current portion		2,992	3,006
Warrant liability		10	10
Other long term liabilities		1,270	1,104
Total liabilities		32,324	38,089
Common stock		68	62
Additional paid-in capital		402,806	392,103
Accumulated deficit		(366,511)	(357,490)
Accumulated other comprehensive loss		(46)	(42)
Total stockholders' equity	-	36,317	 34,633
Total liabilities and stockholders' equity	\$	68,641	\$ 72,722



Source: Trevena Inc.