

Trevena Reports Second Quarter 2018 Financial Results

- Oliceridine NDA remains on track for a November 2, 2018 FDA decision –
- First license agreements for ex-US development and commercialization of oliceridine add potential revenue streams –
 - Early pipeline continues to advance –

CHESTERBROOK, Pa., Aug. 02, 2018 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ: TRVN) today announced financial results for the quarter ended June 30, 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.

"The second quarter saw important progress towards Trevena's long-term success," said Maxine Gowen, Ph.D., President and Chief Executive Officer. "We remain confident that the oliceridine NDA remains on track for an FDA decision by the November 2, 2018 PDUFA date, and we look forward to discussing the oliceridine data at an Advisory Committee meeting, likely in October. In addition, the second quarter saw us secure two important ex-US licensing transactions for oliceridine, strengthen our leadership team with important medical and commercial hires, and continue a smooth transition to Carrie Bourdow's assumption of the CEO role."

Second quarter and recent corporate highlights

- Prescription Drug User Fee Act (PDUFA) date for oliceridine: November 2, 2018.
 Oliceridine is an investigational product under FDA review for the management of moderate to severe acute pain where parenteral opioid analgesia is warranted and was designed to provide the pain relief of IV opioids with fewer associated adverse effects. The FDA has informed the Company that it intends to convene an advisory committee meeting, likely in October, to discuss the oliceridine NDA. If oliceridine is approved by the FDA, and following DEA scheduling, the Company expects the commercial launch of oliceridine in the first half of 2019.
- Licensed oliceridine for development and commercialization in South Korea and China. 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. (Nhwa) announced that they have entered an exclusive license agreement for the development and commercialization of oliceridine in China. Under these agreements, Trevena has received a total of \$5.5 million in upfront payments, and it is eligible for further regulatory and commercial milestones and

royalties. Nhwa has since exercised its option to exclusive rights to manufacture oliceridine for potential distribution in China. The Company continues to pursue its strategy to outlicense oliceridine in additional territories.

- Successful completion of Phase 1 study of TRV250 for acute migraine. In June, the Company announced the successful completion of its first-time-in-human Phase 1 study of TRV250, a biased delta receptor agonist that the Company is developing for the treatment of acute migraine. Preclinical data suggested that the novel selective signaling mechanism of TRV250 might avoid the seizure liability that has limited development of therapeutics targeting the delta receptor. Data from this healthy volunteer study showed safety, tolerability, and pharmacokinetics supporting the advancement of TRV250 to Phase 2 proof of concept evaluation in patients.
- National Institute on Drug Abuse studying TRV734 as a potentially differentiated therapy for maintenance treatment of opioid dependence. The Company is supporting NIDA-funded efforts to evaluate the biased mu opioid receptor ligand TRV734, an orally available analog of oliceridine, as a potential maintenance treatment for opioid dependence. Nonclinical studies performed by NIDA scientists and presented at the recent College of Problems in Drug Dependence conference suggest that biased mu opioid receptor ligands may offer an alternative to current opioid maintenance therapies. The Company has completed two Phase 1 trials of TRV734 in healthy volunteers; in these studies, TRV734 showed CNS activity, pharmacokinetics, and safety and tolerability supporting potential Phase 2 trials.
- Continued advancement of preclinical non-narcotic analgesic program. The Company continues to evaluate a set of novel S1P modulators that may offer a new non-narcotic approach to managing chronic pain. The Company expects to complete characterization of the lead compounds in 2018 to determine if any merit IND-enabling studies to support Phase 1 clinical trials.
- Carrie Bourdow selected as next CEO. In April, the Company announced that Dr.
 Gowen 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.
- Strengthened leadership team. In May, the Company announced the appointment of Mark A. Demitrack, M.D., as Senior Vice President and Chief Medical Officer. Dr. Demitrack brings over 20 years of industry experience at large and small biopharmaceutical companies where he has led numerous CNS programs pre- and post-approval. In June, the Company announced the addition of several senior hires for the commercial and medical affairs leadership teams.

Financial results

For the second quarter of 2018, Trevena reported a net loss attributable to common stockholders of \$9.3 million, or \$0.13 per share, compared with a net loss attributable to common stockholders for the second quarter of 2017 of \$20.4 million, or \$0.35 per share. Research and development expenses were \$5.1 million in the second quarter of 2018

compared to \$15.5 million for the same period in 2017; general and administrative expenses were \$5.9 million, compared to \$4.4 million for the second quarter of 2017. Cash, cash equivalents, and marketable securities were \$63.5 million as of June 30, 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.

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 data from the Phase 1 study of TRV250 supports the advancement of the compound to Phase 2 proof of concept evaluation in patients, whether the nonclinical studies performed by NIDA suggest that TRV734 may offer an alternative to current opioid maintenance therapies, 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 oliceridine NDA remains on track for an FDA decision by the November 2, 2018 PDUFA date; 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, including whether the commercial launch of oliceridine will occur in the first half of 2019; 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, in thousands except share and per share data)

		June 30,			
		2018		2017	
Revenue	\$	2,500	\$	-	\$
Operating expenses:					
General and administrative		5,926		4,385	
Research and development		5,128		15,499	
Restructuring charges		41		-	
Total operating expenses	<u> </u>	11,095		19,884	
Loss from operations		(8,595)		(19,884)	
Other income (expense)		36		(548)	
Loss before income tax expense	<u> </u>	(8,559)		(20,432)	
Foreign income tax expense		(745)		-	
Net loss	\$	(9,304)	\$	(20,432)	\$
Per share information:					
Net loss per share of common stock,					
basic and diluted	\$	(0.13)	\$	(0.35)	\$
Weighted average shares		00.004.004		50 204 002	
outstanding, basic and diluted		69,664,994		58,381,868	

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

	June 30, 2018	Dece	December 31, 2	
Assets				
Current assets:				
Cash and cash equivalents	\$ 24,036	\$	16,5	

Marketable securities	39,462			49,5
Alliance revenue receivable		2,250		
Prepaid expenses and other current assets		1,543		1,3
Total current assets		67,291		67,4
Restricted cash		1,414		1,4
Property and equipment, net	3,613			3,8
Intangible asset, net	10			
Total assets			\$	72,7
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	592	\$	1,4
Accrued expenses and other current liabilities		3,651		4,3
Current portion of loans payable, net	12,494			12,4
Deferred revenue		3,000		
Deferred rent		65		
Total current liabilities		19,802		18,2
Loans payable, net	10,873			15,7
Capital leases, net of current portion	25			
Deferred rent, net of current portion	2,926			3,0
Warrant liability		6		
Other long term liabilities		-		1,1
Total liabilities		33,632		38,0
Common stock		74		
Additional paid-in capital	4	414,457		392,1
Accumulated deficit	(375,815)			(357,4
Accumulated other comprehensive loss		(20)		(
Total stockholders' equity	38,696			34,6
Total liabilities and stockholders' equity	\$	72,328	\$	72,7

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Source: Trevena Inc.