

August 3, 2017



# Trevena Reports Second Quarter 2017 Financial Results and Provides Corporate Update

*– OLINVO program on track for NDA submission in September/October 2017 –*

*– First-time-in-human study of TRV250 for acute treatment of migraine remains on track; results expected in 2H 2017 –*

CHESTERBROOK, Pa., Aug. 03, 2017 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced financial results for the quarter ended June 30, 2017 and provided an update on its pipeline of investigational products.

“The second quarter saw continued progress towards our goal of delivering an innovative new option for patients who are at risk of adverse events associated with IV opioids like morphine,” said Maxine Gowen, Ph.D., chief executive officer. “We have now completed our Phase 3 clinical development for OLINVO and successfully completed our pre-NDA meetings with the FDA. In addition, we have refined our commercial strategy to lay the groundwork for a successful commercial launch. With the comparative data from our successful APOLLO pivotal efficacy studies, as well as data and investigator observations from more real-world use in the ATHENA open label study, we believe the value of OLINVO will resonate with potential prescribers who want to improve the care of hospital patients suffering severe pain.”

## Second quarter and recent corporate highlights

- **OLINVO™ (oliceridine injection) program remains on track for a new drug application (NDA) submission in September/October 2017.** In July 2017, the Company announced that enrollment in the ATHENA open-label safety study was complete to support the NDA file, with 772 patients treated with OLINVO across more than 40 sites. In addition, the Company successfully completed a chemistry, manufacturing, and controls (CMC) Type B pre-NDA meeting and a preclinical and clinical Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA). All pre-NDA activities remain on track to support an NDA submission to the FDA in September/October of 2017.
- **Hosted an Analyst Day featuring four leading experts in acute pain management in the hospital.** In July, the Company hosted an Analyst Day where it provided an update on its clinical portfolio, including new data and commercial strategy for the OLINVO program:
  - The Company outlined its commercial strategy for OLINVO, including its plans to initially focus on patients who require IV opioids and are at greater risk of opioid-

related adverse effects (ORAEs). Specifically, the Company expects to target medical education and post-approval promotion to eight physician specialties with 80 select procedures and diagnoses where pain is most severe and/or prolonged, and where procedure, comorbidity, or demographic factors place patients at elevated risk of ORAEs. These patients comprise approximately 7 to 9 million annual hospital inpatients in the United States.

- New analyses of the Premier Perspective® Hospital Database quantified the clinical and economic burden of illness associated with ORAEs in the 80 procedures and diagnoses where the Company will initially focus its commercialization efforts. These analyses showed that patients undergoing these procedures require substantial doses of IV opioids despite multimodal analgesia, and that the prevalence and costs associated with ORAEs are significant.
- Topline data from the ATHENA open-label safety study highlighted the successful use of OLINVO, including in the procedures and patient populations the Company will focus on at commercial launch. The most frequent procedures were orthopedic, gynecologic, colorectal, general, and plastic surgeries. OLINVO was administered by titration in post-anesthesia recovery rooms, as-needed by bolus injection, and by patient-controlled analgesia. Patients at risk of ORAEs were common, including patients over 65 years old and obese patients. Discontinuation rates were less than 5% for lack of efficacy or for adverse effects.
- Investigator-reported observations from the ATHENA study included a retrospective chart review at one site that found that colorectal surgery patients who received OLINVO showed return of bowel function 28 hours faster than similar patients at the same site treated with conventional opioids prior to the ATHENA study ( $p=0.0001$  vs. historical control).
- **Continued publication and medical conference presentation of OLINVO data.**The Company presented data from the APOLLO-1 and APOLLO-2 Phase 3 pivotal efficacy studies of OLINVO at several medical conferences, including the 42<sup>nd</sup> Annual Regional Anesthesiology and Acute Pain Medicine Meeting (ASRA), the 36<sup>th</sup> Annual Scientific Meeting of the American Pain Society (APS), and the 32<sup>nd</sup> Annual Meeting of the Society for Ambulatory Anesthesia (SAMBA). In addition, the Company published original nonclinical research in the Journal of Pharmacology and Experimental Therapeutics, showing that the OLINVO mechanism of action may avoid triggering the opioid-induced hyperalgesia (OIH) associated with conventional opioids. Published research has shown that OIH may prolong and exacerbate pain in patients treated with conventional opioids.
- **First-time-in-human study of TRV250 currently ongoing.** TRV250 is under investigation as a potential new mechanism of action for the acute treatment of migraine. The study is a single ascending dose trial in healthy volunteers and is evaluating the safety, tolerability, and pharmacokinetics of subcutaneous and oral TRV250. The Company continues to expect results in the second half of 2017.

- **Disclosed new S1P receptor modulation program.** In July, the Company disclosed a new preclinical lead optimization program targeting S1P receptors with a novel mechanism that has demonstrated activity in preclinical models of chemotherapy-induced peripheral neuropathy, neuropathic pain, and inflammatory pain. The Company's compounds are all new chemical entities, expected to be non-addictive, and use a new mechanism of action that in preclinical models avoids the immune suppression associated with approved and investigational S1P receptor targeted drugs.
- **Attended National Institutes of Health meeting on the development of novel, improved pain medications.** In June, Trevena participated in an NIH summit entitled "Cutting Edge Science Meeting Series to End the Opioid Crisis: Development of Safe, Effective, Non-Addictive Pain Treatments". The event brought together scientists, government officials, and leading industry representatives to discuss new approaches to pain management that have the potential to reduce risks to patients and communities who have suffered from the opioid crisis while still providing treatment options for patients in serious pain.

## **Financial results**

For the second quarter of 2017, Trevena reported a net loss attributable to common stockholders of \$20.4 million, or \$0.35 per share, compared with a net loss attributable to common stockholders for the second quarter of 2016 of \$19.2 million, or \$0.37 per share. Research and development expenses were \$15.5 million in the second quarter of 2017 compared to \$17.2 million for the same period in 2016; general and administrative expenses were \$4.4 million, compared to \$3.7 million for the second quarter of 2016.

Cash, cash equivalents, and marketable securities were \$84.2 million as of June 30, 2017, which the Company expects will fund operations into the third quarter of 2018, including submitting the NDA to the FDA in September or October of 2017, advancing TRV250 through a first-time-in-human study, and the continued progression of the Company's pipeline.

## **About Trevena**

Trevena, Inc. is a biopharmaceutical company developing innovative therapies based on breakthrough science to benefit patients and healthcare providers confronting serious medical conditions. The Company's lead program is OLINVO™ (oliceridine injection), which has successfully completed three successful Phase 3 trials for the management of moderate-to-severe acute pain. Trevena has discovered four novel and differentiated drug candidates, including OLINVO. Trevena also has discovered TRV250, in early clinical development for the treatment of acute migraine. The Company maintains an early stage portfolio of drug discovery programs.

## **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 the interpretation of the topline results from the APOLLO and ATHENA trials, whether the existing clinical data is sufficient to support the Company’s NDA to FDA, and whether results of the TRV250 first-time-in-human study will be available in the second half of 2017; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including whether the pre-NDA meetings with FDA were successful and whether the Company will submit the OLINVO NDA in September or October of 2017; availability of funding sufficient for the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; 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 the plans for the initial focus of the Company’s commercial strategy, whether the Company has laid the groundwork for a successful commercial launch of OLINVO, and whether the value of OLINVO will resonate with potential prescribers; 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Collaboration revenue	\$ -	\$ 1,875	\$ -	\$ 3,750
Operating expenses:				
General and administrative	4,385	3,697	9,264	7,615
Research and development	15,499	17,203	31,595	32,956
Total operating expenses	19,884	20,900	40,859	40,571
Loss from operations	(19,884 )	(19,025 )	(40,859 )	(36,821 )
Other income (expense)	(548 )	(191 )	(287 )	(174 )
Net loss	\$ (20,432 )	\$ (19,216 )	\$ (41,146 )	\$ (36,995 )
Per share information:				
Net loss per share of common stock, basic and diluted	(\$0.35 )	(\$0.37 )	(\$0.71 )	(\$0.71 )

Weighted average shares outstanding, basic  
and diluted

58,381,868

52,174,569

57,642,379

51,762,467

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

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,037	\$ 24,266
Marketable securities	70,163	86,335
Prepaid expenses and other current assets	3,462	1,788
Total current assets	87,662	112,389
Property and equipment, net	2,921	1,059
Restricted cash	1,413	1,193
Intangible asset, net	12	13
Total assets	\$ 92,008	\$ 114,654
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,290	\$ 8,749
Accrued expenses and other current liabilities	2,822	8,208
Current portion of loans payable, net	7,093	5,039
Deferred rent	56	52
Total current liabilities	12,261	22,048
Loans payable, net	20,895	13,270
Capital leases, net of current portion	15	18
Deferred rent, net of current portion	2,465	187
Warrant liability	19	75
Other long term liabilities	747	475
Total liabilities	36,402	36,073
Common stock	59	56
Additional paid-in capital	382,375	364,148
Accumulated deficit	(326,771 )	(285,625 )
Accumulated other comprehensive income (loss)	(57 )	2
Total stockholders' equity	55,606	78,581
Total liabilities and stockholders' equity	\$ 92,008	\$ 114,654

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