

May 4, 2017



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

- *Successfully completed two positive Phase 3 pivotal efficacy studies of OLINVO™ (oliceridine injection) –*
- *OLINVO program on track for NDA submission in fourth quarter of 2017 –*
- *Clinical development of TRV250 for episodic migraine initiated with first subjects dosed in Phase 1 trial –*

KING OF PRUSSIA, Pa., May 04, 2017 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ:TRVN) today announced financial results for the quarter ended March 31, 2017 and provided an update on its ongoing clinical programs.

“This quarter marked a key milestone for our OLINVO program, with the delivery of robust data that we believe will support our new drug application and demonstrates the potential value of OLINVO for the management of moderate-to-severe acute pain in the hospital,” said Maxine Gowen, Ph.D., chief executive officer. “There remains a critical unmet need for patients who require IV opioids to manage pain but are at risk for poor outcomes from opioid-related adverse effects. Our successful Phase 3 data showed not only significant efficacy of OLINVO versus placebo to support approval, but also showed the potential for fewer gastrointestinal and respiratory adverse effects while providing comparable pain relief to a commonly used morphine regimen.”

## First quarter and recent corporate highlights

- **Announced positive top-line results from two Phase 3 pivotal efficacy studies of OLINVO™ (oliceridine injection) for moderate-to-severe pain.** In February, the Company announced positive data from the APOLLO-1 and APOLLO-2 studies of OLINVO in moderate-to severe-acute pain following hard tissue and soft tissue surgeries, respectively. OLINVO demonstrated significant analgesic efficacy compared to placebo in both studies for all three tested dosing regimens. Consistent with Phase 2b results, a 0.35 mg dose regimen provided comparable pain relief to a common IV morphine regimen and showed potential to reduce opioid-related adverse effects on multiple measures of respiratory safety and gastrointestinal tolerability.
- **OLINVO program remains on track for a new drug application (NDA) submission in 4Q 2017.** As of March 31, 2017, approximately 600 patients have been treated with OLINVO in the ongoing open-label, multi-procedure ATHENA safety study. In addition, the Company has successfully completed a chemistry, manufacturing, and controls Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA), and all

pre-NDA activities remain on track to support an NDA submission to the FDA in the fourth quarter of 2017.

- **Presentation of Phase 3 OLINVO data at medical conferences.** In April, the Company announced two presentations of results from the APOLLO-1 and APOLLO-2 pivotal efficacy studies of OLINVO at the 42<sup>nd</sup> Annual Regional Anesthesiology and Acute Pain Medicine Meeting, representing the first scientific presentations of the Phase 3 OLINVO data.

The Company also today announced a poster presentation highlighting the APOLLO-1 data at the Society for Ambulatory Anesthesia (SAMBA) 32<sup>nd</sup> Annual Meeting taking place May 4 - 6 in Scottsdale, Arizona. David Soergel, M.D., chief medical officer, also will highlight APOLLO-1 and APOLLO-2 data at a sponsored symposium on May 5<sup>th</sup> entitled "Consequences of Poorly Controlled Acute Pain and New Frontiers in Opioid Pharmacotherapy."

Later this month, the Company will be making multiple presentations during the 36<sup>th</sup> Annual Scientific Meeting of the American Pain Society (APS). Mike Lark, Ph.D., chief scientific officer, and David Soergel, M.D., chief medical officer, will present pre-clinical and clinical data, respectively, from the OLINVO program as part of a panel entitled "Biased ligands: is basic science finally starting to pay off?" at the Spring Pain 2017 conference running in partnership with APS. The Company will also be making two poster presentations at the APS meeting.

- **Initiated clinical development of TRV250 for treatment of episodic migraine.** In April, the Company initiated the dosing of healthy volunteers for the first-time-in human study of TRV250. This study aims to evaluate the safety, tolerability, and pharmacokinetics of TRV250 dosed subcutaneously and orally. TRV250 is a new chemical entity targeting a novel mechanism of action for treating migraine.

## **Financial results**

For the first quarter of 2017, Trevena reported a net loss attributable to common stockholders of \$20.7 million, or \$0.36 per share, compared with a net loss attributable to common stockholders for the first quarter of 2016 of \$17.8 million, or \$0.35 per share. Research and development expenses were \$16.1 million in the first quarter of 2017 compared to \$15.8 million for the same period in 2016; general and administrative expenses were \$4.9 million, compared to \$3.9 million for the first quarter of 2016.

Cash, cash equivalents, and marketable securities were \$97.9 million as of March 31, 2017, which the Company expects will fund operations into the third quarter of 2018, including funding enrollment in the Phase 3 ATHENA study by mid-year sufficient to support the submission of the NDA for OLINVO, submitting the NDA to the FDA in the fourth quarter 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 has discovered four novel and differentiated drug candidates, including OLINVO™ (oliceridine injection). Trevena also has discovered TRV250, in Phase 1 development for the treatment of migraine, and TRV734 for pain. 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, including the interpretation of the top-line results from the APOLLO trials, whether such data will support the Company’s new drug application and demonstrate the value of OLINVO, whether OLINVO has the potential for fewer gastrointestinal and respiratory adverse effects while providing comparable pain relief to morphine, and the expected timing of the NDA submission for oliceridine; the uncertainties inherent in conducting clinical trials; expectations for regulatory approvals, including whether the Phase 3 data will support FDA approval of oliceridine for the management of moderate-to-severe pain; 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 whether physicians, patients, and payers will conclude that the oliceridine development program has shown consistent differentiation from morphine across multiple clinical trials; 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)

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
Collaboration revenue	\$ -	\$ 1,875

Operating expenses:		
General and administrative	4,879	3,918
Research and development	16,096	15,753
Total operating expenses	<u>20,975</u>	<u>19,671</u>
Loss from operations	(20,975 )	(17,796 )
Other income	261	17
Net loss	<u>\$ (20,714 )</u>	<u>\$ (17,779 )</u>

Per share information:

Net loss per share of common stock, basic and diluted	<u>(\$0.36 )</u>	<u>(\$0.35 )</u>
Weighted average shares outstanding, basic and diluted	<u>56,894,672</u>	<u>51,350,365</u>

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

	March 31, 2017	December 31, 2016
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,655	\$ 24,266
Marketable securities	79,253	86,335
Prepaid expenses and other current assets	2,930	1,788
Total current assets	<u>100,838</u>	<u>112,389</u>
Property and equipment, net	1,096	1,059
Intangible asset, net	13	13
Restricted cash	1,193	1,193
Total assets	<u>\$ 103,140</u>	<u>\$ 114,654</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 4,712	\$ 8,749
Accrued expenses and other current liabilities	2,367	8,208
Current portion of loans payable, net	3,912	5,039
Deferred rent	54	52
Total current liabilities	<u>11,045</u>	<u>22,048</u>
Loans payable, net	23,999	13,270
Capital leases, net of current portion	16	18
Deferred rent, net of current portion	173	187
Warrant liability	40	75
Other long term liabilities	567	475
Total liabilities	<u>35,840</u>	<u>36,073</u>
Common stock	57	56
Additional paid-in capital	373,631	364,148
Accumulated deficit	(306,339 )	(285,625 )
Accumulated other comprehensive income (loss)	(49 )	2
Total stockholders' equity	<u>67,300</u>	<u>78,581</u>
Total liabilities and stockholders' equity	<u>\$ 103,140</u>	<u>\$ 114,654</u>

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