May 6, 2021

Trevena Reports First Quarter 2021 Results

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Company reaffirms YE target of 100 formulary approvals for OLINVYK®

Announces new OLINVYK clinical outcomes study to further examine potential benefit on respiratory, GI, and cognitive function

TRV027 selected for two large, multi-site COVID-19 studies led by NIH / Vanderbilt University Medical Center and REMAP-CAP

TRV045 IND filing remains on track for 1H 2021 with a lead target indication of diabetic neuropathic pain

$97.7M cash at Q1 funds operations through YE 2022

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Company to host conference call today, May 6th, 2021, at 8:00 a.m. ET

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CHESTERBROOK, Pa., May 06, 2021 (GLOBE NEWSWIRE) -- **Trevena, Inc. (Nasdaq: TRVN)**, a biopharmaceutical company focused on the development and commercialization of novel medicines for patients with central nervous system (CNS) disorders, today reported its financial results for the first quarter ended March 31, 2021, and provided an overview of its recent operational highlights.

“In the first quarter, we made significant progress across our business. We continued to expand awareness of OLINVYK with key customers and announced an exciting outcomes study to further enhance the value proposition,” said Carrie Bourdow, President and Chief Executive Officer of Trevena, Inc. “In parallel, we advanced our pipeline with major new studies for TRV027 in COVID-19 patients, in collaboration with two of the most prominent platform trial networks in the world, and we selected diabetic neuropathic pain as the initial indication for TRV045.”

First Quarter 2021 and Recent Corporate Highlights:

OLINVYK (oliceridine) injection Milestones

- **Established a solid foundation for launch.** The Company deployed a virtual field team at the end of February. Over 60 accounts are in various stages of OLINVYK review and 10 accounts have already added OLINVYK to formulary. Despite the

impact of COVID-19, the Company is encouraged by the early progress and reaffirms its year-end goal of 100 formulary approvals.

- **Announced clinical outcomes study examining potential respiratory, GI, and cognitive benefits.** Today, the Company announced that it has initiated an open-label, multi-site, differentiation study to further characterize the impact of OLINVYK on respiratory, gastrointestinal (GI), and cognitive function outcomes in the postoperative setting. The study, which will enroll approximately 200 adults undergoing major surgery, will be led by clinical outcomes research experts from Cleveland Clinic. Respiratory safety will be assessed by continuous monitoring. Additional outcomes will include GI tolerability as measured by GI complete response, and cognitive function as measured by standardized somnolence, sedation, and delirium assessment scales. The Company expects patient enrollment to begin in Q3 2021.

- **Published compelling health economic models.** In April 2021, the Company presented two health economic models for OLINVYK at the AMCP 2021 Annual Meeting. Both models demonstrate substantial overall total cost of care savings for hospitals when using OLINVYK compared to IV morphine in postoperative care. They were developed using adverse event (AE) incidence rates from the OLINVYK Phase 3 program and a conservative, low-end estimate of AE costs based on government and published literature sources.

Pipeline Milestones

- **Advanced TRV027 in two large COVID-19 trials led by NIH / VUMC and REMAP-CAP, with TRV027 studied in up to 600 patients.** Today, the Company announced that TRV027, its novel AT_1 receptor selective agonist, has been selected for an NIH-funded, multi-arm, multi-site trial in COVID-19 patients, with Vanderbilt University Medical Center (VUMC) as the lead coordinating site. TRV027 will be administered in up to 300 patients. The trial is part of the NIH's ACTIV public-private partnership, an initiative that seeks to prioritize and expedite the development of promising COVID-19 treatments and vaccines.

  In April 2021, the Company announced that TRV027 had been selected for an international, multi-arm, multi-site Phase 2/3 trial in COVID-19 patients. TRV027 will be administered in conjunction with an ACE inhibitor in 200-300 patients. The trial is being conducted and funded as part of REMAP-CAP, a global clinical trial network led by experts in pandemic response and financially supported by an array of governments and research organizations worldwide.

- **Announced diabetic neuropathic pain as lead indication for TRV045, with IND on track for 1H 2021.** The Company today announced it will be filing the IND for TRV045, its novel S1P receptor modulator, with a lead indication of diabetic neuropathic pain (DNP). DNP is a painful condition with significant need for new treatment options, due to poor efficacy and tolerability of current available therapies. TRV045 offers a non-opioid based approach, and its novel pharmacologic class may offer unique advantages in the treatment of DNP and other CNS indications. The NIH, with whom the Company has an ongoing collaboration for this program, is also continuing its evaluation of TRV045 for epilepsy.

Financial Results for First Quarter 2021

For the first quarter of 2021, the Company reported a net loss attributable to common stockholders of $9.8 million, or $0.06 per share, compared to $5.7 million, or $0.06 per share, for the first quarter of 2020. This increase is primarily related to increases in commercialization activities for OLINVYK.

Cash and cash equivalents were $97.7 million as of March 31, 2021, which the Company believes will be sufficient to fund the Company's operating expenses and capital expenditure requirements through the fourth quarter of 2022.

Conference Call and Webcast Information

The Company will host a conference call and webcast with the investment community on May 6, 2021, at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and Chief Executive Officer, Bob Yoder, Senior Vice President and Chief Commercial Officer, Mark Demitrack, M.D., Senior Vice President and Chief Medical Officer, and Barry Shin, Senior Vice President and Chief Financial Officer.

Title:	Trevena First Quarter 2021 Financial Results Conference Call and Webcast
Date:	Thursday, May 6, 2021
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 855-465-0180 International: 484-756-4313 Conference ID: 3884579
Webcast:	https://www.trevena.com/investors/events-presentations/ir-calendar

About OLINVYK® (oliceridine) injection

OLINVYK is a new chemical entity approved by the FDA in August 2020. OLINVYK contains oliceridine, a Schedule II controlled substance with a high potential for abuse similar to other opioids. It is indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. OLINVYK is available in 1 mg/1 mL and 2 mg/2 mL single-dose vials, and a 30 mg/30 mL single-patient-use vial for patient-controlled analgesia (PCA). Approved PCA doses are 0.35 mg and 0.5 mg and doses greater than 3 mg should not be administered. The cumulative daily dose should not exceed 27 mg. Please see Important Safety Information, including the BOXED WARNING, and full prescribing information at www.OLINVYK.com.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative medicines for patients with CNS disorders. The Company has one approved product in the United States, OLINVYK® (oliceridine) injection, indicated

in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. The Company's novel pipeline is based on Nobel Prize winning research and includes four differentiated investigational drug candidates: TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, TRV045 for epilepsy and chronic neuropathic pain, and TRV027 for acute respiratory distress syndrome and abnormal blood clotting in COVID-19 patients.

For more information, please visit www.Trevena.com

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 and trials of its therapeutic candidates, plans for potential future product candidates, commercialization of approved drug products and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "objective," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," "ongoing," or the negative of these terms or 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 commercialization of any approved drug product, the status, timing, costs, results and interpretation of the Company's clinical trials or any future trials of any of the Company's investigational drug candidates; the uncertainties inherent in conducting clinical trials; expectations for regulatory interactions, submissions and approvals, including the Company's assessment of the discussions with the FDA or other regulatory agencies about any and all of its programs; uncertainties related to the commercialization of OLINVYK; available funding; uncertainties related to the Company's intellectual property; uncertainties related to the ongoing COVID-19 pandemic, 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:

Dan Ferry
Managing Director
LifeSci Advisors, LLC
daniel@lifesciadvisors.com
(617) 430-7576

PR & Media Contact:

Sasha Bennett
Director
Clyde Group
Sasha.Bennett@clydegroup.com
(239) 248-3409

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

	Three Months Ended March 31,	
	2021	**2020**
Product revenue	$ 209	$ -
Total revenue	209	-
Operating expenses:		
Cost of goods sold	163	-
General and administrative	7,368	3,632
Research and development	2,636	2,191
Total operating expenses	10,167	5,823
Loss from operations	(9,958)	(5,823)
Other income	116	98
Net loss	$ (9,842)	$ (5,725)
Per share information:		
Net loss per share of common stock, basic and diluted	($0.06)	($0.06)
Weighted average shares outstanding, basic and diluted	160,508,373	96,332,324

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

	March 31, 2021	**December 31, 2020**
Assets		

Current assets:		
Cash and cash equivalents	$ 97,720	$ 109,403
Accounts receivable, net	296	71
Insurance recovery	9,000	9,000
Prepaid expenses and other current assets	2,575	570
Total current assets	109,591	119,044
Restricted cash	1,310	1,310
Property and equipment, net	2,145	2,253
Right-of-use lease assets	5,022	5,119
Other assets	428	13
Total assets	$ 118,496	$ 127,739
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	$ 2,220	$ 1,693
Accrued expenses and other current liabilities	1,568	5,168
Estimated settlement liability	9,000	9,000
Current portion of lease liabilities	725	703
Total current liabilities	13,513	16,564
Leases, net of current portion	6,911	7,101
Warrant liability	3	6
Total liabilities	20,427	23,671
Common stock	161	160
Additional paid-in capital	550,264	546,422
Accumulated deficit	(452,356)	(442,514)
Total stockholders' equity	98,069	104,068
Total liabilities and stockholders' equity	$ 118,496	$ 127,739

Trevena®

Source: Trevena Inc.