March 9, 2021

Trevena, Inc. Reports Fourth Quarter and Full Year 2020 Results

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OLINVYK™ approved in U.S.; customer-facing teams now fully deployed

Primary study completion for TRV027 in COVID-19 patients expected in 1H 2021

IND for TRV045 ($S1P_1$ receptor modulator) on track for 1H 2021; focus in epilepsy and neuropathic pain

Year-end cash of $109.4M funds operations through YE 2022

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Company to host conference call today, March 9th, 2021, at 8:00 a.m. ET

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CHESTERBROOK, Pa., March 09, 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 fourth quarter and full year ended December 31, 2020, and provided an overview of its 2020 and 2021 year-to-date operational highlights.

“2020 was a year of unprecedented achievement for Trevena. We secured U.S. approval of OLINVYK, laid the groundwork for a successful field launch, and partnered with leading institutions to significantly advance our pipeline – all while navigating the challenges that COVID-19 posed to our industry and our communities,” said Carrie Bourdow, President and Chief Executive Officer of Trevena, Inc. “We enter 2021 with focus and resilience, as we look to deliver a successful first year of launch for OLINVYK and achieve multiple milestone events across our pipeline.”

2020 and 2021 YTD Corporate Highlights:

OLINVYK™ (oliceridine) injection Milestones

- **Obtained FDA approval and DEA scheduling.** In August 2020, the U.S. FDA approved OLINVYK in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. In October 2020, the U.S. DEA classified oliceridine as a Schedule II controlled substance.

  The Company is reiterating its commitment to the ethical promotion of OLINVYK.

OLINVYK is a novel and differentiated alternative to existing IV analgesics. In those patients for whom an IV opioid is necessary to manage their acute pain, the Company's goal is to replace conventional IV opioids, not to increase opioid usage.

- **Launched commercial and field medical teams in February.** The Company today announced it has recently completed full deployment of its customer-facing team, including Medical Science Liaisons, Regional Sales Managers, Key Account Managers, and sales representatives. Multiple institutions and ambulatory surgery centers are in the process of reviewing OLINVYK for formulary inclusion. The Company has set a target of 100 formulary acceptances by year-end.

- **Completed foundational launch activities.** Following DEA scheduling, the Company made OLINVYK commercially available across all three vial presentations (1 mg/1 mL and 2 mg/2 mL single-dose vials; 30 mg/30 mL single-patient-use vials for patient-controlled analgesia) and announced contracts in place with the three major wholesalers covering the majority of the acute care business.

  In January 2021, the Company completed a comprehensive product dossier for OLINVYK, including head-to-head data versus IV morphine and health economic models, for use by hospital formulary committees. The Company also finalized all J- and C-code submissions with the Centers for Medicare and Medicaid (CMS) and completed market access resources for customers to facilitate reimbursement of OLINVYK.

- **Continued to expand body of published peer-reviewed literature.** In 2020, the Company announced four new publications of OLINVYK data, with the number of publications from the development program now totaling 24. These findings provide additional insight into the differentiated safety and tolerability profile of OLINVYK and are available to healthcare providers as they consider the use of OLINVYK in their patients.

- **Supported development progress made by ex-U.S. partner.** In June 2020, the Company announced that Jiangsu Nhwa Pharmaceutical Co., its partner in China, was approved by the Chinese National Medical Products Administration (NMPA) to initiate clinical trials for OLINVYK. Jiangsu Nhwa holds an exclusive license agreement for the development and commercialization of OLINVYK in China.

Pipeline Milestones

- **Announced new pipeline asset: TRV027 for COVID-19 patients.** In June 2020, the Company entered into a collaboration with Imperial College London (ICL) to investigate TRV027, a novel AT_1 receptor selective agonist, as a potential treatment for acute lung damage / abnormal clotting associated with COVID-19. TRV027's mechanism of action received significant scientific interest, including a publication in *Circulation*, highlighting its hypothesized reparative effects in the lungs and other major organs.

  ICL initiated a 60-person study with a primary objective of assessing the effect of TRV027 on abnormal clotting in COVID-19 patients. ICL expects the primary completion date to be in 1H 2021.

- **Commenced partnership with NIH to evaluate TRV045 for epilepsy and chronic neuropathic pain; IND filing on track for 1H 2021.** In March 2020, the Company announced that the National Institutes of Health (NIH) had begun evaluating TRV045, a novel S1P receptor modulator in nonclinical animal models, as a potential treatment for epilepsy. In May 2020, NIH also began evaluating TRV045 in nonclinical animal models as a treatment for various pain conditions, including inflammatory and neuropathic pain. Data demonstrating efficacy in animal models of neuropathic pain and epilepsy were presented in December 2020 at the 59th Annual Meeting for the American College of Neuropsychopharmacology (ACNP).

- **Identified novel oral dose formulation for delta receptor selective agonist, TRV250.** The Company today announced that following the pause of clinical activity in 2020 due to COVID-19, it advanced formulation work for TRV250 that has yielded a novel oral dose form. This differentiated formulation could extend the Company's market exclusivity an additional five years to 2041. The Company has initiated IND-enabling activities with this oral dosage form, which it believes offers significant advantages for exploring multiple CNS disease states.

Financial Milestones

- **Strengthened balance sheet.** The Company significantly bolstered its financial position in 2020, including a successful $57.5 million public offering of common stock following approval of OLINVYK, and receipt of a $3 million milestone payment from its partner in China in connection with this approval. The Company today reported $109.4 million in cash and cash equivalents as of December 31, 2020.

Financial Results for Fourth Quarter and Full Year 2020

For the fourth quarter of 2020, the Company reported a net loss attributable to common stockholders of $11.9 million, or $0.08 per share, compared to $6.4 million, or $0.07 per share, for the fourth quarter of 2019. For the full year ended December 31, 2020, net loss attributable to common stockholders was $29.4 million, or $0.23 per share, compared to $24.9 million, or $0.27 per share, for the year ended December 31, 2019. This increase is primarily due to activities in preparation for commercial launch of OLINVYK.

Cash and cash equivalents were $109.4 million as of December 31, 2020, 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 March 9, 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, Barry Shin, Senior Vice President and Chief Financial Officer, and Gregory Hammer, M.D., Professor of Anesthesiology, Stanford University Medical Center.

Title:	Trevena Fourth Quarter 2020 & Full Year 2020 Financial Results Conference Call and Webcast

Date:	Tuesday, March 9, 2021
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: (855) 465-0180 International: (484) 756-4313 Conference ID: 7276985
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 novel 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 also has four novel and differentiated investigational drug candidates: TRV250 for the acute treatment of migraine, TRV734 for maintenance treatment of opioid use disorder, and TRV027 for acute lung injury / abnormal blood clotting in COVID-19 patients. The Company has also identified TRV045, a novel S1P receptor modulator that may offer a new approach to treating a variety of CNS disorders.

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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
Product revenue	$ 69	$ -	$ 69	$ -
License revenue	-	31	3,000	31
Total revenue	69	31	3,069	31
Operating expenses:				
Cost of goods sold	182	-	182	-
General and administrative	8,227	3,640	19,248	13,212
Research and development	3,674	2,861	13,124	13,291

Impairment of property and equipment	-	-	-	108
Total operating expenses	12,083	6,501	32,554	26,611
Loss from operations	(12,014)	(6,470)	(29,485)	(26,580)
Other income	143	25	416	1,709
Loss before income tax expense	(11,871)	(6,445)	(29,069)	(24,871)
Foreign income tax expense	-	-	(300)	-
Net loss	$ (11,871)	$ (6,445)	$ (29,369)	$ (24,871)
Per share information:				
Net loss per share of common stock, basic and diluted	($0.08)	($0.07)	($0.23)	($0.27)
Weighted average shares outstanding, basic and diluted	158,012,954	92,777,480	127,623,859	91,677,963

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 109,403	$ 32,305
Accounts receivable, net	71	-
Marketable securities	-	3,500
Insurance recovery	9,000	-
Prepaid expenses and other current assets	570	1,683
Total current assets	119,044	37,488
Restricted cash	1,310	1,309
Property and equipment, net	2,253	2,705
Right-of-use lease assets	5,119	5,472
Other assets	13	20
Total assets	$ 127,739	$ 46,994
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	$ 1,693	$ 1,047
Accrued expenses and other current liabilities	5,168	2,403

Estimated settlement liability	9,000	-
Current portion of loans payable, net	-	5,037
Current portion of lease liabilities	703	620
Total current liabilities	16,564	9,107
Leases, net of current portion	7,101	7,804
Warrant liability	6	5
Total liabilities	23,671	16,916
Common stock	160	94
Additional paid-in capital	546,422	443,129
Accumulated deficit	(442,514)	(413,145)
Total stockholders' equity	104,068	30,078
Total liabilities and stockholders' equity	$ 127,739	$ 46,994

Source: Trevena Inc.