March 12, 2020

# Trevena Reports Fourth Quarter and Full Year 2019 Results

***PDUFA date of August 7, 2020 for IV oliceridine; FDA considers NDA resubmission complete***

***Initiated proof-of-concept studies for acute migraine (TRV250) and opioid use disorder (TRV734)***

***Announces NIH collaboration to evaluate TRV045 for epilepsy***

***Updated guidance on extended cash runway, funding operations into Q1 2021***

--

*Company to host conference call today, March 12, 2020, at 8:00 a.m. ET*

CHESTERBROOK, Pa., March 12, 2020 (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, 2019, and provided an overview of its 2019 and 2020 year-to-date operational highlights.

“In 2019, we delivered on our plan to establish Trevena as a leading innovator in the treatment of CNS disorders. We completed a significant amount of work to thoroughly address the FDA complete response letter for oliceridine, which positioned us to successfully resubmit the NDA earlier this year. Additionally, we advanced our pipeline, initiating two proof-of-concept studies for acute migraine and opioid use disorder, as well as a collaboration with NIH to evaluate TRV045 for epilepsy,” said Carrie Bourdow, President and Chief Executive Officer of Trevena. “We enter 2020 with the same focus and commitment, preparing for the expected approval of oliceridine in the second half of the year, as well as advancing our pipeline assets.”

**2019 and 2020 YTD Corporate Highlights:**

**IV Oliceridine Milestones**

- **Resubmitted NDA and received PDUFA goal date of August 7, 2020.**In February 2020, the Company resubmitted the NDA for oliceridine to the FDA, after successfully completing all activities requested in the complete response letter, including a multi-dose healthy volunteer QT study, nonclinical work to confirm levels of an inactive metabolite, and drug product validation reports.

  In March 2020, the Company announced that FDA had acknowledged receipt of the

resubmitted NDA. In their acknowledgement letter, FDA stated that the Company's resubmission was a complete, Class 2 response to the Agency's action letter. A PDUFA goal date has been set for August 7, 2020.

- **Continued to expand body of published peer-reviewed literature.**In 2019, the Company announced the publication of data from both pivotal Phase 3 trials and the Phase 3 "real world" open-label safety study. These data will serve as a critical element of the oliceridine launch.

**CNS Pipeline Milestones**

- **Initiated TRV250 acute migraine PoC study.** In November 2019, the Company initiated a proof-of-concept (PoC) study evaluating TRV250 for the treatment of acute migraine and associated anxiety. This randomized, double-blind, single-dose, placebo-controlled study will enroll approximately 120 migraine patients in a validated nitroglycerin (NTG) human migraine provocation model.

  The primary endpoint of the study is reduction of sustained NTG-induced headaches; secondary outcomes include overall safety measures and reduction of symptomatic anxiety. The Company continues to expect reporting topline data in 2H 2020.

- **Initiated TRV734 opioid use disorder PoC study sponsored and funded by NIDA.** In December 2019, the Company announced the initiation of a PoC study evaluating TRV734 as a potential maintenance therapy for opioid use disorder. This randomized, double-blind, four-period, placebo- and positive-controlled study will enroll approximately 50 opioid-dependent patients.

  The primary endpoint of the study is reduction of acute opioid craving symptoms. The study will also evaluate suppression of withdrawal signs, neurocognitive changes, and overall safety.

- **Announced collaboration with NIH to evaluate TRV045 for epilepsy.**In March 2019, the Company announced its identification of TRV045 as the lead candidate for its novel S1P receptor modulator program. TRV045 has a unique mechanism of action that holds potential as a treatment for a variety of CNS disorders.

  The Company today announced it entered into a collaboration with the U.S. National Institutes of Health (NIH) to evaluate the potential of TRV045 as a treatment for epilepsy. NIH is assessing TRV045 within its Epilepsy Therapy Screening Program.

**Financial and Corporate Milestones**

- **Updated guidance on cash runway, into Q1 2021.**The Company today announced $35.8 million in cash, cash equivalents, and marketable securities as of December 31, 2019, which it believes to be sufficient to fund the Company's operating expenses and capital expenditure requirements into Q1 2021.

- **Strengthened leadership team.** In February 2020, the Company announced the appointment of Scott Applebaum as Chief Legal and Compliance Officer and Senior

Vice President of Regulatory Affairs. Mr. Applebaum brings over 20 years of experience in a variety of senior leadership roles at both large and small companies at various stages of development and commercialization in the biopharmaceuticals sector.

In July 2019, the Company announced the appointment of Barry Shin as Senior Vice President and Chief Financial Officer. Mr. Shin brings over 17 years of investment banking and corporate advisory experience, focused on the biopharmaceutical sector.

## Financial Results for Fourth Quarter and Full Year 2019

For the fourth quarter of 2019, the Company reported a net loss attributable to common stockholders of $6.4 million, or $0.07 per share, compared to $8.0 million, or $0.10 per share, for the fourth quarter of 2018. For the full year ended December 31, 2019, net loss attributable to common stockholders was $24.9 million, or $0.27 per share, compared to $30.8 million, or $0.42 per share, for the year ended December 31, 2018. This decrease is primarily due to a reduction in headcount associated with the 2018 restructuring and reduction in force, as well as a decrease in research and development expenses from the completion of the Phase 1 clinical trial for TRV250.

Cash, cash equivalents, and marketable securities were $35.8 million at December 31, 2019. The Company believes that its cash and cash equivalents and marketable securities as of December 31, 2019, together with interest thereon, to be sufficient to fund the Company's operating expenses and capital expenditure requirements into the first quarter of 2021.

## Conference Call and Webcast Information

The Company will host a conference call and webcast with the investment community on March 12, 2020, at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and Chief Executive Officer, Mark Demitrack, SVP and Chief Medical Officer, Barry Shin, SVP and Chief Financial Officer, and Timothy Beard, M.D., Chair of the Department of Surgery at Summit Medical Group.

| | |
|---|---|
| | Trevena Fourth Quarter 2019 & Full Year 2019 Financial Results |
| **Title:** | Conference Call and Webcast |
| **Date:** | Thursday, March 12, 2020 |
| **Time:** | 8:00 a.m. ET |
| **Conference Call Details:** | Toll-Free: 877-451-6152<br>International: 201-389-0879<br>Conference ID: 13699727<br>https://www.trevena.com/investors/events-presentations/ir-calendar |
| **Webcast:** | http://public.viavid.com/index.php?id=138309 |

## About Oliceridine

Oliceridine is a G protein-selective mu-opioid receptor agonist in development for the management of moderate-to-severe acute pain in hospitals or other controlled clinical settings where intravenous therapy is warranted. It is a new chemical entity with a novel mechanism of action that enables more selective targeting of newly discovered pathways

with the potential for fewer side effects. Oliceridine is an investigational product and has not been approved by FDA or any other regulatory agency. If approved, the Company expects that oliceridine will be classified as a Schedule II controlled substance.

**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 four novel and differentiated investigational drug candidates, including IV oliceridine, for the management of moderate to severe acute pain in hospitals, TRV250 for the acute treatment of migraine, and TRV734 for maintenance treatment of opioid use disorder. The Company has also identified TRV045, a novel S1P receptor modulator that may offer a new, non-opioid approach to treating a variety of CNS disorders.

**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 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 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 FDA, the timing of FDA's decision on the oliceridine NDA; available funding ; uncertainties related to the Company's intellectual property; 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

**Company Contact:**
Bob Yoder

SVP and Chief Business Officer
Trevena, Inc.
(610) 354-8840

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

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| License and related revenue | $ 31 | $ 232 | $ 31 | $ 5,732 |
| Operating expenses: | | | | |
| General and administrative | 3,640 | 4,073 | 13,212 | 18,979 |
| Research and development | 2,861 | 2,747 | 13,291 | 15,824 |
| Restructuring charges | - | 1,363 | - | 1,427 |
| Impairment of property and equipment | - | - | 108 | - |
| Total operating expenses | 6,501 | 8,183 | 26,611 | 36,230 |
| Loss from operations | (6,470 ) | (7,951 ) | (26,580 ) | (30,498 ) |
| Other income (expense) | 25 | (25 ) | 1,709 | 459 |
| Loss before income tax expense | (6,445 ) | (7,976 ) | (24,871 ) | (30,039 ) |
| Foreign income tax expense | - | - | - | (745 ) |
| Net loss | $ (6,445 ) | $ (7,976 ) | $ (24,871 ) | $ (30,784 ) |
| Per share information: | | | | |
| Net loss per share of common stock, basic and diluted | ($ 0.07 ) | ($ 0.10 ) | ($ 0.27 ) | ($ 0.42 ) |
| Weighted average shares outstanding, basic and diluted | 92,777,480 | 82,323,393 | 91,677,963 | 73,558,548 |

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

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | | |

| | | |
|---|---|---|
| Current assets: | | |
| Cash and cash equivalents | $ 32,305 | $ 32,892 |
| Marketable securities | 3,500 | 28,590 |
| Prepaid expenses and other current assets | 1,683 | 607 |
| Total current assets | 37,488 | 62,089 |
| Restricted cash | 1,309 | 1,303 |
| Property and equipment, net | 2,705 | 3,387 |
| Right-of-use lease assets | 5,472 | - |
| Other assets | 20 | - |
| Total assets | $ 46,994 | $ 66,779 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable, net | $ 1,047 | $ 1,416 |
| Accrued expenses and other current liabilities | 2,403 | 3,295 |
| Current portion of loans payable, net | 5,037 | 12,562 |
| Current portion of lease liabilities | 620 | 10 |
| Deferred rent | - | 207 |
| Total current liabilities | 9,107 | 17,490 |
| Loans payable, net | - | 4,811 |
| Leases, net of current portion | 7,804 | 20 |
| Deferred rent, net of current portion | - | 2,931 |
| Warrant liability | 5 | 1 |
| Total liabilities | 16,916 | 25,253 |
| Common stock | 94 | 82 |
| Additional paid-in capital | 443,129 | 429,727 |
| Accumulated deficit | (413,145 ) | (388,274 ) |
| Accumulated other comprehensive income (loss) | - | (9 ) |
| Total stockholders' equity | 30,078 | 41,526 |
| Total liabilities and stockholders' equity | $ 46,994 | $ 66,779 |

Source: Trevena Inc.