UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 30, 2020**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36193**	**26-1469215**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

955 Chesterbrook Boulevard, Suite 110
Chesterbrook, PA 19087
(Address of principal executive offices and zip code)

(610) 354-8840
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	TRVN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 30, 2020, Trevena, Inc. (the "***Company***") issued a press release announcing that oliceridine has been classified as a Schedule II controlled substance by the U.S. Drug Enforcement Administration (the "DEA"). With DEA scheduling now complete, the Company expects to make OLINVYK™ (oliceridine) injection available for distribution in November. The Company also announced that it had cash and cash equivalents of $112.7 million as of September 30, 2020. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated October 30, 2020
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TREVENA, INC.

Date: October 30, 2020

By: /s/ Barry Shin
Barry Shin
Senior Vice President &Chief Financial Officer

Exhibit 99.1

Trevena, Inc. Announces DEA Scheduling of OLINVYK™ (oliceridine) injection

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OLINVYK commercial supply on track and available in November

Company funded through Q4 2022, including OLINVYK commercialization

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Company to host conference call at 8:30 a.m. ET on Monday, November 2nd, 2020

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CHESTERBROOK, PA., Oct. 30, 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 announced that oliceridine has been classified as a Schedule II controlled substance by the U.S. Drug Enforcement Administration (DEA). With DEA scheduling now complete, the Company expects to make OLINVYK available for distribution in November.

“I am pleased that OLINVYK is now an FDA approved and scheduled product – two major milestones achieved in 2020,” said Carrie Bourdow, President and Chief Executive Officer of Trevena, Inc. “We made the decision earlier this year to begin manufacturing commercial product, so that physicians could have access to OLINVYK for their hospitalized acute pain patients as soon as possible upon approval and DEA scheduling. We look forward to making OLINVYK available for ordering in November.”

Each year, approximately 45 million hospital patients in the United States receive drugs like IV morphine to treat their acute pain. OLINVYK is an IV opioid that is the first new chemical entity in this drug class in decades and is distinct from drugs like IV morphine. OLINVYK has no active metabolites and requires no dosage adjustment in renal-impaired patients, a large patient population with significant medical complications. In addition, OLINVYK delivers IV opioid efficacy with a rapid 2-5 minute onset of action.

OLINVYK was studied in over 1,500 patients, including medically complex patients such as the elderly and obese, and across a variety of surgical procedures.

As a new chemical entity, OLINVYK was required to be scheduled by the DEA following its approval by the FDA in August 2020. A Schedule II assignment applies to drugs that should only be administered by a healthcare professional in controlled clinical settings. All current IV opioids used in the hospital setting are classified as Schedule II substances.

The Company also today announced cash and cash equivalents of $112.7 million as of September 30, 2020, which the Company expects will be sufficient to fund operating expenses, including the commercialization of OLINVYK, through year-end 2022.

Conference Call and Webcast Information

The Company will host a conference call and webcast with the investment community on Monday, November 2nd, 2020, at 8:30 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and Chief Executive Officer, Robert Yoder, Chief Commercial Officer, Mark Demitrack, M.D., Chief Medical Officer, and Barry Shin, Chief Financial Officer.

Title:	Conference Call to Provide Update on Commercial Launch Activities for OLINVYK
Date:	Monday, November 2nd, 2020
Time:	8:30 a.m. ET
Conference Call Details:	Toll-Free: 1-877-451-6152 International: 1-201-389-0879 Conference ID: 13712808
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 including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and tapentadol. 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. 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, non-opioid 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.

For more information, please contact:

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