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): **January 27, 2022**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36193		**26-1469215**
(Commission File No.)		(IRS Employer Identification No.)

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

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

Not applicable
(Former name or former address, if changed since last report.)

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 January 27, 2022, the Company issued a press release announcing that China's National Medical Products Administration (NMPA) has accepted submission of a New Drug Application (NDA) for oliceridine injection. The NDA was submitted by Trevena's partner, Jiangsu Nhwa Pharmaceutical, and follows completion by Nhwa of a Phase 3 bridging trial for OLINVYK (oliceridine) injection, a novel IV analgesic that has been approved in the United States by the Food and Drug Administration (FDA) for use in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate 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

Number	Description
99.1	Press Release dated January 27, 2022
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: January 27, 2022

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

Exhibit 99.1

Trevena Announces Submission of New Drug Application in China for OLINVYK® by its Partner Jiangsu Nhwa Pharmaceutical

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Submission supported by data from a Phase 3 bridging study of oliceridine injection compared to IV morphine, conducted in China by Nhwa

Trevena is eligible to receive future success payments upon approval and commercialization milestones, as well as a 10% royalty on net sales in China

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CHESTERBROOK, Pa., January 27, 2022 (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 China's National Medical Products Administration (NMPA) has accepted submission of a New Drug Application (NDA) for oliceridine injection. The NDA was submitted by Trevena's partner, Jiangsu Nhwa Pharmaceutical, and follows completion by Nhwa of a Phase 3 bridging trial for OLINVYK (oliceridine) injection, a novel IV analgesic that has been approved in the United States by the Food and Drug Administration (FDA) for use in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

"We are pleased to see the data presented in Nhwa's NDA submission are consistent with data from our registration studies in the US," said Carrie Bourdow, President and CEO of Trevena. "We are confident that Nhwa is the right strategic partner to advance OLINVYK in China and believe that this collaboration has the potential to create significant value for our stakeholders over the years ahead."

Trevena executed an exclusive License Agreement in 2018 with Nhwato develop, manufacture, and commercialize OLINVYK in China and is eligible to receive regulatory and commercial milestone payments as well a 10% royalty on net sales in China.

Nhwa's submission to the NMPA included data from two clinical bridging studies in Chinese patients, based on feedback from China's NMPA: a dose-escalation, open-label, single-dose study to evaluate the pharmacokinetics and safety profile; and a randomized, double-blind, positive-controlled Phase 3 bridging study in subjects with moderate to severe acute pain after abdominal surgery to evaluate the analgesic efficacy and safety of OLINVYK compared with IV morphine.

The results of the Phase 3 bridging study show that the safety and pharmacokinetic profile of oliceridine in Chinese patients is consistent with the data from global studies and demonstrates safety and tolerability in Chinese populations. The launch of OLINVYK in China, if approved by the NMPA, will help to address the significant unmet need in acute pain management.

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 diabetic neuropathic pain and epilepsy, and TRV027 for acute respiratory distress syndrome and abnormal blood clotting in COVID-19 patients.

For more information, please visit www.Trevena.com

About Jiangsu Nhwa Pharmaceuticals

Jiangsu Nhwa Pharmaceutical Co., Ltd., is a Chinese pharmaceutical company committed to setting new standards in CNS healthcare. Nhwa endeavors to provide innovative, high quality medicines to CNS patients with serious unmet medical needs. Nhwa offers a growing portfolio of more than 100 marketed products covering more than 6000 hospitals throughout China, including antipsychotics, anesthetics and analgesics, and neurological products. For more than 60 years, Nhwa has focused on CNS medicine, and every member of Nhwa's approximately 3,000-strong workforce is dedicated to improving patient health and outcomes.

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.

Important Safety Information
WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CENTRAL NERVOUS SYSTEM (CNS) DEPRESSANTS

ADDICTION, ABUSE, AND MISUSE – OLINVYK exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing OLINVYK, and monitor all patients regularly for the development of behaviors or conditions.

LIFE-THREATENING RESPIRATORY DEPRESSION – Serious, life-threatening, or fatal respiratory depression may occur with use of OLINVYK. Monitor for respiratory depression, especially during initiation of OLINVYK or following a dose increase.

NEONATAL OPIOID WITHDRAWAL SYNDROME – Prolonged use of OLINVYK during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

RISK FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS – Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

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 discussions with FDA; 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 approved product; 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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