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): **May 15, 2024**

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 2.02 Results of Operations and Financial Condition.

On May 15, 2024, Trevena, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024, and provided an overview of its 2024 year-to-date operational highlights. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

The information under this caption and contained in the press release attached hereto as Exhibit 99.1 is furnished by the Company in accordance with Securities Exchange Commission Release No. 33-8216. This information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date of this Current Report, except as shall be expressly set forth by specific reference in such a filing.

Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

As previously disclosed, on March 6, 2024, the Company received a letter from Nasdaq stating that, for the last 30 consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share required for continued inclusion on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement") and that the Company was not eligible for a second 180-day extension period because it did not comply with the $5,000,000 minimum stockholders' equity initial listing requirement for The Nasdaq Capital Market. As permitted under Nasdaq rules, the Company appealed Nasdaq's determination and requested a hearing before a Nasdaq Hearings Panel (the "Panel"). The hearing took place on May 2, 2024 (the "Appeal Hearing").

On April 5, 2024, the Company received an additional letter from Nasdaq notifying it that the Company no longer complied with the requirement under Nasdaq Listing Rule 5550(b)(1) to maintain a minimum of $2.5 million in stockholders' equity for continued listing on the Nasdaq Capital Market (the "Equity Standard Requirement"). At the Appeal Hearing, the Company presented its plan to regain and maintain compliance with both the Minimum Bid Price Requirement and the Equity Standard Requirement.

On May 13, 2024, the Company received a decision letter from the Panel granting it an extension until August 28, 2024, subject to certain conditions, to regain compliance with the Nasdaq continued listing requirements, including the Minimum Bid Price Requirement and Equity Standard Requirement. All delisting actions are stayed during the additional extension period granted by the Panel following the Appeal Hearing. While the Company is investigating a range of options available to it to regain compliance with the Minimum Bid Price Requirement and Equity Standard Requirement, there can be no assurance that it will be able to regain compliance with the Nasdaq continued listing requirements before dates required by Nasdaq or at all.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press Release dated May 15, 2024
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: May 15, 2024

By: /s/ Barry Shin
Barry Shin
Executive Vice President, Chief Operating Officer & Chief Financial Officer

Exhibit 99.1

Trevena Reports First Quarter 2024 Results and Provides Business Update

TRV045, novel S1P receptor modulator for chronic pain and epilepsy, continues to demonstrate a favorable tolerability profile

Ongoing clinical PK study with optimized formulation of TRV045 advances, with data expected 2H 2024

CHESTERBROOK, Pa., May 15, 2024 (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, 2024 and provided an overview of its recent operational highlights.

“TRV045 clinical development continued to progress in the first quarter, and we believe its novel MOA, once daily, oral dosing and favorable tolerability profile, has the potential to address the significant unmet need for non-opioid therapies in pain and for novel mechanisms in epilepsy” said Carrie Bourdow, President and CEO of Trevena.

First Quarter 2024 and Recent Corporate Highlights

- **TRV045 program.** TRV045 previously demonstrated positive results in two proof-of-concept studies, supporting further study in patients suffering from neuropathic pain and epilepsy. Across all three completed Phase 1 studies, TRV045 has demonstrated a favorable tolerability profile, and this has been consistent in the ongoing clinical PK study of the optimized formulation of TRV045. Data from this clinical PK study, as well as the ongoing reproductive and sub-chronic toxicology studies are expected in 2H 2024. The NIH-supported Epilepsy Therapy Screening Program (ETSP) continues to study TRV045 in other in vivo epilepsy models, including exploring TRV045 as a potential disease-modifying agent for the prevention of seizures, with data expected in mid-2024.

- **OLINVYK strategic review.** The Company continues its review of strategic alternatives for OLINVYK. There can be no assurance regarding the schedule for completion of the strategic review process, that this strategic review process will result in the Company pursuing any transaction or that any transaction, if pursued, will be completed. Potential strategic alternatives that may be explored or evaluated include, but are not limited to, a sale, license, divestiture or discontinuation of US commercial sales of OLINVYK.

- **Refocused resources.** Company continues in efforts to find efficiencies in operations, with recent cost reductions totaling $3.5-$4.0 million on an annualized basis, including cost savings from an approximately 35% reduction in force since year end 2023.

Financial Results and Other Updates for First Quarter 2024

For the first quarter of 2024, the Company reported a net loss attributable to common stockholders of $7.7 million, or $0.36 per share, compared to $7.8 million, or $0.81 per share in the first quarter of 2023. Cash and cash equivalents were $23.6 million as of March 31, 2024.

On May 13, 2024, the Company received a decision letter from the Nasdaq Hearings Panel granting the Company an extension until August 28, 2024, subject to certain conditions, to regain compliance with the Nasdaq continued listing requirements, including the minimum bid price and shareholders' equity requirements. All delisting actions are stayed during the additional extension period granted by the Panel following the Appeal Hearing. While the Company is investigating a range of options to regain compliance with the Nasdaq continued listing requirements, there can be no assurance that the Company will be able to regain compliance before the dates required by Nasdaq or at all.

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 three differentiated investigational drug candidates: TRV045 for diabetic neuropathic pain and epilepsy, TRV250 for the acute treatment of migraine and TRV734 for maintenance treatment of opioid use disorder.

For more information, please visit www.Trevena.com

About TRV045

TRV045 is a novel, highly selective sphingosine-1-phosphate subtype 1 ($S1P_1$) receptor modulator being developed as a potential treatment for acute and chronic neuropathic pain secondary to diabetic peripheral neuropathy. Through a collaboration with the National Institutes of Health, Trevena is also exploring TRV045 as a potential treatment for epilepsy.

S1P receptors are located throughout the body, including the central nervous system, where they are believed to play a role in modulating neurotransmission and membrane excitability.

Trevena's discovery efforts have identified a family of compounds that are highly selective for the $S1P_1$ receptor. TRV045 reversed thermal hyperalgesia, a measure of neuropathic pain, in nonclinical models of diabetic peripheral neuropathy and chemotherapy-induced peripheral neuropathy. TRV045 was not associated with lymphopenia and produced no changes in blood pressure, heart rate, or respiratory function at or above pharmacologically active doses in nonclinical studies. TRV045 is an investigational product and is not yet approved by the FDA. Subjects in both studies referenced in this press release were enrolled outside of the United States, and the studies were not conducted under the Investigational New Drug Application for TRV045.

About OLINVYK® (oliceridine) injection

OLINVYK is a new chemical entity approved by the FDA in August 2020. OLINVYK contains oliceridine, an opioid, which is 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: SERIOUS AND LIFE-THREATENING RISKS FROM USE

OF OLINVYK

Addiction, Abuse, and Misuse

Because the use of 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 prior to prescribing and reassess all patients regularly for the development of these behaviors and conditions.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of OLINVYK, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of OLINVYK are essential.

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of OLINVYK and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Neonatal Opioid Withdrawal Syndrome

If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

INDICATIONS AND USAGE

OLINVYK is an opioid agonist indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, reserve OLINVYK for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:

- Have not been tolerated or are not expected to be tolerated.
- Have not provided adequate analgesia or are not expected to provide adequate analgesia.

The cumulative total daily dose should not exceed 27 mg.

CONTRAINDICATIONS

OLINVYK is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Known hypersensitivity to oliceridine (e.g. anaphylaxis)

WARNINGS AND PRECAUTIONS

- OLINVYK contains oliceridine, a Schedule II controlled substance, that exposes users to the risks of addiction, abuse, and misuse. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed OLINVYK. Assess risk, counsel, and monitor all patients receiving opioids.
- Serious, life-threatening respiratory depression has been reported with the use of opioids, even when used as recommended, especially in patients with chronic pulmonary disease, or in elderly, cachectic and debilitated patients. The risk is greatest during initiation of OLINVYK therapy, following a dose increase, or when used with other drugs that depress respiration. Proper dosing of OLINVYK is essential, especially when converting patients from another opioid product to avoid overdose. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status.
- Opioids can cause sleep-related breathing disorders including central sleep apnea (CSA) and sleep-related hypoxemia with risk increasing in a dose-dependent fashion. In patients who present with CSA, consider decreasing the dose of opioid using best practices for opioid taper.
- Profound sedation, respiratory depression, coma, and death may result from the concomitant use of OLINVYK with benzodiazepines and/or other CNS depressants (e.g., non-benzodiazepine sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, other opioids, or alcohol). Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate, prescribe the lowest effective dose, and minimize the duration.
- Use of OLINVYK for an extended period of time during pregnancy can result in withdrawal in the neonate that may be life-threatening. Observe newborns for signs of neonatal opioid withdrawal syndrome and manage accordingly. Advise pregnant women using opioids for a prolonged period of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

- OLINVYK was shown to have mild QTc interval prolongation in thorough QT studies where patients were dosed up to 27 mg. Total cumulative daily doses exceeding 27 mg per day were not studied and may increase the risk for QTc interval prolongation. Therefore, the cumulative total daily dose of OLINVYK should not exceed 27 mg.
- Increased plasma concentrations of OLINVYK may occur in patients with decreased Cytochrome P450 (CYP) 2D6 function or normal metabolizers taking moderate or strong CYP2D6 inhibitors; also in patients taking a moderate or strong CYP3A4 inhibitor, in patients with decreased CYP2D6 function who are also receiving a moderate or strong CYP3A4 inhibitor, or with discontinuation of a CYP3A4 inducer. These patients may require less frequent dosing and should be closely monitored for respiratory depression and sedation at frequent intervals. Concomitant use of OLINVYK with CYP3A4 inducers or discontinuation of a moderate or strong CYP3A4 inhibitor can lower the expected concentration, which may decrease efficacy, and may require supplemental doses.
- Opioid-Induced Hyperalgesia (OIH) occurs when an opioid analgesic paradoxically causes an increase in pain, or an increase in sensitivity to pain. This differs from tolerance where increasing doses are required to maintain the desired effect. Symptoms of OIH include, but may not be limited to, increased levels of pain upon dose increase, decreased levels of pain upon dose decrease, or pain from ordinarily non-painful stimuli (allodynia). These symptoms may suggest OIH only if there is no evidence of disease progression, opioid tolerance, withdrawal, or addictive behavior. If OIH is suspected, carefully consider appropriately decreasing the dose of the current opioid analgesic or opioid rotation.
- Cases of adrenal insufficiency have been reported with opioid use (usually greater than one month). Presentation and symptoms may be nonspecific and include nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If confirmed, treat with physiologic replacement doses of corticosteroids and wean patient from the opioid.
- OLINVYK may cause severe hypotension, including orthostatic hypotension and syncope in ambulatory patients. There is increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics). Monitor these patients for signs of hypotension. In patients with circulatory shock, avoid the use of OLINVYK as it may cause vasodilation that can further reduce cardiac output and blood pressure.
- Avoid the use of OLINVYK in patients with impaired consciousness or coma. OLINVYK should be used with caution in patients who may be susceptible to the intracranial effects of CO_2 retention, such as those with evidence of increased intracranial pressure or brain tumors, as a reduction in respiratory drive and the resultant CO_2 retention can further increase intracranial pressure. Monitor such patients for signs of sedation and respiratory depression, particularly when initiating therapy.
- As with all opioids, OLINVYK may cause spasm of the sphincter of Oddi, and may cause increases in serum amylase. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms.

- OLINVYK may increase the frequency of seizures in patients with seizure disorders and may increase the risk of seizures in vulnerable patients. Monitor patients with a history of seizure disorders for worsened seizure control.
- Do not abruptly discontinue OLINVYK in a patient physically dependent on opioids. Gradually taper the dosage to avoid a withdrawal syndrome and return of pain. Avoid the use of mixed agonist/antagonist (e.g., pentazocine, nalbuphine, and butorphanol) or partial agonist (e.g., buprenorphine) analgesics in patients who are receiving OLINVYK, as they may reduce the analgesic effect and/or precipitate withdrawal symptoms.
- OLINVYK may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery.
- Although self-administration of opioids by patient-controlled analgesia (PCA) may allow each patient to individually titrate to an acceptable level of analgesia, PCA administration has resulted in adverse outcomes and episodes of respiratory depression. Health care providers and family members monitoring patients receiving PCA analgesia should be instructed in the need for appropriate monitoring for excessive sedation, respiratory depression, or other adverse effects of opioid medications.

ADVERSE REACTIONS

Adverse reactions are described in greater detail in the Prescribing Information.

The most common (incidence ≥10%) adverse reactions in Phase 3 controlled clinical trials were nausea, vomiting, dizziness, headache, constipation, pruritus, and hypoxia.

MEDICAL INFORMATION

For medical inquiries or to report an adverse event, other safety-related information or product complaints for a company product, please contact the Trevena Medical Information Contact Center at 1-844-465-4686 or email MedInfo@Trevena.com.

You are encouraged to report suspected adverse events of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

PLEASE see www.OLINVYK.com for full prescribing information including BOXED warning and important safety information

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 expectations surrounding the continued advancement of the Company's product pipeline; the potential safety and efficacy of the Company's product candidates and their regulatory and clinical development; the Company's intention to pursue strategic alternatives for OLINVYK and the ability of any such strategic alternative to provide shareholder value; the expected financial and operational impacts of the Company's decision to reduce commercial support for OLINVYK; 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 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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TREVENA, INC.
Condensed Statements of Operations
(Unaudited, in thousands except share and per share data)

	Three Months Ended Mar 31,	
	2024	**2023**
Product revenue	$ 20	$ 6
Total revenue	20	6
Operating expenses:		
Cost of goods sold	88	127
Selling, general and administrative	5,845	6,089
Research and development	3,965	3,909
Total operating expenses	9,898	10,125
Loss from operations	(9,878)	(10,119)
Other income (expense)	2,200	2,300
Net loss	(7,678)	(7,819)
Unrealized gain on marketable securities	-	1
Comprehensive loss	$ (7,678)	$ (7,818)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.36)	$ (0.81)
Weighted average shares outstanding, basic and diluted	21,303,390	9,594,072

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 23,552	$ 32,975
Prepaid expenses and other current assets	2,426	2,230
Total current assets	25,978	35,205
Restricted cash	540	540
Property and equipment, net	1,107	1,195
Right-of-use lease assets	3,512	3,665
Total assets	$ 31,137	$ 40,605
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable, net	$ 2,327	$ 2,303
Accrued expenses and other current liabilities	3,839	4,239
Current portion of lease liabilities	1,041	1,012
Total current liabilities	7,207	7,554
Loans payable, net	31,317	30,809
Leases, net of current portion	4,153	4,424
Warrant liability	3,114	5,475
Total liabilities	45,791	48,262
Common stock	18	17
Additional paid-in capital	581,067	580,387
Accumulated deficit	(595,739)	(588,061)
Total stockholders' (deficit) equity	(14,654)	(7,657)
Total liabilities and stockholders' (deficit) equity	$ 31,137	$ 40,605