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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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

Date of Report (Date of earliest event reported): **June 26, 2023**

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**TREVENA, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of incorporation)

**001-36193**  
(Commission  
File No.)

**26-1469215**  
(IRS Employer  
Identification No.)

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**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.)

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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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

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**Item 8.01 Other Events.**

On June 26, 2023, Trevena, Inc. (the “Company”) issued a press release announcing new topline OLINVYK data from the ARTEMIS study. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

The information set forth in this Item 8.01 and furnished hereto as Exhibit 99.1 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 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release dated June 26, 2023</a>
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

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**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: June 26, 2023

By: /s/ Barry Shin

Barry Shin

Senior Vice President & Chief Financial Officer

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**Trevena Announces New Topline OLINVYK Data Highlighting  
Reduced Cost per Admission from ARTEMIS Real-World Outcomes Study**

*OLINVYK-treated patients (n=201) had a statistically significant ~\$8,750 (19%) lower cost per admission and ~1.4 day (20%) reduced average length of hospital stay, compared to matched patients treated with other IV opioids (n=982)*

*New respiratory data from VOLITION ~200 patient real-world outcomes study using continuous respiratory monitoring expected 3Q 2023*

CHESTERBROOK, Pa., June 26, 2023 (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 new topline OLINVYK data from the ARTEMIS study.

The ARTEMIS study was an electronic medical records (EMR) based assessment focused on clinical and health resource utilization outcomes at Cleveland Clinic and Wake Forest Baptist Health. The study reviewed OLINVYK-treated patients in the ~200 patient VOLITION study with comparable surgical patients (matched patients) treated with other IV opioids, at the same institutions and during the study period.

New topline data includes data from OLINVYK-treated patients (n=105) and matched patients (n=525) at Cleveland Clinic, as well as measures of cost per admission at both Wake Forest Baptist Health and Cleveland Clinic for OLINVYK-treated and matched patients. Initial ARTEMIS data from Wake Forest Baptist Health was previously announced based on OLINVYK-treated patients (n=96) compared to matched patients (n=457) at that site.

“We are pleased that the use of OLINVYK versus other IV opioids demonstrated a statistically significant reduced cost per admission and a reduced average length of stay, which we believe are important considerations as hospitals look to manage resources,” said Carrie Bourdow, President and CEO of Trevena. “These data are consistent with prior health economic analyses we have conducted, and we believe these differences will be meaningful to key healthcare decision makers.”

*ARTEMIS (EMR-Based) Topline Results*

- **Overall Data from Cleveland Clinic and Wake Forest Baptist Health.** OLINVYK-treated patients (n=201) had a \$8,756 (19%) reduction in average cost per admission (p<0.0001) and 1.4-day (20%) reduction in average overall hospital length of stay (p<0.0001) compared to matched patients (n=982) treated with other IV opioids. Based on the data we have to date, there was not a statistically significant difference in the average duration of time in the post-anesthesia care unit (PACU) between OLINVYK-treated and matched patients.
  - **Cleveland Clinic Results.** OLINVYK-treated patients (n=105) had a \$7,102 reduction in average cost per admission (p=0.00043) and a 0.9-day reduction in average overall hospital length of stay (p=0.0181) compared to matched patients (n=525) treated with other IV opioids at Cleveland Clinic.
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**Wake Forest Baptist Health Results.** OLINVYK-treated patients (n=96) had a \$10,339 reduction in average cost per admission ( $p<0.0001$ ) compared to matched patients (n=457) treated with other IV opioids at Wake Forest Baptist Health. The Company previously announced that OLINVYK-treated patients at this site had a 1.6 day reduction in average overall hospital length of stay compared to matched patients treated with other IV opioids ( $p<0.0001$ ).

#### *ARTEMIS Study Details*

ARTEMIS is an electronic medical record (EMR) based analysis that compared the health outcomes of VOLITION study patients with a matched population of patients, who underwent similar surgical procedures but were treated with other IV opioids, at the same institutions and during the same general time period as VOLITION. Matching was conducted with a greedy matching algorithm, using a propensity scoring method with eight different demographic and clinical characteristics including age, sex, type and duration of surgery, measures of overall surgical and medical morbidity, and type of hospital insurance. Cost weights were calculated using a national dataset, and data was controlled for relevant covariates.

The Company previously announced initial topline ARTEMIS data from Wake Forest Baptist Health (n=96 OLINVYK-treated patients; n=457 matched patients treated with other IV opioids). New topline data is now available from Cleveland Clinic (n=105 OLINVYK-treated patients; n=525 matched patients treated with other IV opioids), as well as for cost per admission for both Wake Forest Baptist Health and Cleveland Clinic.

While an EMR analysis does not provide definitive data of group differences as seen in a prospectively randomized study, we believe EMR data bring a unique perspective to an understanding of how drugs may perform in the real world.

#### *VOLITION Study Details*

VOLITION is a real-world, open-label, multi-site, post-approval clinical outcomes study in 203 adult patients undergoing major non-cardiac surgery. IV OLINVYK was dosed as the first-line analgesic during post-operative care, with a 1.5mg loading dose of OLINVYK at surgical closure, and 0.35mg to 0.5mg of OLINVYK, as needed, administered with a PCA device, with a 6-minute lockout period. Additional boluses ( $\leq 1$  mg) of OLINVYK were available if needed as soon as 15 minutes after the initial 1.5 mg loading dose.

The average age of patients in VOLITION was 57.1 years (range 19 to 89), with approximately equal representation of men and women. Approximately 85% of patients underwent an abdominal surgical intervention, such as partial or total colectomy, enterotomy or other open abdominal procedures. A majority of patients had significant morbidity at the time of surgery as reflected by ASA status, and their respiratory risk was intermediate to high risk, graded using the PRODIGY risk score. The average duration of the surgery was 4.7 hours (range of 1.2 to 12.6 hours).

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## 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](http://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.

## 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.

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### Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, 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, as total daily doses greater than 27 mg may increase the risk for QTc interval prolongation.

### CONTRAINDICATIONS

OLINVYK is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the 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.
  - Prolonged use of opioids 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 OLINVYK for a prolonged period of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.
  - Profound sedation, respiratory depression, coma, and death may result from the concomitant use of OLINVYK with benzodiazepines 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.
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- 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.
  - 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<sub>2</sub> retention, such as those with evidence of increased intracranial pressure or brain tumors, as a reduction in respiratory drive and the resultant CO<sub>2</sub> 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.
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## ADVERSE REACTIONS

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

The most common (incidence  $\geq 10\%$ ) 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](mailto:MedInfo@Trevena.com).

You are encouraged to report suspected adverse events of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call **1-800-FDA-1088**.

**Please see Full Prescribing Information, including Boxed Warning.**

## 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<sup>®</sup> (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](http://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 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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**For more information, please contact:**

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