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): **August 11, 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 2.02 Results of Operations and Financial Condition

On August 11, 2022, Trevena, Inc. (the "Company") issued a press release announcing its financial results and other business updates for the quarter ended June 30, 2022. 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press Release dated August 11, 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: August 11, 2022

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

Exhibit 99.1

Trevena Reports Second Quarter 2022 Results and Provides Business Update

OLINVYK post-approval strategy advances with positive topline cognitive function data and continued enrollment in VOLITION clinical outcomes study

Phase 1 study for TRV045, a novel S1P receptor modulator, on track for year-end data readout; single ascending dose and food effect study segments fully enrolled

TRV045 demonstrated potential antiepileptic effect in multiple preclinical models

Cash balance of $49.5 million at Q2 provides cash runway to mid-2023 with previously announced strategic allocation of resources and cost reductions

Company to host conference call today, August 11, 2022 at 8:00 a.m. ET

CHESTERBROOK, Pa., August 11, 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 reported its financial results for the second quarter ended June 30, 2022 and provided an overview of its recent operational highlights.

"We recognize the macro headwinds our hospital customers are facing and have made disciplined choices around our business to efficiently commercialize OLINVYK with our refocused sales and medical affairs team. The recently signed Vizient contract will also help us reach important hospital decision-makers and further supports OLINVYK's potential clinical and health economic benefits," said Carrie Bourdow, President and CEO of Trevena. "We're also responding to our customers during this time by continuing to provide new OLINVYK data versus IV morphine in important areas such as respiratory and cognitive function adverse events where there is a need to improve acute pain patients' outcomes. Lastly, I'm pleased that we've advanced our novel S1P receptor modulator, TRV045, towards Phase 1 completion and I'm excited about the potential opportunity in both diabetic neuropathic pain and epilepsy."

Second Quarter 2022 and Recent Corporate Highlights

OLINVYK (oliceridine) injection Milestones

- **Continued progress on launch execution.** We continue to see hospital utilization of OLINVYK and the addition of new accounts in the second quarter. In July, Trevena entered into a multi-year agreement with Vizient, Inc., a leading hospital performance improvement company, which will allow for broad OLINVYK access for enhanced savings for member hospitals. Vizient serves more than half of U.S. hospitals in its customer network that includes 97% of the U.S. academic medical centers, 50% of acute care hospitals and 20% of the ambulatory surgical centers. Trevena will work with Vizient to educate its members on the clinical and health economic benefits of OLINVYK as an alternative to IV morphine.

- **Announced results from cognitive function study that demonstrated statistically significant reduced impact on neurocognitive functioning vs IV morphine on primary endpoint.** OLINVYK was studied in a randomized, double-blind placebo-controlled dose-ranging design, in collaboration with the Netherlands-based Center for Human Drug Research. Subjects received single intravenous doses of OLINVYK 1 mg and 3 mg, or morphine 5 mg and 10 mg, or placebo, using a partial-block crossover design. On the primary endpoint, OLINVYK showed a statistically significant reduction in sedation versus IV morphine, measured by saccadic eye movement peak velocity, a sensitive laboratory measure of sedating action of medications. On several of the prespecified secondary outcome measures, OLINVYK showed a statistically significant difference or trend compared to IV morphine, despite the relatively small sample size, across a range of neurocognitive measures and motor performance. The Company expects to submit these results at scientific meetings in the coming months.

  "I believe these data are a very important addition to the scientific evidence on OLINVYK and should be of great interest to practicing clinicians", said Ashish Khanna, MD, Associate Professor of Anesthesiology and Vice Chair of Research, at Atrium Health Wake Forest Baptist Medical Center; "Any reduction in neurocognitive impairment has potentially significant implications for postoperative recovery, where getting the patient out of bed and moving as soon as possible is a critical component of modern multimodal approaches to post-surgical care. If these study outcomes translate into clinical practice, they may potentially result in meaningful reductions in length of stay, improved ambulation, and avoidance of falls."

- **VOLITION Clinical Outcomes Study on track to conclude enrollment later this year.** The Company expects enrollment in the VOLITION study to conclude later this year. The VOLITION study is being led by clinical outcomes research experts from the Cleveland Clinic and the Wake Forest Baptist Health Medical Center. The study is assessing the potential impact of OLINVYK on respiratory, gastrointestinal (GI) and cognitive function outcomes in the postoperative setting.

Pipeline Updates

- **Phase 1 study of TRV045, in development for diabetic neuropathic pain, remains on track for completion in 2H 2022.** Phase 1 study has continued to progress with full enrollment in the single ascending dose and food effect segments of the study. The Company expects to complete the remaining multiple ascending dose portion later this year.

- **NIH epilepsy program studying TRV045 advances with positive preclinical data.** Data showed evidence of acute prevention of seizures and evidence of efficacy in two different complex models of refractory epilepsy. The Company plans to prepare the data to move forward into clinical development for a potential epilepsy indication.

Financial Results for Second Quarter 2022

For the second quarter of 2022, the Company reported a net loss attributable to common stockholders of $15.0 million, or $0.09 per share, compared to $14.0 million, or $0.09 per share, for the second quarter of 2021.

Cash and cash equivalents were $49.5 million as of June 30, 2022, which the Company believes will be sufficient to fund the Company's operating expenses and capital expenditure requirements to mid-2023. The cash balance does not include net proceeds from the Company's July 2022 registered direct offering of preferred shares.

Conference Call and Webcast Information

The Company will host a conference call and webcast with the investment community on August 11, 2022, at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and Chief Executive Officer, Patricia Drake, Chief Commercial Officer, Mark Demitrack, M.D., Senior Vice President and Chief Medical Officer, and Barry Shin, Chief Financial Officer.

Title:	Trevena Second Quarter 2022 Financial Results Conference Call & Webcast
Date:	Thursday, August 11, 2022
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: 1-877-704-4453 International: 1-201-389-0920 Conference ID: 13730949

The conference call will be webcast live from the Company's website and will be available via the following links:

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1557037&tp_key=b050aa54b6

The webcast should be accessed 15 minutes prior to the conference call start time. A replay of the webcast will be available following the conclusion of the live broadcast and will be accessible on the Company's website.

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: 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.

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.
- 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_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 Full Prescribing Information, including Boxed Warning.

About TRV045

TRV045 is a novel, 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.

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

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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Trevena, Inc.

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

	Three Months Ended Jun 30,		Six Months Ended Jun 30,	
	2022	2021	2022	2021
Product revenue	$ -	$ 178	$ -	$ 387
License revenue	-	-	20	-
Total revenue	-	178	20	387
Operating expenses:				
Cost of goods sold	216	258	423	421
Selling, general and administrative	10,306	10,545	21,320	17,913
Research and development	4,291	3,449	9,550	6,085
Total operating expenses	14,813	14,252	31,293	24,419
Loss from operations	(14,813)	(14,074)	(31,273)	(24,032)
Other income	(168)	52	(97)	168
Net loss	$ (14,981)	$ (14,022)	$ (31,370)	$ (23,864)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.09)	$ (0.09)	$ (0.19)	$ (0.15)
Weighted average shares outstanding, basic and diluted	165,527,087	163,370,485	165,523,567	161,936,680

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 19,589	$ 66,923
Marketable securities	29,934	-
Inventories	2,990	2,352
Prepaid expenses and other current assets	3,270	1,448
Total current assets	55,783	70,723
Restricted cash	2,911	1,311
Property and equipment, net	1,631	1,841
Right-of-use lease assets	4,474	4,706
Other assets	3	1,543
Total assets	$ 64,802	$ 80,124
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	$ 2,719	$ 4,547
Accrued expenses and other current liabilities	5,951	3,847
Current portion of lease liabilities	839	792
Total current liabilities	9,509	9,186
Loans payable, net	13,472	-
Leases, net of current portion	5,879	6,309
Total liabilities	28,860	15,495
Common stock	165	165
Additional paid-in capital	561,332	558,566
Subscription receivable	(23)	-
Accumulated deficit	(525,472)	(494,102)
Accumulated other comprehensive income (loss)	(60)	-
Total stockholders' equity	35,942	64,629
Total liabilities and stockholders' equity	$ 64,802	$ 80,124