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): **November 15, 2021**

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 7.01 Regulation FD Disclosure

On November 15, 2021, Trevena, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. 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 November 15, 2021
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: November 15, 2021

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

Exhibit 99.1

Trevena Reports Third Quarter 2021 Results

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Advanced OLINVYK commercial launch with expanded field medical team and additional target markets

Announced new OLINVYK cognitive function study vs. IV morphine, enrollment expected to start in Q1 2022

Initiated enrollment for Cleveland Clinic-led OLINVYK outcomes study, topline data expected in mid-2022

Progressed TRV027 with NIH / ACTIV-4 trial for COVID-19 on track for topline data in mid-2022

$78.6M cash at Q3 funds operations through YE 2022

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Company to host conference call today, November 15th, 2021, at 8:00 a.m. ET

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CHESTERBROOK, PA, November 15, 2021 (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 third quarter ended September 30, 2021 and provided an overview of its recent operational highlights.

"As we advance the OLINVYK commercial launch, we have continued to hear positive feedback on its performance in the post-operative setting. This feedback has helped us refine our launch strategy and post-approval plan, which we believe will help position us for success as hospitals begin to reopen and in-person engagement resumes," said Carrie Bourdow, President and CEO of Trevena. "We have also continued to make progress on our pipeline, with the recent announcement of positive TRV027 proof-of-concept data, and other exciting developments."

Third Quarter 2021 and Recent Corporate Highlights:

- **Strengthened senior leadership team with appointment of new Chief Commercial Officer.** In November, the Company announced the appointment of Patricia Drake to Chief Commercial Officer. Ms. Drake brings more than 30 years of experience holding U.S. and global commercial roles in marketing, sales, and strategy, and she has successfully launched multiple products in the hospital market. In conjunction, Bob Yoder will take on the role of Chief Business Officer and Head of Commercial Operations.

OLINVYK (oliceridine) injection Milestones

- **Implemented new launch initiatives to address ongoing pandemic challenges.** The Company today announced it has completed its field medical team expansion to 10 Medical Science Liaisons (MSLs). Based on feedback from the field, the MSLs play an important role in accessing key decision-makers in target institutions. The Company expects that this additional headcount will enable the full MSL team to target ~500 physicians at top academic medical centers and other large institutions.

  As part of an expansion of its customer targeting strategy, the Company today announced that it has added burn centers to its list of priority targets. Every year in the U.S., there are ~30,000 burn-related hospitalizations with an average length of stay of 8-9 days. IV opioids are an essential component of pain management in this setting, and there remains a need for analgesic options that provide rapid, long-lasting acute pain relief.

- **Announced new cognitive function study.** The Company today announced a new post-approval study designed to assess the impact of OLINVYK on cognitive function compared to IV morphine. Cognitive function will be assessed using NeuroCart, a well validated CNS test battery that is widely used to test a broad range of CNS drugs and includes a comprehensive array of objective and subjective measures. The study will also include pain model testing using the cold pressor test and PK assessment. Study enrollment is expected to begin in Q1 2022 with topline data by mid-2022.

- **Advanced two ongoing post-approval studies, with enrollment in progress.** The respiratory physiology study, led by Leiden University Medical Center, is evaluating the role of age and weight in a comparative analysis of the effect of OLINVYK and morphine on respiratory function. Study completion is expected by year-end, with topline data shortly thereafter.

  The VOLITION study, led by clinical outcomes research experts from the Cleveland Clinic, is assessing the impact of OLINVYK on respiratory, gastrointestinal (GI), and cognitive function outcomes in the postoperative setting. In August, the Company announced that Wake Forest Baptist Health Medical Center was joining the study. The study is expected to enroll ~200 adults undergoing major surgery, with topline data expected in mid-2022.

- **Presented two posters at ANESTHESIOLOGY® 2021 highlighting safety and tolerability data in two complex patient populations.** Both presentations reported the incidence of opioid-related adverse events (ORAEs) in obese patients (BMI > 30 kg/m^2) and in patients with stage 3 or higher chronic kidney disease (CKD) from the OLINVYK Phase 3 real world open-label safety study. Obese patients were not at an increased risk for developing ORAEs, despite having a higher incidence of medical comorbidities compared to non-obese patients. Patients with stage 3 or higher CKD were not at an increased risk for developing ORAEs, compared to patients with stage 1-2 CKD.

Pipeline Milestones

- **Announced positive TRV027 proof-of-concept data in COVID-19 patients.** In September, the Company provided the results from an analysis of 30 patients, which provided initial evidence of TRV027's potential to improve biomarker / clinical endpoints associated with COVID-19 disease severity and progression. TRV027 was associated with a 92% probability of a beneficial treatment effect on D-dimer levels, a coagulation biomarker associated with critical illness and mortality. Additionally, patients treated with TRV027 experienced a 12-day reduction in average length of hospital stay compared to treatment with placebo. The study was led and funded by Imperial College London.

TRV027 is currently being evaluated in two global, multi-site, multi-arm COVID-19 platform trials: ACTIV-4 Host Tissue led by Vanderbilt University Medical Center / NIH in the U.S. and REMAP-CAP in the U.K. Combined, both studies are expected to generate TRV027 efficacy and safety data in ~600 patients. Topline data from the ACTIV-4 trial is expected in mid-2022.

- **Filed IND for TRV045.** In November, the Company received a clinical hold letter from FDA regarding certain Phase 1 study design elements. Responding to the FDA's comments, the Company has refiled the IND and is prepared to initiate the Phase 1 program once the Agency provides final feedback.

Financial Results for Third Quarter 2021

For the third quarter of 2021, the Company reported a net loss attributable to common stockholders of $13.9 million, or $0.08 per share, compared to $5.6 million, or $0.04 per share, for the third quarter of 2020. This increase is primarily related to increases in commercialization activities for OLINVYK.

Cash and cash equivalents were $78.6 million as of September 30, 2021, which the Company believes will be sufficient to fund the Company's operating expenses and capital expenditure requirements through the fourth quarter of 2022.

Conference Call and Webcast Information

The Company will host a conference call and webcast with the investment community on November 15, 2021, at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and CEO; Bob Yoder, Senior Vice President, Chief Business Officer & Head of Commercial Operations; Patricia Drake, Senior Vice President and Chief Commercial Officer; Mark Demitrack, M.D., Senior Vice President and Chief Medical Officer; Barry Shin, Senior Vice President and Chief Financial Officer; and Paul F. Rider, M.D. FACS, FASCRS, Professor of Surgery, Division Chief, Colon & Rectal Surgery, University of South Alabama College of Medicine.

Title:	Trevena Third Quarter 2021 Financial Results Conference Call and Webcast
Date:	Monday, November 15, 2021
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: (855) 465-0180 International: (484) 756-4313 Conference ID: 2279839
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. 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.

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.

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.

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

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

	Three Months Ended Sept 30,		Nine Months Ended Sept 30,	
	2021	2020	2021	2020
Product revenue	$ 112	$ -	$ 499	$ -
License revenue	69	3,000	69	3,000
Total revenue	181	3,000	568	3,000
Operating expenses:				
Cost of goods sold	199	-	620	-
Selling, general and administrative	10,438	4,089	28,351	11,021
Research and development	3,404	4,301	9,489	9,450
Total operating expenses	14,041	8,390	38,460	20,471
Loss from operations	(13,860)	(5,390)	(37,892)	(17,471)
Other income	89	139	257	273
Loss before income tax expense	(13,771)	(5,251)	(37,635)	(17,198)
Foreign income tax expense	-	(300)	-	(300)
Net loss	$ (13,771)	$ (5,551)	$ (37,635)	$ (17,498)
Per share information:				
Net loss per share of common stock, basic and diluted	($0.08)	($0.04)	($0.23)	($0.15)
Weighted average shares outstanding, basic and diluted	164,510,570	144,335,143	162,811,136	117,420,221

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

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 78,646	$ 109,403
Accounts receivable, net	103	71
Inventories	1,310	-
Insurance recovery	-	9,000
Prepaid expenses and other current assets	2,345	570
Total current assets	82,404	119,044
Restricted cash	1,311	1,310
Property and equipment, net	1,947	2,253
Right-of-use lease assets	4,815	5,119
Other assets	1,171	13
Total assets	$ 91,648	$ 127,739
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	$ 2,969	$ 1,693
Accrued expenses and other current liabilities	3,678	5,168
Estimated settlement liability	-	9,000
Current portion of lease liabilities	770	703
Total current liabilities	7,417	16,564
Leases, net of current portion	6,516	7,101
Warrant liability	-	6
Total liabilities	13,933	23,671
Common stock	165	160
Additional paid-in capital	557,707	546,422
Subscription receivable	(8)	-
Accumulated deficit	(480,149)	(442,514)
Total stockholders' equity	77,715	104,068
Total liabilities and stockholders' equity	$ 91,648	$ 127,739