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 9, 2021**

TREVENA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36193**	**26-1469215**
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

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

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

n/a
(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.**

The information under this caption and contained in the press release attached hereto as Exhibit 99.1 is furnished by Trevena, Inc. (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.

On August 12, 2021, the Company issued a press release announcing its financial results for the quarter ended June 30, 2021. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

Item 5.02 **Departure of Directors or Certain Officers; Election of Directors, Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

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(b) On August 9, 2021, Scott Applebaum, Chief Legal and Compliance Officer, Senior Vice President of Regulatory Affairs, and Corporate Secretary of Trevena, Inc. formally notified the Company of his resignation, effective as of August 31, 2021. Mr. Applebaum's resignation was not the result of any disagreement with the Company.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.	Description

99.1	Press Release dated August 12, 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: August 12, 2021

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

Exhibit 99.1

Trevena Reports Second Quarter 2021 Results

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Company reaffirms YE goal of 100 formulary wins

OLINVYK respiratory physiology study currently enrolling, topline data expected by YE 2021

NIH / Vanderbilt University Medical Center-led trial evaluating TRV027 currently enrolling COVID-19 patients

Cleveland Clinic outcomes study investigating potential benefit of OLINVYK on respiratory, GI, and cognitive function on track to enroll patients in Q3

TRV045 IND filing for diabetic neuropathic pain on track for Q3

$91M cash at Q2 funds operations through YE 2022

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Company to host conference call today, August 12th, 2021, at 8:00 a.m. ET

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CHESTERBROOK, PA, August 12, 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 second quarter ended June 30, 2021 and provided an overview of its recent operational highlights.

"With only five months in the field, our sales team has continued to make progress with hospital formularies on the OLINVYK launch, and we've begun to roll out our post-approval clinical study plan to further differentiate its unique clinical profile," said Carrie Bourdow, President and CEO of Trevena. "Additionally, we achieved meaningful milestones in our pipeline, with trials underway for TRV027 and TRV734 in collaboration with world-class research partners."

Second Quarter 2021 and Recent Corporate Highlights:

OLINVYK (oliceridine) injection Milestones

- **Continued focus on launch execution.** 123 accounts are in various stages of OLINVYK review and 35 accounts have added OLINVYK to formulary. With the first full quarter of the launch complete, the Company reaffirms its year-end goal of 100 formulary approvals.

- **Start-up activities for clinical outcomes study with Cleveland Clinic in progress.** In May, the Company announced a new study assessing the impact of OLINVYK on respiratory, gastrointestinal (GI), and cognitive function outcomes in the postoperative setting. The study is being led by clinical outcomes research experts from Cleveland Clinic. Patient enrollment is on track to begin this quarter. The Company expects to report topline data in mid-2022.

- **Initiated respiratory physiology study in elderly / obese subjects.** In July, the Company announced a new study evaluating the role of age and weight in a comparative analysis of the effect of OLINVYK and morphine on respiratory function. The study is being led by a world-renowned research group that specializes in the effects of opioid medications on human respiratory physiology. Patient enrollment is ongoing and on track to support topline data by year-end 2021.

- **Supported clinical development progress made by ex-U.S. partner.** In July, the Company announced that Jiangsu Nhwa Pharmaceutical, the Company's partner in China, had enrolled the first patient in their Phase 3 trial for OLINVYK. Nhwa is conducting and funding this trial to support an NDA regulatory filing in China. The Company expects to receive approval and commercialization milestones, and a 10% royalty on net sales in China.

Pipeline and Corporate Milestones

- **Advanced TRV027 in nationwide NIH / VUMC-led COVID-19 trial evaluating TRV027.** In July, the Company announced that the first COVID-19 patient had been enrolled in the NIH-funded ACTIV-4 Host Tissue trial led by Vanderbilt University Medical Center (VUMC). TRV027, the Company's novel AT_1 receptor selective agonist, will be dosed in ~300 patients. The study is evaluating the impact of four investigational agents on recovery, supplemental oxygen use, need for mechanical ventilation, organ failure, and mortality.

- **On track to file IND for TRV045 in Q3 2021.** The Company is pursuing a lead indication of diabetic neuropathic pain (DNP). DNP is a significant market opportunity, with over 5 million people affected by this painful condition and few therapeutic options that provide adequate analgesia. TRV045, the Company's novel $S1P_1$ receptor modulator, may offer a unique, non-opioid based approach to the treatment of DNP and other CNS indications.

- **Announced resumption of NIH-led study for TRV734 in opioid use disorder patients.** In June, the Company announced that the National Institute on Drug Abuse (NIDA) had resumed recruiting patients for its proof-of-concept study for TRV734, the Company's novel mu-opioid receptor selective agonist. NIDA is conducting and funding this study to evaluate TRV734 as a potential maintenance therapy for opioid use disorder (OUD).

- **Added to Russell 2000®, Russell 3000®, and Russell Microcap® indexes.** In June, the Company announced it had been added to the small-cap Russell 2000® Index, the broad-market Russell 3000® Index, and the Russell Microcap® Index, effective as of June 28th, 2021. Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies.

Financial Results for Second Quarter 2021

For the second quarter of 2021, the Company reported a net loss attributable to common stockholders of $14.0 million, or $0.09 per share, compared to $6.2 million, or $0.06 per share, for the second quarter of 2020. This increase is primarily related to increases in commercialization activities for OLINVYK.

Cash and cash equivalents were $91.0 million as of June 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 August 12, 2021, at 8:00 a.m. Eastern Time featuring remarks by Carrie Bourdow, President and Chief Executive Officer, Bob Yoder, Senior Vice President and Chief Commercial Officer, Mark Demitrack, M.D., Senior Vice President and Chief Medical Officer, and Barry Shin, Senior Vice President and Chief Financial Officer.

Title:	Trevena Second Quarter 2021 Financial Results Conference Call and Webcast
Date:	Thursday, August 12, 2021
Time:	8:00 a.m. ET
Conference Call Details:	Toll-Free: (855) 465-0180 International: (484) 756-4313 Conference ID: 6799504
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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(Unaudited, in thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Product revenue	$ 178	$ -	$ 387	$ -
Total revenue	178	-	387	-
Operating expenses:				
Cost of goods sold	258	-	421	-
Selling, general and administrative	10,545	3,300	17,913	6,932
Research and development	3,449	2,958	6,085	5,149
Total operating expenses	14,252	6,258	24,419	12,081
Loss from operations	(14,074)	(6,258)	(24,032)	(12,081)
Other income	52	36	168	134
Net loss	$ (14,022)	$ (6,222)	$ (23,864)	$ (11,947)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.09)	$ (0.06)	$ (0.15)	$ (0.12)
Weighted average shares outstanding, basic and diluted	163,370,485	111,297,428	161,936,680	103,814,876

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 90,952	$ 109,403
Accounts receivable, net	137	71
Inventories	1,045	-
Insurance recovery	9,000	9,000
Prepaid expenses and other current assets	1,998	570
Total current assets	103,132	119,044
Restricted cash	1,310	1,310
Property and equipment, net	2,039	2,253
Right-of-use lease assets	4,921	5,119
Other assets	799	13
Total assets	$ 112,201	$ 127,739
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable, net	$ 2,374	$ 1,693
Accrued expenses and other current liabilities	2,852	5,168
Estimated settlement liability	9,000	9,000
Current portion of lease liabilities	748	703
Total current liabilities	14,974	16,564
Leases, net of current portion	6,718	7,101
Warrant liability	1	6
Total liabilities	21,693	23,671
Common stock	165	160
Additional paid-in capital	556,721	546,422
Accumulated deficit	(466,378)	(442,514)
Total stockholders' equity	90,508	104,068
Total liabilities and stockholders' equity	$ 112,201	$ 127,739