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 2, 2018**

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 200
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))

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 2, 2018, the Company issued a press release announcing its financial results for the quarter ended June 30, 2018. A copy of the press release is furnished hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Description
99.1	Press Release dated August 2, 2018

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated August 2, 2018

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 2, 2018

By: /s/ John Hamill
John Hamill
Interim Principal Financial Officer and Accounting Officer

Exhibit 99.1

Trevena Reports Second Quarter 2018 Financial Results

– Oliceridine NDA remains on track for a November 2, 2018 FDA decision –

– First license agreements for ex-US development and commercialization of oliceridine add potential revenue streams –

– Early pipeline continues to advance –

CHESTERBROOK, PA, August 2, 2018 – Trevena, Inc. (NASDAQ: TRVN) today announced financial results for the quarter ended June 30, 2018 and provided an update on its pipeline of differentiated new chemical entities, including its lead asset, oliceridine, currently under review by the U.S. Food and Drug Administration (FDA) for potential approval this year.

"The second quarter saw important progress towards Trevena's long-term success," said Maxine Gowen, Ph.D., President and Chief Executive Officer. "We remain confident that the oliceridine NDA remains on track for an FDA decision by the November 2, 2018 PDUFA date, and we look forward to discussing the oliceridine data at an Advisory Committee meeting, likely in October. In addition, the second quarter saw us secure two important ex-US licensing transactions for oliceridine, strengthen our leadership team with important medical and commercial hires, and continue a smooth transition to Carrie Bourdow's assumption of the CEO role."

Second quarter and recent corporate highlights

- **Prescription Drug User Fee Act (PDUFA) date for oliceridine: November 2, 2018.** Oliceridine is an investigational product under FDA review for the management of moderate to severe acute pain where parenteral opioid analgesia is warranted and was designed to provide the pain relief of IV opioids with fewer associated adverse effects. The FDA has informed the Company that it intends to convene an advisory committee meeting, likely in October, to discuss the oliceridine NDA. If oliceridine is approved by the FDA, and following DEA scheduling, the Company expects the commercial launch of oliceridine in the first half of 2019.

- **Licensed oliceridine for development and commercialization in South Korea and China**. In April, the Company and privately held Pharmbio Korea Inc. announced that they have entered into an exclusive license agreement for the development and commercialization of oliceridine in South Korea. In May, the Company and Jiangsu Nhwa Pharmaceutical Co. Ltd. (Nhwa) announced that they have entered an exclusive license agreement for the development and commercialization of oliceridine in China. Under these agreements, Trevena has received a total of $5.5 million in upfront payments, and it is eligible for further regulatory and commercial milestones and royalties. Nhwa has since exercised its option to exclusive rights to manufacture oliceridine for potential distribution in China. The Company continues to pursue its strategy to outlicense oliceridine in additional territories.

- **Successful completion of Phase 1 study of TRV250 for acute migraine.** In June, the Company announced the successful completion of its first-time-in-human Phase 1 study of TRV250, a biased delta receptor agonist that the Company is developing for the treatment of acute migraine. Preclinical data suggested that the novel selective signaling mechanism of TRV250 might avoid the seizure liability that has limited development of therapeutics targeting the delta receptor. Data from this healthy volunteer study showed safety, tolerability, and pharmacokinetics supporting the advancement of TRV250 to Phase 2 proof of concept evaluation in patients.

- **National Institute on Drug Abuse studying TRV734 as a potentially differentiated therapy for maintenance treatment of opioid dependence.** The Company is supporting NIDA-funded efforts to evaluate the biased mu opioid receptor ligand TRV734, an orally available analog of oliceridine, as a potential maintenance treatment for opioid dependence. Nonclinical studies performed by NIDA scientists and presented at the recent College of Problems in Drug Dependence conference suggest that biased mu opioid receptor ligands may offer an alternative to current opioid maintenance therapies. The Company has completed two Phase 1 trials of TRV734 in healthy volunteers; in these studies, TRV734 showed CNS activity, pharmacokinetics, and safety and tolerability supporting potential Phase 2 trials.

- **Continued advancement of preclinical non-narcotic analgesic program.** The Company continues to evaluate a set of novel S1P modulators that may offer a new non-narcotic approach to managing chronic pain. The Company expects to complete characterization of the lead compounds in 2018 to determine if any merit IND-enabling studies to support Phase 1 clinical trials.

- **Carrie Bourdow selected as next CEO**. In April, the Company announced that Dr. Gowen will retire on October 1, 2018 and will continue to serve on the Trevena Board of Directors. The Board of Directors has selected Carrie L. Bourdow, who currently serves as Trevena's Executive Vice President and Chief Operating Officer, to be the Company's next President and Chief Executive Officer, effective October 1, 2018.

- **Strengthened leadership team.** In May, the Company announced the appointment of Mark A. Demitrack, M.D., as Senior Vice President and Chief Medical Officer. Dr. Demitrack brings over 20 years of industry experience at large and small biopharmaceutical companies where he has led numerous CNS programs pre- and post-approval. In June, the Company announced the addition of several senior hires for the commercial and medical affairs leadership teams.

Financial results

For the second quarter of 2018, Trevena reported a net loss attributable to common stockholders of $9.3 million, or $0.13 per share, compared with a net loss attributable to common stockholders for the second quarter of 2017 of $20.4 million, or $0.35 per share. Research and development expenses were $5.1 million in the second quarter of 2018 compared to $15.5 million for the same period in 2017;

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general and administrative expenses were $5.9 million, compared to $4.4 million for the second quarter of 2017. Cash, cash equivalents, and marketable securities were $63.5 million as of June 30, 2018. The Company expects this amount, together with interest thereon and proceeds from oliceridine ex-U.S. licensing activities, to be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from today's date.

For additional details, please see the Company's Form 10-Q, which will be filed with the SEC today.

About Trevena

Trevena, Inc. is a biopharmaceutical company focused on providing better, safer therapies to patients in pain. The Company has leveraged breakthrough science to discover and develop its investigational product, oliceridine injection, for the management of moderate-to-severe acute pain. Oliceridine has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration and is intended to provide healthcare providers an innovative new option for patients who require an intravenous opioid. The Company also has an early stage pipeline of new chemical entities targeting novel mechanisms of action, including TRV250 for acute migraine, neuropathic pain, and other indications.

Cautionary note on 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 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, including whether the data from the Phase 1 study of TRV250 supports the advancement of the compound to Phase 2 proof of concept evaluation in patients, whether the nonclinical studies performed by NIDA suggest that TRV734 may offer an alternative to current opioid maintenance therapies, whether the Company's novel set of S1P modulators may offer a new, non-narcotic approach to managing chronic pain, and whether the Company will complete characterization of the S1P lead compounds in 2018; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including whether the oliceridine NDA remains on track for an FDA decision by the November 2, 2018 PDUFA date; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements, including whether the Company's cash, cash equivalents, and marketable securities, together with interest thereon and proceeds from oliceridine ex-U.S. licensing activities, will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from today's date; uncertainties related to

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the Company's intellectual property; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates, including whether the commercial launch of oliceridine will occur in the first half of 2019; 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.

Contacts

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	$ 2,500	$ -	$ 2,500	$ -
Operating expenses:				
General and administrative	5,926	4,385	10,998	9,264
Research and development	5,128	15,499	9,726	31,595
Restructuring charges	41	-	64	-
Total operating expenses	11,095	19,884	20,788	40,859
Loss from operations	(8,595)	(19,884)	(18,288)	(40,859)
Other income (expense)	36	(548)	708	(287)
Loss before income tax expense	(8,559)	(20,432)	(17,580)	(41,146)
Foreign income tax expense	(745)	-	(745)	0
Net loss	$ (9,304)	$ (20,432)	$ (18,325)	$ (41,146)
Per share information:				
Net loss per share of common stock, basic and diluted	($0.13)	($0.35)	($0.27)	($0.71)
Weighted average shares outstanding, basic and diluted	69,664,994	58,381,868	67,127,711	57,642,379

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

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 24,036	$ 16,557
Marketable securities	39,462	49,543
Alliance revenue receivable	2,250	-
Prepaid expenses and other current assets	1,543	1,393
Total current assets	67,291	67,493
Restricted cash	1,414	1,413
Property and equipment, net	3,613	3,805
Intangible asset, net	10	11
Total assets	$ 72,328	$ 72,722
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 592	$ 1,424
Accrued expenses and other current liabilities	3,651	4,303
Current portion of loans payable, net	12,494	12,425
Deferred revenue	3,000	-
Deferred rent	65	61
Total current liabilities	19,802	18,213
Loans payable, net	10,873	15,725
Capital leases, net of current portion	25	31
Deferred rent, net of current portion	2,926	3,006
Warrant liability	6	10
Other long term liabilities	-	1,104
Total liabilities	33,632	38,089
Common stock	74	62
Additional paid-in capital	414,457	392,103
Accumulated deficit	(375,815)	(357,490)
Accumulated other comprehensive loss	(20)	(42)
Total stockholders' equity	38,696	34,633
Total liabilities and stockholders' equity	$ 72,328	$ 72,722
