

**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): July 13, 2020

Trevi Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38886
(Commission
File Number)

45-0834299
(IRS Employer
Identification No.)

195 Church Street, 14th Floor
New Haven, Connecticut
(Address of Principal Executive Offices)

06510
(Zip Code)

Registrant's telephone number, including area code: (203) 304-2499

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 (see General Instruction A.2. below):

- 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 per share	TRVI	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 8.01 Other Events.

On July 13, 2020, Trevi Therapeutics, Inc. (the “Company”) announced the completion of the pre-specified sample size re-estimation (the “SSRE”) analysis for its ongoing PRISM Phase 2b/3 trial of Haduvio™ (nalbuphine ER) for severe pruritus in patients with prurigo nodularis.

Based on the SSRE analysis, the independent Data Monitoring Committee (the “DMC”) recommended that the trial size should be increased from an initial enrollment target of 240 to 360 subjects, which maintains the statistical power for the primary endpoint of the trial. The DMC’s recommendation was based on a pre-specified interim conditional power assessment conducted after approximately 45% of the initial targeted number of patients were evaluable for the primary endpoint of the trial. Based on the DMC’s recommendation, the Company plans to increase the size of the trial to 360 subjects.

The Company has increased the number of active sites in the PRISM trial to more than 60 sites globally, and approximately 140 subjects have enrolled in the study. Based on the increased size of the trial and considering COVID-19 related restrictions, the Company expects to complete enrollment in the third quarter of 2021 and report top-line data in the fourth quarter of 2021.

The Company intends to propose Haduvio as the trade name for the nalbuphine ER investigational product and will therefore use that name in its materials going forward. Haduvio is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.

Forward-Looking Statements

Statements contained in this current report on Form 8-K regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties and actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the impact of the COVID-19 pandemic on the Company’s clinical trials, business and operations; the expected timing of enrollment, and for reporting top-line data from, the Company’s Phase 2b/3 PRISM trial of Haduvio in patients with prurigo nodularis; the Company’s business plans and objectives, including future plans or expectations for the Company’s product candidates; and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” and similar expressions. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties regarding the success, cost, and timing of the Company’s product candidate development activities and ongoing and planned clinical trials; uncertainties regarding the scope, timing and severity of the COVID-19 pandemic, the impact of the COVID-19 pandemic on the Company’s clinical operations and actions taken in response to the pandemic; uncertainties regarding the Company’s ability to execute on its strategy; the risk that positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical trials; potential regulatory developments in the United States and foreign countries; uncertainties inherent in estimating future expenses, capital requirements and other financial results; as well as other risks and uncertainties set forth in the quarterly report on Form 10-Q for the quarter ended March 31, 2020 filed with the Securities and Exchange Commission and in subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this current report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TREVI THERAPEUTICS, INC.

Date: July 13, 2020

By: /s/ Jennifer L. Good

Name: Jennifer L. Good

Title: President and Chief Executive Officer