

**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): December 4, 2020

CORTEXYME, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38890
(Commission
File Number)

90-1024039
(I.R.S. Employer
Identification No.)

269 East Grand Ave.
South San Francisco, California
(Address of principal executive offices)

94080
(Zip Code)

Registrant's telephone number, including area code: (415) 910-5717

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 240.13d-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, par value \$0.001 per share	CRTX	Nasdaq Global Select Market

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 December 4, 2020, Cortexyme, Inc. (the “Company”) announced that the Company’s independent Data Monitoring Committee (the “DMC”) conducted a pre-planned interim analysis and recommended that the Company continue its Phase 2/3 GAIN Trial of atuzaginstat (COR388) as planned to the one-year endpoint.

The interim analysis included approximately 300 patients who have reached six months of treatment in the GAIN Trial, a randomized, double-blind, placebo-controlled study of 40 and 80 mg twice a day of atuzaginstat. As part of the interim analysis, the DMC looked for futility, overwhelming efficacy ($p < 0.005$ on both co-primary outcomes) and a sample size increase if needed to improve powering, as well as safety. Based on the interim analysis, topline data for the fully enrolled population of 643 subjects after the full one-year treatment period is expected on time in December 2021. The Company remains blinded to all data.

Atuzaginstat targets the toxic proteases, or gingipains, produced by *P. gingivalis*, which have been discovered in greater than 90% of Alzheimer’s disease patients and shown to produce Alzheimer’s pathology and neurodegeneration in infected animals. *P. gingivalis* is best known as a keystone bacterium in the development of periodontal disease.

The GAIN (GingipAIN Inhibitor for Treatment of Alzheimer’s Disease) Trial is a Phase 2/3 trial evaluating the efficacy, safety and tolerability of atuzaginstat, the Company’s investigational gingipain inhibitor, in patients with mild to moderate Alzheimer’s disease. The co-primary endpoints for the GAIN Trial are mean change in ADAS-Cog 11 and ADCS-ADL from baseline to 48 weeks versus placebo. Secondary and exploratory endpoints include change in CDR-SB, NPI, MMSE, Winterlight Speech Assessment, MRI volumetric measures and biomarkers of infection. The GAIN Trial also includes a sub-study measuring the efficacy of COR388 on symptoms of periodontal disease including gingival pocket depth.

The Company’s management will discuss the interim analysis during a conference call beginning at 5:30 a.m. Pacific Standard Time on December 4, 2020.

Forward-Looking Statements

This report contains “forward-looking statements” that are subject to substantial risks and uncertainties. Forward-looking statements contained in this report may be identified by the use of words such as “anticipate,” “expect,” “believe,” “will,” “may,” “should,” “estimate,” “project,” “outlook,” “forecast” or other similar words. Examples of forward-looking statements include, among others, statements regarding the timing and success of the Company’s clinical trials and related data, including the outcome and results of the GAIN Trial, the potential of atuzaginstat to treat Alzheimer’s disease, the timing of announcements and updates relating to the Company’s clinical trials and related data, and the potential therapeutic benefits, safety and efficacy of the Company’s product candidate and/or library of compounds. Forward-looking statements are based on the Company’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict and could cause actual results to differ materially from what the Company expects. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, but are not limited to, the risks and uncertainties described in the section titled “Risk Factors” in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 16, 2020, the Company’s Quarterly Report on Form 10-Q filed with the SEC on November 12, 2020, and other reports as filed with the SEC. Forward-looking statements contained in this report are made as of this date, and the Company undertakes no duty to update such information except as required under applicable law.

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.

CORTEXYME, INC.

By: /s/ Caryn G. McDowell

Title: Chief Legal and Administrative Officer and Corporate Secretary

Date: December 4, 2020