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): January 25, 2022

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

Delaware	**001-38890**	**90-1024039**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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 January 26, 2022, Cortexyme, Inc. (the "Company") announced that it received a letter from the U.S. Food and Drug Administration (the "FDA") on January 25, 2022, placing a full clinical hold on atuzaginstat's (COR388) Investigational New Drug application (IND 134303). The Company plans to provide additional updates pending continued engagement with FDA.

The Company is immediately implementing a cost reduction program to rationalize operations and to allow continued support for planned clinical milestones, providing an expected cash runway through 2024. The Company intends to prioritize development of its next generation gingipain inhibitor, COR588, in Alzheimer's disease. COR588 is currently completing a Phase 1 SAD/MAD study and results are expected in the second quarter 2022. In addition, the Company plans to explore strategic alternatives for its coronavirus program and non-Alzheimer's indications for COR388. The Company intends to provide a more detailed update on its pipeline and anticipated milestones for 2022 in the near future.

Forward-Looking Statements

Statements in this Current Report on Form 8-K contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained herein may be identified by the use of words such as "anticipate," "expect," "believe," "plans," "intends," "will," "may," "should," "estimate," "project," "outlook," "runway," "forecast," "potential" or other similar words. Examples of forward-looking statements include, among others, the strategic development path for atuzaginstat, including with respect to COR388, COR588, and other programs and indications; its business plans, pipeline, strategy, planned clinical trials and timeline, prospects, and milestone expectations; the expected cash runway; the timing and success of the company's clinical trials and related data, including plans and the ability to conduct and/or complete current and additional studies, including the Phase 1 SAD/MAD study; the implementation of cost reduction measures; the potential of atuzaginstat to treat Alzheimer's disease and other indications; the timing of announcements and updates relating to its clinical trials and related data; the potential therapeutic benefits, safety and efficacy of the Company's product candidate or library of compounds; and statements about its ability to obtain, and the timing relating to, further development of atuzaginstat, regulatory submissions and interactions with regulators, and related response and decisions, including with respect to the Company's full clinical hold, and approvals with respect to the Company's drug product candidate. 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 1, 2021, its Quarterly Report on Form 10-Q filed with the SEC on October 29, 2021, and other reports as filed with the SEC. Forward-looking statements contained in this Current Report on Form 8-K 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

Date: January 26, 2022

Title: Chief Legal and Administrative Officer
and Corporate Secretary