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 26, 2021

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 **94080**
(Address of principal executive offices) **(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 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On January 26, 2021, Cortexyme, Inc. (the "Company") issued a press release, which provided a pipeline update and anticipated milestones for 2021. The Company also reported on a preliminary and unaudited basis estimated cash and investments as of December 31, 2020 on a pro forma basis. These are preliminary estimates based on currently available information and do not present all necessary information for a complete understanding of the Company's financial condition as of December 31, 2020, or the Company's results of operations for the year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this report.

The information in Item 2.02 of this Current Report on From 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing, regardless of any general incorporation language in such filing.

ITEM 8.01 OTHER EVENTS

On January 26, 2021, the Company issued a press release titled "Cortexyme Announces Pipeline Update and Anticipated 2021 Milestones." A copy of the press release is attached 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 January 26, 2021.
104	Interactive Data File (embedded within the Inline XBRL document).

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, 2021

Title: Chief Legal and Administrative Officer and Corporate Secretary

Exhibit 99.1

Investor Contact:
Chris Lowe
Cortexyme, Inc.
Chief Financial Officer
clowe@cortexyme.com

Media Contact:
Hal Mackins
For Cortexyme, Inc.
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(415) 994-0040

Cortexyme Announces Pipeline Update and Anticipated 2021 Milestones

— Based upon successful completion of the GAIN Trial's interim analysis, pipeline expansion announced for 2021
— Atuzaginstat to be studied in the PEAK trial, a new Phase 2 study for Parkinson's disease
— COR588, a novel lysine gingipain inhibitor, on track to enter the clinic in Q3 2021
— Top-line data in 643 subject Alzheimer's disease pivotal GAIN Trial on schedule to be announced in Q4 2021
— Top-line data in 233 subject periodontal disease clinical study to be announced in Q4 2021
— Current cash position projected to fund operations into 2023
— GAIN open-label extension (OLE) rollover to date has been approximately 90% of eligible participants

SOUTH SAN FRANCISCO, Calif. – January 26, 2021 – Cortexyme, Inc. (Nasdaq: CRTX), a clinical stage biopharmaceutical company pioneering potential therapeutics for Alzheimer's and other degenerative diseases, today announced a corporate update and highlighted key milestones anticipated in 2021.

"2020 was a year of numerous corporate and clinical accomplishments. We exceeded our enrollment target in the pivotal GAIN Trial for Alzheimer's disease on schedule and completed a successful interim analysis in December 2020. The interim analysis was a capstone to our continually growing foundation of evidence, including clinical biomarker data supporting *P. gingivalis* infection in Alzheimer's subjects and high OLE conversion, which supports the gingipain hypothesis and expansion of our pipeline. Following our successful IPO in 2019 and secondary offering in 2020, we project cash on hand will fund our current clinical development plans through 2023," said Casey Lynch, Cortexyme's chief executive officer, co-founder, and chair.

Ms. Lynch continued: "We expect 2021 to be another exciting and productive year. Data from researchers around the world supporting a potential role of gingipains in Parkinson's disease is compelling, and we are excited to expand testing of atuzaginstat into this new and important area of unmet medical need. We look forward to providing additional updates on our development programs during the year."

Anticipated Key Milestones for 2021

Atuzaginstat in Mild to Moderate Alzheimer's Disease (AD)

- The pivotal GAIN Trial's final top-line data read out for atuzaginstat in patients with mild to moderate Alzheimer's disease is planned in Q4 2021.
- Enrollment into the U.S. GAIN Trial OLE is robust despite the ongoing global pandemic, with approximately 90% of eligible subjects in the United States continuing in the open label portion of the study. Completion of enrollment in the GAIN OLE is expected in Q4 2021.

Atuzaginstat in Periodontal Disease (PiD)

- GAIN Trial top-line data for atuzaginstat in periodontal disease is planned in Q4 2021. The GAIN Trial includes a periodontal substudy of 233 subjects with efficacy data on typical regulatory endpoints of pocket depth and clinical attachment level at 6 months and 1 year.

Atuzaginstat in Parkinson's Disease (PD)

- The placebo controlled, multicenter Phase 2 study of atuzaginstat in patients with Parkinson's disease, the PEAK Trial (Parkinson's gingipain inhibitor Trial), has begun study start-up activities. The first patient in is expected in Q3 2021.

Pipeline Progress

- COR588 IND-enabling studies are proceeding according to expectations and a first-in- human study is expected to begin in Q3 2021. COR588 is a unique small molecule lysine gingipain inhibitor with once daily oral dosing that Cortexyme intends to position in periodontal disease and other new indications.
- Two arginine gingipain inhibitors, COR788 and COR822, have been selected as lead compounds to progress toward IND-enabling studies, including manufacturing scale-up and dose range-finding toxicology studies based on their properties of potency, selectivity, pharmacologic efficacy, and pharmacokinetics. Arginine gingipain is a distinct target associated with *P. gingivalis* that contributes to bacterial survival, replication and toxicity. An arginine gingipain inhibitor may be used as monotherapy in new indications or potentially additively with lysine gingipain inhibitors, like atuzaginstat. Both molecules have novel composition of matter (patent pending), are brain penetrant and orally available.
- Announcements of new original research including potential clinical studies in additional indications are expected during 2021.

Cash Position and Financial Update

Cortexyme ended the fourth quarter of 2020 with approximately $184.3 million in cash and investments on a proforma basis. The Company projects that its cash and investments will be sufficient to fund its planned operations into 2023.

About Cortexyme

Cortexyme, Inc. (Nasdaq: CRTX) is a clinical stage biopharmaceutical company pioneering upstream therapeutic approaches designed to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. Based upon the evidence generated to date, Cortexyme is currently advancing its lead therapeutic candidate, atuzaginstat (COR388), in the GAIN Trial, an ongoing Phase 2/3 clinical trial in patients with mild to moderate Alzheimer's disease. Cortexyme is targeting a specific, infectious pathogen found in the brain of Alzheimer's patients and tied to neurodegeneration and neuroinflammation in animal models. To learn more about Cortexyme, visit www.cortexyme.com or follow @Cortexyme on Twitter.

Forward-Looking Statements

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this press release 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 we make regarding our business plans, strategy, timeline, prospects and milestone expectations; the timing and success of our clinical trials and related data, including with respect to the GAIN and PEAK trials; the potential of atuzaginstat to treat Alzheimer's disease, periodontal disease, Parkinson's disease and other potential indications; our ability to fund planned operating and capital expenditures; the timing of announcements and updates relating to our clinical trials and related data; the timing of and our ability to enroll patients into our clinical trials; the potential therapeutic benefits, safety and efficacy of our product candidate or library of compounds; statements about our ability to obtain, and the timing relating to, regulatory submissions and approvals with respect to our drug product candidate; and expected cash runway and financial update. Forward-looking statements are based on Cortexyme'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 we expect. 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 our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 16, 2020, our 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 press release are made as of this date, and Cortexyme undertakes no duty to update such information except as required under applicable law.

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