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): March 17, 2020

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 Conditions

On March 17, 2020, Cortexyme Inc., (the "Company") issued a press release announcing its financial results for its fourth quarter and fiscal year ended December 31, 2019. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this Item 2.02. (including Exhibit 99.1) is being furnished and shall not be deemed "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 deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press release dated March 17, 2020 titled "Cortexyme Announces Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update."

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/ Christopher Lowe

Date: March 17, 2020

Title: Chief Financial Officer

Exhibit 99.1

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

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

Cortexyme Announces Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

— Following initial public offering and private placement, Cortexyme is well capitalized and focused on high quality execution of the Phase 2/3 GAIN Trial

— Interim analysis for the GAIN Trial on track to be completed before year-end 2020, with top-line results from study's final analysis expected in Q4 2021

SOUTH SAN FRANCISCO, Calif. — March 17, 2020 — Cortexyme, Inc. (Nasdaq: CRTX), a clinical stage biopharmaceutical company pioneering a novel, disease-modifying therapeutic approach to treat what it believes to be a key underlying cause of Alzheimer's and other degenerative diseases, today announced financial results for the fourth quarter and full year 2019 and provided an update on its business.

"Throughout 2019, Cortexyme made strong progress toward our goal of stemming the tide of Alzheimer's disease by halting its progression," said Casey Lynch, Cortexyme's chief executive officer, co-founder, and chair. "As we move through 2020, we are highly focused on the execution of the GAIN Trial, which has enrolled more than 300 patients and for which top-line results are anticipated in Q4 2021. At the same time, we continue to research and publish new data that sheds light on the gingipain hypothesis for Alzheimer's causation and the potential clinical utility of COR388, our lead investigational gingipain inhibitor. With a strong balance sheet and a talented, growing team, we're committed to delivering for all of our stakeholders, especially the neurodegenerative disease patients and caregivers that have been vocal in their calls for new therapeutic options."

Recent Business Updates and Upcoming Milestones

GAIN Trial Updates

- Earlier this month, the company provided an update on its progress enrolling patients in the GAIN Trial, its Phase 2/3 clinical trial of COR388 versus placebo in patients with mild to moderate Alzheimer's disease. The study has now enrolled more than 300 patients and is expected to complete enrollment in Q4 2020. In addition, the GAIN Trial includes a periodontal sub-study in which sites with a dental sub-investigator are assessing efficacy endpoints against periodontal disease, including pocket depth, at baseline, six months, and one year. Periodontal disease is not a criterion for enrollment in the GAIN Trial or the sub-study, and yet more than 90% of patients enrolled in the sub-study to date had moderate to severe periodontal disease at baseline.

- In February 2020, the company announced that, following discussion with the FDA, it intends to conduct an interim analysis for overwhelming efficacy in the GAIN Trial. The analysis, currently planned before year-end 2020, will be conducted after approximately 100 patients in each of the GAIN Trial's three arms complete six months of treatment. Cortexyme continues to expect top-line results from the GAIN Trial's final analysis in the fourth quarter of 2021. The co-primary endpoints for both analyses will be change from baseline in ADAS-Cog11 and CDR-SB versus placebo.
- In January 2020, the company announced initiation of an open-label extension (OLE) for the GAIN Trial in the United States. Upon completing the 48-week placebo-controlled period of the GAIN Trial, participants in the GAIN Trial's placebo and active arms may be eligible to enroll in the OLE study, where they will receive 80 mg of COR388 twice daily for an additional 48 weeks. The first patient in the OLE is expected in Q2 2020.

Advancing a New Understanding of Alzheimer's Causation and Treatment

As COR388 moves through late-stage clinical development, Cortexyme and external collaborators continue to present and publish new research to advance our understanding of the gingipain hypothesis for Alzheimer's pathogenesis and the clinical potential of COR388.

This spring, Cortexyme's publication and presentation plans include three data sets at meetings that have either been canceled or become virtual events as a result of the evolving COVID-19 situation. Cortexyme expects to be able to share these presentations on the News & Events > Presentations page of its investor website, ir.cortexyme.com, as they are available. These presentations are:

- An abstract and roundtable at the International Association for Dental Research 2020 General Session. This conference, which would've been held March 18-21, 2020 in Washington, D.C., has been canceled, but conference organizers expect to publish accepted abstracts online at a later date.
- An abstract on COR388's potential to decrease fragmentation of ApoE in the Alzheimer's disease central nervous system at the American Chemical Society (ACS) National Meeting and Expo. This meeting, originally planned for March 22-26 in Philadelphia, PA, has similarly been canceled, but the ACS anticipates making abstracts available as well.
- An abstract at the AAT-AD/PD Advances in Alzheimer's and Parkinson's Therapies meeting demonstrating that *in vivo* infection of primary neurons by *P. gingivalis* results in an Alzheimer's-like phenotype. This meeting was originally scheduled for April 2-5, 2020, but will now be held virtually.

Recent scientific presentations and publications from the fourth quarter of 2019 and early 2020 are detailed below:

- In January 2020, Cortexyme scientists and collaborators published new data in *Pharmacology Research and Perspectives* revealing further detail about the pharmacodynamics and utility of COR388. Researchers reported that COR388 demonstrates dose-dependent gingipain target engagement in a naturally occurring *P. gulae* infection, including in difficult to reach bacterial biofilm niches. *P. gulae* is the only other bacterial species known to secrete gingipains. COR388 drug was efficacious in improving downstream pathology of the infection, namely gingival pocket depth, a symptom of periodontal disease which affects approximately 65 million Americans. In addition, gingipain antigens and *P. gulae* DNA were found in the brains of aged dogs, indicating that *P. gulae* can also migrate from the oral cavity to the brain in a manner similar to that seen for *P. gingivalis* in Alzheimer's patients.

- In December 2019, COR388 was the subject of a presentation at the 12th Clinical Trials in Alzheimer's (CTAD) Conference centered on two findings related to the growing interest in ApoE fragmentation as a potential pathogenic mechanism in sporadic Alzheimer's disease.
    - Cells infected with P. gingivalis exhibited gingipain-dependent ApoE cleavage activity that generated ApoE fragments similar to what was seen in the brains and cerebrospinal fluid (CSF) of patients with Alzheimer's disease. Furthermore, *P. gingivalis'* gingipains cleaved ApoE4 more readily than ApoE3. Finally, in the infected cells, COR388 alone was sufficient to block ApoE fragmentation.
    - In a Phase 1b trial, COR388 reduced ApoE fragments in human CSF. Cortexyme's Phase 1 clinical development program for COR388 included cohorts of healthy volunteers and subjects with Alzheimer's disease. In addition to assessing safety and initial clinical activity, investigators also assessed the level of ApoE fragmentation in the CSF of nine subjects with Alzheimer's disease. Six subjects received 50mg of COR388 twice daily while three subjects received placebo. After 28 days, a statistically significant decrease in ApoE fragments (both ApoE4 and ApoE3) was observed in subjects treated with COR388 versus those treated with placebo. Cortexyme believes this is a downstream indication of target engagement of gingipains in the brain by COR388.

Corporate Updates

- In addition to other ongoing pipeline screening activities, Cortexyme is now screening its proprietary library of small molecules for a possible treatment for coronaviruses. The virus responsible for COVID-19, SARS-CoV2, expresses a cysteine protease known as Mpro or 3CLpro that is required for replication, and this cysteine protease has been previously validated as a therapeutic target for coronaviruses. Molecular modeling indicates that Cortexyme's library may potentially include inhibitors to this protease, and the company is screening these compounds for potential activity in collaboration with academic and government researchers.

Financial Results for the Quarter Ended December 31, 2019

Cash, Cash Equivalents and Marketable Securities: Cash, cash equivalents, and short and long-term marketable securities as of December 31, 2019, were $116.6 million. In February 2020, Cortexyme completed a successful private placement offering, raising approximately $117.6 million after expenses. Cortexyme expects current cash, cash equivalents and marketable securities plus the net proceeds of the private placement in February 2020 will be sufficient to fund its operating and capital expenditures through 2021 and the completion of the GAIN Trial.

Research and Development (R&D) Expenses: For the quarter ended December 31, 2019, R&D expenses were $10.0 million. The expense was primarily due to costs related to the research and development of COR388 and the GAIN Trial.

General and Administrative (G&A) Expenses: For the quarter ended December 31, 2019, G&A expenses were $2.9 million. The expense was primarily attributable to personnel-related expenses, insurance, professional and legal fees, and stock-based compensation.

Net Loss: For the quarter ended December 31, 2019, net loss was $12.4 million, or a loss of $0.46 per basic share.

About Cortexyme, Inc.

Cortexyme (Nasdaq: CRTX) is a clinical stage biopharmaceutical company pioneering a novel, disease-modifying therapeutic approach to treat what it believes to be a key underlying cause of Alzheimer's disease and other degenerative diseases. Cortexyme is targeting a specific, infectious pathogen found in the brain of Alzheimer's patients and tied to neurodegeneration and neuroinflammation in animal models. The company's lead investigational medicine, COR388, is the subject of the GAIN Trial, an ongoing Phase 2/3 clinical study in patients with mild to moderate Alzheimer's. 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 and prospects, cash forecasts, the timing and success of our clinical trials and related data, 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, and the potential therapeutic benefits, safety and efficacy of our product candidate or library of compounds. 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, 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.

— see attached financial tables —

Cortexyme, Inc. Condensed Statements of Operations
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended December 31, 2019	Year Ended December 31, 2019
Operating expenses:		
Research and development	$ 10,027	$ 30,214
General and administrative	2,922	8,954
Total operating expenses	12,949	39,168
Loss from operations	(12,949)	(39,168)
Interest income	570	2,188
Interest expense	—	—
Change in fair value of derivative liability	—	—
Net loss	(12,379)	(36,980)
Other comprehensive income/ (loss):		
Unrealized gain / (loss) on available for sales securities	(36)	109
Total comprehensive income/(loss)	$ (12,415)	$ (36,871)
Net loss per share – basic and diluted	(0.46)	(1.94)

Cortexyme, Inc. Condensed Balance Sheets
(Unaudited)
(In thousands, per share amounts)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,214	$ 24,872
Short term investments	48,650	46,844
Prepaid expenses and other current assets	6,192	868
Total current assets	106,056	72,584
Property and equipment, net	709	283
Operating lease right-of-use assets	625	—
Long term investments	16,763	—
Other assets	217	10
Total assets	$124,370	$ 72,877
LIABILITIES AND STOCKHOLDERS' EQUITY / (DEFICIT)		
Current liabilities:		
Accounts Payable	3,075	495
Accrued expenses and other current liabilities	5,817	962
Total current liabilities	8,892	1,457
Total liabilities	8,892	1,457
Redeemable convertible preferred stock	—	104,046
Total stockholders' equity / (deficit)	115,478	(32,626)
Total liabilities and stockholders' equity / (deficit)	$124,370	$ 72,877

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