

**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 28, 2022

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 240.13e-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, 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 February 1, 2022, Cortexyme, Inc. (the “Company”) issued a press release relating to the Company’s pipeline update and anticipated milestones for 2022. The Company also reported on a preliminary and unaudited basis its estimated cash, cash equivalents, and investments of \$126.7 million as of December 31, 2021. The Company has not completed preparation of its financial statements for the fourth quarter or full year of 2021. The cash, cash equivalents and investments presented as of December 31, 2021 are preliminary and unaudited and are thus inherently uncertain and subject to change as the Company completes its financial results for 2021. The Company is in the process of completing its customary year-end close and review procedures as of and for the year ended December 31, 2021, and there can be no assurance that its final results for this period will not differ from these preliminary, unaudited amounts. The Company’s independent registered public accounting firm has not audited, reviewed, compiled, or performed any procedures with respect to such preliminary data for the fourth quarter and year ended December 31, 2021.

The information in Item 2.02 of this Current Report on Form 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 2.05 Costs Associated with Exit or Disposal Activities.

On February 2, 2022, the Board of Directors (the “Board”) of the Company approved the previously announced cost reduction program (the “Plan”) to rationalize operations and to allow continued support for the needs of its business following the clinical hold on atuzaginstat’s (COR388) Investigational New Drug application (IND 134303). Under the Plan, the Company is reducing headcount by approximately 53% through a reduction in its workforce. A majority of the reduction in force will take place by March 2022, and the remainder will be completed by July 2022. As a result, the Company expects to realize estimated annualized operating expense savings of approximately \$8.3 million in the year ending December 31, 2022 (excluding share-based compensation and any one-time costs related to strategic actions).

In connection with the Plan, the Company estimates that it will incur expenses of approximately \$1.9 million to \$2.1 million, substantially all of which will be cash expenditures and other costs relating to the Plan through the first quarter of 2023. These estimates are subject to a number of assumptions, and actual results may differ. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Plan.

ITEM 5.02 Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.*Departure of Executive Officers and Directors*

On February 1, 2022, the Company announced the departure of Casey C. Lynch, the Company’s President, Chief Executive Officer and Chairperson of the Board, and Stephen S. Dominy, M.D., the Company’s Chief Scientific Officer and a member of the Board, effective as of January 28, 2022 (the “Departure Date”).

In connection with the departure of each of Ms. Lynch and Dr. Dominy from the Company, the Company entered into a separation agreement (the “Separation Agreements”) with each of Ms. Lynch and Dr. Dominy on February 2, 2022 providing for (i) a release of claims against the Company, (ii) cash severance payments of \$604,000 in the case of Ms. Lynch, which equals to twelve months of Ms. Lynch’s 2021 base salary, to be paid in a lump sum, and cash severance payments of \$326,250 in the case of Dr. Dominy, which equals to nine months of Dr. Dominy’s 2021 base salary, to be paid in a lump sum; and (iii) certain health care continuation benefits. The Separation Agreements also provide for an accelerated vesting of stock options or other equity awards held by each of Ms. Lynch

and Dr. Dominy such that the number of shares subject to such stock options or other equity awards that would have vested had she or he remained an employee for one month after the Departure Date and an extension of the post-termination exercise period for all vested stock options or other equity awards held by each of Ms. Lynch and Dr. Dominy through the twelve-month period following the Departure Date. In addition, in the event the Company consummates a change in control of control within three months after the Departure Date, subject to satisfaction of specified conditions, Ms. Lynch and Dr. Dominy would also be entitled to additional cash severance and COBRA coverage, payment of target annual bonus, and accelerated vesting with respect to their equity awards.

The foregoing descriptions of the terms of the Separation Agreements are not complete and are qualified in their entirety by reference to the complete texts of the Separation Agreements, copies of which will be filed as exhibits to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Resignation of Directors; Appointment of Interim Principal Executive Officer and Director

On January 28, 2022, the Company appointed Christopher Lowe, the Company's Chief Operating Officer ("COO") and Chief Financial Officer ("CFO"), to serve as the Interim Chief Executive Officer ("Interim CEO") of the Company. Mr. Lowe will retain his titles as COO, CFO and Treasurer. In his role as an Interim CEO, Mr. Lowe will also serve as the Company's principal executive officer, in addition to his role as a principal financial officer. Mr. Lowe, 53, has served as the Company's COO since February 2021 and as the Company's CFO since January 2019. From June 2018 until January 2019, Mr. Lowe served as a consultant to the Company and the Company's interim Chief Financial Officer through his capacity as a partner at FLG Partners. Mr. Lowe has also served as the Managing Partner of the Innventus Fund at Innventure since January 2017 and he has served as a partner at FLG Partners since January 2014 and its Managing Partner since January 2018. Prior to joining the Company, Mr. Lowe served as the Interim Chief Executive Officer and Chief Financial Officer of Hansen Medical from February 2014 to July 2016, and he served as the Chief Business Officer and Chief Financial Officer of Anthera Pharmaceuticals from September 2007 to June 2013. Mr. Lowe has served as a director and chair of the audit committee of Vincerx Pharma since December 2020. Mr. Lowe previously served as a director for Inspyr Therapeutics from September 2016 to December 2018, a director of EpiBiome from May 2016 to June 2018, and a director and chair of the audit committee of Asante Solutions from December 2014 to October 2015. Mr. Lowe holds a B.S. in Business Administration from California Polytechnic State University and an M.B.A. from St. Mary's University.

Ms. Lynch and Dr. Dominy tendered their resignation from the Board, effective as of January 31, 2022. Neither departure was a result of any disagreement with the Company, its Board or management.

On February 2, 2022, the Board appointed Mr. Lowe to serve on the Board as a Class III Director, to fill the vacancy resulting from Ms. Lynch's resignation from the Board. Mr. Lowe will serve until his term expires at the annual meeting of stockholders to be held in 2022 and until his successor is elected and qualified or until his earlier death, resignation or removal. There are no arrangements or understandings between Mr. Lowe and/or any other persons pursuant to which he was selected as the Company's Interim CEO or appointed as a director of the Board. There are also no family relationships between Mr. Lowe and any of the Company's directors or executive officers, and Mr. Lowe does not have any direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K. In connection with his appointment as Interim CEO and a director of the Board, Mr. Lowe will not receive any change in compensation or benefits.

On February 2, 2022, the Board also appointed David A. Lamond to serve as Chairperson of the Board.

ITEM 8.01 Other Events.

On February 1, 2022, the Company announced the following anticipated milestones for 2022:

COR588 in Mild to Moderate Alzheimer's Disease

- COR588 is currently completing a Phase 1 SAD/MAD trial in a cohort of healthy participants in Australia with study results expected in the second quarter of 2022.
- Following the Phase 1 study, and subject to continued interactions with U.S. Food and Drug Administration (the "FDA"), the Company plans to advance COR588 to a Phase 2 trial to assess dose ranging, biomarker response, and further evaluate the safety profile.

Atuzaginstat (COR388) in Oncology for Prevention of Oral Squamous Cell Carcinoma

- The Company is announcing a potential new indication for its lysine gingipain inhibitor, atuzaginstat (COR388), to prevent the development of oral/head and neck squamous cell carcinoma (O/HNSCC). *P. gingivalis* infection is associated with the development of O/HNSCC, and also with a significantly worse overall survival in patients with *P. gingivalis* positive O/HNSCC.
- The Company will be sharing a comprehensive update of evidence generated to date. The company held a pre-IND meeting with FDA and plans to submit an IND to the Division of Oncology in the first quarter of 2022.

Atuzaginstat (COR388) in Mild to Moderate Alzheimer's Disease

- The Company will provide additional updates on atuzaginstat, as appropriate, pending continued engagement with FDA.
- The Company intends to utilize the robust data set from the GAIN Trial to inform the ongoing development of its next generation lysine gingipain inhibitor, COR588, for Alzheimer's disease, in addition to developing atuzaginstat for non-Alzheimer's indications, such as periodontal disease and select oncology indications where *P. gingivalis*-driven infection contributes to disease progression.

Atuzaginstat (COR388) in Periodontal Disease

- The Company intends to develop an oral formulation of its proprietary gingipain inhibitors, including atuzaginstat, to address periodontal disease in a non-systemic way that engages and inhibits gingipains from *P. gingivalis*, penetrating and disrupting biofilms directly in the oral cavity.

COR803 in Coronavirus Infection

- COR803 is a novel patent-pending small molecule 3CLpro inhibitor discovered and developed by the Company based on its expertise in cysteine protease inhibition. 3CLpro, or Mpro, is a validated antiviral drug target shown to be essential in viral replication of SARS-CoV-2.
- The Company is progressing IND-enabling preclinical studies for COR803.

Forward-Looking Statements

Certain 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," "plan," "intend," "will," "may," "should," "estimate," "project," "outlook," "runway," "forecast," "potential" or other similar words. Examples of forward-looking statements include, among others, statements relating to the Company's cash position; its expectations regarding the timing of the Plan and cost savings and expenses associated therewith; the strategic development path for atuzaginstat, including with respect to COR388, COR588, and other programs and indications, including with respect to COR803; its business plans, internal and external development of the pipeline, strategy, planned FDA submissions and clinical trials and timeline, prospects, and milestone expectations; the timing and success of the Company's clinical trials and related data, including plans and the ability to initiate, conduct and/or complete current and additional studies; 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 and other programs or indications, regulatory submissions and interactions with regulators, and related response and decisions, 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 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.

SIGNATURE

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: February 2, 2022