

**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): May 9, 2022

CORTEXYME, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38890
(Commission
File Number)

90-1024039
(IRS Employer
Identification No.)

269 East Grand Ave.
South San Francisco, California
(Address of Principal Executive Offices)

94080
(Zip Code)

(415) 910-5717
(Registrant's Telephone Number, Including Area Code)

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 (see General Instructions A.2. below):

- 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 8.01 Other Events.

On May 10, 2022, Cortexyme, Inc. (“Cortexyme”) issued a press release announcing the entry into an Agreement and Plan of Merger and Reorganization, dated May 9, 2022, by and among Cortexyme, Quince Merger Sub I, Inc., a wholly owned subsidiary of Cortexyme, Quince Merger Sub II, LLC, a wholly owned subsidiary of Cortexyme, Novosteo Inc. and Fortis Advisors LLC. A copy of the press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Forward-Looking Statements

Statements in this news release contain “forward-looking statements” that are subject to substantial risks and uncertainties. Forward-looking statements contained in this news release may be identified by the use of words such as “believe,” “expect,” “intend,” “potential,” “will” or other similar words. Examples of forward-looking statements include, among others, the ability of the parties to consummate the proposed merger transaction, satisfaction of closing conditions precedent to the consummation of the proposed merger transaction, potential delays in consummating the merger and the ability of Cortexyme to timely and successfully achieve the anticipated benefits of the merger transaction, cash sufficiency forecast, the strategic development path for atuzaginstat and NOV004; 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 timing of announcements and updates relating to its clinical trials and related data; the potential therapeutic benefits, safety and efficacy of the combined company’s product candidate or library of compounds; and statements about its ability to obtain, and the timing relating to, further development of its clinical candidates and other programs or indications, regulatory submissions and interactions with regulators. 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 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 Cortexyme’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 1, 2022, and other reports as filed with the SEC. Forward-looking statements contained in this news release are made as of this date, and Cortexyme undertakes no duty to update such information except as required under applicable law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release, dated May 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

Dated: May 10, 2022

CORTEXYME, INC.

By: /s/ Christopher Lowe

Christopher Lowe
Interim Chief Executive Officer, Chief Financial
Officer and Chief Operating Officer, Director



Cortexyme Announces Agreement to Acquire Novosteo

Expanding pipeline with addition of targeted therapeutics to treat rare skeletal diseases, bone cancer and injury

Strengthening leadership team with appointment of Novosteo executives Dr. Dirk Thye as CEO and

Dr. Karen Smith as CMO of combined company

Planning corporate name change to Quince Therapeutics to reflect broadening of therapeutic pipeline

SOUTH SAN FRANCISCO, Calif. – May 10, 2022 – Cortexyme, Inc. (Nasdaq: CRTX), a clinical-stage biopharmaceutical company dedicated to improving the lives of patients diagnosed with degenerative diseases, today announced that it entered into an agreement under which the company plans to acquire Novosteo, a privately-held biotech company focused on targeted therapeutics to treat rare skeletal diseases, bone cancer and injury. Upon completion of the transaction, Novosteo stockholders will own approximately 15.5% of the combined company. The transaction, which has been approved by the Boards of Directors of both companies, is expected to close within the next 30 days.

David Lamond, chairman of Cortexyme's Board of Directors, said, "The acquisition of Novosteo adds a highly promising set of assets and meaningfully expands the breadth of our management team. We continue to review additional strategic actions that may opportunistically build upon our growing rare and degenerative disease focus. On behalf of Cortexyme's Board, I would like to thank Chris Lowe for his leadership as interim CEO and guiding us through this acquisition."

Dr. Dirk Thye, chief executive officer of Novosteo, commented, "We have assembled a highly experienced and impressive team to aggressively pursue the company's next stage of growth. We intend to capitalize on the combined assets of Novosteo and Cortexyme by driving our therapeutic candidates through development, expanding our targeted drug discovery platform, and pursuing new business development opportunities."

Pipeline Expansion with NOV004, a Precision Bone Growth Molecule for Rare Disease

The acquisition of Novosteo expands Cortexyme's drug development pipeline into rare disease indications with the addition of NOV004, a bone targeting molecule designed to accelerate fracture repair, including in patients with osteogenesis imperfecta. Key highlights of the compound include:

- NOV004 is engineered to specifically target and concentrate at the bone fracture site, leading to higher concentrations of a therapeutic anabolic peptide over longer periods of time directly at the site of injury. This improved retention at the bone fracture surface stimulates a robust healing response in preclinical studies.
- In preclinical fracture studies, NOV004 increased new bone production three-fold and resulted in bone that is almost twice as dense as bone treated with a non-targeted therapeutic. At three weeks post fracture, NOV004 treatment reached pre-fracture strength and more than doubled control strength. Notably, these effects are seen with normal physiology, as well as in osteogenesis imperfecta – a rare bone disease caused by a congenital defect in the genetic code for collagen.

- NOV004's ability to increase bone production and stability could result in significant mobility gain in distance and speed as early as 12 days post-fracture in animal studies.
- With IND-enabling studies completed, NOV004 is expected to enter Phase 1 clinical studies in 2023 and progress to a lead indication in osteogenesis imperfecta.

Upon completion of the transaction, the company will have capital resources of approximately \$120 million in cash, cash equivalents and investments as of March 31, 2022, on a proforma basis with which to fund its combined operating requirements.

Leadership and Governance

Upon the close of the acquisition, the company will appoint Novosteo executives Dr. Dirk Thye as chief executive officer, and Dr. Karen Smith as chief medical officer of Cortexyme, adding experienced leadership to support its next stage of growth. Dr. Dirk Thye and Philip Low, PhD, a current director of Novosteo, will also join the company's Board of Directors upon close of the transaction.

The company also plans to operate under a new name – Quince Therapeutics, Inc. – and begin trading under the ticker symbol “QNCX” in the coming months. At that time, the company will present an overview of its pipeline development plans, clinical activity updates, and anticipated milestones.

“The acquisition of Novosteo reflects the strategic expansion of our pipeline, which remains focused on bringing innovative therapeutics to diseases with high unmet clinical needs,” said Chris Lowe, Cortexyme's interim chief executive officer. “We are excited about the addition of Novosteo's targeted therapy platform and extensive preclinical data to our expanding therapeutic pipeline. I believe the appointments of Dr. Dirk Thye as CEO and Dr. Karen Smith as CMO will bring exceptional expertise to lead the company.”

Advisors

Cooley LLP acted as legal advisor to Cortexyme and Wilson Sonsini Goodrich & Rosati acted as legal advisor to Novosteo.

About Cortexyme

Cortexyme, Inc. (Nasdaq: CRTX) is a clinical stage biopharmaceutical company dedicated to improving the lives of patients diagnosed with rare and degenerative diseases. The company's innovative pipeline includes a precision bone growth molecule and drug-targeting platform to treat rare skeletal diseases, bone cancer and injury, in addition to small molecule therapeutics targeting the infectious pathogen *P. gingivalis*' role in degenerative disease progression, including for indications such as periodontal disease, oral potentially malignant disorders, and Alzheimer's disease, among others. To learn more about Cortexyme, visit www.cortexyme.com or follow @Cortexyme on Twitter.

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