

**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): **February 24, 2021**

Fortress Biotech, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35366
(Commission File Number)

20-5157386
(IRS Employer
Identification No.)

2 Gansevoort Street, 9th Floor
New York, New York 10014
(Address of Principal Executive Offices)

(781) 652-4500
(Registrant's telephone number, including area code)

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.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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	F BIO	Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	F BIO P	Nasdaq Capital 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).

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 February 24, 2021, Cyprium Therapeutics, Inc. ("Cyprium"), a Fortress Biotech, Inc. ("Fortress") partner company, and Sentyln Therapeutics, Inc. ("Sentyln"), a U.S.-based specialty pharmaceutical company owned by the Zydus Group, announced the execution of an asset purchase agreement (the "Agreement") to commit development funding for and acquire Cyprium's proprietary rights to CUTX-101, its Copper Histidine product candidate for the treatment of Menkes disease. Under the terms of the Agreement, Sentyln will make an upfront cash payment to Cyprium, provide additional cash payments upon the achievement of certain regulatory milestones, and pay royalties and commercial milestone payments based on the net sales of CUTX-101. Cyprium will retain development responsibility of CUTX-101 through approval of the New Drug Application ("NDA") by the U.S. Food and Drug Administration ("FDA"), and Sentyln will be responsible for commercialization of CUTX-101 as well as progressing newborn screening activities. Continued development of CUTX-101 will be overseen by a Joint Steering Committee consisting of representatives from Cyprium and Sentyln.

Under the Agreement, Cyprium is eligible to receive up to \$20 million in development and regulatory cash milestones, consisting of \$8 million upfront, \$3 million upon FDA acceptance of the NDA filing and \$9 million upon NDA approval, as well as potential sales milestones totaling up to \$255 million. Royalties on CUTX-101 net sales are also payable, with 6% due on that portion of annual net sales up to \$75 million, 17.5% due on that portion of annual net sales between \$75 million and \$100 million, and 25% due on that portion of annual net sales over \$100 million. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101.

The Agreement includes customary representations, warranties, conditions, covenants, and indemnification rights and obligations of Cyprium and Sentyln. Fortress issued a press release to announce Cyprium's execution of the Agreement. A copy of such press release is being filed as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed herewith:

Exhibit Number	Description
99.1	Press Release issued by Fortress Biotech, Inc., dated February 24, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Fortress Biotech, Inc.
(Registrant)

Date: February 24, 2021

By: /s/ Lindsay A. Rosenwald, M.D.
Lindsay A. Rosenwald, M.D.
Chairman, President and Chief Executive Officer



Cyprium Therapeutics, a Fortress Biotech Partner Company, and Sentyln Therapeutics, a Wholly-owned Subsidiary of the Zydus Group, Sign Development and Asset Purchase Agreement for Cyprium Therapeutics' Copper Histidinate Product Candidate for Treatment of Menkes Disease

Sentyln acquires CUTX-101, Copper Histidinate, for \$20 million in upfront and regulatory milestone payments through NDA approval, as well as potential sales milestones plus royalties

Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101

Rolling submission of New Drug Application to the FDA for CUTX-101 on track to begin in the third quarter of 2021 and to be completed during the fourth quarter of 2021

New York, NY & Solana Beach, CA, February 24, 2021 – Cyprium Therapeutics, Inc. (“Cyprium”), a Fortress Biotech, Inc. (Nasdaq: FBIO) (“Fortress”) partner company, and Sentyln Therapeutics, Inc. (“Sentyln”), a U.S.-based specialty pharmaceutical company owned by the Zydus Group, today announced the execution of an asset purchase agreement to commit development funding for and acquire Cyprium’s proprietary rights to CUTX-101, its Copper Histidinate product candidate for the treatment of Menkes disease. Under the terms of the agreement, Sentyln will make an upfront cash payment to Cyprium, provide additional cash payments upon the achievement of certain regulatory milestones, and pay royalties and commercial milestone payments based on the net sales of CUTX-101. Cyprium will retain development responsibility of CUTX-101 through approval of the New Drug Application (“NDA”) by the U.S. Food and Drug Administration (“FDA”), and Sentyln will be responsible for commercialization of CUTX-101 as well as progressing newborn screening activities. Continued development of CUTX-101 will be overseen by a Joint Steering Committee consisting of representatives from Cyprium and Sentyln.

“We are very pleased to partner with Sentyln to potentially expedite the development and commercialization of CUTX-101. The drug has demonstrated a compelling safety and efficacy profile in topline analysis for the treatment of Menkes disease. We look forward to working with Sentyln to begin the rolling submission of the NDA to the FDA this year. If approved, CUTX-101 will provide a major breakthrough and fill a significant unmet need for children suffering from this rare, fatal pediatric disease,” said Lung S. Yam, M.D., Ph.D., President and Chief Executive Officer of Cyprium.

Matt Heck, Co-founder, President & Chief Executive Officer of Sentyln, commented, “Our mission, at the Zydus Group, has been to provide healthcare professionals with access to innovative treatment solutions that enable them to meet the needs of individual patients. We are excited to collaborate with Cyprium in order to broaden our pediatric rare disease portfolio and commercialize CUTX-101, a potentially transformative product, for children with Menkes disease, an unmet healthcare need.”

Fortress’ Chairman, President and Chief Executive Officer, Lindsay A. Rosenwald, M.D., added, “This transaction with Sentyln further validates the Fortress business model of identifying and developing promising treatments for patients, while pursuing partnership opportunities that potentially maximize shareholder value. We are thrilled with the progress Cyprium has made developing this treatment for Menkes disease and look forward to working with Sentyln to make CUTX-101 available to patients.”

Under the agreement, Cyprium is eligible to receive up to \$20 million in upfront development and regulatory cash milestones through NDA approval, as well as potential sales milestones. Royalties on CUTX-101 net sales ranging from the mid-single digits up to the mid-twenties are also payable. Cyprium will retain 100% ownership over any FDA priority review voucher that may be issued at NDA approval for CUTX-101. Torrey Partners advised Cyprium on this transaction.

About Menkes Disease

Menkes disease is a rare X-linked recessive pediatric disease caused by gene mutations of copper transporter ATP7A. The minimum birth prevalence for Menkes disease is believed to be 1 in 34,810 live male births, and potentially as high as 1 in 8,664 live male births, based on recent genome-based ascertainment (Kaler SG, Ferreira CR, Yam LS. Estimated birth prevalence of Menkes disease and ATP7A-related disorders based on the Genome Aggregation Database (gnomAD). Molecular Genetics and Metabolism Reports 2020 June 5;24:100602). The condition is characterized by distinctive clinical features, including sparse and depigmented hair (“kinky hair”), connective tissue problems, and severe neurological symptoms such as seizures, hypotonia, failure to thrive, and neurodevelopmental delays. Mortality is high in untreated Menkes disease, with many patients dying before the age of three years old. Milder versions of ATP7A mutations are associated with other conditions, including Occipital Horn Syndrome and ATP7A-related Distal Motor Neuropathy. Currently, there is no FDA-approved treatment for Menkes disease and its variants.

About CUTX-101 (Copper Histidinate)

CUTX-101 is in clinical development to treat patients with Menkes disease. CUTX-101 is a subcutaneous injectable formulation of Copper Histidinate manufactured under current good manufacturing practice (“cGMP”) and physiological pH. In a Phase 1/2 clinical trial conducted by Stephen G. Kaler, M.D., M.P.H., at the National Institutes of Health (“NIH”), early treatment of patients with Menkes disease with CUTX-101 led to an improvement in neurodevelopmental outcomes and survival. In August 2020, Cyprium reported positive topline clinical efficacy results for CUTX-101, demonstrating statistically significant improvement in overall survival for Menkes disease subjects who received early treatment (ET) with CUTX-101, compared to an untreated historical control (HC) cohort, with a nearly 80% reduction in the risk of death. A Cyprium-sponsored expanded access protocol for patients with Menkes disease is ongoing at multiple U.S. medical centers.

About Sentyln Therapeutics

Sentyln Therapeutics is a San Diego-based commercial-stage specialty pharma company that specializes in acquiring, developing and launching unique products. The company was acquired by the Zydus Group in 2017. Sentyln’s highly experienced and knowledgeable management team has previously built multiple successful pharmaceutical companies. With a focus on commercialization, Sentyln looks to source effective and well differentiated products across a broad spectrum of therapeutic areas. Sentyln is committed to the highest ethical standards and compliance with all applicable laws, regulations, and industry guidelines.

About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs nearly 25,000 people worldwide, including 1,400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com.

About Cyprium Therapeutics

Cyprium Therapeutics, Inc. (“Cyprium”) is focused on the development of novel therapies for the treatment of Menkes disease and related copper metabolism disorders. In March 2017, Cyprium entered into a Cooperative Research and Development Agreement (“CRADA”) with the Eunice Kennedy Shriver National Institute of Child Health and Human Development (“NICHD”), part of the NIH, to advance the clinical development of CUTX-101 (Copper Histidinate injection) for the treatment of Menkes disease. In addition, Cyprium and NICHD entered into a worldwide, exclusive license agreement to develop and commercialize adeno-associated virus (AAV)-based gene therapy, called

AAV-ATP7A, to deliver working copies of the copper transporter that is defective in patients with Menkes disease, and to be used in combination with CUTX-101. CUTX-101 was granted FDA Breakthrough Therapy, Fast Track and Rare Pediatric Disease Designations, and both CUTX-101 and AAV-ATP7A have received FDA Orphan Drug Designation previously. Additionally, the European Medicines Agency previously granted Orphan Drug Designation to CUTX-101. Cyprium was founded by Fortress Biotech, Inc. (Nasdaq: FBIO) and is based in New York City. For more information, visit www.cypriumtx.com.

About Fortress Biotech

Fortress Biotech, Inc. (“Fortress”) is an innovative biopharmaceutical company that was ranked in Deloitte’s 2019 and 2020 Technology Fast 500™, annual rankings of the fastest-growing North American companies in the technology, media, telecommunications, life sciences and energy tech sectors, based on percentages of fiscal year revenue growth over three-year periods. Fortress is focused on acquiring, developing and commercializing high-potential marketed and development-stage pharmaceutical products and product candidates. The company has five marketed prescription pharmaceutical products and over 25 programs in development at Fortress, at its majority-owned and majority-controlled partners and at partners it founded and in which it holds significant minority ownership positions. Such product candidates span six large-market areas, including oncology, rare diseases and gene therapy, which allow it to create value for shareholders. Fortress advances its diversified pipeline through a streamlined operating structure that fosters efficient drug development. The Fortress model is driven by a world-class business development team that is focused on leveraging its significant biopharmaceutical industry expertise to further expand the company’s portfolio of product opportunities. Fortress has established partnerships with some of the world’s leading academic research institutions and biopharmaceutical companies to maximize each opportunity to its full potential, including Alexion Pharmaceuticals, Inc., AstraZeneca, City of Hope, Fred Hutchinson Cancer Research Center, St. Jude Children’s Research Hospital and Nationwide Children’s Hospital. For more information, visit www.fortressbiotech.com.

Forward-Looking Statements

This press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. As used below and throughout this press release, the words “we”, “us” and “our” may refer to Fortress individually or together with one or more partner companies, as dictated by context. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; our dependence on third-party suppliers; risks relating to the COVID-19 outbreak and its potential impact on our employees’ and consultants’ ability to complete work in a timely manner and on our ability to obtain additional financing on favorable terms or at all; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our Securities and Exchange Commission filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as may be required by law, and we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The information contained herein is intended to be reviewed in its totality, and any stipulations, conditions or provisos that apply to a given piece of information in one part of this press release should be read as applying *mutatis mutandis* to every other instance of such information appearing herein.

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