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 31, 2021**

Fortress Biotech, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35366**	**20-5157386**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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	FBIO	Nasdaq Capital Market
9.375% Series A Cumulative Redeemable Perpetual Preferred Stock	FBIOP	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.

Acquisition of Proprietary Rights to Qbrexza®

On March 31, 2021, Journey Medical Corporation ("Journey"), a Fortress Biotech Inc. ("Fortress") partner company, issued a press release announcing that Journey and Dermira, Inc., a subsidiary of Eli Lilly and Company ("Dermira"), had executed an asset purchase agreement (the "APA") pursuant to which Journey would acquire (the "Acquisition") Dermira's proprietary rights to Qbrexza® (glycopyrronium), a prescription cloth towelette approved to treat primary axillary hyperhidrosis in people nine years of age and older. Under the terms of the APA, Journey will make an upfront $12.5 million cash payment to Dermira, and Dermira will be eligible to receive cash payments of up to $144 million in the aggregate upon the achievement of certain milestones. In addition, royalties ranging from the lower teen digits to the upper teen digits will be payable on sales of Qbrexza® products, which royalty amounts are subject to 50% diminution in the event of loss of exclusivity due to the introduction of an authorized generic. The APA includes customary representations, warranties, conditions, covenants, and indemnification rights and obligations of Journey and Dermira. Subject to receipt of required third-party approvals, the Acquisition is anticipated to close in the second quarter of 2021. A copy of such press release is furnished as Exhibit 99.1 to this report.

The foregoing description of the terms of the APA does not purport to be complete and is qualified in its entirety by reference to the full text of the APA, which will be filed with Fortress' Quarterly Report on Form 10-Q for the quarter ending on March 31, 2021. Fortress intends to redact certain confidential portions of the Agreement because such confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Qbrexza® Patent Litigation

Upon completion of the Acquisition, Journey will become substituted for Dermira as the plaintiff in U.S. patent litigation commenced by Dermira on October 21, 2020 in the U.S. District Court of Delaware (the "Patent Litigation") against Perrigo Pharma International DAC ("Perrigo") alleging infringement of certain patents covering Qbrexza® (the "Qbrexza® Patents"), which are included among the proprietary rights to Qbrexza® to be acquired pursuant to the APA. The Patent Litigation was initiated following the submission by Perrigo, in accordance with the procedures set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), of an Abbreviated New Drug Application, or ANDA. The ANDA seeks approval to market a generic version of Qbrexza®. prior to the expiration of the Qbrexza® Patents and alleges that the Qbrexza® Patents are invalid. Perrigo is subject to a 30-month stay preventing it from selling a generic version, but that stay is set to expire on March 9, 2023. Trial in the Patent Litigation is scheduled for September 19, 2022. Fortress cannot make any predictions about the final outcome of this matter or the timing thereof.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit Number	Description
99.1	Press Release issued by Journey Medical Corporation dated April 1, 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: April 1, 2021

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

Exhibit 99.1

Journey Medical Corporation Enters into a Definitive Agreement with Dermira, Inc., a Wholly-Owned Subsidiary of Eli Lilly and Company, to Acquire QBREXZA®

The first and only prescription cloth towelette approved to treat primary axillary hyperhidrosis in people nine-years of age and older is Journey Medical's seventh marketed dermatology product

Scottsdale, AZ and New York, NY – April 1, 2021 – Journey Medical Corporation ("Journey Medical"), a partner company of Fortress Biotech, Inc. (NASDAQ: FBIO) ("Fortress"), today announced that it has entered into a definitive agreement to acquire QBREXZA (glycopyrronium) in the U.S. from Dermira, Inc., a wholly-owned subsidiary of Eli Lilly and Company.

The transaction is expected to close early in the second quarter of this year. QBREXZA generated $24 million in net sales in the U.S. in 2020.

QBREXZA is the only topical product to be approved by the U.S. Food and Drug Administration (FDA) for treatment of primary axillary hyperhidrosis in adult and pediatric populations (ages nine-years and older) and is self-administered by patients. Additionally, QBREXZA is noted as a first-line treatment therapy for primary axillary hyperhidrosis by the International Hyperhidrosis Society (IHHS).

Claude Maraoui, President and Chief Executive Officer of Journey Medical, stated, "We are thrilled to expand our footprint in dermatology with the addition of QBREXZA to our growing portfolio of prescription dermatology brands. Acquiring QBREXZA will allow us to provide an accessible and convenient product to the millions of Americans who seek relief from excessive underarm sweating, many of whom remain undiagnosed and untreated."

In two key pivotal trials within adult and pediatric patients with primary axillary hyperhidrosis, use of QBREXZA resulted in clinically meaningful improvements in gravimetrically measured sweat production and disease severity, as measured by the Axillary Sweating Daily Diary, which was a validated, disease-specific patient-reported outcome developed in consultation with the FDA. The safety and efficacy of QBREXZA have been established in clinical trials with treatment for up to 48 weeks.

Hyperhidrosis is a condition of sweating beyond what is physiologically required for normal thermal regulation and affects an estimated 4.8% of the U.S. population, or approximately 15 million people.[1] Of these, 65 percent, or nearly 10 million people, suffer from sweating localized to the underarms (axillary disease). Studies have demonstrated that excessive sweating often impedes normal daily activities and can also result in occupational, emotional, psychological, social and physical impairment.[1,2]

Lindsay A. Rosenwald, M.D., Chairman, President and Chief Executive Officer of Fortress, added, "The acquisition of QBREXZA marks continued progress for our partner company, Journey Medical, and demonstrates the success of Fortress' unique business model, which is designed to acquire and rapidly advance potentially transformative products and product candidates to patients."

For additional information about QBREXZA, please visit https://www.QBREXZA.com/.

About QBREXZA® (glycopyrronium) cloth
QBREXZA (pronounced kew brex' zah) is an anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adult and pediatric patients, nine years of age and older. QBREXZA is applied directly to the skin and is designed to block sweat production by inhibiting sweat gland activation. For more information visit **www.QBREXZA.com**.

Important Safety Information
Contraindications: QBREXZA is contraindicated in patients with medical conditions that can be exacerbated by the anticholinergic effect of QBREXZA (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren's syndrome).

Warnings and Precautions
Worsening of Urinary Retention: QBREXZA should be used with caution in patients with a history or presence of documented urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, distended bladder), especially in patients with prostatic hypertrophy or bladder-neck obstruction. Instruct patients to discontinue use immediately and consult a physician should any of these signs or symptoms develop. Patients with a history of urinary retention were not included in the clinical studies.

Control of Body Temperature: In the presence of high ambient temperature, heat illness (hyperpyrexia and heat stroke due to decreased sweating) can occur with the use of anticholinergic drugs such as QBREXZA. Advise patients using QBREXZA to watch for generalized lack of sweating when in hot or very warm environmental temperatures and to avoid use if not sweating under these conditions.

Operating Machinery or an Automobile: Transient blurred vision may occur with use of QBREXZA. If blurred vision occurs, the patient should discontinue use until symptoms resolve. Patients should be warned not to engage in activities that require clear vision such as operating a motor vehicle or other machinery or performing hazardous work until the symptoms have resolved**.**

Adverse Reactions
The most common adverse reactions seen in ≥2% of subjects treated with QBREXZA were dry mouth (24.2%), mydriasis (6.8%), oropharyngeal pain (5.7%), headache (5.0%), urinary hesitation (3.5%), vision blurred (3.5%), nasal dryness (2.6%), dry throat (2.6%), dry eye (2.4%), dry skin (2.2%) and constipation (2.0%). Local skin reactions, including erythema (17.0%), burning/stinging (14.1%) and pruritus (8.1%) were also common.

Drug Interactions
Anticholinergics: Coadministration of QBREXZA with anticholinergic medications may result in additive interaction leading to an increase in anticholinergic adverse effects.

Avoid coadministration of QBREXZA with other anticholinergic-containing drugs.

Instructions for Administering QBREXZA
Instruct patients to use one cloth to apply QBREXZA to both axillae by wiping the cloth across one underarm, ONE TIME. Using the same cloth, apply the medication to the other underarm, ONE TIME.
Inform patients that QBREXZA can cause temporary dilation of the pupils and blurred vision if it comes in contact with the eyes.

Instruct patients to wash their hands with soap and water immediately after discarding the used cloth.

Use in Specific Populations
Pregnancy: There are no available data on QBREXZA use in pregnant women to inform a drug-associated risk for adverse developmental outcomes.

Lactation: There are no data on the presence of glycopyrrolate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for QBREXZA and any potential adverse effects on the breastfed infant from QBREXZA or from the underlying maternal condition.

Renal Impairment: The elimination of glycopyrronium is severely impaired in patients with renal failure.

Please see **Full Prescribing Information**

About Journey Medical Corporation
Journey Medical Corporation ("Journey Medical") is focused on identifying, acquiring and strategically commercializing innovative, differentiated dermatology products through its efficient sales and marketing model. The company currently markets seven products that help treat and heal common skin conditions. The Journey Medical team is comprised of industry experts with extensive experience commercializing some of the most successful prescription dermatology brands. Journey Medical is located in Scottsdale, Arizona and is a partner company of Fortress Biotech, Inc. (NASDAQ:FBIO). For additional information about Journey Medical, visit www.journeymedicalcorp.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 seven 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 pertaining to an unfavorable outcome in the ongoing Paragraph IV litigation involving QBREXZA to which Journey Medical recently became a party and/or generic competition resulting therefrom; 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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1. *Doolittle et. al., Hyperhidrosis: An Update on Prevalence and Severity in the United States. Arch Dermatol Res. 308:743-749, 2016.*
2. *Kamudoni, et al., The impact of hyperhidrosis on patients' daily life and quality of life: a qualitative investigation. Health and Quality of Life Outcomes, 15(1). 2017.*