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 19, 2023

KRYSTAL BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38210**	**82-1080209**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

2100 Wharton Street, Suite 701
Pittsburgh, Pennsylvania 15203
(Address of principal executive offices, including Zip Code)
Registrant's telephone number, including area code: (412) 586-5830

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	**KRYS**	**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).

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 7.01 Regulation FD Disclosure.

On May 19, 2023, Krystal Biotech, Inc. (the "Company") issued a press release announcing U.S. Food and Drug Administration ("FDA") approval of VYJUVEK™ (beremagene geperpavec-svdt) for the treatment of patients six months of age or older with either recessive or dominant Dystrophic Epidermolysis Bullosa. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The Company will be hosting an investor conference call and webcast to discuss the FDA approval of VYJUVEK on Friday, May 19, 2023, at 6 pm ET. To register and participate in the conference call, please go to: https://www.netroadshow.com/events/login?show=d32d1c5d&confId=51401. For those unable to listen to the live conference call, a replay will be available on the Investors section of the Company's website at www.krystalbio.com.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, 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, or incorporated by reference in any filing with the Securities and Exchange Commission ("SEC") by the Company under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events

In connection with the FDA approval, the Company is filing certain updated risk factors with this Current Report on Form 8-K for the purpose of supplementing and updating disclosures contained in the Company's prior filings with the SEC, including those discussed under the heading "Risk Factors," in the Company's prospectus supplement filed pursuant to Rule 424(b)(5) under the Securities Act of 1933, as amended, on May 8, 2023 with the SEC. The updated risk factors are filed herewith as Exhibit 99.2 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 19, 2023.
99.2	Updated Risk Factors
104	Cover Page Interactive Data file (embedded within the Inline XBRL document)

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.

Date: May 19, 2023

KRYSTAL BIOTECH, INC.

By: /s/ Krish S. Krishnan
Name: Krish S. Krishnan
Title: Chairman and Chief Executive Officer

Krystal Biotech Receives FDA Approval for the First-Ever Redosable Gene Therapy, VYJUVEK™ (beremagene geperpavec-svdt) for the Treatment of Dystrophic Epidermolysis Bullosa

- Dystrophic Epidermolysis Bullosa (DEB) is a serious rare genetic disease that affects the skin and mucosal tissues and is caused by one or more mutations in the *COL7A1* gene, resulting in lack of production of functional type VII collagen (COL7) protein
- VYJUVEK is a topical gel that addresses the genetic cause of DEB by restoring functional copies of the *COL7A1* gene to patients and is the only medicine available for patients in the US
- VYJUVEK is approved for the treatment of patients six months of age or older with either recessive or dominant DEB
- VYJUVEK is approved to be administered by a healthcare professional either in a healthcare professional setting (e.g., clinic) or a home setting
- Data from the pivotal Phase 3 (GEM-3) trial, published in the *New England Journal of Medicine*, demonstrated that the trial met its primary endpoint of complete wound healing at six months and its key secondary endpoint of complete wound healing at three months
- Rare Pediatric Disease Priority Review Voucher granted
- Company to host investor conference call on Friday, May 19, 2023 at 6:00 pm ET

PITTSBURGH, May 19, 2023 (GLOBE NEWSWIRE) – Krystal Biotech, Inc. (the Company) (NASDAQ: KRYS), a biotechnology company focused on developing and commercializing genetic medicines for patients with rare diseases, today announced the US Food and Drug Administration (FDA) has approved VYJUVEK™ (beremagene geperpavec-svdt) for the treatment of patients six months of age or older with dystrophic epidermolysis bullosa (DEB). VYJUVEK is designed to address the genetic root cause of DEB by delivering functional copies of the human *COL7A1* gene to provide wound healing and sustained functional COL7 protein expression with redosing. VYJUVEK is the first-ever redosable gene therapy and the first and only medicine approved by the FDA for the treatment of DEB, both recessive and dominant, that can be administered by a healthcare professional in either a healthcare professional setting or in the home.

DEB is a rare and serious disease that affects the skin and mucosal tissues caused by one or more mutations in the *COL7A1* gene. The *COL7A1* gene is responsible for the production of functional COL7 protein that forms anchoring fibrils necessary to bind the dermis (inner layer of the skin) to the epidermis (outer layer of the skin). The lack of functional anchoring fibrils in DEB patients leads to extremely fragile skin that blisters and tears with minor friction or trauma. DEB patients suffer from open wounds, which lead to recurrent skin infections and fibrosis that can cause fusion of fingers and toes, and ultimately increase the risk of developing an aggressive form of skin cancer.

“This is a devastating disease,” said M. Peter Marinkovich, M.D., primary investigator of the GEM-3 trial, Director of the Blistering Disease Clinic at Stanford Health Care and Associate Professor of Dermatology at the Stanford University School of Medicine. “Until now, doctors and nurses had no way to stop blisters and wounds from developing on dystrophic EB patient skin and all we could do was to give them bandages and helplessly watch as new blisters formed. VYJUVEK topical gene therapy changes all of this. VYJUVEK both heals patient wounds and prevents skin from re-blistering because it actually corrects the underlying skin defect of dystrophic EB. Because it’s safe and easy to apply directly to wounds, it doesn't require a lot of supporting technology or specialized expertise, making VYJUVEK highly accessible even to patients who live far away from specialized centers."

The FDA approval of VYJUVEK is based on two clinical studies. The GEM-1/2 trial was an intra-patient, open label, single center, randomized, placebo-controlled study showing that repeat topical applications of VYJUVEK were associated with durable wound closure, full-length cutaneous COL7 expression, and anchoring fibril assembly with minimal reported adverse events. The GEM-3 trial was an intra-patient, double-blinded, multi-center, randomized, placebo-controlled study that met both its primary endpoint of complete wound healing at six months and its key secondary endpoint of complete wound healing at three months. VYJUVEK was well tolerated with no drug-related serious adverse events or discontinuations due to treatment-related events.

“Data from our GEM-1/2 trial and our GEM-3 trial, published in *Nature Medicine* and the *New England Journal of Medicine*, respectively, demonstrated the strength of both studies showing that VYJUVEK safely and effectively improved wound healing,” said Suma Krishnan, President, Research & Development, Krystal Biotech, Inc. “For so many years, all we have been able to offer DEB patients was palliative care, but now, based on the strength of the Company’s clinical trial data, there is a safe and effective FDA approved treatment.”

“Today’s landmark approval of VYJUVEK as the first redosable gene therapy ushers in a whole new paradigm to treat genetic diseases and is an important milestone for patients affected by DEB as well as their families and caregivers," said Krish S. Krishnan, Chairman and Chief Executive Officer of Krystal Biotech, Inc. "We offer our sincere gratitude to DEB patients, caregivers, investigators, US regulators, and our employees who made this approval possible. For Krystal, this is a transformative achievement that highlights our commitment to developing and commercializing novel therapies for patients with rare diseases and demonstrates Krystal’s capability as a fully-integrated company ready to launch and bring VYJUVEK to patients as quickly as possible and deliver additional transformative medicines to patients as we advance our pipeline.”

VYJUVEK is expected to be available in the United States in the third quarter of 2023, and the Company will begin the promotion of VYJUVEK immediately. To meet the needs of patients, caregivers, and families as they start and continue their VYJUVEK treatment journey, the Company has developed Krystal Connect, a personalized support program. The program includes resources that can answer questions about VYJUVEK, verify health benefits, support treatment planning and administration and provide information about financial assistance for eligible patients. For more information, patients, caregivers and healthcare professionals can call Krystal Connect at 1-844-5-KRYSTAL.

With this approval, the FDA issued the Company a Rare Pediatric Disease Priority Review Voucher (PRV), which confers priority review to a subsequent drug application that would not otherwise qualify for priority review. The PRV program is designed to encourage the development of new drugs for the prevention or treatment of rare diseases.

“With the FDA approval of VYJUVEK, the DEB population has reached a monumental milestone in the treatment of this horrible disorder. Our hopes have now been realized for a safe and effective treatment for one of the most devastating symptoms of the disorder,” said Brett Kopelan, Executive Director of debra of America, the national organization dedicated to improving the lives of all people living with EB in the US. Mr. Kopelan added, “we thank Krystal for their dedication and commitment to bringing VYJUVEK to fruition. People living with DEB will now have a significant chance of having an improved quality of life and debra will

continue to work closely with Krystal to assure patients have ready access to VYJUVEK."

Outside of the US, the European Medicines Agency has granted VYJUVEK orphan drug designation and PRIME (PRIority MEdicines) eligibility for the treatment of DEB. The Company anticipates starting the official Marketing Authorization Application procedure in the second half of 2023 with a potential approval in 2024. The Company is also working with the Pharmaceuticals and Medical Devices Agency in Japan to study VYJUVEK and seek approval for potential launch in 2025.

Visit VYJUVEK.com for more information, including full Prescribing Information.

Investor Conference Call and Webcast

The Company will host an investor conference call and webcast to discuss the FDA's approval of VYJUVEK on Friday, May 19, 2023, at 6 pm ET.

To register and participate in the conference call, please go to: https://www.netroadshow.com/events/login?show=d32d1c5d&confId=51401. For those unable to listen to the live conference call, a replay will be available on the Investors section of the Company's website at www.krystalbio.com.

About VYJUVEK

VYJUVEK is a non-invasive, topical, redosable gene therapy designed to deliver two copies of the *COL7A1* gene when applied directly to DEB wounds. VYJUVEK was designed to treat DEB at the molecular level by providing the patient's skin cells the template to make normal COL7 protein, thereby addressing the fundamental disease-causing mechanism.

Indication

VYJUVEK is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients six months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse drug reactions (incidence >5%) were itching, chills, redness, rash, cough, and runny nose. These are not all the possible side effects with VYJUVEK. Call your healthcare provider for medical advice about side effects.

To report SUSPECTED ADVERSE REACTIONS, contact Krystal Biotech, Inc. at 1-844-557-9782 or FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

Contraindications

None.

Warnings and Precautions

VYJUVEK gel must be applied by a healthcare provider.

After treatment, patients and caregivers should be careful not to touch treated wounds and dressings for 24 hours.

Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from the first dressing change with a virucidal agent, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste. Dispose of the subsequent used dressings in a sealed plastic bag in household waste.
Patients should avoid touching or scratching wound sites or wound dressings.

In the event of an accidental exposure flush with clean water for at least 15 minutes.

For more information, see full US Prescribing Information.

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRYS) is a biotechnology company focused on developing and commercializing genetic medicines for patients with rare diseases. The Company's wide-ranging pipeline is based on its proprietary redosable HSV vector. Headquartered in Pittsburgh, Pennsylvania, the Company is led by an experienced management team, is fully-integrated, and has core capabilities in viral vector design, vector optimization, gene therapy manufacturing, and commercialization. For more information, please visit http://www.krystalbio.com, and follow @KrystalBiotech on LinkedIn and Twitter.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company including statements regarding the timing of the commercial availability of VYJUVEK in the U.S., Europe, and Japan and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including uncertainties associated with regulatory applications for marketing approvals, and such other important factors as are set forth under the caption "Risk Factors" in the Company's annual and quarterly reports on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

CONTACT:
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Updated Risk Factors

Risks Related to Our Business

We have limited experience as a commercial company and the sales, marketing, and distribution of VYJUVEK or any future approved products may be unsuccessful or less successful than anticipated.

We recently received FDA approval of VYJUVEK, and we have initiated a commercial launch of VYJUVEK in the United States. As a company, we have no prior experience commercializing a drug. The success of our commercialization efforts is difficult to predict and subject to the effective execution of our business plan, including, among other things, the continued development of our internal sales, marketing, and distribution capabilities and our ability to navigate the significant expenses and risks involved with the development and management of such capabilities. For example, our commercial launch may not develop as planned or anticipated, which may require us to, among others, adjust or amend our business plan and incur significant expenses. Further, given our lack of experience commercializing products, we do not have a track record of successfully executing a commercial launch. If we are unsuccessful in accomplishing our objectives and executing on our business plan, or if our commercialization efforts do not develop as planned, we may not be able to successfully commercialize VYJUVEK and any future approved products, we may require significant additional capital and financial resources, we may not become profitable, and we may not be able to compete against more established companies in our industry.

If we are unable to expand our marketing and distribution capabilities or collaborate with third parties to market and sell VYJUVEK or future product candidates for which we obtain marketing approval, we may be unable to generate sufficient product revenue.

To successfully commercialize any products that may result from our development activities, we need to continue to expand our marketing and distribution capabilities, either on our own or in collaboration with others. The development of our marketing and distribution effort is, and will continue to be, expensive and time-consuming and could delay any further product launch. We cannot be certain that we will be able to develop this capability successfully. We may enter into collaborations regarding VYJUVEK, or any future approved product candidates, with other entities to utilize their established marketing and distribution capabilities. However, we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize VYJUVEK or any future product candidates, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded sales, distribution and marketing operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of VYJUVEK and any future product candidates, if approved.

The market for VYJUVEK, and any future product candidates for which we obtain marketing approval, may be smaller than we expect.

We focus our research and product development on genetic medicines for patients with rare diseases. We base our market opportunity estimates on a variety of factors, including our estimates of the number of people who have these diseases, the potential scope of our approved product labels, the subset of people with these diseases who have the potential to benefit from treatment with VYJUVEK or any future product candidates, various pricing scenarios, and our understanding of reimbursement policies for rare diseases in particular countries. These estimates are based on many assumptions and may prove incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. Estimating market opportunities can be particularly challenging for rare indications, such as the ones we currently address, as epidemiological data is often more limited than for more prevalent indications and can require additional assumptions to assess potential patient populations. For example, as we begin to commercialize VYJUVEK in the United States and learn more about market dynamics and engage with regulators on additional potential marketing approvals, our view of our product's initial potential market opportunity will become more refined. Further, utilization of VYJUVEK per patient is expected to decrease over time as the overall wound burden is lowered. If we are unable to successfully commercialize VYJUVEK or any future product candidates with attractive market opportunities, our future product revenues may be smaller than anticipated, and our business may suffer. The addressable patient population in the United States and internationally may turn out to be lower than expected, or patients

may not be otherwise amenable to treatment with our products, all of which would adversely affect our business, financial condition, results of operations and prospects.