
**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): August 18, 2022

KRYSTAL BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38210
(Commission
File Number)

82-1080209
(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))

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 August 18, 2022, Krystal Biotech, Inc. (the “Company”) issued a press release announcing the U.S. Food and Drug Administration’s (the “FDA”) acceptance of the Company’s Biologics License Application (“BLA”) for beremagene geperpavec (“B-VEC”), as further described below in Item 8.01 of this Current Report on Form 8-K. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this item 7.01, including Item 99.1 attached here, is being furnished and 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On August 18, 2022, the FDA accepted the Company’s BLA for B-VEC for the treatment of patients with dystrophic epidermolysis bullosa. The application has been granted Priority Review designation and the FDA has set a Prescription Drug User Fee Act action date of February 17, 2023. The FDA stated in its BLA filing communication letter that it is not currently planning to hold an advisory committee meeting to discuss the application.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated August 18, 2022.
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: August 18, 2022

KRYSTAL BIOTECH, INC.

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

FDA Accepts Krystal Biotech's Biologics License Application for Dystrophic Epidermolysis Bullosa

- FDA granted Priority Review designation
- PDUFA target action date is February 17, 2023
- FDA stated that it is not currently planning to hold an advisory committee meeting

August 18, 2022

PITTSBURGH, August 18, 2022 (GLOBE NEWSWIRE) – Krystal Biotech, Inc. (the “Company”) (NASDAQ: KRYS), the leader in redosable gene therapy, today announced that the US Food and Drug Administration (FDA) has accepted for filing the Company’s Biologics License Application (BLA) for B-VEC for the treatment of patients with dystrophic epidermolysis bullosa (DEB). The application has been granted Priority Review designation, and the Prescription Drug User Fee Act (PDUFA) action date is February 17, 2023. The FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the application.

“We are delighted to receive the FDA’s acceptance of our BLA submission and move one step closer to potentially bringing a medicine to fundamentally treat DEB patients,” said Suma Krishnan, Co-Founder and President, Research & Development of Krystal Biotech. “We are committed to working closely with the FDA to bring this potential, first-ever treatment to patients living with DEB as quickly as possible.”

The BLA submission for B-VEC is supported by data from two placebo controlled clinical trials - the GEM-3 trial ([NCT04491604](#)) and the GEM-1/2 trial ([NCT03536143](#)).

Priority Review designation is granted to applications for medicines that treat a serious condition, and if approved, would provide a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition. B-VEC was previously granted Fast Track designation and Regenerative Medicine Advanced Therapy (RMAT) by the FDA for the treatment of DEB.

The Company plans to submit a marketing authorization application to the European Medicines Agency (EMA) in the second half of 2022.

About Dystrophic Epidermolysis Bullosa (DEB)

DEB is a rare and severe disease that affects the skin and mucosal tissues. It is caused by one or more mutations in a gene called *COL7A1*, which is responsible for the production of the protein type VII collagen (COL7) that forms anchoring fibrils that 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 from minor friction or trauma. DEB patients suffer from open wounds, which leads to skin infections, fibrosis which can cause fusion of fingers and toes, and ultimately an increased risk of developing an aggressive form of squamous cell carcinoma which, in severe cases, can be fatal.

About B-VEC

B-VEC is an investigational non-invasive, topical, redosable gene therapy designed to deliver two copies of the *COL7A1* gene when applied directly to DEB wounds. B-VEC 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.

The FDA and EMA have each granted B-VEC orphan drug designation for the treatment of DEB, and the FDA has granted B-VEC fast track designation and rare pediatric designation for the treatment of DEB. In addition, the FDA granted Regenerative Medicine Advanced Therapy (RMAT) to B-VEC for the treatment of DEB and the EMA granted Priority Medicines (PRIME) eligibility for B-VEC to treat DEB.

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRY5) is a pivotal-stage gene therapy company leveraging its proprietary, redosable gene therapy platform and in-house manufacturing capabilities to develop life-changing medicines for patients with serious diseases, including rare diseases in skin, lung, and other areas. 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 about the timing of the submission of the Company's EMA marketing authorization application, 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 review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates including B-VEC, the sufficiency of cash resources and need for additional financing 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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Source: Krystal Biotech, Inc.
