
**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 27, 2023

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 2.02 Results of Operation and Financial Condition.

On February 27, 2023, Krystal Biotech, Inc., a Delaware corporation (the “Company”), announced its fiscal year 2022 financial results. A copy of the Company’s press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

The information concerning financial results in this Form 8-K and in Exhibit 99.1 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information concerning financial results in this Form 8-K and in Exhibit 99.1 shall not be incorporated into any registration statement or other document filed with the Securities and Exchange Commission by the Company, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated February 27, 2023
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: February 27, 2023

KRYSTAL BIOTECH, INC.

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

Krystal Biotech Announces Fourth Quarter and Full Year 2022 Financial Results and Operational Progress

February 27, 2023

- *B-VEC PDUFA date May 19, 2023*
- *Data from the pivotal Phase 3 (GEM-3) trial of B-VEC for dystrophic epidermolysis bullosa published in the New England Journal of Medicine*
 - *Four pipeline clinical trials in dermatology, respiratory and aesthetics to initiate in 2023*
- *Strong balance sheet, closing the quarter with \$383.8 million in cash, cash equivalents and investments*

PITTSBURGH, February 27, 2022 (GLOBE NEWSWIRE) – [Krystal Biotech, Inc.](#), (the “Company”) (NASDAQ: KRYS), a biotechnology company focused on developing and commercializing genetic medicines, today reported financial results and key operational updates for the fourth quarter and year ending December 31, 2022.

“In 2022, we were focused on advancing B-VEC toward approval and getting commercially prepared for a potential launch this year, and I thank the entire Krystal team for their dedication and perseverance in helping us achieve our objectives,” said Krish S. Krishnan, Chairman and CEO of Krystal Biotech, Inc. He added, “Our focus in 2023 will be on advancing our pipeline and demonstrating the breadth of our gene delivery platform. We plan to have ASTRA, our second manufacturing facility, operational early this year which will enable us to advance our pipeline products in a timely manner.”

Dermatology

B-VEC (beremagene geperpavec) for Dystrophic Epidermolysis Bullosa (DEB)

- On January 5, 2023, the Company was [notified](#) by the U.S. Food & Drug Administration (FDA) that the Prescription Drug User Fee Act (PDUFA) date for the Company’s Biologics License Application (BLA) for B-VEC for the treatment of patients with DEB, will be May 19, 2023 and that proposed labeling discussions would begin no later than April 20, 2023. All clinical and manufacturing inspections conducted by the FDA as part of the BLA review process are now successfully complete.
- In December 2022, the results of the B-VEC pivotal Phase 3 GEM-3 trial were [published](#) in the *New England Journal of Medicine (NEJM)*. The GEM-3 trial was a randomized, double-blind, intra-patient, placebo-controlled, multi-center study designed to evaluate the efficacy and safety of B-VEC for the treatment of DEB. Two editorials were also published in the same issue of *NEJM* on the GEM-3 trial.
- The Company submitted a request for Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) in November 2022 for B-VEC for the treatment of DEB in patients 6 months and older. The Company was informed by the EMA in

January 2023 to modify the PIP waiver request to include patients between birth and 6 months. The Company is modifying the application so that the MAA procedure can officially start in the second half of 2023 with an approval expected in early 2024.

Rare Dermatological Pipeline

- The Company expects to initiate dosing in the Phase 2 cohort of its KB105-02 (JADE-1) trial in the first half of 2023. The Phase 2 cohort will enroll both pediatric and adult patients with TGM1 deficient autosomal recessive congenital ichthyosis for assessment of KB105 safety and efficacy. Details of the Phase 1/2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732.
- The Company plans to file an investigational new drug application (IND) for KB104 for the treatment of Netherton Syndrome in 2023.

Respiratory

KB407 for the treatment of Cystic Fibrosis (CF)

- The Company [announced](#) in August 2022, that the FDA had accepted its IND application to evaluate KB407 in a clinical trial to treat patients with CF. The Company is working closely with the Therapeutics Development Network of the Cystic Fibrosis Foundation to validate its clinical protocol and plans to initiate a Phase 1 dose ranging clinical (CORAL-1) trial in the US in the first half of 2023 to assess safety and preliminary efficacy. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05095246. The Company is presently screening patients for enrollment in a Phase 1 clinical trial in Australia to study safety and determine frequency of dosing application.
- In November 2022, the Company [presented](#) new preclinical data at the North American Cystic Fibrosis Conference, including assessments of KB407 biodistribution in the lungs of non-human primates following inhaled delivery.

KB408 for the treatment of Alpha-1 Antitrypsin Deficiency (AATD)

- The Company is completing preclinical and manufacturing activities for KB408 and expects to initiate a Phase 1 clinical trial for the treatment of AATD in the second half of 2023.

Aesthetics

KB301 for the treatment of Aesthetic Indications

- In November 2022, the Company [announced](#) up to nine months of durability results from the extension cohort of KB301 Phase 1 (PEARL-1) study in patients aged 55 to 76. Details of the PEARL-1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.
- The Company plans to initiate a Phase 2 (PEARL-2) study for the treatment of fine lines in 2023 following completion of a smaller proof-of-concept study in lateral canthal lines.

Fourth Quarter and Full Year 2022 Financial Results:

- Cash, cash equivalents, and investments totaled \$383.8 million on December 31, 2022.
- Research and development expenses for the fourth quarter ended December 31, 2022 were \$10.7 million, compared to \$9.0 million for the fourth quarter 2021, and \$42.5 million for the year ended December 31, 2022, compared to \$27.9 million for the year ended December 31, 2021.
- General and administrative expenses for the fourth quarter ended December 31, 2022 were \$24.0 million, compared to \$12.9 million for the fourth quarter 2021, and \$77.7 million for the year ended December 31, 2022, compared to \$40.4 million for the year ended December 31, 2021.
- Net losses for the quarters ended December 31, 2022 and 2021 were \$32.1 million and \$21.8 million, or \$(1.25) and \$(0.94) respectively, per common share (basic and diluted). Net losses for the years ended December 31, 2022 and 2021 were \$140.0 million and \$69.6 million, or \$(5.49) and \$(3.13), respectively, per common share (basic and diluted).
- For additional information on the Company's financial results for the year ended December 31, 2022, please refer to the Form 10-K filed with the Securities and Exchange Commission.

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](#).

About Jeune Aesthetics, Inc.

Jeune Aesthetics, Inc., a wholly-owned subsidiary of Krystal Biotech, Inc., is a biotechnology company leveraging a clinically validated gene-delivery platform to develop products to fundamentally address – and reverse – the biology of aging and/or damaged skin. For more information, please visit <http://www.jeuneinc.com>.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Krystal Biotech, Inc., including statements about the B-VEC PDUFA date of May 19, 2023; our focus in 2023 on advancing our pipeline and demonstrating the breadth of our gene delivery platform; our plans to have our second manufacturing facility operational; the timing of the Company's EMA marketing authorization application for B-VEC; our expectations regarding initiating dosing in the Phase 2 cohort of our KB105-02 (JADE-1) trial; our plans to file an investigational new drug application for KB104; our plan to initiate a Phase 1 dose ranging clinical (CORAL-1) trial for KB407 in the US in the first half of 2023; our plans to initiate a Phase 1 clinical trial for KB408 for

the treatment of AATD; our plans for the commencement of a Phase 2 study of KB301; 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 release.

CONTACT:

Investors and Media:

Meg Dodge

Krystal Biotech

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Condensed Balance Sheet:

(In thousands)	December 31, 2022	December 31, 2021
Balance sheet data:		
Cash and cash equivalents	\$ 161,900	\$ 341,246
Short-term investments	217,271	96,850
Long-term investments	4,621	64,371
Total assets	558,450	626,295
Total liabilities	36,219	32,719
Total stockholders' equity	\$ 522,231	\$ 593,576

Consolidated Statement of Operations:

(In thousands, except shares and per share data)	Three Months Ended December 31,		
	2022	2021	Change
Expenses			
Research and development	10,741	\$ 9,010	\$ 1,731
General and administrative	24,030	12,867	11,163
Total operating expenses	34,771	21,877	12,894
Loss from operations	(34,771)	(21,877)	(12,894)
Other Income (Expense)			
Interest and other income, net	2,719	71	2,648
Net loss	\$ (32,052)	\$ (21,806)	\$ (10,246)
Net loss per common share: Basic and diluted	\$ (1.25)	\$ (0.94)	
Weighted-average common shares outstanding: Basic and diluted	25,680,520	23,096,530	

(In thousands, except shares and per share data)	Years Ended December 31,		
	2022	2021	Change
Expenses			
Research and development	\$ 42,461	\$ 27,884	\$ 14,577
General and administrative	77,735	40,391	37,344
Litigation settlement	25,000	—	25,000
Total operating expenses	145,196	68,275	76,921
Loss from operations	(145,196)	(68,275)	(76,921)
Other Income (Expense)			
Interest and other income, net	5,221	197	5,024
Interest expense	—	(1,492)	1,492
Total other income (expense)	5,221	(1,295)	6,516
Net loss	\$ (139,975)	\$ (69,570)	\$ (70,405)
Net loss per common share: Basic and diluted	\$ (5.49)	\$ (3.13)	
Weighted-average common shares outstanding: Basic and diluted	25,491,721	22,196,846	

