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 9, 2022

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))

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 May 9, 2022, Krystal Biotech, Inc., a Delaware corporation (the "Company"), announced its financial results for the quarter ending March 31, 2022. 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.

Exhibit No.	Description
99.1	Press Release, dated May 9, 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: May 9, 2022

KRYSTAL BIOTECH, INC.

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

Krystal Biotech Announces First Quarter 2022 Financial Results and Reports Updates on Operational Progress

May 9, 2022

- Biologics License Application for B-VEC remains on track to file in the US in 2Q 2022 and Marketing Authorization in the EU on track to file in 2H 2022
- FDA allows dosing at a patient's home in the Open Label Extension Study of B-VEC for the treatment of DEB
- Positive Clinical Phase 1 (Pearl-1 Study) Efficacy Results for KB301 reported by Jeune Aesthetics, Inc., Krystal Biotech's subsidiary
- Strong balance sheet, closing the quarter with $468.0 million in cash, cash equivalents and investments

PITTSBURGH, May 9, 2022 (GLOBE NEWSWIRE) – Krystal Biotech, Inc., (the "Company") (NASDAQ: KRYS), the leader in redosable gene therapy, today reported financial results and key operational progress updates for the first quarter ending March 31, 2022.

"Our primary objective in 2022 is to prepare for the potential approval and launch of B-VEC in the U.S." said Krish S. Krishnan, chairman and chief executive officer. "We also remain focused on our B-VEC global regulatory filings and advancing our robust pipeline and we are fortunate to have a team with unwavering commitment and the financial strength to do so."

Program Highlights & Upcoming Events:

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

- On track to file a biologics license application ("BLA") with the U.S. Food and Drug Administration ("FDA") in 2Q 2022 and a marketing authorization application with the European Medicines Agency ("EMA") in 2H 2022.
- New GEM-3 Phase 3 results for B-VEC were presented at the 2022 American Academy of Dermatology Annual Meeting.
- Following feedback from the FDA, the Company plans to offer DEB patients enrolled in the GEM-3 open label extension study the ability to be dosed in-home by a health care professional. Further study details are available at www.clinicaltrials.gov under NCT identifier NCT04917887.

- Results from the Phase 1 and 2 study of B-VEC for the treatment of DEB were published in *Nature Medicine* which provided a comprehensive analysis of the data showing that repeat topical applications of B-VEC were associated with durable wound closure, full-length cutaneous type VII collagen (COL7) expression, and anchoring fibril assembly with minimal reported adverse events.

KB407 for treatment of Cystic Fibrosis ("CF")

- Phase 1 clinical trial of inhaled KB407 in patients with CF in Australia is expected to start in 2Q 2022. Details of the Phase 1 study are available at www.clinicaltrials.gov under NCT identifier NCT05095246.
- Anticipate filing an investigational new drug ("IND") application and initiating a Phase 1 trial clinical program in the U.S. in 2H 2022.

KB105 for the treatment of Autosomal Recessive Congenital Ichthyosis ("ARCI")

- Dosing the next cohort in the ongoing Phase 1/2 clinical trial of KB105 for the treatment of TGM1-deficient ARCI is on track to resume in 2022 and details of the Phase 1/2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732.

KB104 for Netherton Syndrome

- The Company continues to work towards an investigational new drug filing ("IND"), which is anticipated later this year.

KB301 for Aesthetic Indications

- Jeune Aesthetics, Inc., the Company's wholly-owned subsidiary, announced positive proof-of-concept efficacy data from Cohort 2 of the PEARL-1 study of KB301, with subjects from the trial to roll over into enrollment in a durability trial to look for duration of effect and for long term safety monitoring.
- Complete results from Cohort 1 focused on safety were presented at the 2021 Society for Investigative Dermatology Annual Meeting.
- Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.

Corporate Highlights:

- Jeune Aesthetics, Inc. announced its formation and installation of a Scientific Advisory Board, comprised of industry leaders to serve as strategic advisors assisting with program strategy and clinical development.
- In January 2022, Jing Marantz, M.D., PhD, MBA resigned from the Board of Directors to accept the position of Chief Business Officer with the Company and E. Rand Sutherland, M.D., MPH was appointed as a member of the Board of Directors.

Financial results for the quarter ended March 31, 2022:

- Cash, cash equivalents, and investments totaled $468.0 million on March 31, 2022.
- Research and development expenses for the first quarter ended March 31, 2022 were $9.3 million, compared to $6.2 million for the first quarter 2021.
- General and administrative expenses for the first quarter ended March 31, 2022 were $15.9 million, compared to $8.2 million for first quarter 2021.
- Net losses for the quarters ended March 31, 2022 and 2021 were $50.0 million and $15.8 million, or $(1.99) and $(0.74), respectively, per common share (basic and diluted).
- For additional information on the Company's financial results for the first quarter ended March 31, 2022, refer to form 10-Q filed with the SEC.

About Krystal Biotech, Inc.
Krystal Biotech, Inc. (NASDAQ: KRYS) 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.

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 clinical utility of B-VEC, at home dosing, the timing of the Company's BLA submission and EMA marketing authorization application, timing of the KB407 Phase 1 clinical trial program in Australia and the U.S., timing of dosing the next cohort in the ongoing Phase 1/2 clinical trial of KB105, timing of an IND filing for KB104, 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.

CONTACTS:
Investors and Media:
Meg Dodge
Krystal Biotech
mdodge@krystalbio.com

Source: Krystal Biotech, Inc.

Consolidated Balance Sheet Data:

(In thousands)	March 31, 2022	December 31, 2021
Balance sheet data:		
Cash and cash equivalents	$ 269,303	$ 341,246
Short-term investments	165,329	96,850
Long-term investments	33,339	64,371
Total assets	616,874	626,295
Total liabilities	68,320	32,719
Total stockholders’ equity	$ 548,554	$ 593,576

Consolidated Statement of Operations:

(In thousands, except shares and per share data)	Three Months Ended March 31, 2022	2021	Change
Expenses			
Research and development	$ 9,314	$ 6,201	$ 3,113
General and administrative	15,908	8,152	7,756
Litigation settlement	25,000	—	25,000
Total operating expenses	50,222	14,353	35,869
Loss from operations	(50,222)	(14,353)	(35,869)
Other Income (Expense)			
Interest and other income, net	257	33	224
Interest expense	—	(1,492)	1,492
Total other income (expense)	257	(1,459)	1,716
Net loss	$ (49,965)	$ (15,812)	$ (34,153)
Net loss per common share: Basic and diluted	$ (1.99)	$ (0.74)	
Weighted-average common shares outstanding: Basic and diluted	25,114,453	21,253,508	

Krystal