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): November 8, 2021

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 2.02 Results of Operation and Financial Condition.

On November 8, 2021, Krystal Biotech, Inc., a Delaware corporation (the "Company"), announced its financial results for the quarter ending September 30, 2021. 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 November 8, 2021
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: November 8, 2021

KRYSTAL BIOTECH, INC.

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

Exhibit 99.1

Krystal Biotech Reports Third Quarter 2021 Financial Results and Provides Update on Operational Progress

– Top-line results from the pivotal GEM-3 study of B-VEC in dystrophic epidermolysis bullosa (DEB) on track for 4Q21

– Enrollment in Phase 1 proof-of-concept study (PEARL-1 study) to treat aesthetic skin conditions is complete

– Strong balance sheet with September 30, 2021 cash, cash equivalents, and investments of $362.3 million

PITTSBURGH, November 8, 2021 – Krystal Biotech, Inc., ("Krystal") (NASDAQ: KRYS), the leader in redosable gene therapies for rare diseases, today reported financial results and key operational progress updates for the third quarter ending September 30, 2021.

"We've had a productive third quarter and the momentum continues to build with topline data expected from the pivotal GEM-3 trial evaluating B-VEC this quarter," said Krish Krishnan, Chairman and CEO of Krystal Biotech, Inc. "If positive, this will be a significant milestone for patients living with DEB and strong validation of our redosable gene therapy platform. Outside of the B-VEC program, we are on track to open enrollment in our Phase 1 study of KB407 for cystic fibrosis in Australia and deliver Phase 1 proof-of-concept efficacy data for KB301 from our wholly-owned subsidiary, Jeune Aesthetics in early 2022. As we continue to advance and grow our pipeline, we are also expanding our manufacturing footprint with continued progress on our second facility – ASTRA – which we expect will come online in 2022."

Program Highlights & Upcoming Events:

B-VEC for DEB

- The Company recently announced completion of the pivotal GEM-3 trial of topical B-VEC for the treatment of DEB, and expects topline data in the fourth quarter of 2021. Details of the pivotal Phase 3 study can be found at www.clinicaltrials.gov under NCT identifier NCT04491604.
- Enrollment of DEB patients into the open label extension ("OLE") study, including patients who participated in the Phase 3 study as well as new participants who were unable to participate in the Phase 3 study who meet all enrollment criteria, is ongoing. Details of the OLE study can be found at www.clinicaltrails.gov under NCT identifier NCT04917874.

KB407 for Cystic Fibrosis

- More detailed results from the Good Laboratory Practice toxicology and biodistribution study were presented in a poster at the virtual 2021 North American Cystic Fibrosis ("CF")Conference that took place November 2-5.
- Krystal expects to initiate a Phase 1 clinical trial of inhaled KB407 in patients with CF in Australia in the fourth quarter of 2021 following the announcement that the Bellberry Human Research Ethics Committee granted approval to conduct the study. The Company plans to initiate a clinical trial of KB407 in patients with CF in the U.S. in 2022.

KB105 for TGM1-ARCI

- Dosing in the next cohort in the ongoing Phase 2 clinical trial of KB105 for the treatment of TGM1-deficient autosomal recessive congenital ichthyosis ("TGM1-ARCI") is on track to resume in 2022.

KB301 for Aesthetic Indications

- Jeune Aesthetics, Inc. ("Jeune"), the Company's wholly-owned subsidiary, is currently conducting a Phase 1 proof-of-concept study of intradermal KB301, designed to deliver the human *COL3A1* gene to enable increased endogenous production of type III collagen. Details of the study can be found at www.clinicaltrails.gov under NCT identifier NCT04540900.
- Enrollment in the second cohort is complete and Jeune expects to announce initial data, including efficacy data, in early 2022.
- Jeune will present results from in vitro and in vivo proof-of-concept studies for KB303, the company's preclinical pipeline candidate designed to enable the targeted delivery of human elastin as a novel therapeutic option to improve skin elasticity at the upcoming virtual American Society for Dermatologic Surgery 2021 meeting, being held on November 19-21.

KB104 for Netherton Syndrome

- The Company continues to work towards an IND filing, which is anticipated in 2022.

Corporate Highlights:

- In September 2021, the Company announced the appointment of Laurent Goux as the General Manager of Europe. Mr. Goux has more than 20 years of global biotechnology experience, including serving as the Head of Global Strategic Marketing and Market Access at Galderma.
- In October 2021, the Company announced the launch of a no-charge genetic testing program for all types of Epidermolysis Bullosa ("EB"). The goal of the program, called Krystal Decode DEB™, is to help patients with the dystrophic form of this genetic condition, also known as DEB, get a definitive diagnosis sooner, with highly accurate results obtained with a blood or cheek swab sample.

Financial results for the quarter ended September 30, 2021:

- Cash, cash equivalents, and investments totaled $362.3 million on September 30, 2021, compared to $271.3 million as of December 31, 2020.
- Research and development expenses for the third quarter ended September 30, 2021 were $6.1 million, compared to $5.1 million for the third quarter 2020, and $18.9 million for the nine months ended September 30, 2021, compared to $12.3 million for the nine months ended September 30, 2020.
- General and administrative expenses for the third quarter ended September 30, 2021 were $9.6 million, compared to $4.6 million for third quarter 2020, and $27.5 million for the nine months ended September 30, 2021, compared to $10.3 million for the nine months ended September 30, 2020.
- Net losses for the quarters ended September 30, 2021 and 2020 were $15.6 million and $9.6 million, or $(0.70) and $(0.49), respectively, per common share (basic and diluted). Net losses for the nine months ended September 30, 2021 and 2020 were $47.8 million and $21.8 million or $(2.18) and $(1.18), respectively, per common share (basic and diluted)
- For additional information on the Company's financial results for the third quarter ended September 30, 2021, refer to form 10-Q filed with the U.S. Securities and Exchange Commission.

About Krystal Biotech

Krystal Biotech, Inc. (NASDAQ:KRYS) is a pivotal-stage gene therapy company leveraging its novel, redosable gene therapy platform and in-house manufacturing capabilities to develop therapies to treat serious rare diseases. 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 Krystal Biotech, Inc., including but not limited to statements about the development of Krystal's product candidates,and the expected timing for ASTRA coming online; 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: the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or trials will be indicative of the results of ongoing or future trials, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, the availability or commercial potential of product candidates, 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 Krystal'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 Krystal's views as of the date of this release. Krystal anticipates that subsequent events and developments will cause its views to change. However, while Krystal 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 Krystal's views as of any date subsequent to the date of this release.

CONTACTS:

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Consolidated Balance Sheet Data:

(In thousands)	September 30, 2021	December 31, 2020
Balance sheet data:		
Cash and cash equivalents	$ 286,614	$ 268,269
Working capital	310,033	259,606
Total assets	451,095	310,844
Total liabilities	42,858	18,760
Total stockholders' equity	$ 408,237	$ 292,084

Consolidated Statement of Operations:

(In thousands, except shares and per share data)	Three Months Ended September 30, 2021	2020	Change
Expenses			
Research and development	$ 6,080	$ 5,100	$ 980
General and administrative	9,572	4,580	4,992
Total operating expenses	15,652	9,680	5,972
Loss from operations	(15,652)	(9,680)	(5,972)
Other Income (Expense)			
Interest and other income, net	63	70	(7)
Total other income (expense)	63	70	(7)
Net loss	$ (15,589)	$ (9,610)	$(5,979)
Net loss per common share: Basic and diluted	$ (0.70)	$ (0.49)	
Weighted-average common shares outstanding: Basic and diluted	22,212,266	19,676,016	

(In thousands, except shares and per share data)	Nine Months Ended September 30, 2021	2020	Change
Expenses			
Research and development	$ 18,875	$ 12,264	$ 6,611
General and administrative	27,524	10,315	17,209
Total operating expenses	46,399	22,579	23,820
Loss from operations	(46,399)	(22,579)	(23,820)
Other Income (Expense)			
Interest and other income, net	127	795	(668)
Build to suit interest expense	(1,492)	—	(1,492)
Total other income (expense)	(1,365)	795	(2,160)
Net loss	$ (47,764)	$ (21,784)	$ (25,980)
Net loss per common share: Basic and diluted	$ (2.18)	$ (1.18)	
Weighted-average common shares outstanding: Basic and diluted	21,893,656	18,477,495	

Source: Krystal Biotech, Inc.