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): March 10, 2020

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**

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 March 10, 2020, Krystal Biotech, Inc., a Delaware corporation (the "Company"), announced its fiscal year 2019 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.

Exhibit No.	Description
99.1	Press Release, dated March 10, 2020.

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: March 10, 2020

KRYSTAL BIOTECH, INC.

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

Krystal Biotech Reports 2019 Financial Results and Business Progress

Phase 3 trial of B-VEC (Beremagene Geperpavec, previously "KB103") to treat dystrophic epidermolysis bullosa ("DEB") to start in 1H 2020

Interim results on Phase 1/2 clinical study on KB105 to be announced in 1H 2020

Planned filing of two Investigational New Drug Applications ("INDs"), one for rare skin disease and another for an aesthetic skin indication, in 2H 2020

Company strengthens portfolio with four new patents covering B-VEC, KB105 and the STAR-D platform

PITTSBURGH, March 10, 2020 – Krystal Biotech Inc., ("Krystal") (NASDAQ: KRYS), a gene therapy company developing medicines to treat dermatological diseases, announces financial results for 2019 and an update on its business progress.

Krish S. Krishnan, chairman and chief executive officer of Krystal Biotech stated, "2020 is expected to be an exciting year for Krystal as we get ready to commence the pivotal study of B-VEC, and announce interim Phase 1/2 clinical results on KB105 in the first half of 2020. In January, we hired a chief commercial officer to build out our market access and commercial team for the anticipated launch of B-VEC and also broke ground on our second cGMP manufacturing facility, ASTRA, a 100,000 square foot facility that will be built-out and validated over the next 12-15 months to serve our future pipeline products. On the research front, our research, clinical and regulatory teams are working to initiate a Phase 1 clinical study in an aesthetic skin indication and file an IND for a third rare disease indication in the second half of 2020.

"2019 was a busy year for Krystal as we worked to become fully-integrated in the gene therapy space. On the clinical front, we announced positive results from the Phase 1/2 results of B-VEC to treat DEB and the initiation of a Phase 1/2 clinical study of KB105 for the treatment of TGM1-deficient autosomal recessive congenital ichthyosis ("ARCI") in October. On the manufacturing front, we initiated manufacturing of our Phase 3 clinical material at ANCORIS, our first cGMP facility for the clinical and future commercial production of B-VEC, that was completed early in 2020. We strengthened our patent portfolio with the issuance of our first foreign patent for B-VEC and broadened our platform patent for skin-targeted therapeutics as well as methods of its use for delivering any effector of interest to the skin."

2019 and Recent Corporate Highlights

Manufacturing

- On January 24, 2020, we announced the ground-breaking of the second commercial gene therapy facility in Findlay Township, Pennsylvania. The facility, named ASTRA, will have the capacity to produce commercial gene therapy medicines to treat patients suffering from debilitating rare diseases. The ASTRA facility is being designed as a state-

of-the-art cGMP manufacturing facility that, beyond expanding Krystal's current production platform, will allow the in-house incorporation of raw material preparation, excipient manufacturing, testing, packaging, labeling and distribution, fully-integrating all components of the supply chain from starting materials to patient experience. The ASTRA facility will initially be used as a commercial back up facility for B-VEC, which is being developed for the treatment of dystrophic epidermolysis bullosa, a rare and devastating skin disorder, and expand to produce investigational and commercial material for our pipeline products.

- In January 2019, we completed the construction of our first commercial scale cGMP-compliant manufacturing facility, ANCORIS, to enhance supply chain control, increase supply capacity for clinical trials and ensure commercial demand is met in the event that B-VEC and our other product candidates receive marketing approval. The clinical material for the pivotal trial has been produced and initial commercial launch material of B-VEC will be produced at ANCORIS.

Product Development

- In October 2019, we announced positive results from our Phase 1/2 clinical trial of B-VEC at Stanford University. For more information on the B-VEC Phase 1/2 clinical trial, visit: http://ir.krystalbio.com/news-releases/news-release-details/krystal-biotech-announces-final-update-phase-12-clinical-trial. We plan on commencing the pivotal trial in the first half of 2020.
- In September 2019, we initiated the Phase 1/2 clinical trial of KB105. We anticipate announcing interim Phase 1/2 clinical results in the first half of 2020.

Intellectual Property

- In January 2020, Krystal diversified its patent estate through the issuance of U.S. patent number 10,525,090, covering KB105, as well as medical applications of this product for treating autosomal recessive congenital ichthyosis (ARCI). We believe the speed in which the patent prosecution was successfully concluded for this application is indicative of Krystal's pioneering work in HSV-based gene therapies in the field of dermatology.
- In December 2019, Krystal strengthened its international patent portfolio covering B-VEC, when the European Patent Office issued an intent to grant European patent application number 16826873 directed, in part, to pharmaceutical compositions comprising B-VEC, as well as uses thereof.
- In October 2019, the U.S. Patent and Trademark Office ("USPTO") granted Krystal patent number 10,441,614, covering its fully integrated vector platform, STAR-D, for skin-targeted therapeutics, as well as methods of its use for delivering any effector of interest to the skin. This new U.S. patent provides further validation of Krystal's novel work in the field of rare skin diseases leveraging its HSV-1-based gene therapy technologies.

- In September 2019, the Australian patent office granted Krystal its first foreign patent (application number 2016401692) in Australia for B-VEC. This patent covers pharmaceutical compositions comprising B-VEC, as well as medical uses such as the treatment of wounds, disorders, or diseases of the skin, particularly those found in epidermolysis bullosa patients].

Financing

- On June 27, 2019, Krystal completed a public offering of 2,500,000 shares of its common stock to the public at $40.00 per share. Net proceeds to Krystal from the offering were $93.8 million after deducting underwriting discounts and commissions and other offering expenses payable by Krystal. On July 3, 2019, the underwriters exercised their option to purchase an additional 353,946 shares of common stock at $40.00 per share for additional net proceeds of $13.3 million after deducting underwriting discounts and commissions.

Other Developments

- During the first two months of 2020, we strengthened Krystal's senior management team with the addition of Jennifer Chien as chief commercial officer, Kathryn Romano as chief accounting officer, and J. Christopher Naftzger as chief legal officer and corporate secretary.
- On October 10, 2019, the European Medicines Agency (EMA) issued a positive opinion on Krystal's application for orphan indication of KB105, which is currently in clinical development for treatment of patients with ARCI, which is associated with transglutaminase 1 (TGM-1).
- On March 29, 2019, the EMA granted access to its PRIME (PRIority MEdicines) scheme for B-VEC.

Financial Results for the Year Ended December 31, 2019

- Cash, cash equivalents and short-term investments totaled $193.7 million on December 31, 2019.
- Research and development expenses for the year ended December 31, 2019 were $15.6 million, compared to $7.8 million for 2018.
- General and administrative expenses for the year were $6.5 million, compared to $4.2 million for 2018.
- Net losses for the years ended December 31, 2019 and 2018 were $19.1 million and $10.9 million or ($1.20) and ($0.97) per common share (basic and diluted), respectively.

For additional information on Krystal's financial results for the year ended December 31, 2019, refer to form 10K filed with the SEC.

About Krystal Biotech

Krystal Biotech, Inc. (NASDAQ:KRYS) is a gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from dermatological diseases. For more information, please visit http://www.krystalbio.com.

About B-VEC

B-VEC (Beremagene Geperpavec, previously "KB103") is Krystal's lead product candidate that seeks to use gene therapy to treat dystrophic epidermolysis bullosa, or DEB, an incurable skin blistering condition caused by a lack of collagen in the skin. B-VEC is a replication-defective, non-integrating viral vector that has been engineered employing Krystal's STAR-D platform to deliver functional human COL7A1 genes directly to the patients' dividing and non-dividing skin cells. HSV-1 is Krystal's proprietary vector that can penetrate skin cells more efficiently than other viral vectors. Its high payload capacity allows it to accommodate large or multiple genes and its low immunogenicity makes it a suitable choice for direct and repeat delivery to the skin.

About KB105

KB105 is Krystal's second product candidate, currently in preclinical development, and seeks to use gene therapy to treat patients with TGM1-deficient ARCI. KB105 is a replication-defective, non-integrating viral vector that has been engineered employing Krystal's STAR-D platform to deliver functional human TGM1 gene directly to the patients' dividing and non-dividing skin cells. HSV-1 is Krystal's replication-deficient, non-integrating viral vector that can penetrate skin cells more efficiently than other viral vectors. Its high payload capacity allows it to accommodate large or multiple genes and its low immunogenicity makes it a suitable choice for direct and repeat delivery to the skin.

About the STAR-D Gene Therapy Platform

Krystal's **S**kin **TAR**geted **D**elivery platform, or STAR-D platform, is a proprietary gene therapy platform consisting of an engineered viral vector and skin-optimized gene transfer technology that Krystal is employing to develop off-the-shelf treatments for dermatological diseases for which there are no known effective treatments. The company believes that the STAR-D platform provides an optimal approach for treating dermatological conditions due to the nature of the HSV-1 viral vector it has created. Certain inherent features of the HSV-1 virus, combined with the ability to strategically modify the virus in the form employed as a gene delivery backbone, provide the STAR-D platform with several advantages over other viral vector platforms for use in dermatological applications.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Krystal, including but not limited to statements about the development of Krystal's product candidates, such as plans for the design, conduct and timelines of ongoing clinical trials of bercolagene telserpavec ("B-VEC") and KB105, the clinical utility of B-VEC and KB105 and Krystal's plans for filing of regulatory approvals and efforts to bring B-VEC and KB105 to market, the market opportunity for and the potential market acceptance of B-VEC and KB105, plans to pursue research and development of other product candidates, the sufficiency of Krystal's existing cash resources 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 including B-VEC and KB105, 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:

Investors:
Ashley R. Robinson
LifeSci Advisors
arr@lifesciadvisors.com

Media:
Darren Opland, PhD
LifeSci Communications
darren@lifescicomms.com

Source: Krystal Biotech, Inc.