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 4, 2019

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 7.01 Regulation FD Disclosure.

On November 4, 2019, Krystal Biotech, Inc., a Delaware corporation (the "Company"), announced its third quarter 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 November 4, 2019.

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 4, 2019

KRYSTAL BIOTECH, INC.

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

Krystal Biotech Reports Third Quarter 2019 Financial and Operating Results

Alignment with FDA on GMP Commercial Manufacturing Process for KB103 (Bercolagene telserpavec, "B-VEC")

KB105 granted Fast Track Designation by the FDA

Platform patent for delivering any effector to the skin granted by USPTO

PITTSBURGH, Nov. 4, 2019 – Krystal Biotech Inc., ("Krystal") (NASDAQ: KRYS), a gene therapy company developing medicines to treat dermatological diseases, announced financial results for third quarter 2019, recent corporate highlights and upcoming milestones.

"Following our CMC meeting, we believe we have a scalable GMP commercial process in place to fulfill future patient demand and anticipate a modest impact to our previously disclosed B-VEC timeline," said Krish S. Krishnan, chairman and chief executive officer of Krystal Biotech. "We plan on announcing our agreement with the FDA on trial design and endpoints prior to initiating the B-VEC pivotal trial."

Corporate Highlights

CMC alignment and End of Phase 2 meeting

- CMC alignment with the U.S. Food and Drug Administration (FDA) includes a) support for the proposed commercial manufacturing process, b) the proposed analytical methods and corresponding qualification and validation plans – inclusive of key release assays such as potency, purity and identity and c) the comparability protocol, which helps assess how similar the product derived from our GMP process runs in our Ancoris facility is to the original product used in the Phase 1/2 trial of KB103. Analytical methods are used to assess how reliably and consistently the key product characteristics can be determined in order to ensure patients receive safe and effective product.
- Following alignment with the FDA on our commercial process and engineering run, we plan to initiate manufacturing of our Phase 3 clinical material at Krystal's Ancoris GMP facility in early November. We anticipate releasing this Phase 3 clinical material in 1Q 2020 and will initiate the B-VEC Phase 3 pivotal trial following release of Phase 3 material.
- We expect to meet with the FDA before the end of 2019 to finalize trial design and endpoints for the upcoming pivotal trial of B-VEC. Earlier this year B-VEC received RMAT designation from the FDA and PRIME eligibility from the EMA.

Positive results from Phase 1/2 trial of B-VEC

- In October 2019, we announced positive results from our Phase 1/2 of B-VEC that commenced in December 2018 at Stanford University. Safety data from all patients showed that B-VEC was well tolerated with no adverse events reported. The Phase 1 portion of the trial commenced in May 2018 at Stanford University, and we announced positive interim results from this clinical study on two patients in October 2018. The Phase 2 portion of the trial commenced in December 2018 at Stanford University, and we announced positive interim results from this clinical study on two patients in June 2019. In addition, we enrolled two additional patients in the Phase 2 study in June 2019.
- In the combined Phase 1 and Phase 2 study, 9 out of 10 wounds treated with B-VEC closed completely (100%). The average time to 100% wound closure on all B-VEC treated wounds in combined Phase 1 and Phase 2 study was 17.4 days (median 14 days). In the combined study, the average duration of wound closure on two patients following 100% wound closure as of the last follow up was 113 days (median 110 days). We are in conversations with the FDA to get alignment on GMP commercial manufacturing process and agreement on pivotal endpoints and plan to initiate our pivotal study of B-VEC shortly thereafter.

KB105

- In September 2019, we initiated a Phase 1/2, first in-human trial of our second product candidate, KB105 (GEM-3 trial), an HSV-1 based gene therapy engineered to deliver a human transglutaminase-1 (TGM1) gene to patients with TGM1-deficient autosomal recessive congenital ichthyosis (ARCI). TGM1-deficient ARCI is a debilitating rare skin disease characterized by excessive, thick scaling of the skin, causing multiple chronic health conditions. There are approximately 23,000 cases of TGM1-deficient ARCI worldwide and about 400 new cases per year globally. We have dosed two patients in the GEM-3 trial and anticipate announcing interim results in 1H 2020.
- In October 2019, the FDA granted Fast Track designation to KB105, the company's HSV-1 based gene therapy engineered to deliver a functional human TGM1 gene in patients with TGM1 deficient ARCI. KB105 is currently in a Phase 1/2 clinical study (GEM-3) with interim data expected in mid-2020. Fast Track Designation is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the Fast Track Designation provision is to help facilitate development and expedite the review and potential approval of drugs to treat serious and life-threatening conditions. Sponsors of drugs that receive Fast Track Designation have the opportunity for more frequent interactions with the FDA review team throughout the development program. These can include meetings to discuss study design, data required to support approval, or other aspects of the clinical program. Additionally, products that have been granted Fast Track Designation may be eligible for priority review of a New Drug Application (NDA) and the FDA may consider reviewing portions of an NDA before the sponsor submits the complete application (Rolling Review).
- In October 2019, the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) granted orphan drug designation to KB105 for the treatment of TGM1 deficient ARCI. Orphan designation in the EU allows Krystal Biotech to benefit from a number of key incentives, including reduced regulatory fees, protocol assistance, and market exclusivity, to develop a medicine for the treatment of a rare disease affecting not more than five in 10,000 people in the European Union. KB105 was previously granted orphan drug designation by the FDA in August 2018 and is eligible for the pediatric review voucher (PRV).

Patents

- In October 2019, the US Patent and Trademark Office ("USPTO") granted the Company 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 the Company'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 the Company its first foreign patent (application number 2016401692) in Australia for its lead product candidate 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. The Australian patent complements the Company's two existing US patents for B-VEC.

Pipeline

- We are planning on filing an IND on KB104 for the treatment of Netherton Syndrome and an IND for KB301 (an undisclosed aesthetic condition) in 1H 2020.

Financial results for the quarter ended September 30, 2019

- Cash, cash equivalents and short-term investments totaled $203.2 million on September 30, 2019.
- Research and development expenses for the third quarter ended September 30, 2019 were $3.9 million, compared to $1.9 million for third quarter 2018.
- General and administrative expenses for the third quarter ended September 30, 2019 were $1.5 million, compared to $1.1 million for third quarter 2018.
- Net losses for the quarters ended September 30, 2019 and 2018 were $4.3 million and $2.8 million or ($0.25) and ($0.26) per common share (basic and diluted), respectively.

For additional information on the Company's financial results for the quarter ended September 30, 2018, refer to form 10-Q filed as with the SEC.

About KB103

KB103 is Krystal's lead product candidate, currently in clinical development, 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. KB103 is a replication-defective, non-integrating viral vector that has been engineered using the HSV-1 virus employing Krystal's STAR-D platform to deliver functional human COL7A1 genes directly to the patients' dividing and non-dividing skin cells. Krystal's vector 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 Dystrophic Epidermolysis Bullosa, or DEB

Dystrophic epidermolysis bullosa, or DEB, is an incurable, often fatal skin blistering condition caused by a lack of collagen protein in the skin. It is caused by mutations in the gene coding for type VII collagen, or COL7, a major component of the anchoring fibrils, which anchor the epidermis to the underlying dermis, and provide structural adhesion in a normal individual. The lack of COL7 in DEB patients causes blisters to occur in the dermis as a result of separation from the epidermis. This makes the skin incredibly fragile, leading to blistering or skin loss at the slightest friction or knock. It is progressive and incredibly painful.

The most severe form of DEB is recessive DEB, or RDEB, which is caused by null mutations in the COL7A1 gene. DEB also occurs in the form of dominant DEB, or DDEB, which is considered to be a milder form of DEB. There are no known treatments which affect the outcome of either form of the disease, and the current standard of care for DEB patients is limited to palliative treatments. Krystal is developing KB-103 for the treatment of the broad DEB population, including both recessive and dominant forms of the disease.

About KB105

KB105 is Krystal's second product candidate, currently in clinical development, seeks to use gene therapy to treat patients with TGM-1 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 TGM-1 gene directly to the patients' dividing and non-dividing skin cells.

About Autosomal Recessive Congenital Ichthyosis

Transglutaminase 1 (TGM-1) is an essential epidermal enzyme that facilitates the formation of the epidermal barrier, which prevents dehydration, and protects the skin from unwanted toxins and surface microorganisms. The loss of TGM-1-activity results in the severe genetic skin disease autosomal recessive congenital ichthyosis (ARCI). Most patients with a TGM-1-deficiency exhibit life-long pronounced scaling with increased trans epidermal water loss (TEWL). The scales are plate-like, often of a dark color, and cover the whole-body surface area. Erythroderma is either absent or minimal. Such patients usually have ectropion and, at times, eclabium, hypoplasia of joint and nasal cartilage, scarring alopecia, especially at the edge of the scalp, and palmoplantar keratoderma. Additional complications include episodes of sepsis, fluid and electrolyte imbalances due to impaired skin barrier function, and failure to thrive, especially during neonatal period and infancy. Severe heat intolerance, and nail dystrophy are also frequently observed. TGM-1-deficient ARCI is associated with increased mortality in the neonatal period and has a dramatic impact on quality of life. No efficient treatment is available; current therapy only relieves some symptoms. There are approximately 23,000 cases of TGM1 deficient ARCI worldwide and about 400 new cases per year globally.

About the STAR-D Gene Therapy Platform

Krystal has developed a proprietary gene therapy platform, the Skin TARgeted Delivery platform, or STAR-D platform, that consists of an engineered HSV-1 viral vector and skin-optimized gene transfer technology, to develop off-the-shelf treatments for dermatological diseases. We believe that the STAR-D platform provides an optimal approach for treating dermatological conditions due to the nature of the vector. 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.

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.

Forward-Looking Statements

This press release includes certain disclosures that contain “forward-looking statements,” including, without limitation, statements regarding development timelines for KB103, the ability of KB103 to be a transformative treatment option for DEB patients and the ability of our Ancoris manufacturing facility to supply KB103 for the forthcoming clinical trial . You can identify forward-looking statements because they contain words such as “anticipate”, “believes” and “expects.” Forward-looking statements are based on Krystal’s current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees nor assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Krystal’s filings with the Securities and Exchange Commission, including its registration statement on Form S-3, and in its Forms 10-K and 10-Q, as modified or supplemented from time to time, under the caption “Risk Factors.”

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Source: Krystal Biotech, Inc.