Krystal Biotech Announces Third Quarter 2022 Financial Results and Operational Highlights

November 7, 2022

- *Received US FDA filing acceptance of B-VEC BLA with Priority Review designation for treatment of dystrophic epidermolysis bullosa; PDUFA target action date of February 17, 2023*
- *Notified of no Advisory Committee meeting or a need for Risk Evaluation and Mitigation Strategies following mid-cycle BLA review for the B-VEC application*
- *Received positive opinion from EMA Pediatric Committee on the Pediatric Investigation Plan for B-VEC for treatment of dystrophic epidermolysis bullosa; on track to submit a marketing authorization application in fourth quarter of 2022*
- *Strong balance sheet, closing the quarter with $407.0 million in cash, cash equivalents and investments*

PITTSBURGH, Nov. 07, 2022 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc., (the "Company") (NASDAQ: KRYS), a biotechnology company focused on developing and commercializing genetic medicines for patients with rare diseases, today reported financial results and key operational progress updates for the third quarter ended September 30, 2022.

"In the third quarter we continued building our commercial footprint in anticipation of a US and an EU launch in 2023, while working closely with the FDA during the review cycle," said Krish S. Krishnan, Chairman & Chief Executive Officer at Krystal Biotech. "In the next few months, we intend to initiate dosing in our KB407, KB105 and KB301 clinical trials where we have commenced clinical site identification and qualification activities."

Dermatology

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

- In October, following mid-cycle BLA review, the Company was informed that the FDA does not plan on holding an Advisory Committee meeting and has also not identified a need for Risk Evaluation and Mitigation Strategies for the B-VEC application.
- In September, the Company received a positive opinion from the European Medical Agency (EMA) Pediatric Committee on the Pediatric Investigation Plan for B-VEC for the treatment of DEB with no additional studies required. We are on track to submit a Marketing Authorization Application (MAA) in the fourth quarter of 2022.
- In August, the FDA accepted and granted Priority Review designation for the B-VEC Biologics License Application (BLA).

Rare dermatological pipeline

- The Company anticipates patient dosing in the ongoing Phase 1/2 clinical trial of KB105 for the treatment of TGM1-deficient autosomal recessive congenital ichthyosis in early 2023. Details of the Phase 1/2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732.
- The Company continues to work towards an investigational new drug filing (IND) for KB104 for the treatment of Netherton Syndrome, which is now anticipated in the first half of 2023.

Respiratory

KB407 for the treatment of Cystic Fibrosis (CF)

- In August, the Company announced that the U.S. FDA has accepted the KB407 IND Application to evaluate KB407 for the treatment of cystic fibrosis in a Phase 1 clinical trial. The Company plans to initiate the trial in the fourth quarter of 2022.
- The Company continues to screen patients for enrollment in the Phase 1 clinical study of inhaled KB407 (CORAL-1/AU study) and plans to initiate dosing in the fourth quarter of 2022. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05095246.

Aesthetics

KB301 for the treatment of Aesthetic Indications

- In the second quarter of 2022, following completion of the PEARL-1 efficacy study, a subset of subjects were rolled over into a durability trial to evaluate KB301's duration of effect following dosing in the Phase 1 efficacy trial. The Company plans on announcing top line results from the durability trial in the fourth quarter of 2022. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.
- The Company intends to start a Phase 2 clinical study (PEARL-2) for the treatment of wrinkles and improvements in skin quality attributes in the first half of 2023 following agreement with the FDA on measurement of primary efficacy endpoints.

Financial results for the quarter ended September 30, 2022:

- Cash, cash equivalents, and investments totaled $407.0 million on September 30, 2022.
- Research and development expenses for the quarter ended September 30, 2022 were $11.5 million, compared to $6.1 million for the quarter ended September 30, 2021 and $31.7 million for the nine months ended September 30, 2022, compared to $18.9 million for the nine months ended September 30, 2021.
- General and administrative expenses for the quarter ended September 30, 2022 were $19.9 million, compared to $9.6 million for the quarter ended September 30, 2021 and $53.7 million for the nine months ended September 30, 2022, compared to $27.5 million for the nine months ended September 30, 2021.
- Net losses for the quarters ended September 30, 2022 and 2021 were $29.9 million and $15.6 million, or $(1.17) and $(0.70), respectively, per common share (basic and diluted). Net losses for the nine months ended September 30, 2022 and 2021 were $107.9 million and $47.8 million, or $(4.24) and $(2.18), respectively, per common share (basic and diluted).
- For additional information on the Company's financial results for the quarter ended September 30, 2022, please refer to the Form 10-Q filed with the SEC.

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 clinical utility of B-VEC, the timing of the Company's EMA marketing authorization application for B-VEC, 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, timing of announcement of results from the durability trial of KB301 and 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
mdodge@krystalbio.com

Consolidated Balance Sheet Data:

(In thousands)	September 30, 2022	December 31, 2021
Balance sheet data:		
Cash and cash equivalents	$ 186,409	$ 341,246
Short-term investments	208,011	96,850
Long-term investments	12,557	64,371
Total assets	576,379	626,295
Total liabilities	35,607	32,719
Total stockholders' equity	$ 540,772	$ 593,576

Consolidated Statement of Operations:

(In thousands, except shares and per share data)	Three Months Ended September 30,		
	2022	2021	Change

Expenses			
Research and development	$ 11,516	$ 6,080	$ 5,436
General and administrative	19,935	9,572	10,363
Total operating expenses	31,451	15,652	15,799
Loss from operations	(31,451)	(15,652)	(15,799)
Other Income (Expense)			
Interest and other income, net	1,601	63	1,538
Total other income (expense)	1,601	63	1,538
Net loss	$ (29,850)	$ (15,589)	$ (14,261)
Net loss per common share: Basic and diluted	$ (1.17)	$ (0.70)	
Weighted-average common shares outstanding: Basic and diluted	25,619,125	22,212,266	

	Nine Months Ended September 30,		
(In thousands, except shares and per share data)	**2022**	**2021**	**Change**
Expenses			
Research and development	$ 31,720	$ 18,875	$ 12,845
General and administrative	53,705	27,524	26,181
Litigation settlement	25,000	—	25,000
Total operating expenses	110,425	46,399	64,026
Loss from operations	(110,425)	(46,399)	(64,026)
Other Income (Expense)			
Interest and other income, net	2,502	127	2,375
Interest expense	—	(1,492)	1,492
Total other income (expense)	2,502	(1,365)	3,867
Net loss	$ (107,923)	$ (47,764)	$ (60,159)
Net loss per common share: Basic and diluted	$ (4.24)	$ (2.18)	
Weighted-average common shares outstanding: Basic and diluted	25,428,097	21,893,656	

Source: Krystal Biotech, Inc.