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

August 8, 2022

- Biologics License Application for B-VEC filed with the FDA on June 22, 2022
- FDA accepts IND on KB407 for the treatment of Cystic Fibrosis
- Strong balance sheet, closing the quarter with $438.5 million in cash, cash equivalents and investments

PITTSBURGH, Aug. 08, 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 second quarter ending June 30, 2022.

"The B-VEC BLA filing is the first and only FDA filing for the treatment of dystrophic epidermolysis bullosa that fundamentally addresses the underlying genetic pathology of this devastating disease," said Krish S. Krishnan, Chairman & Chief Executive Officer at Krystal Biotech. "We are committed to driving progress for the DEB patient community, and look forward to the FDA's review of our filing." He added, "I am tremendously proud of what the Company has accomplished so far this year, and we anticipate a productive second half of the year as we advance the development of several of our pipeline candidates and prepare for the potential global launch of B-VEC."

Program Highlights & Upcoming Events:

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

- Filed and announced a biologics license application (BLA) with the U.S. Food and Drug Administration (FDA) on June 22, 2022.
- New data on GEM-3 Phase 3 results for B-VEC were presented at the Society for Investigative Dermatology Annual Meeting on May 19, 2022. The full presentation is available in the Investors section of the Company's website.
- Marketing Authorization Application for B-VEC is anticipated to be filed with the European Medical Agency (EMA) in 2H 2022.
- Published information about the Company's HSV-1 based vector platform in *Cell & Gene Therapy Insights* discussing the benefits of viral vector-based gene replacement.

KB407 for the treatment of Cystic Fibrosis ("CF")

- FDA accepted IND of KB407 for the treatment of CF. Anticipate initiating a Phase 1 clinical trial (CORAL-1/US study) in CF patients in the US in 2H 2022.
- The Company has begun screening patients for enrollment in the Phase 1 clinical study of inhaled KB407 (CORAL-1/AU study) and plans to initiate dosing in 2H 2022. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05095246.

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 2H 2022 and details of the Phase 1/2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732.

KB104 for the treatment of Netherton Syndrome

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

KB301 for the treatment of Aesthetic Indications

- On March 22, 2022, Jeune Aesthetics, Inc., the Company's wholly-owned subsidiary, announced positive proof-of-concept efficacy data with respect to fine lines and wrinkles in the upper cheek, lower cheek and the knee from Cohort 2 of the PEARL-1 study of KB301. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.
- Subjects from Cohort 2 were rolled over into a durability trial to look for duration of effect following completion of the PEARL-1 study and for long term safety monitoring. The Company anticipates announcing results from the durability trial in Q4 2022.
- The Company anticipates commencing a Phase 2 study of KB301 in Q4 2022 or Q1 2023.

Financial results for the quarter ended June 30, 2022:

- Cash, cash equivalents, and investments totaled $438.5 million on June 30, 2022.
- Research and development expenses for the quarter ended June 30, 2022 were $10.9 million, compared to $6.6 million for the quarter ended June 30, 2021 and $20.2 million for the six months ended June 30, 2022, compared to $12.8 million for the six months ended June 30, 2021.
- General and administrative expenses for the quarter ended June 30, 2022 were $17.9 million, compared to $9.8 million for the quarter ended June 30, 2021 and $33.8 million for the six months ended June 30, 2022, compared to $18.0 million for the six months ended June 30, 2021.
- Net losses for the quarters ended June 30, 2022 and 2021 were $28.1 million and $16.4 million, or $(1.10) and $(0.74), respectively, per common share (basic and diluted). Net losses for the six months ended June 30, 2022 and 2021 were $78.1 million and $32.2 million, or $(3.08) and $(1.48), respectively, per common share (basic and diluted).
- For additional information on the Company's financial results for the quarter ended June 30, 2022, please refer to the 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, 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.

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Consolidated Balance Sheet Data:

(In thousands)	June 30, 2022	December 31, 2021
Balance sheet data:		
Cash and cash equivalents	$ 218,720	$ 341,246
Short-term investments	206,845	96,850
Long-term investments	12,902	64,371
Total assets	601,324	626,295
Total liabilities	42,143	32,719
Total stockholders' equity	$ 559,181	$ 593,576

Consolidated Statement of Operations:

	Three Months Ended June 30,		
(In thousands, except shares and per share data)	**2022**	**2021**	**Change**
Expenses			
Research and development	$ 10,890	$ 6,594	$ 4,296
General and administrative	17,863	9,799	8,064
Total operating expenses	28,753	16,393	12,360
Loss from operations	(28,753)	(16,393)	(12,360)

Other Income (Expense)			
Interest and other income, net	645	30	615
Total other income (expense)	645	30	615
Net loss	$ (28,108)	$ (16,363)	$ (11,745)
Net loss per common share: Basic and diluted	$ (1.10)	$ (0.74)	
Weighted-average common shares outstanding: Basic and diluted	25,545,167	22,204,659	

	Six Months Ended June 30,		
(In thousands, except shares and per share data)	**2022**	**2021**	**Change**
Expenses			
Research and development	$ 20,204	$ 12,795	$ 7,409
General and administrative	33,771	17,951	15,820
Litigation settlement	25,000	—	25,000
Total operating expenses	78,975	30,746	48,229
Loss from operations	(78,975)	(30,746)	(48,229)
Other Income (Expense)			
Interest and other income, net	902	64	838
Interest expense	—	(1,492)	1,492
Total other income (expense)	902	(1,428)	2,330
Net loss	$ (78,073)	$ (32,174)	$ (45,899)
Net loss per common share: Basic and diluted	$ (3.08)	$ (1.48)	
Weighted-average common shares outstanding: Basic and diluted	25,331,000	21,731,711	

Source: Krystal Biotech, Inc.