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

May 10, 2021

Completed enrollment in pivotal GEM-3 study of B-VEC in dystrophic epidermolysis bullosa (DEB)

Strong balance sheet with March 31, 2021 cash, cash equivalents and short-term investments of $403.4 million

PITTSBURGH, May 10, 2021 (GLOBE NEWSWIRE) -- 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 first quarter ending March 31, 2021.

"This year has already been, and will continue to be, a busy period for Krystal and I would like to thank our employees for their commitment, passion and resiliency during a global pandemic," said Krish Krishnan, Chairman and CEO of Krystal Biotech, Inc. "We look forward to continued progress across the organization, including initiating clinical testing of our first respiratory program, making headway on our 2nd GMP manufacturing facility, and announcing top line pivotal data for B-VEC later this year."

Program Highlights & Upcoming Events:

B-VEC for DEB

- During the first quarter, the Company completed enrollment in the ongoing pivotal GEM-3 trial and finalized the statistical analysis plan (SAP) based on feedback from the FDA.
- Topline data from the study is anticipated in 4Q21.
- Details of the pivotal Phase 3 study can be found at www.clinicaltrials.gov under NCT identifier NCT04491604.

KB105 for TGM1-ARCI

- The Company is on track to provide an update on this program in 1H21. The update will consist of safety, TGM1 expression level and efficacy data from the 4th patient enrolled. Data from this patient, together with the data from the three initial patients will help determine next steps.
- Details of the Phase 1/2 study can be found at www.clinicaltrials.gov under NCT identifier NCT04047732.

KB407 for Cystic Fibrosis

- In April 2021, the Company announced data from the GLP toxicology and biodistribution study which demonstrated in vivo safety of repeat, nebulized doses of KB407 in nonhuman primates. More detailed data will be presented at a future scientific conference.
- The Company intends to initiate a Phase 1 study of KB407 in 3Q21.

KB408 for Alpha-1 Antitrypsin Deficiency

- In April 2021, Krystal announced initial positive proof-of-concept data from preclinical studies of KB408 in mice. Additional preclinical studies are ongoing, and more detailed data will be presented at a future scientific conference.

KB301 for Aesthetic Indications

- In May 2021, detailed safety data from the first cohort in the ongoing Phase 1 study of KB301 for aesthetic skin indications was presented at the Society of Investigative Dermatology (SID) Annual Meeting.
- Initial efficacy data from the Phase 1 study is anticipated in 2H21.

KB104 for Netherton Syndrome

- The Company continues to work towards an IND filing, which is anticipated in 2H21.

Corporate Highlights:

- In May 2021, the Company announced the appointment of Andy Orth as Chief Commercial Officer. Mr. Orth has more than 25 years of global biotechnology experience, most recently in the role of Senior Vice President, Head of US Business at Alnylam Pharmaceuticals.
- In March 2021, the Company announced the appointment of Dr. Bhuhsan Hardas, M.D., MBA as President of Jeune, Inc. the Company's wholly owned subsidiary that is leveraging Krystal's clinically validated gene delivery platform to fundamentally address – and reverse – the biology of aging and/or damaged skin. Before joining Jeune, Dr. Hardas served as Chief Scientific Officer, Executive Vice President, Global Head of Licensing at Almirall and previously served as Chief

Medical Officer of Allergan's Dermatology and Medical Aesthetics business.

- In February 2021, the Company completed a public offering of 2,211,538 shares of its common stock, including 288,461 shares purchased by the underwriters, at $65.00 per share. Net proceeds to the Company from the offering were $134.9 million.
- In January 2021, 262,500 shares of common stock were issued pursuant to our at-the-market equity offering program ("ATM Program") for net proceeds of $16.9 million, resulting in a remaining $132.5 million available for issuance under the ATM Program. The Company also incurred $172 thousand of other offering expenses related to the ATM Program.

Financial results for the quarter ended March 31, 2021:

- Cash, cash equivalents and short-term investments totaled $403.4 million on March 31, 2021.
- Research and development expenses for the first quarter ended March 31, 2021 were $6.2 million, compared to $3.5 million for the first quarter 2020.
- General and administrative expenses for the first quarter ended March 31, 2021 were $8.2 million, compared to $2.4 million for first quarter 2020.
- Net losses for the quarters ended March 31, 2021 and 2020 were $15.8 million and $5.3 million, or $(0.74) and $(0.31) respectively, per common share (basic and diluted).
- For additional information on the Company's financial results for the first quarter ended March 31, 2021, refer to form 10-Q filed with the SEC.

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.

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, such as plans for the design, conduct and timelines of ongoing pre-clinical and clinical trials of beremagene geperpavec ("B-VEC"), KB105, KB104, KB301, KB407, and KB408; the clinical utility of B-VEC, KB105, KB104, KB301, KB407 and KB408, and Krystal's plans for filing of regulatory approvals and efforts to bring B-VEC, KB105, KB104, KB301, KB407 and KB408 to market; the market opportunity for and the potential market acceptance of B-VEC, KB105, KB104, KB301, KB407 and KB408; plans to pursue research and development of other product candidates; the sufficiency of Krystal's existing cash resources; the unanticipated impact of COVID-19 on Krystal's business operations, pre-clinical activities and clinical trials; 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, KB105, KB104, KB301, KB407 and KB408, 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.

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Consolidated Balance Sheet Data:

(In thousands)	March 31, 2021	December 31, 2020
Balance sheet data:		
Cash and cash equivalents	$ 402,172	$ 268,269
Working capital	396,681	259,606
Total assets	$ 443,018	$ 310,844
Total liabilities	12,366	18,760
Total stockholders' equity	$ 430,652	$ 292,084

Consolidated Statement of Operations:

(In thousands, except shares and per share data)	Three Months Ended March 31,		
	2021	2020	Change

Expenses			
Research and development	$ 6,201	$ 3,525	$ 2,676
General and administrative	8,152	2,421	5,731
Total operating expenses	14,353	5,946	8,407
Loss from operations	(14,353)	(5,946)	(8,407)
Other Income (Expense)			
Interest and other income, net	33	605	(572)
Build to suit interest expense	(1,492)	—	(1,492)
Total other income (expense)	(1,459)	605	(2,064)
Net loss	(15,812)	(5,341)	(10,471)
Net loss applicable to stockholders	$ (15,812)	$ (5,341)	$ (10,471)
Net loss attributable to common stockholders per share: Basic and diluted	$ (0.74)	$ (0.31)	
Weighted-average common shares outstanding: Basic and diluted	21,253,508	17,359,356	

Source: Krystal Biotech, Inc.