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

August 9, 2021

- Top-line data from the pivotal GEM-3 study of B-VEC in dystrophic epidermolysis bullosa (“DEB”) on track for 4Q21
- Initiation of Phase 1 study of inhaled KB407 for the treatment of cystic fibrosis expected in 3Q21
- Our wholly-owned subsidiary Jeune Aesthetics, Inc. initiated dosing in the efficacy cohort of the PEARL-1 study of intradermal KB301 for aesthetic skin conditions
- Strong balance sheet with June 30, 2021 cash, cash equivalents and marketable securities of $389.1 million

PITTSBURGH, Aug. 09, 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 second quarter ending June 30, 2021.

“We are pleased with the progress we have made this quarter on multiple fronts. Not only has the Krystal team continued to advance three clinical stage programs including the pivotal GEM-3 trial, we have also grown the commercial side of our organization and made significant headway on the construction of our 2nd GMP manufacturing facility,” said Krish S. Krishnan, Chairman and Chief Executive Officer of Krystal Biotech, Inc. “The remainder of 2021 promises to be even more exciting as we look forward to reporting pivotal data on B-VEC, Jeune announcing initial efficacy data for KB301 in aesthetic skin conditions, and initiating a Phase 1 trial to evaluate our first pulmonary candidate - KB407 for the treatment of cystic fibrosis.”

Program Highlights & Upcoming Events:

B-VEC for DEB

- The Company continued to advance the pivotal GEM-3 trial and is on track to announce top-line data in 4Q21. Details of the pivotal Phase 3 study can be found at www.clinicaltrials.gov under NCT identifier NCT04491604.
- During the second quarter the Company began enrolling patients into an open label extension (“OLE”) study, including patients who participated in the Phase 3 study and new patients who meet all enrollment criteria. Details of the OLE study can be found at www.clinicaltrials.gov under NCT identifier NCT04917874.

KB407 for Cystic Fibrosis

- Following the initial announcement of data from the GLP toxicology and biodistribution study of repeat doses of KB407 in nonhuman primates in April 2021, the Company will present more detailed results from this study in a poster at the North American Cystic Fibrosis Conference (“NACFC”), taking place September 30 - October 2.
- The Company is on track to initiate a Phase 1 study of KB407 in 3Q21.

KB105 for TGM1-ARCI

- In July 2021, the Company announced data from the fourth patient dosed in the Phase 1/2 trial evaluating topical KB105 for the treatment of TGM1-deficient autosomal recessive congenital ichthyosis ("TGM1-ARCI"). These data showed that repeat KB105 dosing continued to be well tolerated with no adverse events or evidence of immune response.
- Krystal plans to discuss these data with patients and key opinion leaders to help inform next steps. In particular, the Company will assess the optimal dosing frequency as well as additional clinical endpoints, including a novel scale designed for ichthyosis. The Company intends to complete these discussions by the end of the year and continue dosing in a Phase 2 trial in 2022.

KB301 for Aesthetic Indications

- In August 2021, Jeune Aesthetics, Inc., a wholly-owned subsidiary of Krystal Biotech Inc., announced the initiation of dosing in the efficacy cohort of the PEARL-1 (Phase 1) study of KB301 for aesthetic skin indications. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.
- Initial efficacy data from this study is anticipated in 4Q21.

Financial results for the quarter ended June 30, 2021:

- Cash, cash equivalents, and marketable securities totaled $389.1 million on June 30, 2021, compared to $271.3 million as of December 31, 2020.

- Research and development expenses for the second quarter ended June 30, 2021 were $6.6 million, compared to $3.6 million for the second quarter 2020, and $12.8 million for the six months ended June 30, 2021, compared to $7.2 million for the six months ended June 30, 2020.
- General and administrative expenses for the second quarter ended June 30, 2021 were $9.8 million, compared to $3.3 million for first quarter 2020, and $18.0 million for the six months ended June 30, 2021, compared to $5.7 million for the six months ended June 30, 2020.
- Net losses for the quarters ended June 30, 2021 and 2020 were $16.4 million and $6.8 million, or $(0.74) and $(0.37) respectively, per common share (basic and diluted). Net losses for the six months ended June 30, 2021 and 2020 were $32.2 million and $12.2 million or $(1.48) and $(0.68), respectively, per common share (basic and diluted)
- For additional information on the Company's financial results for the second quarter ended June 30, 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)	June 30, 2021	December 31, 2020
Balance sheet data:		
Cash and cash equivalents	$ 329,527	$ 268,269
Working capital	351,808	259,606
Total assets	443,556	310,844
Total liabilities	25,016	18,760
Total stockholders' equity	$ 418,540	$ 292,084

Consolidated Statement of Operations:

	Three Months Ended June 30,		
(In thousands, except shares and per share data)	**2021**	**2020**	**Change**
Expenses			
Research and development	$ 6,594	$ 3,639	$ 2,955
General and administrative	9,799	3,315	6,484
Total operating expenses	16,393	6,954	9,439
Loss from operations	(16,393)	(6,954)	(9,439)
Other Income (Expense)			

Interest and other income, net	30	121	(91)
Total other income (expense)	30	121	(91)
Net loss	$ (16,363)	$ (6,833)	$ (9,530)
Net loss per common share: Basic and diluted	$ (0.74)	$ (0.37)	
Weighted-average common shares outstanding: Basic and diluted	22,204,659	18,383,941	

	Six Months Ended June 30,		
(In thousands, except shares and per share data)	**2021**	**2020**	**Change**
Expenses			
Research and development	$ 12,795	$ 7,164	$ 5,631
General and administrative	17,951	5,735	12,216
Total operating expenses	30,746	12,899	17,847
Loss from operations	(30,746)	(12,899)	(17,847)
Other Income (Expense)			
Interest and other income, net	64	725	(661)
Build to suit interest expense	(1,492)	—	(1,492)
Total other income (expense)	(1,428)	725	(2,153)
Net loss	$ (32,174)	$ (12,174)	$ (20,000)
Net loss per common share: Basic and diluted	$ (1.48)	$ (0.68)	
Weighted-average common shares outstanding: Basic and diluted	21,731,711	17,871,648	

Source: Krystal Biotech, Inc.