



Krystal Biotech Reports that KB103 Received Clearance From RAC Review and Announces Third Quarter 2017 Financial Results

November 13, 2017

PITTSBURGH, Nov. 13, 2017 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (NASDAQ:KRY5), a gene therapy company advancing "off-the-shelf," topical and intra-dermal treatments for dermatological diseases, today reported financial results for the third quarter ended September 30, 2017, and provided an update on the company's recent corporate progress.

"We were pleased to complete a successful IPO on the Nasdaq Capital Market in September, and are now well-capitalized to advance our gene therapy product portfolio, particularly KB103, our lead product candidate for Dystrophic Epidermolysis Bullosa (DEB)," said Krish S. Krishnan, Chairman & Chief Executive Officer of Krystal Biotech. "Last week, our Phase 1/2 protocol for KB103 received clearance from RAC review and we are currently preparing to file an Investigational Drug Application (IND) for KB103 in the first quarter of 2018 and initiating a Phase 1/2 clinical trial in DEB shortly thereafter."

Third Quarter Highlights

Pipeline Update

- Phase 1/2 protocol for KB103 to treat DEB received clearance from Recombinant DNA Advisory Committee (RAC) review.
- KB103 granted Orphan Drug Designation by the Office of Orphan Product Development (OOPD).
- Presented preclinical data assessing the in vitro and in vivo delivery of HSV-1 mediated KB103 at EB2017, the 5th World Conference on EB Research in Salzburg, Austria.

Corporate Update

- In September, Krystal completed an initial public offering raising approximately \$41.0 million in net proceeds.
- In November, Krystal received funding totaling \$770,000 from the EB Research Partnership (EBRP) and the EB Medical Research Foundation (EBMRF). EBRP and EBMRF have provided this funding following a highly competitive application and screening process overseen by EBRP's Scientific Advisory Board (SAB), which is composed of leading scientists and physicians.

Financial Results for the Third Quarter

- Cash totaled \$52.6 million at September 30, 2017.
- Research and development expenses for the third quarter were \$1.4 million.
- General and administrative expenses for the third quarter were \$0.7 million.

About KB103

KB103 is Krystal's lead product candidate, currently in preclinical development and 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 employing Krystal's STAR-D platform to deliver functional human COL7A1 genes directly to the patients' dividing and non-dividing skin cells. HSV-1 is Krystal's replication-deficient, non-integrating viral vector that 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 Krystal Biotech

Krystal Biotech, Inc. (NASDAQ:KRY5) 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 the development of KB103, including the timing of filing of an IND and commencing a Phase 1/2 clinical trial... You can identify forward-looking statements because they contain words such as "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 or 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-1, as amended from time to time, under the caption "Risk Factors."

CONTACT

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Krystal Biotech, Inc. (formerly Krystal Biotech, LLC)
Condensed Balance Sheets

(In thousands, except shares, units, per share and per unit data)	September 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets		
Cash	\$ 52,570	\$ 1,923
Prepaid research and development expenses	48	246
Total current assets	52,618	2,169
Property and equipment, net	55	13
Total assets	\$ 52,673	\$ 2,182
Liabilities, Convertible Preferred Stock and Stockholders' and Members' Equity (Deficit)		
Current liabilities		
Accounts payable	\$ 550	\$ 42
Accrued expenses and other current liabilities	1,925	1
Total current liabilities	2,475	43
Accrued interest	-	7
Related party convertible promissory notes	-	698
Convertible promissory notes	-	1,145
Total liabilities	2,475	1,893
Commitments and contingencies		
Convertible preferred stock		
Convertible preferred stock; \$0.00001 par value; 20,000,000 shares authorized, 2,061,773 shares issued, and no shares outstanding at September 30, 2017 (unaudited); no shares authorized, issued, or outstanding at December 31, 2016	-	-
Total convertible preferred stock	-	-
Stockholders' and members' equity (deficit)		
Common stock; \$0.00001 par value; 80,000,000 shares authorized, 10,237,247 shares issued and outstanding at September 30, 2017 (unaudited); no shares authorized, issued, or outstanding at December 31, 2016	-	-
Common units; no common units authorized, issued, or outstanding at September 30, 2017 (unaudited); no par value; 3,490,884 units authorized, issued, and outstanding at December 31, 2016	-	-
Preferred units; no par value; no preferred units authorized, issued, or outstanding at September 30, 2017 (unaudited); no par value; 179,613 units authorized, issued, and outstanding at December 31, 2016 (aggregate liquidation preference of \$1,406)	-	1,406
Additional paid-in capital	57,875	33
Accumulated deficit	(7,677)	(1,150)
Total stockholders' and members' equity	50,198	289
Total liabilities, convertible preferred stock and stockholders' and members' equity	\$ 52,673	\$ 2,182

Krystal Biotech, Inc. (formerly Krystal Biotech, LLC)
Condensed Statements of Operations
(Unaudited)

(In thousands, except shares, units, per share and per unit data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Expenses				
Research and development	\$ 1,355	\$ 241	\$ 2,120	\$ 339
General and administrative	738	81	1,154	184

Total operating expenses	2,093		322		3,274		523
Loss from operations	(2,093))	(322))	(3,274))	(523)
Other Expense							
Interest expense, net	(3,180))	-		(3,253))	-
Total other expense	(3,180))	-		(3,253))	-
Net loss	(5,273))	(322))	(6,527))	(523)
Net loss applicable to stockholders and members	\$ (5,273))	\$ (322))	\$ (6,527))	\$ (523)
Net loss attributable to common stockholders per share: Basic and diluted	\$ (1.26))	\$ (8.48))	\$ (1.75))	\$ (40.20)
Weighted-average common shares and common units outstanding: Basic and diluted	4,183,075		37,982		3,725,825		13,016

Krystal Biotech, Inc. (formerly Krystal Biotech, LLC)
Condensed Statements of Cash Flows
(Unaudited)

(In thousands)	Nine Months Ended September 30,	
	2017	2016
Operating Activities		
Net loss	\$ (6,527)) \$ (523)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	9	1
Stock-based compensation expense	188	7
Non-cash interest expense	3,263	-
(Increase) decrease in		
Prepaid research and development expenses	198	(12)
Increase in		
Accounts payable	271	62
Accrued expenses and other current liabilities	835	15
Net cash used in operating activities	(1,763)) (450)
Investing Activities		
Purchases of property and equipment	(51)) (6)
Net cash used in investing activities	(51)) (6)
Financing Activities		
Proceeds from the issuance of convertible promissory notes	2,299	-
Issuance of common stock and common units, net	43,162	100
Issuance of preferred stock and preferred units	7,000	754
Net cash provided by financing activities	52,461	854
Net increase in cash	50,647	398
Cash at beginning of period	1,923	-
Cash at end of period	\$ 52,570	\$ 398
Supplemental Disclosures of Non-Cash Investing and Financing Activities		
Conversion of common units to preferred units	\$ -	\$ 100
Conversion of convertible promissory notes to preferred stock	\$ 4,142	\$ -
Conversion of preferred stock to common stock	\$ 12,661	\$ -
Unpaid deferred offering costs	\$ 1,327	\$ -

Source: Krystal Biotech, Inc.