Krystal Biotech Announces Third Quarter 2023 Financial Results and Provides Business Update

November 6, 2023

- 284 VYJUVEK Patient Start Forms and $8.6 million in VYJUVEK U.S. net product revenue as of the end of the third quarter
- Cohort 1 completed in Phase 1 clinical trial of KB407 for the treatment of CF
- First patient dosed in Phase 1 Clinical Trial of KB707 in patients with locally advanced or metastatic solid tumor malignancies
- IND cleared for KB408 for the treatment of AATD
- Strong balance sheet, closing the quarter with $598.6 million in cash, cash equivalents and investments

PITTSBURGH, Nov. 06, 2023 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs, today reported financial results and key business updates for the third quarter ended September 30, 2023.

"The third quarter was highlighted by strong commercial execution of the VYJUVEK launch, advancement of the oncology program into the clinic and continued momentum in the CF program," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "With respect to the VYJUVEK launch, our guiding vision is centered around optimizing the patient experience, and we have and will continue to work tirelessly to ensure that each patient's journey, with respect to starting on VYJUVEK and staying on it, is smooth, timely and hassle free."

VYJUVEK®
(beremagene geperpavec-svdt, or B-VEC)

For the treatment of Dystrophic Epidermolysis Bullosa (DEB)

- The Company received 284 Patient Start Forms from 136 unique prescribers as of the end of the third quarter of 2023:
  - 20% of the start forms were generated from patients with dominant DEB;
  - 33% of the start forms were from patients 10 years of age or younger; and
  - Patient compliance on VYJUVEK is currently tracking at 96%.
- The Company has received positive coverage determinations from all major commercial national health plans. Optional Medicaid fee-for-service states initiated coverage in July. The Company expects to receive positive coverage from most mandatory states in the fourth quarter of 2023 and the balance in the first quarter of 2024.
- In October, the Company filed for a Marketing Authorization for B-VEC with the European Medical Agency and anticipates approval in the EU in the second half of 2024.
- Following acceptance of the open label extension study of B-VEC by Japan's Pharmaceuticals and Medical Devices Agency in July 2023, the Company initiated the extension study and dosed 5 patients. Following completion of the open label extension study, the Company intends to file a Japanese New Drug Application for B-VEC for DEB in the first half of 2024. Details of the trial can be found at https://rctportal.niph.go.jp/en under JRCT ID jRCT2053230075.

Respiratory

KB407 for the treatment of Cystic Fibrosis (CF)

- Cohort 1 of the Phase 1 (CORAL-1) study has been enrolled and completed. No severe or serious adverse events were observed in patients treated in Cohort 1 of the CORAL-1 study. We are working to initiate Cohort 2 of the CORAL-1 study following safety review by the Data Monitoring Committee. The CORAL-1 study is a multi-center, dose-escalation trial of KB407 in patients with CF, regardless of their underlying genotype. The Company anticipates announcing data from the Phase 1 study in 2024. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05504837.

KB408 for the treatment of Alpha-1 Antitrypsin Deficiency (AATD)

- In September, the Company announced that the U.S. Food and Drug Administration (FDA) had cleared the Company's Investigational New Drug (IND) application for KB408 for the treatment of AATD and granted KB408 Orphan Drug Designation. The Company expects to dose the first patient in a Phase 1 clinical trial (SERPINA-1) in the first quarter of

2024.

Oncology

KB707 for the treatment of solid tumors

- In October, the first patient was dosed in the Phase 1 (OPAL-1) study to evaluate intratumoral KB707 in patients with locally advanced or metastatic solid tumor malignancies. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT05970497.

- The Company presented preclinical data in multiple oncology models at the Society for Immunotherapy of Cancer's annual meeting on November 3 and 4, 2023. Combinatorial IL-2 and IL-12 expressed from the Company's platform technology was shown in one presentation, to provide a synergistic effect in a melanoma model, suppressing treated and non-treated tumor outgrowth, enhancing survival, and eliciting a durable memory response sufficient for recurrent tumor control. Similarly, the Company presented that non-invasive inhalation of vector-encoded IL-2 and IL-12 was found to be both safe and effective in treating lung tumors in a metastasis model, resulting in long-term survival after single or repeated cancer cell challenge, suggestive of prolonged adaptive immunity.

- The Company is on track to file an amendment to the existing KB707 IND in the fourth quarter of 2023 to allow the Company to evaluate inhaled KB707 in a clinical trial to treat tumors in a patient's lungs. The Company expects to dose the first patient with inhaled KB707 in the first half of 2024.

- In October, the United States Patent & Trademark Office issued to the Company U.S. Patent No. 11,779,660 entitled Viral Vectors for Cancer Therapy.

Dermatology

- The Company remains on track to commence the Phase 2 cohort of its KB105-02 (JADE-1) trial for the treatment of TGM1-ARCI in 2024 and plans to file an IND application with the FDA and to initiate a clinical trial of KB104 to treat patients with Netherton Syndrome in late 2024.

Aesthetics

KB301 for the treatment of aesthetic indications

- In April, Jeune Aesthetics, Inc., a wholly-owned subsidiary of the Company, announced the dosing of the first subject in the Phase 1, Cohort 3 study of KB301 for the improvement of lateral canthal lines at rest. The study is on-going, and the Company plans to announce results from this study in the first half of 2024. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.

Business

- In August, the Company sold its Rare Pediatric Disease Priority Review Voucher (PRV) for $100 million. The Company was awarded the PRV in connection with the FDA's accelerated approval of VYJUVEK for the treatment of DEB for patients 6 months of age and older.

- In August, the Company began research and development operations in its second commercial scale CGMP biologics manufacturing facility, ASTRA, a 155,000 sq. ft. state-of-the-art CGMP facility with comprehensive end-to-end capabilities.

Financial results for the quarter ended September 30, 2023:

- Cash, cash equivalents, and investments totaled $598.6 million on September 30, 2023.
- The Company recorded its first sales for patients that began treatment in August 2023 and the resulting product revenues, net totaled $8.6 million for the quarter ended September 30, 2023.
- Cost of goods sold totaled $223 thousand for the quarter ended September 30, 2023. Prior to receiving FDA approval for VYJUVEK in May 2023, costs associated with the manufacturing of VYJUVEK were expensed as research and development expense. As such, a portion of the cost of inventory sold during the period was expensed prior to FDA approval.
- The Company recorded a gain of $100 million for the sale of the rare pediatric disease Priority Review Voucher.
- Research and development expenses for the quarter ended September 30, 2023 were $10.6 million, inclusive of $2.3 million of stock-based compensation, compared to $11.5 million, inclusive of stock-based compensation of $2.2 million for the quarter ended September 30, 2022.

- Selling, general, and administrative expenses for the quarter ended September 30, 2023 were $23.7 million, inclusive of stock-based compensation of $6.0 million, compared to $19.9 million, inclusive of stock-based compensation of $6.9 million, for the quarter ended September 30, 2022.
- Net income (loss) for the quarters ended September 30, 2023 and 2022 was $80.7 million and $(29.9) million, or $2.88 and $(1.17), respectively, per common share (basic) and $2.79 and $(1.17), respectively per common share (diluted).
- For additional information on the Company's financial results for the quarter ended September 30, 2023, please refer to the Form 10-Q filed with the SEC.

Financial results for the nine months ended September 30, 2023:

- The Company recorded its first sales for patients that began treatment in August 2023 and the resulting product revenues, net totaled $8.6 million for the nine months ended September 30, 2023.
- Cost of goods sold totaled $223 thousand for the nine months ended September 30, 2023. Prior to receiving FDA approval for VYJUVEK in May 2023, costs associated with the manufacturing of VYJUVEK were expensed as research and development expense. As such, a portion of the cost of inventory sold during the period was expensed prior to FDA approval.
- The Company recorded a gain of $100 million for the sale of the rare pediatric disease Priority Review Voucher.
- Research and development expenses for the nine months ended September 30, 2023 were $35.1 million, inclusive of stock-based compensation of $7.7 million, compared to $31.7 million, inclusive of stock-based compensation of $5.5 million for the nine months ended September 30, 2022.
- Selling, general, and administrative expenses for the nine months ended September 30, 2023 were $73.6 million, inclusive of stock-based compensation of $22.4 million, compared to $53.7 million, inclusive of stock-based compensation of $18.1 million for the nine months ended September 30, 2022.
- Net income (loss) for the nine months ended September 30, 2023 and 2022 were $2.2 million and $(107.9) million, or $0.08 and $(4.24), respectively, per common share (basic) and $0.08 and $(4.24), respectively, per common share (diluted).
- For additional information on the Company's financial results for the nine months ended September 30, 2023, please refer to the Form 10-Q filed with the SEC.

Conference Call

Krystal Biotech will host a conference call to discuss its third quarter 2023 financial results and business highlights today, November 6, 2023, at 8:30 a.m. ET. To access the live call, please preregister: https://www.netroadshow.com/events/login?show=15609a11&confId=57029.

A replay of the conference call will be available on the Investors section of the Company's website at https://www.krystalbio.com for 30 days following the event.

About VYJUVEK

VYJUVEK is a non-invasive, topical, redosable gene therapy designed to deliver two copies of the *COL7A1* gene when applied directly to DEB wounds. VYJUVEK was designed to treat DEB at the molecular level by providing the patient's skin cells the template to make normal COL7 protein, thereby addressing the fundamental disease-causing mechanism.

Indication

VYJUVEK is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients six months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse drug reactions (incidence >5%) were itching, chills, redness, rash, cough, and runny nose. These are not all the possible side effects with VYJUVEK. Call your healthcare provider for medical advice about side effects.

To report SUSPECTED ADVERSE REACTIONS, contact Krystal Biotech, Inc. at 1-844-557-9782 or FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

Contraindications

None.

Warnings and Precautions

VYJUVEK gel must be applied by a healthcare provider.

After treatment, patients and caregivers should be careful not to touch treated wounds and dressings for 24 hours.

Wash hands and wear protective gloves when changing wound dressings. Disinfect bandages from the first dressing change with a virucidal agent, and dispose of the disinfected bandages in a separate sealed plastic bag in household waste. Dispose of the subsequent used dressings in a sealed plastic bag in household waste.

Patients should avoid touching or scratching wound sites or wound dressings.

In the event of an accidental exposure flush with clean water for at least 15 minutes.

For more information, see full U.S. Prescribing Information

About Orphan Drug Designation

Orphan Drug Designation is granted by the FDA to investigational therapies addressing rare medical diseases or conditions that affect fewer than 200,000 people in the U.S. Orphan drug status provides benefits to drug developers, including assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees and seven years of post-approval marketing exclusivity.

About Fast Track Designation

Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and treat a serious or unmet medical need, enabling drugs to reach patients sooner. Clinical programs with Fast Track designation may benefit from early and frequent communication with the FDA throughout the regulatory review process, and such clinical programs may be eligible to apply for Accelerated Approval and Priority Review if relevant criteria are met.

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRYS) is a commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK® is the Company's first commercial product, the first-ever redosable gene therapy, and the only medicine approved by the FDA for the treatment of dystrophic epidermolysis bullosa. The Company is rapidly advancing a robust preclinical and clinical pipeline of investigational genetic medicines in respiratory, oncology, dermatology, ophthalmology, and aesthetics. Krystal Biotech is headquartered in Pittsburgh, Pennsylvania. 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. or Jeune Aesthetics, Inc., including statements about the Company's commercial launch of VYJUVEK, including its expectations regarding positive coverage determinations; the Company's anticipation of potential B-VEC approval in the EU in the second half of 2024; the Company's intention to file a Japanese New Drug Application for B-VEC for DEB in the first half of 2024; the Company's expectation that it will announce data from the Phase 1 study of KB407 in 2024; the Company's plan to dose the first patient in the Phase 1 clinical trial of KB408 in the first quarter of 2024; the Company's plans to file an amendment to the existing KB707 IND in the fourth quarter of 2023 and to dose the first patient with inhaled KB707 in a clinical trial to treat tumors in a patient's lungs in the first half of 2024; the Company's plans to initiate the Phase 2 cohort of the KB105-02 (JADE-1) trial in 2024; the Company's plans to file an IND application and initiate a clinical trial of KB104 in late 2024; the Company's expectation that it will announce results of the Phase 1, Cohort 3 study of KB301 for the improvement of lateral canthal lines at rest in the first half of 2024, 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 VYJUVEK or product candidates, 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 press 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 press release.

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Consolidated Balance Sheet Data:

(In thousands)	September 30, 2023	December 31, 2022
	(unaudited)	
Balance sheet data:		
Cash and cash equivalents	$ 373,241	$ 161,900
Short-term investments	188,828	217,271
Long-term investments	36,548	4,621

Total assets	790,350	558,450
Total liabilities	34,402	36,219
Total stockholders' equity	$ 755,948	$ 522,231

Consolidated Statements of Operations:

	Three Months Ended September 30,		
	2023	2022	Change
(In thousands, except shares and per share data)	**(unaudited)**		
Revenue			
Product revenues, net	$ 8,556	$ —	$ 8,556
Expenses			
Cost of goods sold	223	—	223
Research and development	10,629	11,516	(887)
Selling, general, and administrative	23,697	19,935	3,762
Total operating expenses	34,549	31,451	3,098
Loss from operations	(25,993)	(31,451)	5,458
Other Income			
Gain from sale of Priority Review Voucher	100,000	—	100,000
Interest and other income, net	6,740	1,601	5,139
Net income (loss)	$ 80,747	$ (29,850)	$ 110,597
Net loss per common share:			
Basic	$ 2.88	$ (1.17)	
Diluted	$ 2.79	$ (1.17)	
Weighted-average common shares outstanding:			
Basic	28,042,130	25,619,125	
Diluted	28,892,226	25,619,125	

	Nine Months Ended September 30,		
	2023	2022	Change
(In thousands, except shares and per share data)	**(unaudited)**		
Revenue			
Product revenues, net	$ 8,556	$ —	$ 8,556
Expenses			
Cost of goods sold	223	—	223
Research and development	35,061	31,720	3,341
Selling, general, and administrative	73,637	53,705	19,932
Litigation settlement	12,500	25,000	(12,500)
Total operating expenses	121,421	110,425	10,996
Loss from operations	(112,865)	(110,425)	(2,440)
Other Income			
Gain from sale of Priority Review Voucher	100,000	—	100,000
Interest and other income, net	15,105	2,502	12,603
Net income (loss)	$ 2,240	$ (107,923)	$ 110,163
Net loss per common share:			
Basic	$ 0.08	$ (4.24)	
Diluted	$ 0.08	$ (4.24)	
Weighted-average common shares outstanding:			
Basic	26,812,278	25,428,097	
Diluted	27,384,539	25,428,097	



Source: Krystal Biotech, Inc.