Krystal Biotech Announces Fourth Quarter and Full Year 2023 Financial Results and Provides Business Updates

February 26, 2024

- *Net product revenue of $42.1M in 4Q and $50.7M for the year*
- *New England Journal of Medicine publication of the use of B-VEC eyedrop formulation*
- *Reached alignment with FDA to enable approval of B-VEC eyedrop formulation for the treatment of lesions in the eye of DEB patients*
- *First patient dosed in Phase 1 KB408 trial for the treatment of AATD; five active clinical trials in 2024*
- *Strong balance sheet, closing the year with $594.1M in cash and investments*

PITTSBURGH, Feb. 26, 2024 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a commercial-stage biotechnology company, today reported financial results and key business updates for the fourth quarter and year ending December 31, 2023.

"2023 was an inflection point for Krystal with the approval and launch of VYJUVEK, the first-ever FDA approved therapy for dystrophic epidermolysis bullosa and only medicine that delivers the corrective power of gene therapy in an easy-to-apply, redosable, topical gel formulation that can be administered at home," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "Our U.S. commercial launch trajectory is tracking closely to that of the best recent rare disease launches with $50.7 million in net product revenue only six months since approval, supported by high patient and physician demand, broad access, and high compliance. We look forward to expanding VYJUVEK access in the U.S. and globally in the years to come, while advancing our clinical pipeline and reinforcing our leadership in redosable gene therapy."

VYJUVEK for the treatment of Dystrophic Epidermolysis Bullosa (DEB)

- The Company recorded $42.1 million and $50.7 million in VYJUVEK U.S. net product revenue for the fourth quarter and full year 2023, respectively. Gross margin for the fourth quarter was 93%.
- As of February 2024, the Company had secured 35% of the 1,200 identified patient base in patient start forms, as well as 228 reimbursement approvals for VYJUVEK while patient compliance with once weekly treatment while on drug was 96% at end of December 2023 and continues to remain high to date.
- In January 2024, the Company received a permanent J-code (J3401) for VYJUVEK, which facilitates efficient and accurate billing and reimbursement, including under U.S Medicaid plans. As of February 2024, positive access has been achieved for 97% of lives covered under commercial plans and 88% of lives covered under Medicaid.
- In November 2023, the European Medicines Agency validated the Company's Marketing Authorization Application (MAA) for B-VEC for the treatment of DEB in patients from birth, and the MAA is now under review with a decision anticipated in 2H 2024.
- In December 2023, B-VEC was granted Orphan Drug Designation (ODD) status for the treatment of DEB by the Japan Ministry of Health, Labour and Welfare, a designation which confers specific benefits, including priority review of applications, extended registration validity, and reduced development costs. The Company is conducting a fully enrolled open label extension study of B-VEC in Japan to support regulatory approval. Details of the study can be found at jrct.niph.go.jp under JRCT ID jRCT2053230075. The Company anticipates filing a Japan New Drug Application in 2H 2024 enabling a potential authorization in 2025.

Respiratory

KB407 for the treatment of cystic fibrosis (CF)

- In January 2024, the Company initiated dosing in Cohort 2 of the Phase 1 CORAL-1 study. CORAL-1 is a multi-center, dose-escalation study evaluating KB407 in patients with CF, regardless of their underlying genotype. No severe or serious adverse events were observed in patients treated in Cohort 1 of the CORAL-1 study. 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 February 2024, the Company dosed the first patient in the KB408 Phase 1 SERPENTINE-1 study for the treatment of Alpha-1 Antitrypsin Deficiency. SERPENTINE-1 is a Phase 1 open-label, single dose escalation study in adult patients with AATD with a PI*ZZ genotype. Three planned dose levels of KB408 will be evaluated in up to 12 patients to evaluate the safety, tolerability, and proof-of-mechanism of KB408. Cohorts 1 and 2 will focus predominantly on safety with dose escalation and pharmacodynamic activity in the lung will be assessed at the highest dose by bronchoscopy in Cohort 3.

Details about the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier: NCT06049082. The Company is working closely with the Alpha-1 Foundation and their Therapeutic Development Network on the SERPENTINE-1 study and intends to announce interim data from the study in 2H 2024. In September 2023, the United States Food and Drug Administration (FDA) granted ODD to KB408 for the treatment of AATD.

- Preclinical pharmacology data for KB408 was presented at the European Society of Gene & Cell Therapy Congress that was held in October 2023.

Ophthalmology

- In February 2024, the Company announced the publication in the *New England Journal of Medicine* of clinical data on the compassionate use of B-VEC, administered as an eyedrop, to treat a patient suffering from ocular complications of DEB.
- In February 2024, the FDA agreed with the Company's proposed single arm, open label study in approximately 10 patients to enable approval of B-VEC eyedrops to treat ocular complications which are thought to affect over 25% of DEB patients. The Company plans to initiate this study in 2H 2024.
- In January 2024, the United States Patent and Trademark Office, or USPTO, issued U.S. Patent No. 11,865,148, covering methods of delivering human transgenes to the eye using replication-incompetent HSV-1.

Oncology

KB707 for the treatment of solid tumors

- In January 2024, the FDA cleared an amendment to our previously cleared investigational new drug (IND) application allowing for the evaluation of inhaled KB707 for treatment of patients with locally advanced or metastatic solid tumors of the lung. The Company expects to dose the first patient in the open-label, multi-center, monotherapy, dose escalation and expansion Phase 1 clinical study (KYANITE-1) in 1H 2024. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06228326.
- In February 2024, the FDA granted Fast Track Designation for inhaled KB707 for the treatment of patients with solid tumors with pulmonary metastases that are relapsed or refractory to standard of care therapy. This is the second Fast Track Designation for the KB707 program. Previously, in July 2023, the FDA granted intratumoral KB707 Fast Track Designation for the treatment of anti-PD-1 relapsed/refractory locally advanced or metastatic melanoma.
- Enrollment is ongoing in the Phase 1 (OPAL-1) study to evaluate intratumoral KB707 in patients with locally advanced or metastatic solid tumor malignancies. The first patient in OPAL-1 was dosed in October 2023. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT05970497.
- Preclinical safety and efficacy data for KB707 was presented in November 2023 at the Society for Immunotherapy in Cancer Annual Meeting. Preclinical studies evaluating inhaled KB707 and intratumoral KB707 showed that KB707 treatment resulted in enhanced survival.
- In October 2023, the United States Patent and Trademark Office, or USPTO, issued U.S. Patent No. 11,779,660, covering compositions of matter containing engineered HSV constructs encoding IL-2 and IL-12, including KB707.

Aesthetics

KB301 for the treatment of Aesthetic Indications

- In January 2024, Jeune Aesthetics, Inc. ("Jeune Aesthetics"), a wholly-owned subsidiary of the Company, initiated Cohort 4 of the Phase 1 (Pearl-1) clinical study, an open label study to evaluate KB301 for the improvement of dynamic wrinkles of the décolleté in up to 20 subjects. Cohort 4 is running simultaneously with the Pearl-1 Cohort 3 study evaluating KB301 for the improvement of lateral canthal lines at rest. Jeune Aesthetics expects to announce results for both cohorts in 1H 2024. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.

Financial results for the quarter ended December 31, 2023:

- Cash, cash equivalents, and investments totaled $594.1 million on December 31, 2023.
- The Company recorded net product revenue of $42.1 million from sales of VYJUVEK during the quarter ended December 31, 2023.
- Cost of goods sold totaled $2.9 million for the quarter ended December 31, 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.
- Research and development expenses for the quarter ended December 31, 2023 were $11.4 million, inclusive of

stock-based compensation of $2.4 million compared to $10.7 million for the quarter ended December 31, 2022, inclusive of $2.4 million of stock-based compensation.

- Selling, general and administrative expenses for the quarter ended December 31, 2023 were $24.8 million, inclusive of stock-based compensation of $7.5 million compared to $24.0 million for the quarter ended December 31, 2022, inclusive of stock-based compensation of $7.2 million.
- Net income (loss) for the quarters ended December 31, 2023 and 2022 was $8.7 million and $(32.1) million, or $0.31 and $(1.25) respectively, per common share (basic) and $0.30 and $(1.25) respectively, per common share (diluted).

Financial results for the year ended December 31, 2023

- The Company recorded net product revenue of $50.7 million from sales of VYJUVEK during the year ended December 31, 2023.
- Cost of goods sold totaled $3.1 million for the year ended December 31, 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 year was expensed prior to FDA approval.
- The Company recorded a gain of $100.0 million from the sale of the rare pediatric disease Priority Review Voucher.
- Research and development expenses for the year ended December 31, 2023 were $46.4 million, inclusive of stock-based compensation of $10.1 million compared to $42.5 million for the year ended December 31, 2022, inclusive of $7.9 million of stock-based compensation.
- Selling, general and administrative expenses for the year ended December 31, 2023 were $98.4 million, inclusive of stock-based compensation of $29.9 million compared to $77.7 million for the year ended December 31, 2022, inclusive of stock-based compensation of $25.3 million.
- Net income (loss) for the years ended December 31, 2023 and 2022 was $10.9 million and $(140.0) million, or $0.40 and $(5.49), respectively, per common share (basic) and $0.39 and $(5.49), respectively, per common share (diluted).
- For additional information on the Company's financial results for the year ended December 31, 2023, please refer to the Form 10-K filed with the Securities and Exchange Commission.

Financial Guidance

($ in millions)	**FY 2024 Guidance**
Non-GAAP Research and Development ("R&D") and Selling, General and Administrative ("SG&A") expense (1)	$150.0 - $175.0

(1) Refer to Non-GAAP Financial Measures section below for additional information. Non-GAAP combined R&D and SG&A expense guidance does not include stock-based compensation as we are currently unable to confidently estimate Full Year 2024 stock-based compensation expense. As such, we have not provided a reconciliation from forecasted non-GAAP to forecasted GAAP combined R&D and SG&A Expense in the above. This could materially affect the calculation of forward-looking GAAP combined R&D and SG&A Expense as it is inherently uncertain.

Conference Call

The Company will host an investor webcast on Monday, February 26, 2024 at 8:30 am ET.

Investors and the general public can access the live webcast at https://www.webcaster4.com/Webcast/Page/3018/49928.

For those unable to listen to the live conference call, a replay will be available for 30-days on the Investors section of the Company's website at www.krystalbio.com.

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 U.S. 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 U.S. FDA fees and seven years of post-approval marketing exclusivity.

The orphan drug designation system in Japan aims to support the development of drugs for diseases that affect fewer than 50,000 patients in Japan, for which significant unmet medical need exists. An investigational therapy is eligible to qualify for ODD if there is no approved alternative treatment option or if there is high efficacy or safety compared to existing treatment options expected. Specific measures to support the development of orphan drugs include subsidies for research and development expenditures, prioritized consultation regarding clinical development, reduced consultation fees, tax incentives, priority review of applications, reduced application fees, and extended registration validity period.

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 first 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 X (formerly 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 in the United States and expanding VYJUVEK access in the U.S. and globally; the Company's anticipation of potential B-VEC approval for the treatment of DEB in patients from birth in the EU in 2H 2024; the Company's intention to file a Japanese New Drug Application for B-VEC for the treatment of DEB patients in 2H 2024 enabling a potential authorization in 2025; the Company's plans to announce interim data from its Phase 1 study of KB408 in 2H 2024; the Company's plans to initiate a study in 2H 2024 of B-VEC eyedrops for the treatment of lesions in the eye of DEB patients; the Company expectations regarding dosing of the first patient with inhaled KB707 for the treatment of patients with locally advanced or metastatic solid tumors of the lung in its Phase 1 clinical study in 1H 2024; Jeune Aesthetics' plans to announce results in 1H 2024 of Cohort 4 of its Phase 1 clinical study to evaluate KB301 for the improvement of dynamic wrinkles of the décolleté and Cohort 3 to evaluate KB301 for the improvement of lateral canthal lines at rest; 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. This press release also contains estimates and other statistical data made by independent parties and by the Company that involves a number of assumptions and limitations. Neither the Company nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this press release.

Non-GAAP Financial Measures

This press release includes forward looking combined R&D and SG&A expense guidance that is not required by, or presented in accordance with, U.S. GAAP and should not be considered as an alternative to R&D and SG&A expense or any other performance measure derived in accordance with GAAP. The Company defines non-GAAP combined R&D and SG&A expense as GAAP combined R&D and SG&A expense excluding stock-based compensation. The Company cautions investors that amounts presented in accordance with its definition of non-GAAP combined R&D and SG&A expense may not be comparable to similar measures disclosed by competitors because not all companies calculate this non-GAAP financial measure in the same manner. The Company presents this non-GAAP financial measure because it considers this measure to be an important supplemental measure and believes it is frequently used by securities analysts, investors, and other interested parties in the evaluation of companies in the Company's industry. Management believes that investors' understanding of the Company's performance is enhanced by including this forward-looking non-GAAP financial measure as a reasonable basis for comparing the Company's ongoing results of operations. Management uses this non-GAAP financial measure for planning purposes, including the preparation of the Company's internal annual operating budget and financial projections; to evaluate the performance and effectiveness of the Company's operational strategies; and to evaluate the Company's capacity to expand its business. This non-GAAP financial measure has limitations as an analytical tool, and should not be considered in isolation, or as an alternative to, or a substitute for R&D and SG&A expense or other financial statement data presented in accordance with GAAP in the Company's consolidated financial statements. The Company has not provided a quantitative reconciliation of forecasted non-GAAP combined R&D and SG&A expense to forecasted GAAP combined R&D and SG&A expense because the Company is unable, without making unreasonable efforts, to calculate the reconciling item, stock-based compensation expenses, with confidence. This item, which could materially affect the computation of forward-looking GAAP combined R&D and SG&A expense, is inherently uncertain.

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Condensed Consolidated Balance Sheet:

(In thousands)	December 31, 2023	December 31, 2022
Balance sheet data:		
Cash and cash equivalents	$ 358,328	$ 161,900
Short-term investments	173,850	217,271
Long-term investments	61,954	4,621
Total assets	818,355	558,450
Total liabilities	39,714	36,219
Total stockholders' equity	$ 778,641	$ 522,231

Consolidated Statement of Operations:

	Three Months Ended December 31,		
(in thousands, except shares and per share data)	**2023**	**2022**	**Change**
Revenue			
Product revenue, net	$ 42,143	$ —	$ 42,143
Expenses			
Cost of goods sold	2,871	—	2,871
Research and development	11,370	10,741	629
Selling, general and administrative	24,764	24,030	734
Total operating expenses	39,005	34,771	4,234
Income (loss) from operations	3,138	(34,771)	37,909
Other Income			
Interest and other income, net	7,519	2,719	4,800
Income (loss) before income taxes	10,657	(32,052)	42,709
Income tax expense	(1,965)	—	(1,965)
Net income (loss)	$ 8,692	$ (32,052)	$ 40,744
Net income (loss) per common share			
Basic	0.31	(1.25)	
Diluted	0.30	(1.25)	

Weighted-average common shares outstanding:		
Basic	28,168,776	25,680,520
Diluted	28,817,823	25,680,520

(in thousands, except shares and per share data)	Years Ended December 31, 2023	2022	Change
Revenue			
Product revenue, net	$ 50,699	$ —	$ 50,699
Expenses			
Cost of goods sold	3,094	—	3,094
Research and development	46,431	42,461	3,970
Selling, general and administrative	98,401	77,735	20,666
Litigation settlement	12,500	25,000	(12,500)
Total operating expenses	160,426	145,196	15,230
Income (loss) from operations	(109,727)	(145,196)	35,469
Other Income			
Gain from sale of Priority Review Voucher	100,000	—	100,000
Interest and other income, net	22,624	5,221	17,403
Income (loss) before income taxes	12,897	(139,975)	152,872
Income tax expense	(1,965)	—	(1,965)
Net income (loss)	$ 10,932	$ (139,975)	$ 150,907
Net income (loss) per common share:			
Basic	$ 0.40	$ (5.49)	
Diluted	$ 0.39	$ (5.49)	
Weighted-average common shares outstanding:			
Basic	27,154,190	25,491,721	
Diluted	27,751,809	25,491,721	

Source: Krystal Biotech, Inc.