Krystal Biotech Announces First Quarter 2024 Financial Results and Provides Business Updates

May 6, 2024

Net product revenue of $45.3 million in 1Q and $95.9 million since August
First patient dosed in inhaled KB707 study for locally advanced or metastatic tumors of the lung
Received Fast Track Designations for both inhaled and intratumoral KB707
Strong balance sheet with $622.3 million in cash and investments

PITTSBURGH, May 06, 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 first quarter ending March 31, 2024.

"With strong uptake of VYJUVEK and accelerating enrollment across our growing clinical pipeline, we made great progress this quarter on our mission to deliver transformational genetic medicines to patients with rare and serious diseases," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "Our U.S. VYJUVEK launch continues to progress well, delivering quarter over quarter revenue growth, and is underpinned by robust demand, rapid growth in reimbursement approvals, and high patient compliance. Momentum outside of the U.S. is also accelerating with the successful completion of our clinical study in Japan putting us on a path for our second ex-U.S. regulatory filing before year end. Our focus looking ahead is to continue expanding VYJUVEK access both in the U.S. and abroad, while progressing our deep clinical pipeline through to key data readouts expected to start later this year."

VYJUVEK for the treatment of Dystrophic Epidermolysis Bullosa (DEB)

- The Company recorded $45.3 million in VYJUVEK net product revenue for the first quarter of 2024. Gross margin for the quarter was 95%.
- As of April, the Company has secured over 330 reimbursement approvals for VYJUVEK in the U.S. and positive access has been achieved for 96% of lives covered under commercial and Medicaid plans. In January, the Company received a permanent J-code for VYJUVEK, which facilitates efficient and accurate billing and reimbursement, including under U.S Medicaid plans.
- Patient compliance with once weekly treatment while on drug remains high at 91% as of the end of the quarter.
- In February, the European Medicines Agency (EMA) completed inspections of the Company's manufacturing facility as part of the EMA's review of the Company's Marketing Authorization Application (MAA) for B-VEC for the treatment of DEB in patients from birth. GMP certification and a decision on the MAA are both anticipated in 2H 2024.
- The Company remains on track to file a Japan New Drug Application in 2H 2024, following completion of the efficacy portion of the Japan open label extension study of B-VEC in April, and anticipates a potential authorization in 2025. 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.

Respiratory

KB407 for the treatment of cystic fibrosis (CF)

- In March, the Company completed 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. The Company intends to initiate the third and final cohort in 2Q 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 February, the Company dosed the first patient in the KB408 Phase 1 SERPENTINE-1 study. SERPENTINE-1 is a Phase 1 open label, single dose escalation study in adult patients with AATD with a PI*ZZ genotype. Recruitment is ongoing and details about the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier: NCT06049082. The Company remains on track to report interim data from the study in 2H 2024.

Ophthalmology

B-VEC eyedrops for ocular complications of DEB

- In February, 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, the Company aligned with the U.S. Food and Drug Administration (FDA) on the 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, 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.

Pipeline expansion

- On May 7, 2024, the Company will be presenting preclinical data at the Association for Research in Vision & Ophthalmology 2024 Annual Meeting highlighting the potential of the Company's HSV-1-based gene delivery platform for back of the eye gene delivery.
- The Company is actively evaluating multiple, preclinical-stage genetic medicine candidates for the treatment of diseases of the front and back of the eye.

Oncology

Inhaled KB707 for the treatment of solid tumors of the lung

- In April, the Company dosed the first patient in the open label, multi-center, monotherapy, dose escalation and expansion Phase 1 KYANITE-1 clinical study in patients with locally advanced or metastatic solid tumors of the lung. Recruitment is ongoing and details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06228326.
- In February, 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.

Intratumoral KB707 for the treatment of injectable solid tumors

- In April, the Company successfully completed enrollment in Cohort 3 of the Phase 1 OPAL-1 clinical study in patients with locally advanced or metastatic solid tumor malignancies. The first two dose escalation cohorts of the OPAL-1 study have been cleared and KB707 has been generally well tolerated to date with no study patients experiencing dose-limiting toxicities or drug-related grade ≥3 adverse events. Based on the current rate of enrollment, the Company expects to report interim data in 2H 2024. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT05970497.
- Preclinical data generated in syngeneic mouse models using murine equivalents to KB707 were presented at the American Association for Cancer Research 2024 Annual Meeting that was held in April. Study results demonstrated that interleukin-12 and interleukin-2, delivered intratumorally using the Company's HSV-1-based gene delivery platform, enhanced local and systemic T-cell effector responses consistent with previously reported anti-tumor activity.

Aesthetics

KB301 for the treatment of aesthetic indications

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

Financial Results for the Quarter Ended March 31, 2024:

- Cash, cash equivalents, and investments totaled $622.3 million on March 31, 2024.
- The Company recorded its first sales for patients that began treatment in August 2023 and the resulting product revenue, net totaled $45.3 million for the quarter ended March 31, 2024.
- Cost of goods sold totaled $2.4 million for the quarter ended March 31, 2024. 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 March 31, 2024 were $11.0 million, inclusive of $1.9 million of stock-based compensation, compared to $12.3 million, inclusive of stock-based compensation of $2.5 million for the quarter ended March 31, 2023.
- Selling, general, and administrative expenses for the quarter ended March 31, 2024 were $26.1 million, inclusive of stock-based compensation of $7.4 million, compared to $24.0 million, inclusive of stock-based compensation of $7.9

million, for the quarter ended March 31, 2023.

- Net income for the quarter ended March 31, 2024 was $0.9 million, or $0.03 per common share (basic and diluted). Net loss for the quarter ended March 31, 2023 was $45.3 million, or $1.76 per common share (basic and diluted).
- For additional information on the Company's financial results for the quarter ended March 31, 2024, please refer to the Form 10-Q filed with the SEC.

Financial Guidance

For the year ending December 31, 2024, we continue to anticipate approximately $150 million to $175 million of Non-GAAP Research and Development ("R&D") and Selling, General and Administrative ("SG&A") expense. 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. This could materially affect the calculation of forward-looking GAAP combined R&D and SG&A Expense as it is inherently uncertain. Refer to Non-GAAP Financial Measures section below for additional information.

Conference Call

The Company will host an investor webcast on May 6, 2024, at 8:30 am ET.

Investors and the general public can access the live webcast at: https://www.webcaster4.com/Webcast/Page/3018/50407

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; the Company's beliefs about the timing of potential decisions from the EMA in connection with the Company's MAA for B-VEC for the treatment of DEB in patients from birth; the Company's beliefs about the timing of filing a Japanese New Drug Application for B-VEC for the treatment of DEB patients and a potential Japanese authorization; the Company's expectation regarding the timing of initiating Cohort 3 of its CORAL-1 study evaluating KB407 in patients with cystic fibrosis; the Company's plans to initiate its study of B-VEC eyedrops to treat ocular complications of DEB in 2H 2024; the timing of Jeune Aesthetics' plans to announce results of Cohort 3 and Cohort 4 of its Phase 1 clinical study to evaluate KB301; the expected timing of key data readouts; 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.

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 and depends on various factors, some of which are outside of the Company's control.

CONTACT
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Condensed Consolidated Balance Sheet Data:

(in thousands)	March 31, 2024 (unaudited)	December 31, 2023
Balance sheet data:		

Cash and cash equivalents	$ 359,006	$ 358,328
Short-term investments	179,253	173,850
Long-term investments	83,996	61,954
Total assets	853,296	818,355
Total liabilities	54,054	39,714
Total stockholders' equity	$ 799,242	$ 778,641

Condensed Consolidated Statements of Operations:

	Three Months Ended March 31,		
	2024	**2023**	**Change**
(in thousands, except per share data)	**(unaudited)**		
Revenue			
Product revenue, net	$ 45,250	$ —	$ 45,250
Expenses			
Cost of goods sold	2,419	—	2,419
Research and development	10,957	12,288	(1,331)
Selling, general, and administrative	26,058	24,035	2,023
Litigation settlement	12,500	12,500	—
Total operating expenses	51,934	48,823	3,111
Loss from operations	(6,684)	(48,823)	42,139
Other income			
Interest and other income, net	7,616	3,526	4,090
Net income (loss)	$ 932	$ (45,297)	$ 46,229
Net income (loss) per common share:			
Basic	$ 0.03	$ (1.76)	
Diluted	$ 0.03	$ (1.76)	
Weighted-average common shares outstanding:			
Basic	28,295	25,712	
Diluted	29,291	25,712	

Source: Krystal Biotech, Inc.