Krystal Biotech Announces First Quarter 2025 Financial and Operating Results

May 6, 2025

VYJUVEK approved in Europe for the treatment of DEB patients from birth

$88.2 million in 1Q VYJUVEK revenue and $429.4 million since launch in Q3 2023

Second ophthalmic program in clinic - KB801 for the treatment of neurotrophic keratitis

Upcoming clinical readouts in 2025 - CF, AATD, ocular complications of DEB, and aesthetics

Strong balance sheet, ending the quarter with $765.3 million in cash and investments

PITTSBURGH, May 06, 2025 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the “Company”) (NASDAQ: KRYS) today reported financial results for the first quarter ending March 31, 2025 and provided a business update.

"We were thrilled to receive VYJUVEK approval in Europe, and with the potential expansion to Japan later in the year, we continue to make tremendous progress on our goal of delivering profound long-term benefit to DEB patients around the world,” said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. “With today’s announcement of our second clinical-stage ophthalmology program, the near-term initiation of our registrational study in DEB patients with eye lesions, and upcoming molecular readouts for our rare respiratory disease product candidates, KB407 and KB408, we are pushing forward a broad and expanded pipeline which we expect will ultimately demonstrate the power of HSV-1 based gene delivery in the lung, eye, and skin, and - most importantly - deliver meaningful benefit to patients.”

VYJUVEK® (beremagene geperpavec-svdt, or B-VEC)
for the Treatment of Dystrophic Epidermolysis Bullosa (DEB)

- In April, the European Commission approved VYJUVEK for the treatment of wounds in patients with DEB who have mutations in the collagen type VII alpha 1 chain (*COL7A1*) gene, starting from birth. The Company is on track for its first European launch in Germany in mid-2025.
- The Company recorded $88.2 million in VYJUVEK net product revenue for the first quarter of 2025. Gross margin for the quarter was 94%.
- As of April, the Company has secured over 540 reimbursement approvals for VYJUVEK in the U.S. and continues to maintain strong access nationwide including positive access determinations for 97% of lives covered under commercial and Medicaid plans.
- High patient compliance with weekly treatment while on drug continued at 83% as of the end of the quarter.
- The Company continues to expect a decision by Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) on its Japan New Drug Application (JNDA) in 2H 2025.
- In April, the British Journal of Dermatology published a case highlighting the success of VYJUVEK in promoting durable wound healing following surgical excision of a large squamous cell carcinoma (SCC) in a recessive DEB patient. The treated patient reported complete healing of their over 100 cm^2 post-surgical wound after seven weeks of VYJUVEK therapy. Wound healing benefits were durable, with complete wound closure also observed upon clinical examination at four and ten month post-operative visits.
- In April, the results of the Company’s open label extension (OLE) study of VYJUVEK in DEB patients were published in the American Journal of Clinical Dermatology.

Respiratory

KB407 for the treatment of cystic fibrosis (CF)

- The Company continues to enroll Cohort 3 of CORAL-1, the Company’s multi-center, dose escalation study evaluating KB407 in patients with CF, regardless of their underlying genotype. The Company received full sanctioning of the study protocol by the Cystic Fibrosis Foundation Therapeutic Development Network in January and remains on track for an interim molecular data readout for Cohort 3 patients in mid-2025. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT05504837.

KB408 for the treatment of alpha-1 antitrypsin deficiency (AATD) lung disease

- The Company continues to enroll in Cohort 2 and is working to enroll in Cohort 3 of SERPENTINE-1, the Company’s open label, single dose escalation study in adult patients with AATD with a Pi*ZZ or a Pi*ZNull genotype. Late last year, the Company announced successful *SERPINA1* gene delivery and functional alpha-1 antitrypsin (AAT) expression reaching

therapeutic levels as part of an interim clinical update for Cohorts 1 and 2 of SERPENTINE-1. Inhaled KB408 was safe and well-tolerated at both tested dose levels. The Company expects to report molecular results for the additional Cohort 2 and 3 patients later this year. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT06049082.

Ophthalmology

KB803 for the treatment of ocular complications of DEB

- The Company continues to enroll in its ongoing natural history study to prospectively collect data on the frequency of corneal abrasions in patients with DEB and serve as a run-in period for patients who may be eligible to participate in the Company's registrational Phase 3 study evaluating KB803's effect on ocular complications of DEB. The Company expects to dose the first patient in the registrational KB803 Phase 3 IOLITE study later this month.

KB801 for the treatment of neurotrophic keratitis (NK)

- In April, the U.S. Food and Drug Administration (FDA) cleared the Company's investigational new drug (IND) application to evaluate KB801, the Company's second clinical-stage ophthalmology program, for the treatment of NK. NK is a rare, degenerative corneal disease caused by nerve damage in the eye leading to corneal epithelial defects, ulcers, and perforation, with an estimated prevalence in the range of 10 to 50 cases per 100,000. KB801 was developed using the Company's novel replication-defective, non-integrating HSV-1-based vector and is designed to deliver two transgene copies to the corneal epithelium as an eye drop to enable local nerve growth factor (NGF) production and corneal healing. Recombinant NGF eye drops have been shown to significantly improve corneal healing and are approved for the treatment of NK in multiple jurisdictions worldwide including the United States, but the short half-life of recombinant protein results in rapid clearance from the eye, thereby necessitating burdensome administration six times a day, and may lead to suboptimal treatment outcomes. Eye pain during treatment is also frequently reported.
- In preclinical development, KB801 was shown to efficiently transduce corneal epithelial cells *in vitro* and *in vivo* leading to sustained NGF production in the front of the eye. By transducing the cells of the corneal epithelium to produce and secrete NGF, KB801 has the potential to significantly reduce the treatment burden for patients while also maintaining more consistent NGF levels in the front of the eye. Yesterday, the Company presented preclinical safety and efficacy data supporting the clinical development of KB801 at the Association for Research in Vision and Ophthalmology (ARVO) 2025 Annual Meeting.
- The Company expects to dose the first patient in EMERALD-1, the Company's randomized, double-blind, placebo-controlled, multi-center Phase 1/2 study evaluating KB801 in moderate-to-severe NK patients, later this month.

Oncology

Inhaled KB707 for the treatment of solid tumors of the lung

- Enrollment is ongoing in the Company's KYANITE-1 study, a Phase 1/2 open label, multi-center, dose escalation and expansion study evaluating inhaled KB707, as monotherapy or in combination, in patients with locally advanced or metastatic solid tumors of the lung. Near the end of last year, the Company announced early clinical evidence of monotherapy activity in heavily pre-treated patients with advanced non-small cell lung cancer (NSCLC) treated with inhaled KB707, achieving an objective response rate of 27% and disease control rate of 73% as of data cut-off. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06228326.
- A clinical update on the monotherapy cohort from KYANITE-1 is expected to be presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting next month.

Intratumoral KB707 for the treatment of injectable solid tumors

- The Company continues to enroll in OPAL-1, a Phase 1/2 open label, multi-center, dose escalation and expansion study evaluating intratumoral KB707, either as monotherapy or in combination, 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.

Aesthetics

KB301 for the treatment of dynamic wrinkles of the décolleté

- Jeune Aesthetics is currently developing a décolleté-specific photo numeric scale for advanced clinical development of KB301. Jeune Aesthetics expects to align with the FDA on the scale and enroll the first subject in a multi-center, randomized, placebo-controlled Phase 2 study evaluating KB301 for the treatment of dynamic wrinkles of the décolleté in Q4 2025.

KB304 for the treatment of wrinkles

- In February, Jeune Aesthetics completed enrollment in PEARL-2, an ongoing, randomized and placebo-controlled Phase 1 study evaluating KB304 for the treatment of wrinkles. Jeune Aesthetics expects to report top-line results from the study in 2H 2025. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06724900.

Dermatology

KB105 for the treatment of lamellar ichthyosis

- The Company expects to initiate the Phase 2 portion of its KB105 Phase 1/2 JADE-1 trial evaluating KB105 for the treatment of TGM1-deficient lamellar ichthyosis in pediatric patients in 2026.

Pipeline expansion

- The Company will be presenting preclinical data at the Society for Investigative Dermatology (SID) 2025 Annual Meeting later this week on early-stage dermatology genetic medicine candidates for the treatment of Hailey-Hailey and Darier diseases.

Financial Results for the Quarter Ended March 31, 2025:

- Cash, cash equivalents, and investments totaled $765.3 million as of March 31, 2025.
- Product revenue, net totaled $88.2 million and $45.3 million for the quarters ended March 31, 2025 and March 31, 2024, respectively.
- Cost of goods sold totaled $5.0 million and $2.4 million for the quarters ended March 31, 2025 and March 31, 2024, respectively.
- Research and development expenses for the quarter ended March 31, 2025 were $14.3 million, inclusive of $2.5 million of stock-based compensation, compared to $11.0 million, inclusive of stock-based compensation of $1.9 million for the quarter ended March 31, 2024.
- Selling, general, and administrative expenses for the quarter ended March 31, 2025 were $32.7 million, inclusive of stock-based compensation of $11.0 million, compared to $26.1 million, inclusive of stock-based compensation of $7.4 million, for the quarter ended March 31, 2024.
- Net income for the quarter ended March 31, 2025 was $35.7 million, or $1.24 per common share (basic) and $1.20 per common share (diluted). Net income for the quarter ended March 31, 2024 was $0.9 million, or $0.03 per common share (basic) and $0.03 per common share (diluted).

Financial Guidance

($ in millions)	**FY 2025 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 2025 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 May 6, 2025, at 8:30 am ET.

Investors and the general public can access the live webcast at:
https://www.webcaster4.com/Webcast/Page/3018/52291

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. VYJUVEK is approved in the United States and Europe.

U.S. 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 Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRYS) is a fully integrated, commercial-stage, global biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK®, the Company's first commercial product, is the first-ever redosable gene therapy, and the first genetic medicine approved by the FDA and EMA 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 commercial launch of VYJUVEK in the United States; the commercial launch of VYJUVEK in the EU, including the expectation of the first European launch in Germany in mid-2025; potential marketing authorization for B-VEC in Japan, including timing of regulatory approval; the timing regarding reporting interim molecular data from Cohort 3 of the Company's KB407 clinical trial; the timing regarding reporting results from Cohort 2 and Cohort 3 of the Company's KB408 clinical trial; dosing the first patient in the registrational KB803 Phase 3 IOLITE study later this month; the estimated prevalence of neurotrophic keratitis; the potential of KB801 to significantly reduce the treatment burden for patients while also maintaining more consistent NGF levels in the front of the eye; timing regarding dosing the first patient in EMERALD-1, the Company's randomized, double-blind, placebo-controlled, multi-center Phase 1/2 study evaluating KB801 in moderate-to-severe NK patients; the timing of scale development and enrolling the first subject in a randomized, placebo-controlled Phase 2 study evaluating KB301; the timing of reporting top-line results from Jeune Aesthetics' KB304 study; the timing of initiation of the Phase 2 portion of the KB105 Phase 1/2 study; the potential of the Company's HSV-1 based gene delivery platform; 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; 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, 2025 (unaudited)	December 31, 2024
Balance sheet data:		
Cash and cash equivalents	$ 308,770	$ 344,865
Short-term investments	308,076	252,652
Long-term investments	148,472	152,114
Total assets	1,074,416	1,055,838
Total liabilities	89,742	109,458
Total stockholders' equity	$ 984,674	$ 946,380

Condensed Consolidated Statements of Operations:

	Three Months Ended March 31,		
	2025	2024	Change
(in thousands, except per share data)	(unaudited)		
Revenue			
Product revenue, net	$ 88,183	$ 45,250	$ 42,933
Expenses			
Cost of goods sold	5,028	2,419	2,609
Research and development	14,255	10,957	3,298
Selling, general, and administrative	32,723	26,058	6,665
Litigation settlement	—	12,500	(12,500)
Total operating expenses	52,006	51,934	72
Income (loss) from operations	36,177	(6,684)	42,861
Other income			
Interest and other income, net	7,420	7,616	(196)
Income before income taxes	43,597	932	42,665
Income tax expense	(7,864)	—	(7,864)
Net income	$ 35,733	$ 932	$ 34,801
Net income per common share:			
Basic	$ 1.24	$ 0.03	
Diluted	$ 1.20	$ 0.03	
Weighted-average common shares outstanding:			
Basic	28,815	28,295	
Diluted	29,871	29,291	



Source: Krystal Biotech, Inc.