Krystal Biotech Announces Second Quarter 2025 Financial and Operating Results

August 4, 2025

$96.0 million in 2Q VYJUVEK revenue and $525.4 million since launch in 3Q 2023

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

Strong balance sheet, ending the quarter with $820.8 million in cash and investments

PITTSBURGH, Aug. 04, 2025 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS) today reported financial results for the second quarter ending June 30, 2025 and provided a business update.

"With the approval of VYJUVEK in Europe and Japan, we are on the cusp of a global expansion that will build on our U.S. sales momentum and dramatically expand VYJUVEK access to DEB patients around the world," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "At the same time, we are rapidly approaching key readouts in both the lung and eye. Success in these tissues would be transformational for Krystal, with profound implications for the versatility of our platform and for patients in need."

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

- The Company recorded $96.0 million in VYJUVEK net product revenue for the second quarter of 2025. Gross margin for the quarter was 93%.
- The Company has secured over 575 reimbursement approvals for VYJUVEK in the U.S. and continues to maintain strong access nationwide.
- Patient compliance with weekly treatment while on drug was 82% as of the end of the quarter.
- In July, Japan's Ministry of Health, Labour and Welfare (MHLW) approved VYJUVEK for the treatment of patients with DEB from birth. The Japanese approval allows for dosing at home or in a healthcare setting, with the option for administration by patients or their family members. The Company is on track to launch in Japan before the end of 2025.
- Also in July, the results of the Company's open label extension (OLE) study of VYJUVEK in Japanese DEB patients were published in the Journal of Dermatology. The results of the Japanese OLE study were in agreement with the Phase 3 and OLE studies conducted in the United States, supporting the efficacy and safety of VYJUVEK in Japanese patients with DEB.
- The Company is working to enable first European launch in Germany in 3Q and France in 4Q. Earlier this year, the European Commission (EC) 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 approval granted by the EC allows for flexible VYJUVEK dosing either at home or in a healthcare setting, with the option for patient or caregiver administration if deemed appropriate by a healthcare professional.

Respiratory

KB407 for the treatment of cystic fibrosis (CF)

- The Company has enrolled 4 patients in Cohort 3 of CORAL-1, the Company's multi-center, dose escalation study evaluating KB407 in patients with CF, regardless of their underlying genotype, and expects to provide an interim molecular data readout for Cohort 3 patients before year end. 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 confirmed *SERPINA1* delivery and functional AAT expression with corresponding reductions in free neutrophil elastase in a third patient that underwent bronchoscopy after dosing with KB408 in Cohort 2 of SERPENTINE-1, the Company's open label dose escalation study in adult patients with AATD with a Pi*ZZ or a Pi*ZNull genotype. A total of five patients were dosed in Cohort 2 of which three received bronchoscopies.
- Based on these data, the Company has amended SERPENTINE-1 protocol to investigate repeat dosing at the Cohort 2 dose level (the repeat dose cohort now referred to as "Cohort 2B"). The first patient in Cohort 2B was dosed earlier this month and enrollment in repeat dose cohort is ongoing. Enrollment in single dose cohorts is now closed. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06049082.

Ophthalmology

KB803 for the treatment and prevention of corneal abrasions in DEB patients

- In June, the Company dosed the first patient in IOLITE, the Company's intra-patient, double-blind, multicenter, placebo-controlled Phase 3 study with crossover design evaluating KB803 for the treatment and prevention of corneal abrasions in DEB patients. The primary study endpoint will be the change in the average number of days per month with corneal abrasion symptoms while receiving KB803 versus placebo. Enrollment in IOLITE is ongoing. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT07016750.
- 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 IOLITE.

KB801 for the treatment of neurotrophic keratitis (NK)

- In July, the Company dosed the first patient in EMERALD-1, the Company's 2:1 randomized, double-masked, multicenter, placebo-controlled study evaluating KB801 for the treatment of NK. The primary objective of EMERALD-1 is to evaluate the safety and tolerability of topical ocular administration of KB801 in patients with NK. The secondary objective is evaluation of efficacy based on the proportion of patients with complete durable healing of corneal epithelium at 8 weeks. Enrollment in EMERALD-1 is ongoing. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT06999733.
- In May, 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. Collectively, data presented at ARVO demonstrated that KB801 can efficiently transduce corneal epithelial cells *in vitro* and *in vivo* leading to sustained nerve growth factor (NGF) production in the front of the eye.

Oncology

Inhaled KB707 for the treatment of solid tumors of the lung

- At the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting in June, the Company issued a clinical update on a previously disclosed cohort of heavily pre-treated patients with advanced non-small cell lung cancer (NSCLC) treated with inhaled KB707 as monotherapy in the Company's KYANITE-1 Phase 1/2 study. With an extended follow up and a new data cut-off of April 15, 2025, deepening of responses was observed with an improved objective response rate of 36%. Median duration of response and progression free survival were not reached. Inhaled KB707 continued to be safe and generally well tolerated and amenable to administration in outpatient setting. Treatment-emergent adverse events have been predictable, primarily mild to moderate in severity, and transient, with no Grade 4 or 5 adverse events observed.
- 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 in patients with locally advanced or metastatic solid tumors of the lung. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06228326.

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 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

KB304 for the treatment of wrinkles of the décolleté

- In July, Jeune Aesthetics, Inc. ("Jeune Aesthetics"), a wholly-owned subsidiary of the Company, announced positive safety and efficacy results from PEARL-2, a 2:1 randomized, double-blind, placebo-controlled Phase 1 study evaluating KB304, for the treatment of wrinkles of the décolleté. Meaningful aesthetic improvements across multiple attributes, including wrinkles and elasticity, were reported by the study investigator and subjects alike following KB304 treatment, with clear and statistically significant advantages over placebo. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06724900.
- Based on the broad aesthetic improvements observed with KB304 in PEARL-2, Jeune has selected KB304 for progression into Phase 2 study for the treatment of wrinkles of the décolleté. Jeune Aesthetics recently completed development and validation of a décolleté-specific photonumeric scale to support the Phase 2 evaluation of KB304. Jeune intends to submit the scale to the United States Food and Drug Administration ("FDA") and align on the Phase 2 study protocol in 2H 2025, enabling a potential Phase 2 study start in 1H 2026.

KB301 for the treatment of aesthetic indications

- With the prioritization of KB304 development for the treatment of wrinkles of the décolleté, Jeune is now evaluating alternate aesthetic conditions most suitable for the advanced clinical development of KB301. Jeune previously reported positive safety and efficacy results for KB301 in the treatment of multiple priority aesthetic sites of the face and body, as

well as confirmation of *COL3A1* gene delivery, as part of the now completed PEARL-1 Phase 1 study. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.

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

- In May, the Company presented preclinical data at the Society for Investigative Dermatology (SID) 2025 Annual Meeting on early-stage dermatology genetic medicine candidates for the treatment of Hailey-Hailey and Darier diseases.

Financial Results for the Quarter Ended June 30, 2025:

- Cash, cash equivalents, and investments totaled $820.8 million as of June 30, 2025.
- Product revenue, net totaled $96.0 million and $70.3 million for the quarters ended June 30, 2025 and June 30, 2024, respectively.
- Cost of goods sold totaled $7.2 million and $6.0 million for the quarters ended June 30, 2025 and June 30, 2024, respectively.
- Research and development expenses for the quarter ended June 30, 2025 were $14.4 million, inclusive of $2.6 million of stock-based compensation, compared to $15.6 million, inclusive of stock-based compensation of $2.8 million for the quarter ended June 30, 2024.
- Selling, general, and administrative expenses for the quarter ended June 30, 2025 were $35.2 million, inclusive of stock-based compensation of $11.5 million, compared to $27.6 million, inclusive of stock-based compensation of $10.4 million, for the quarter ended June 30, 2024.
- Net income for the quarter ended June 30, 2025 was $38.3 million, or $1.33 per common share (basic) and $1.29 per common share (diluted). Net income for the quarter ended June 30, 2024 was $15.6 million, or $0.54 per common share (basic) and $0.53 per common share (diluted).
- For additional information on the Company's financial results for the three months ended June 30, 2025, please refer to the Form 10-Q filed with the SEC.

Financial Results for the Six Months Ended June 30, 2025:

- Product revenue, net totaled $184.2 million and $115.5 million for the six months ended June 30, 2025 and June 30, 2024, respectively.
- Cost of goods sold totaled $12.2 million and $8.4 million for the six months ended June 30, 2025 and June 30, 2024, respectively.
- Research and development expenses for the six months ended June 30, 2025 were $28.7 million, inclusive of $5.1 million of stock-based compensation, compared to $26.5 million, inclusive of stock-based compensation of $4.6 million for the six months ended June 30, 2024.
- Selling, general, and administrative expenses for the six months ended June 30, 2025 were $67.9 million, inclusive of stock-based compensation of $22.5 million, compared to $53.7 million, inclusive of stock-based compensation of $17.8 million, for the six months ended June 30, 2024.
- Net income for the six months ended June 30, 2025 was $74.1 million, or $2.57 per common share (basic) and $2.48 per common share (diluted). Net income for the six months ended June 30, 2024 was $16.5 million, or $0.58 per common share (basic) and $0.56 per common share (diluted).
- For additional information on the Company's financial results for the six months ended June 30, 2025, please refer to the Form 10-Q filed with the SEC.

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 August 4, 2025, at 8:30 am ET.

Investors and the general public can access the live webcast at:

https://www.webcaster4.com/Webcast/Page/3018/52772

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, Europe, and Japan.

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 in the United States, Europe, and Japan 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 timing of a global expansion that will build on the Company's U.S. sales momentum and dramatically expand VYJUVEK access to DEB patients around the world; the Company rapidly approaching key readouts in both the lung and eye and that success in these tissues would be transformational for the Company with profound implications for the versatility of the Company's platform; the commercial launch of VYJUVEK in the United States; the expectation of the first European launch of VYJUVEK in Germany in 3Q 2025 and France in 4Q 2025; the Company being on track to launch VYJUVEK in Japan before the end of 2025; the timing regarding reporting interim molecular data from Cohort 3 of the Company's KB407 clinical trial; plans to submit the décolleté-specific photonumeric scale to the FDA and align on the Phase 2 study protocol for KB304 in 2H 2025, enabling a potential Phase 2 study start in 1H 2026; 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

Investors and Media:

Stéphane Paquette, PhD
Krystal Biotech
spaquette@krystalbio.com

Condensed Consolidated Balance Sheet Data:

(in thousands)	June 30, 2025 (unaudited)	December 31, 2024
Balance sheet data:		
Cash and cash equivalents	$ 353,829	$ 344,865
Short-term investments	328,157	252,652
Long-term investments	138,807	152,114
Total assets	1,138,394	1,055,838
Total liabilities	97,747	109,458
Total stockholders’ equity	$ 1,040,647	$ 946,380

Condensed Consolidated Statements of Operations:

	Three Months Ended June 30,		
	2025	2024	Change
(in thousands, except per share data)	(unaudited)		
Revenue			
Product revenue, net	$ 96,042	$ 70,284	$ 25,758
Operating Expenses			
Cost of goods sold	7,165	6,009	1,156
Research and development	14,410	15,583	(1,173)
Selling, general, and administrative	35,160	27,626	7,534
Litigation settlement	—	12,500	(12,500)
Total operating expenses	56,735	61,718	(4,983)
Income from operations	39,307	8,566	30,741
Other income			
Interest and other income, net	7,468	7,479	(11)
Income before income taxes	46,775	16,045	30,730
Income tax expense	(8,442)	(477)	(7,965)
Net income	$ 38,333	$ 15,568	$ 22,765

Net income per common share:				
Basic	$	1.33	$	0.54
Diluted	$	1.29	$	0.53
Weighted-average common shares outstanding:				
Basic		28,910		28,598
Diluted		29,749		29,637

Condensed Consolidated Statements of Operations:

	Six Months Ended June 30, 2025		
	2025	**2024**	**Change**
(in thousands, except per share data)	**(unaudited)**		
Revenue			
Product revenue, net	$ 184,225	$ 115,535	$ 68,690
Operating Expenses			
Cost of goods sold	12,193	8,428	3,765
Research and development	28,666	26,539	2,127
Selling, general, and administrative	67,883	53,685	14,198
Litigation settlement	—	25,000	(25,000)
Total operating expenses	108,742	113,652	(4,910)
Income from operations	75,483	1,883	73,600
Other income			
Interest and other income, net	14,889	15,095	(206)
Income before income taxes	90,372	16,978	73,394
Income tax expense	(16,305)	(477)	(15,828)
Net income	$ 74,067	$ 16,501	$ 57,566
Net income per common share:			
Basic	$ 2.57	$ 0.58	
Diluted	$ 2.48	$ 0.56	
Weighted-average common shares outstanding:			
Basic	28,863	28,446	
Diluted	29,819	29,504	

Source: Krystal Biotech, Inc.