



Krystal Biotech Announces Third Quarter 2025 Financial and Operating Results

November 3, 2025

\$97.8 million in 3Q VYJUVEK revenue and \$623.2 million since U.S. launch

VYJUVEK launched in Germany in 3Q; launched in France and Japan in 4Q

Updated U.S. VYJUVEK label expands eligible patient population and provides greater patient flexibility

FDA grants platform technology designation

CF interim results expected in 4Q

Strong balance sheet, ending the quarter with \$864.2 million in cash and investments

PITTSBURGH, Nov. 03, 2025 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS) today reported financial results for the third quarter ending September 30, 2025 and provided a business update.

"It is immensely gratifying to see a growing number of DEB patients worldwide benefit from access to VYJUVEK, and we look forward to rapidly and sustainably expanding that number in the months ahead," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "With multiple near-term readouts, starting with cystic fibrosis in Q4, and a strong balance sheet, Krystal is well positioned to advance our pipeline and deliver transformative therapies to patients with serious and rare diseases."

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

- The Company recorded \$97.8 million in VYJUVEK net product revenue for the third quarter of 2025. Gross margin for the quarter was 96%.
- The Company has secured over 615 reimbursement approvals for VYJUVEK in the United States and continues to maintain strong access nationwide.
- In September, the United States Food and Drug Administration (FDA) approved a label update which expanded the VYJUVEK eligible patient population to include DEB patients from birth and provided patients greater flexibility with respect to VYJUVEK application, including the option for patients or their caregivers to apply VYJUVEK at home on their own.
- In late August, the Company launched VYJUVEK in Germany, its first commercial launch of VYJUVEK outside of the United States. The Company estimates that approximately 20 patients have been prescribed VYJUVEK therapy across Germany, with over 10 German centers prescribing VYJUVEK to date. The Company has started discussions with payers in Germany and expects pricing negotiations to continue until at least 2H 2026.
- In September, the Haute Autorité de Santé (HAS) in France approved early reimbursed access to VYJUVEK under the post-marketing authorization Accès Précoce AP2 program, including the option to dispense VYJUVEK outside of the hospital setting, and, in October, the Company launched VYJUVEK in France. Also in October, the HAS appraised VYJUVEK as Amélioration du Service Médical Rendu (ASMR) III, a designation which recognizes the added clinical benefit of VYJUVEK and is an important milestone as the Company advances access discussions in France. According to the Transparency Committee of the HAS, only 11% of new medicines reviewed in 2024 were appraised as ASMR I-III. The Company continues to engage with payers in France and expects negotiations to continue for at least the next 15 months.
- In October, the Company launched VYJUVEK in Japan following successful completion of pricing negotiations with Japan's Ministry of Health, Labour and Welfare.
- Also in October, VYJUVEK was awarded the Prix Galien Italia in the Advanced Therapy Medicinal Products category in Italy. The Prix Galien is an international awards program recognizing excellence in scientific innovation that improves the state of human health.
- The Company is also preparing regulatory filings for the United Kingdom and Switzerland, as well as initiating pricing discussions with relevant authorities in other key Western European markets. The timing of European launches outside of France and Germany will depend on the cadence and outcomes of pricing negotiations.
- In addition to the Company's direct VYJUVEK launches in the United States, major European markets, and Japan, the Company is also building a specialty distributor network to support commercialization of VYJUVEK in the rest of world and has executed agreements with leading regional specialty distributors covering key markets in the Middle East, Turkey, and Central and Eastern Europe, with additional network expansion expected in 2026.

Respiratory

KB407 for the treatment of cystic fibrosis (CF)

- The Company continues to enroll 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 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 continues to enroll in repeat dose Cohort 2B of SERPENTINE-1, the Company's open label dose escalation study evaluating KB408 in adult patients with AATD with a Pi*ZZ or a Pi*ZNull genotype, and expects to report interim data for this cohort in 1H 2026. Cohort 2B is designed to evaluate the safety and tolerability of repeat KB408 dosing at the same dose level that was [previously shown](#) to safely deliver *SERPINA1* to the lungs of AATD patients after a single dose. 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

- The Company expects to complete enrollment 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, before year end. 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. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT07016750.

KB801 for the treatment of neurotrophic keratitis (NK)

- The Company continues to enroll 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 eight weeks. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT06999733.
- In October, the FDA granted platform technology designation to the genetically modified, non-replicating herpes simplex virus type 1 viral vector used in KB801. The FDA's platform technology designation program is intended to provide efficiencies in drug development, manufacturing, and review processes for drug product applications that incorporate designated platform technologies, with potential benefits including more frequent engagement with the FDA during clinical development, as well as opportunities to leverage manufacturing and nonclinical safety data from FDA-approved products that incorporate designated platform technologies, such as VYJUVEK, in submissions to the FDA.

Oncology

Inhaled KB707 for the treatment of solid tumors of the lung

- In August, the Company announced that the FDA had granted the Company an End of Phase 2 meeting to discuss the inhaled KB707 program and [early](#) evidence of efficacy for the treatment of non-small cell lung cancer (NSCLC) from KYANITE-1, the Company's ongoing open label, multi-center, dose escalation and expansion Phase 1/2 study. Based on the FDA's feedback, the Company now expects that a single Phase 3 registrational study, evaluating inhaled KB707 in combination with chemotherapy against chemotherapy alone in patients with advanced NSCLC, would be sufficient to support potential registration of inhaled KB707 in combination with chemotherapy as a second-line treatment for NSCLC.
- In support of this potential registrational pathway, the Company has opened a new cohort in KYANITE-1 to evaluate a fixed inhaled dose of KB707 in combination with chemotherapy in patients with advanced NSCLC. Enrollment in KYANITE-1 is ongoing. The Company expects to report interim efficacy data and potential registrational study plans in 2H 2026. 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 has paused enrollment in OPAL-1, the Company's 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. Patients enrolled in OPAL-1 continue to be followed and based on safety and efficacy results from the study, the Company may adjust development plans for intratumoral KB707. 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

- Jeune Aesthetics, Inc. (Jeune), a wholly-owned subsidiary of the Company, remains on track to initiate a Phase 2 study of its lead program KB304 in 1H 2026 following feedback from the FDA on Jeune's validated décolleté-specific photonumeric scale and Phase 2 study design in 2H 2025.

Dermatology

KB111 for the treatment of Hailey-Hailey disease (HHD)

- In October, the FDA cleared the Company's investigational new drug application to evaluate KB111 for the treatment of HHD, a rare genetic disease of the skin linked to mutations in the *ATP2C1* gene and low expression levels of *ATP2C1*-encoded calcium-transporting ATPase type 2C member 1 (ATP2C1) in keratinocytes. HHD is characterized by painful rash and blistering in skin folds, with a relapsing-remitting clinical course aggravated by heat and sweating. Patients with HHD report debilitating symptoms of pain, itch, burning, infections, and body odor, as well severe, negative impacts on quality of life and psychological distress. The prevalence of HHD is not well characterized and is most commonly estimated at roughly 1 per 50,000, although underreporting is possible. Current disease management is supportive in nature and no specific therapy for HHD has been approved by the FDA or the European Medicines Agency. KB111 was developed using the Company's novel replication-defective, non-integrating HSV-1-based vector and is designed to deliver two copies of the full-length, wild-type *ATP2C1* gene following topical application with the goal of increasing functional ATP2C1 levels in the skin to accelerate lesion healing and meaningfully reduce disease burden for HHD patients. The Company presented preclinical data on the KB111 program at the Society for Investigative Dermatology 2025 Annual Meeting earlier this year. Data presented at the meeting demonstrated that KB111 could efficiently deliver *ATP2C1* to keratinocytes *in vitro* and *in vivo* resulting in increased expression of functional ATP2C1.
- The Company expects to dose HHD patients in an intra-patient randomized, double-blind, placebo-controlled, multi-center study evaluating KB111 in 1H 2026.

Financial Results for the Quarter Ended September 30, 2025:

- Cash, cash equivalents, and investments totaled \$864.2 million as of September 30, 2025.
- Product revenue, net totaled \$97.8 million and \$83.8 million for the quarters ended September 30, 2025 and September 30, 2024, respectively.
- Cost of goods sold totaled \$4.3 million and \$6.7 million for the quarters ended September 30, 2025 and September 30, 2024, respectively.
- Research and development expenses for the quarter ended September 30, 2025 were \$14.6 million, inclusive of \$2.6 million of stock-based compensation, compared to \$13.5 million, inclusive of stock-based compensation of \$2.3 million for the quarter ended September 30, 2024.
- Selling, general, and administrative expenses for the quarter ended September 30, 2025 were \$37.6 million, inclusive of stock-based compensation of \$10.6 million, compared to \$28.7 million, inclusive of stock-based compensation of \$11.0 million, for the quarter ended September 30, 2024.
- Net income for the quarter ended September 30, 2025 was \$79.4 million, or \$2.74 per common share (basic) and \$2.66 per common share (diluted). Net income for the quarter ended September 30, 2024 was \$27.2 million, or \$0.95 per common share (basic) and \$0.91 per common share (diluted).
- For additional information on the Company's financial results for the three months ended September 30, 2025, please refer to the Form 10-Q filed with the SEC.

Financial Results for the Nine Months Ended September 30, 2025:

- Product revenue, net totaled \$282.0 million and \$199.4 million for the nine months ended September 30, 2025 and September 30, 2024, respectively.
- Cost of goods sold totaled \$16.5 million and \$15.1 million for the nine months ended September 30, 2025 and September 30, 2024, respectively.
- Research and development expenses for the nine months ended September 30, 2025 were \$43.3 million, inclusive of \$7.7 million of stock-based compensation, compared to \$40.1 million, inclusive of stock-based compensation of \$6.9 million for the nine months ended September 30, 2024.
- Selling, general, and administrative expenses for the nine months ended September 30, 2025 were \$105.3 million,

inclusive of stock-based compensation of \$33.1 million, compared to \$82.3 million, inclusive of stock-based compensation of \$28.9 million, for the nine months ended September 30, 2024.

- Net income for the nine months ended September 30, 2025 was \$153.4 million, or \$5.31 per common share (basic) and \$5.14 per common share (diluted). Net income for the nine months ended September 30, 2024 was \$43.7 million, or \$1.53 per common share (basic) and \$1.47 per common share (diluted).
- For additional information on the Company's financial results for the nine months ended September 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⁾	\$145.0 - \$155.0

(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 November 3, 2025, at 8:30 am ET.

Investors and the general public can access the live webcast at:
<https://www.webcaster5.com/Webcast/Page/3018/53113>.

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 genetic medicine 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 adult and pediatric patients 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 may be applied by a healthcare provider, a caregiver, or the patient.

After treatment, patients and caregivers should be careful not to touch treated wounds and dressings until the next dressing change.

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: KRY5) 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

Statements in this press release about future expectations, plans, and prospects, as well as statements that are not historical facts, including statements about, among other topics, our combined R&D and SG&A expense guidance; our commercial launch of VYJUVEK in the U.S., Europe, Japan, and elsewhere, including our expectations regarding timing of pricing discussions in Germany and France and European launches outside of Germany and France; and our expectations for our product pipeline, including our clinical trial plans, enrollment in clinical trials, and the timing of initiating clinical trials, dosing patients, data read-outs, and FDA submissions and meetings may constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Undue reliance should not be placed on the forward-looking statements in this press release. These statements are not guaranties of future performance and 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 our 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. The Company is providing the information in this press release as of the date hereof and undertakes no duty to update this information unless required by law.

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:

	September 30, 2025	December 31, 2024
	(unaudited)	
<i>(in thousands)</i>		
Balance sheet data:		
Cash and cash equivalents	\$ 392,604	\$ 344,865
Short-term investments	338,465	252,652
Long-term investments	133,113	152,114
Total assets	1,240,094	1,055,838
Total liabilities	102,218	109,458
Total stockholders’ equity	\$ 1,137,876	\$ 946,380

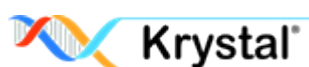
Condensed Consolidated Statements of Operations:

	Three Months Ended September 30,		
	2025	2024	Change
	(unaudited)		
<i>(in thousands, except per share data)</i>			
Revenue			
Product revenue, net	\$ 97,800	\$ 83,841	\$ 13,959
Operating Expenses			
Cost of goods sold	4,263	6,684	(2,421)

Research and development	14,585	13,512	1,073
Selling, general, and administrative	37,578	28,673	8,905
Litigation settlement	—	12,500	(12,500)
Total operating expenses	56,426	61,369	(4,943)
Income from operations	41,374	22,472	18,902
Other income			
Interest and other income, net	6,593	7,297	(704)
Income before income taxes	47,967	29,769	18,198
Income tax benefit (expense)	31,398	(2,589)	33,987
Net income	\$ 79,365	\$ 27,180	\$ 52,185
Net income per common share:			
Basic	\$ 2.74	\$ 0.95	
Diluted	\$ 2.66	\$ 0.91	
Weighted-average common shares outstanding:			
Basic	28,953	28,716	
Diluted	29,833	29,902	

Condensed Consolidated Statements of Operations:

	Nine Months Ended September 30, 2025		Change
	2025	2024	
	(unaudited)		
<i>(in thousands, except per share data)</i>			
Revenue			
Product revenue, net	\$ 282,025	\$ 199,376	\$ 82,649
Operating Expenses			
Cost of goods sold	16,457	15,112	1,345
Research and development	43,251	40,052	3,199
Selling, general, and administrative	105,292	82,339	22,953
Litigation settlement	—	37,500	(37,500)
Total operating expenses	165,000	175,003	(10,003)
Income from operations	117,025	24,373	92,652
Other income			
Interest and other income, net	21,315	22,373	(1,058)
Income before income taxes	138,340	46,746	91,594
Income tax benefit (expense)	15,091	(3,066)	18,157
Net income	\$ 153,431	\$ 43,680	\$ 109,751
Net income per common share:			
Basic	\$ 5.31	\$ 1.53	
Diluted	\$ 5.14	\$ 1.47	
Weighted-average common shares outstanding:			
Basic	28,893	28,537	
Diluted	29,829	29,669	



Source: Krystal Biotech, Inc.