Krystal Biotech Announces Third Quarter 2026 Financial and Operating Results

November 2, 2026

$127.3 million in 3Q VYJUVEK global revenue and $1.1 billion since launch

VYJUVEK pricing negotiations in Germany and Italy completed

KB113 clinical data demonstrate regression in more than 80% of assessed basal cell carcinoma lesions in patients with Gorlin syndrome

Strong balance sheet, ending the quarter with $1.2 billion in cash and investments

Board authorizes share repurchase program of up to $400 million

PITTSBURGH, Nov. 02, 2026 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the “Company” or “Krystal”) (NASDAQ: KRYS) today reported financial results for the third quarter ended September 30, 2026 and provided a business update.

“Continued growth in VYJUVEK revenue is supporting profitability and funding the advancement of our pipeline,” said Krish S. Krishnan, Chairman and Chief Executive Officer of Krystal Biotech. “Our financial strength allows us to invest fully in these programs and our global commercial expansion while returning capital to shareholders. The $400 million share repurchase program, under which we expect to repurchase shares opportunistically over the next two years, reflects our confidence in Krystal’s long-term growth prospects and our commitment to disciplined capital allocation.”

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

The Company recorded $127.3 million in global VYJUVEK net product revenue for the third quarter of 2026, an increase of 30% compared to the prior year third quarter. Gross margin for the quarter was 94%.

Patient demand in the United States continues to grow with over 760 reimbursement approvals secured for VYJUVEK nationwide. Steady expansion of the U.S. prescriber base is supporting continued adoption across the country.

The Company is also expanding its reach across its initial launch markets of Germany, France, and Japan, converting high physician interest and engagement into patient starts and broadening the prescriber base to bring VYJUVEK treatment closer to patients.

Pricing negotiations are now complete in both Germany and Italy, and the Company expects to launch VYJUVEK in Italy in early 2027. Pricing negotiations are ongoing in multiple European countries and the United Kingdom, with decisions expected in Spain later this year, and in France no earlier than 2027. The Company has also submitted a marketing authorization application for VYJUVEK in Australia and expects to submit an application for marketing authorization in Switzerland before year end.

Dermatology

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

Enrollment is complete and dosing is ongoing in HALITE-1, the Company’s open-label, single-arm study evaluating the safety of KB111, administered once weekly for 12 weeks, in patients with HHD. HHD is a genetic disease characterized by painful rash and blistering in skin folds. In addition to pain, patients with HHD reporting debilitating symptoms of itch, burning, infections, and body odor, as well as 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.

A total of five patients have been enrolled in HALITE-1. The Company expects to report interim study results before the end of the year. Details of the study can be found at www.clinicaltrials.gov under NCT identifier: NCT07717346.

The Company has also completed development of its HHD-specific severity scale for the clinical evaluation of KB111. The Company expects to meet with the FDA in the first quarter of 2027, following completion of scale validation, to discuss study results, the scale, and study designs to enable a registrational study start in 2027.

KB113 for the treatment of Gorlin syndrome (GS)

In October, the Company announced a positive clinical update supporting initial proof of concept for KB113 in the treatment of basal cell carcinoma (BCC) in patients with GS. GS is a genetic disease characterized by a greatly increased risk of developing BCCs. Patients with Gorlin syndrome can develop BCCs as early as infancy and may have hundreds of BCCs over their lifetimes requiring frequent and potentially disfiguring surgical procedures. Prevalence data for GS is limited but available data suggest the number of patients with GS in the United States could exceed 10,000.

In the Company’s three patient pilot, multicenter, single-arm, open-label study, more than 80% of assessed BCC lesions showed investigator-assessed clinical regression. Regression was observed in both injected and non-injected lesions, consistent with an abscopal effect. Histologic assessment also confirmed complete clearance of an injected BCC lesion in each patient. KB113 was well tolerated, with all reported adverse events mild or moderate in severity, transient, and resolving during the study.

Building on these positive initial results, the Company has initiated discussions with the FDA regarding the advanced clinical development of KB113 for the treatment of BCCs in patients with GS. The Company will provide an update on its clinical development plans following alignment with the FDA.

Ophthalmology

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

The Company has enrolled three additional patients in its registrational IOLITE study, including one child aged one year. The additional enrollment replaces two patients who withdrew for reasons unrelated to safety and provides supporting evidence for the potential treatment of corneal abrasions in DEB patients from birth. The Company now expects the last patient visit in February 2027 with top-line results reported shortly thereafter. The primary efficacy endpoint is 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)

Enrollment is ongoing in EMERALD-1, the Company's registrational, 1:1 randomized, double-masked, multicenter, placebo-controlled study evaluating KB801 for the treatment of NK. The Company has activated 22 sites across the United States and is close to activating sites in France, Spain and the United Kingdom. Patient enrollment has progressed slower than initially anticipated, reflecting the study's narrowly defined eligibility criteria and the challenges of enrolling patients in a placebo-controlled trial in an indication with an available approved therapy. The Company now expects to complete enrollment of approximately 60 patients in EMERALD-1 and report top-line results in 2027. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT06999733.

Respiratory

KB407 for the treatment of cystic fibrosis (CF)

Three patients are currently being dosed in the Company's ongoing open-label, single-arm study evaluating the safety of repeat-dose KB407 administration over 24 weeks in patients with CF who are ineligible for, do not tolerate, or do not benefit from modulator therapy. The Company expects to enroll and dose three additional patients before year end, with interim study results now anticipated in the first half of 2027. Earlier this year, the Company announced positive interim clinical findings demonstrating successful delivery and expression of wild-type CFTR protein in the lungs of patients treated with KB407. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT05504837.

In the third quarter, the Company was selected for the FDA's Complex Innovative Trial Design (CID) Meeting Program, advancing ongoing discussions regarding the Company's innovative registrational study design. The CID Meeting Program is intended to facilitate and advance the use of complex and novel clinical trial designs and provides the opportunity for increased interaction with the FDA. The Company will share the design and associated statistical analysis of the registrational study following alignment with the FDA and is presently on track to initiate the registrational study in 2027.

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. 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. The Company expects to report interim study results in 2027.

Oncology

Inhaled KB707 for the treatment of non-small cell lung cancer (NSCLC)

KYANITE-1 is an ongoing Phase 1/2 open-label, multi-center, dose escalation and expansion study evaluating inhaled KB707, as monotherapy or in combination with standard of care therapies, in patients with locally advanced or metastatic solid tumors involving the lungs.

Interim clinical results from the KYANITE-1 dose expansion cohort evaluating inhaled KB707 in combination with pembrolizumab were presented at the American Society for Clinical Oncology 2026 Annual Meeting in May and demonstrated antitumor activity in patients with advanced NSCLC, with an objective response rate (ORR) of 31% and a disease control rate (DCR) of 75%. Multiple patients from this cohort remain on treatment and in follow-up with sustained disease control.

The Company is currently enrolling patients with advanced NSCLC in a global KYANITE-1 dose expansion cohort evaluating inhaled KB707 in combination with chemotherapy. An initial dose-optimization phase evaluated the safety and tolerability of the combination regimen in the first 10 patients and informed the selection of the chemotherapy dose for subsequent enrollment. Sites have also been activated in France and Spain. The Company expects to enroll approximately 70 patients to be dosed at the selected combination regimen by mid-2027.

Details of the KYANITE-1 study can be found at www.clinicaltrials.gov under NCT identifier: NCT06228326.

Aesthetics

KB304 for the treatment of wrinkles of the décolleté

Jeune Aesthetics, Inc., a wholly owned subsidiary of the Company, expects to initiate a Phase 2 study of its lead program KB304 in 2027.

Share Repurchase Program

The Company also announced today that its Board of Directors has authorized a share repurchase program under which Krystal may repurchase up to $400 million of its outstanding common stock. Repurchases may be made from time to time through open-market purchases, privately negotiated transactions, or by other means permitted under applicable securities laws, including through purchases compliant with Rule 10b-18 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and trading plans adopted under Rule 10b5-1 under the Exchange Act. The timing and amount of any repurchases will depend on a number of factors, including the market price of Krystal's common stock, market and business conditions, the Company's liquidity and capital requirements, clinical development and commercialization plans, alternative uses of capital, and legal and regulatory requirements. The program has no expiration date, does not obligate Krystal to repurchase any amount of common stock, and the program may be modified, suspended or discontinued at any time at the Company's discretion **.**

Financial Results for the Quarter Ended September 30, 2026:

- Cash, cash equivalents and investments totaled $1.2 billion as of September 30, 2026
- Product revenue, net totaled $127.3 million and $97.8 million for the three months ended September 30, 2026 and September 30, 2025, respectively.
- Cost of goods sold totaled $7.6 million and $4.3 million for the three months ended September 30, 2026 and September 30, 2025, respectively.
- Research and development expenses for the three months ended September 30, 2026 were $14.9 million, inclusive of $2.6 million of stock-based compensation, compared to $14.6 million, inclusive of stock-based compensation of $2.6 million, for the three months ended September 30, 2025.
- Selling, general, and administrative expenses for the three months ended September 30, 2026 were $33.7 million, inclusive of stock-based compensation of $11.3 million, compared to $37.6 million, inclusive of stock-based compensation of $10.6 million, for the three months ended September 30, 2025.
- Net income for the three months ended September 30, 2026 was $63.1 million, or $2.13 per common share (basic) and $2.05 per common share (diluted). Net income for the three months ended September 30, 2025 was $79.4 million, or $2.74 per common share (basic) and $2.66 per common share (diluted).
- For additional information on the Company's financial results for the three months ended September 30, 2026, please refer to the Form 10-Q filed with the SEC.

Financial Results for the Nine Months Ended September 30, 2026:

- Product revenue, net totaled $362.9 million and $282.0 million for the nine months ended September 30, 2026 and September 30, 2025, respectively.
- Cost of goods sold totaled $20.3 million and $16.5 million for the nine months ended September 30, 2026 and September 30, 2025, respectively.
- Research and development expenses for the nine months ended September 30, 2026 were $44.7 million, inclusive of $7.3 million of stock-based compensation, compared to $43.3 million, inclusive of stock-based compensation of $7.7 million, for the nine months ended September 30, 2025.
- Selling, general, and administrative expenses for the nine months ended September 30, 2026 were $114.6 million, inclusive of stock-based compensation of $34.4 million, compared to $105.3 million, inclusive of stock-based compensation of $33.1 million, for the nine months ended September 30, 2025.
- Net income for the nine months ended September 30, 2026 was $173.8 million, or $5.90 per common share (basic) and $5.66 per common share (diluted). 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).
- For additional information on the Company's financial results for the nine months ended September 30, 2026, please refer to the Form 10-Q filed with the SEC.

Financial Guidance

($ in millions)	**FY 2026 Guidance**
Non-GAAP Research and Development ("R&D") and Selling, General and Administrative ("SG&A") expense (1)	$155.0 - $165.0

(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 2026 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 a conference call and webcast on November 2, 2026, at 8:30 am ET.

Investors and the general public can access the live webcast at: https://www.webcaster5.com/Webcast/Page/3018/54689.

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: 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. Krystal Biotech is headquartered in Pittsburgh, Pennsylvania. Visit www.krystalbio.com to learn more or follow us on LinkedIn and X.

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

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are forward-looking statements, including statements regarding: the commercial launch and expansion of VYJUVEK in Europe, Japan, and additional markets (including the timing of launch in Italy, the timing of pricing and reimbursement decisions in Spain and France, and the timing of marketing authorization filings in other jurisdictions); the Company's development plans for its product candidates; the timing of enrollment, data readouts, and regulatory interactions with respect to the Company's clinical trials of its product candidates (including registrational study plans for KB111 and KB407, the timing of interim results for KB111, KB407 and KB408 and top-line results for KB803 and KB801, the Company's plans for the further clinical development of KB113, and the Company's plans to provide updates on the clinical development of KB113 and the KB407 registrational study following alignment with the FDA); the Company's share repurchase program, including the timing, manner and amount of any repurchases; the Company's 2026 financial guidance; and other statements about expectations, plans, and prospects. These statements are often identified by words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions. 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 Company's ability to enroll patients in its clinical trials on anticipated timelines; whether results of early clinical trials, including results observed in a small number of patients, will be indicative of the results of later-stage studies; the outcome of the Company's discussions with the FDA regarding the design of planned clinical trials; the availability, pricing, and commercial potential of VYJUVEK and the Company's product candidates; the amount and timing of any share repurchases, whether the share repurchase program will enhance long-term stockholder value, and the effect of repurchases on the Company's cash position and its ability to fund its operations and development programs; and other important factors 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 forward-looking statements 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, and although the Company may elect to update these statements, 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)	September 30, 2026 (unaudited)	December 31, 2025
Balance sheet data:		
Cash and cash equivalents	$ 462,841	$ 496,304
Short-term investments	449,010	331,487
Long-term investments	282,301	128,066
Total assets	1,586,056	1,333,794
Total liabilities	150,472	114,234
Total stockholders' equity	$ 1,435,584	$ 1,219,560

Condensed Consolidated Statements of Operations:

	Three Months Ended September 30,		
	2026	2025	Change
(in thousands, except per share data)	(unaudited)		
Revenue			
Product revenue, net	$ 127,341	$ 97,800	$ 29,541
Operating Expenses			
Cost of goods sold	7,556	4,263	3,293
Research and development	14,891	14,585	306
Selling, general, and administrative	33,749	37,578	(3,829)
Total operating expenses	56,196	56,426	(230)
Income from operations	71,145	41,374	29,771
Other income			
Interest and other income, net	9,000	6,593	2,407
Income before income taxes	80,145	47,967	32,178
Income tax (expense) benefit	(17,077)	31,398	(48,475)
Net income	$ 63,068	$ 79,365	$ (16,297)
Net income per common share:			
Basic	$ 2.13	$ 2.74	
Diluted	$ 2.05	$ 2.66	
Weighted-average common shares outstanding:			
Basic	29,610	28,953	
Diluted	30,838	29,833	

(in thousands, except per share data)	Nine Months Ended September 30, 2026 (unaudited)	2025 (unaudited)	Change
Revenue			
Product revenue, net	$ 362,920	$ 282,025	$ 80,895
Operating Expenses			
Cost of goods sold	20,316	16,457	3,859
Research and development	44,739	43,251	1,488
Selling, general, and administrative	114,612	105,292	9,320
Total operating expenses	179,667	165,000	14,667
Income from operations	183,253	117,025	66,228
Other income			
Interest and other income, net	24,413	21,315	3,098
Income before income taxes	207,666	138,340	69,326
Income tax (expense) benefit	(33,898)	15,091	(48,989)
Net income	$ 173,768	$ 153,431	$ 20,337
Net income per common share:			
Basic	$ 5.90	$ 5.31	
Diluted	$ 5.66	$ 5.14	
Weighted-average common shares outstanding:			
Basic	29,477	28,893	
Diluted	30,680	29,829	

Source: Krystal Biotech, Inc.