Krystal Biotech Announces First Quarter 2026 Financial and Operating Results

May 4, 2026

$116.4 million in 1Q VYJUVEK global revenue and $846.7 million since launch

Enrollment complete in KB803 (corneal abrasions in DEB patients) registrational study

On track for KB803 and KB801 (NK) registrational data readouts in 2026

FDA grants platform technology designation for KB407 (CF) and KB111 (HHD)

Strong balance sheet, ending the quarter with $1.0 billion in cash and investments

PITTSBURGH, May 04, 2026 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the “Company”) (NASDAQ: KRYS) today reported financial results for the first quarter ending March 31, 2026 and provided a business update.

“Following a successful 2025, we are entering 2026 with strong momentum, including two potential registrational study readouts and continued global expansion for VYJUVEK,” said Krish S. Krishnan, Chairman and Chief Executive Officer of Krystal Biotech. “With three pipeline products receiving platform designation, each development milestone strengthens the regulatory dataset, which could accelerate future programs and potentially reduce development risk. This compounding advantage underscores the value of the platform model we have been building since day one.”

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

The Company recorded $116.4 million in VYJUVEK net product revenue for the first quarter of 2026, an increase of 32% compared to the prior year first quarter. Gross margin for the first quarter of 2026 was 95%.

In the United States, the Company has secured over 695 reimbursement approvals for VYJUVEK and continues to broaden the prescriber base across the country, with over 60 new prescribers in the first quarter of 2026 and over 570 unique prescribers since launch. The Company has also launched patient support initiatives that leverage the recent VYJUVEK label update and increased administration flexibility to help DEB patients and their families conveniently integrate VYJUVEK into lifelong wound healing routines as their standard of care.

Overseas, the Company estimates that over 140 patients in Germany, France and Japan have been prescribed VYJUVEK. Pricing discussions with German and French reimbursement authorities are ongoing. The Company expects negotiations to continue until at least 2H 2026 in Germany and 2027 in France. The Company is also advancing pricing discussions with reimbursement authorities in Italy to enable a potential launch in 2H 2026 and recently initiated pricing discussions with Spanish reimbursement authorities. Based on initial interactions with Spanish authorities, the Company now expects to launch in Spain in 2H 2026. The timing of launch in other European jurisdictions will depend on the cadence and outcomes of regulatory interactions and pricing negotiations.

Ophthalmology

Two registrational readouts anticipated in 2026

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

The Company’s registrational, intra-patient, double-blind, decentralized, placebo-controlled study (IOLITE) with crossover design evaluating KB803 for the treatment and prevention of corneal abrasions in DEB patients is now fully enrolled. A total of 16 patients have been enrolled in the study. The primary efficacy endpoint of IOLITE will be the change in the average number of days per month with corneal abrasion symptoms while receiving KB803 versus placebo. The Company estimates that, as enrolled, IOLITE has at least 90% power to detect an effect size of at least 25% reduction in symptom days, allowing for a dropout rate up to 20%. Powering assumptions are based on the average symptomatic days per month and standard deviation data from subjects enrolled in the natural history study who would be eligible for IOLITE. The Company expects to report top-line results in 4Q 2026. 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 registrational, 1:1 randomized, double-masked, multicenter, placebo-controlled study evaluating KB801 for the treatment of NK. The Company expects to complete full enrollment of 60 patients in EMERALD-1 and announce data before year end. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT06999733.

Respiratory

KB407 for the treatment of cystic fibrosis (CF)

In April, the United States Food and Drug Administration (FDA) granted platform technology designation to the genetically modified, non-replicating herpes simplex virus type 1 viral vector used in KB407, providing the program with the same potential development and manufacturing efficiencies previously granted to KB801. Potential benefits of the designation include shortening of preclinical and chemistry, manufacturing, and controls (CMC) review cycles during development for follow-on products, creating a compounding regulatory advantage.

Based on interactions with the FDA, the Company is initiating an open label, single-arm study to evaluate safety of *repeat dose* KB407 for 24 weeks in five patients with CF who are ineligible for, do not tolerate, or do not benefit from modulator therapy. Dosing is expected to start later this month.

Details of the study can be found at www.clinicaltrials.gov under NCT identifier: NCT05504837. The Company expects to complete enrollment in 2Q 2026 and report results before year end.

Concurrently, the Company is working closely with the FDA, the Cystic Fibrosis Foundation (CFF), and the CF Therapeutics Development Network Coordinating Center at Seattle Children's Research Institute (TDNCC) on an innovative registrational study design and statistical analysis plan that explores using prospectively collected natural history data from the CFF and TDNCC to supplement placebo control data for evaluation of KB407 treatment effect. The Company will share the design and associated statistical analysis of the registrational study following alignment with the FDA, which is anticipated in 2H 2026, and expects to initiate the registrational study in 2027.

Previously, in January, the Company announced the successful delivery and expression of wild-type cystic fibrosis transmembrane conductance regulator protein in the lungs of patients with CF treated with KB407.

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 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.

Dermatology

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

In April, the FDA also granted platform technology designation to the genetically modified, non-replicating herpes simplex virus type 1 viral vector used in KB111, providing the program with the same regulatory efficiencies available for KB801 and KB407. The Company is developing an HHD-specific severity scale necessary for the clinical evaluation of KB111 and expects to complete scale development and validation in 1H 2026. Later this month, the Company also expects to initiate HALITE-1, an open-label study evaluating the safety of *repeat dose* KB111, administered once weekly for 12 weeks, in approximately seven patients with HHD. The Company expects to report HALITE-1 study results in 2H 2026. The Company also plans to submit the results from HALITE-1 along with the registrational study design for discussions with the FDA in 2H 2026 to enable a potential registrational study start in 2027.

Oncology

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

The Company is enrolling patients with advanced NSCLC in a dose expansion cohort of KYANITE-1 evaluating inhaled KB707 in combination with chemotherapy. KYANITE-1 is a Phase 1/2 open label, multi-center, dose escalation and expansion study evaluating inhaled KB707, either as monotherapy or in combination, in patients with locally advanced or metastatic solid tumors of the lung. The Company expects to report interim efficacy data and potential registrational study plans later this year. 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 follow patients previously enrolled 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. The Company will update development plans for intratumoral KB707 as additional safety and efficacy data are collected from the study. 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., a wholly owned subsidiary of the Company, expects to initiate a Phase 2 study of its lead program KB304 in 2027.

Financial Results for the Three Months Ended March 31, 2026:

- Product revenue, net totaled $116.4 million and $88.2 million for the three months ended March 31, 2026 and March 31, 2025, respectively.
- Cost of goods sold totaled $6.3 million and $5.0 million for the three months ended March 31, 2026 and March 31, 2025, respectively.
- Research and development expenses for the three months ended March 31, 2026 were $15.3 million, inclusive of $2.2 million of stock-based compensation, compared to $14.3 million, inclusive of stock-based compensation of $2.5 million for the three months ended March 31, 2025.
- Selling, general, and administrative expenses for the three months ended March 31, 2026 were $41.0 million, inclusive of stock-based compensation of $11.4 million, compared to $32.6 million, inclusive of stock-based compensation of $11.0 million, for the three months ended March 31, 2025.
- Net income for the three months ended March 31, 2026 was $55.9 million, or $1.91 per common share (basic) and $1.83 per common share (diluted). Net income for the three months ended March 31, 2025 was $35.7 million, or $1.24 per common share (basic) and $1.20 per common share (diluted).
- For additional information on the Company's financial results for the three months ended March 31, 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)	$175.0 - $195.0

(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 an investor webcast on May 4, 2026, at 8:30 am ET.

Investors and the general public can access the live webcast at:
https://www.webcaster5.com/Webcast/Page/3018/53916.

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

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, and Japan, including our expectations regarding timing of pricing discussions in Germany and France and pricing discussions with the reimbursement authorities in Italy and Spain and potential commercial launches in those countries in 2H 2026; and our expectations for our product pipeline, including our clinical trial plans, enrollment in our clinical trials, the timing of development and validation of an HHD-specific evaluation scale, and the timing of discussions with the FDA and data read-outs from our clinical trials 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 and 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 expense. 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.

Updated Release

This press release was updated on May 7, 2026, to include a reference to the CF Therapeutics Development Network Coordinating Center at Seattle Children's Research Institute (TDNCC) as a collaborator on the registrational study design and statistical analysis plan. The originally issued press release dated May 4, 2026, remains available as an exhibit to the Company's Form 8-K filed with the SEC on May 4, 2026.

CONTACT

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Condensed Consolidated Balance Sheet Data:

(in thousands)	March 31, 2026 (unaudited)	December 31, 2025
Balance sheet data:		
Cash and cash equivalents	$ 501,313	$ 496,304
Short-term investments	322,092	331,487
Long-term investments	193,485	128,066
Total assets	1,396,967	1,333,794
Total liabilities	120,238	114,234
Total stockholders’ equity	$ 1,276,729	$ 1,219,560

Condensed Consolidated Statements of Operations:

	Three Months Ended March 31,

(in thousands, except per share data)	2026	2025	Change
	(unaudited)		
Revenue			
Product revenue, net	$ 116,357	$ 88,183	$ 28,174
Operating Expenses			
Cost of goods sold	6,323	5,028	1,295
Research and development	15,331	14,256	1,075
Selling, general, and administrative	41,014	32,647	8,367
Total operating expenses	62,668	51,931	10,737
Income from operations	53,689	36,252	17,437
Other income			
Interest and other income, net	7,753	7,345	408
Income before income taxes	61,442	43,597	17,845
Income tax expense	(5,510)	(7,864)	2,354
Net income	$ 55,932	$ 35,733	$ 20,199
Net income per common share:			
Basic	$ 1.91	$ 1.24	
Diluted	$ 1.83	$ 1.20	
Weighted-average common shares outstanding:			
Basic	29,288	28,815	
Diluted	30,507	29,871	

Source: Krystal Biotech, Inc.