Krystal Biotech Announces Third Quarter 2024 Financial Results and Provides Business Updates

November 4, 2024

Net product revenue of $83.8 million in 3Q and $250.1 million since launch in August 2023

JNDA for B-VEC filed and on track for commercial launches in Japan and Europe in 2025

French health authority approved pre-marketing early reimbursed access for B-VEC in France under the Accès Précoce (AP1) program; AP1 program for DEB patients access expected to start in 4Q 2024

Advancing Jeune Aesthetics' KB301 to Phase 2 after positive results in Phase 1

Clinical updates on AATD and oncology program before end of year

Strong balance sheet, ending the quarter with $694.2 million in cash and investments

PITTSBURGH, Nov. 04, 2024 (GLOBE NEWSWIRE) -- Krystal Biotech, Inc. (the "Company") (NASDAQ: KRYS), a commercial-stage biotechnology company, today reported financial results and key business updates for the third quarter ending September 30, 2024.

"I am pleased to report that our U.S. launch continues to track towards our ambitious pre-launch target of achieving 720 reimbursement approvals in the first two years of launch, thanks to our dedicated team and the unambiguous clinical benefit provided by VYJUVEK" said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "With key milestones recently achieved in Europe and Japan and the anticipated initiation of the registrational trial to treat corneal abrasions in DEB patients, we are on the verge of unlocking expansion opportunities for the franchise that will enable us to treat DEB patients globally and comprehensively. More importantly, we continue to progress our deep clinical pipeline. We believe that our successful clinical readout last quarter for Jeune Aesthetics and the upcoming two clinical readouts later this year will showcase the breadth and potential of our redosable platform."

VYJUVEK® for the treatment of Dystrophic Epidermolysis Bullosa (DEB)

- The Company recorded $83.8 million in VYJUVEK net product revenue for the third quarter of 2024. Gross margin for the quarter was 92%.
- As of October, the Company has secured over 460 reimbursement approvals for VYJUVEK in the U.S. and positive access determinations have been achieved for 97% of lives covered under commercial and Medicaid plans.
- High patient compliance with weekly treatment while on drug continued at 87% as of the end of the quarter.
- In September, the Haute Autorité de Santé in France approved pre-marketing early reimbursed access to B-VEC under the Accès Précoce program (AP1). DEB patient access to B-VEC under AP1 is expected to start in 4Q 2024. AP1 allows for early access to innovative therapies in France prior to European regulatory approval when a positive benefit/risk ratio is recognized and when no other therapeutic alternatives are available.
- The European Medicines Agency (EMA)'s review of the Company's Marketing Authorization Application (MAA) for B-VEC for the treatment of DEB is ongoing. Based on recent interactions with the EMA, the Company expects a Committee for Medicinal Products for Human Use (CHMP) opinion on the MAA before year end and anticipates its first European launch in Germany in 1H 2025.
- In October, the Company filed a Japan New Drug Application (JNDA) with Japan's Pharmaceuticals and Medical Devices Agency (PMDA). A decision on the JNDA by the PMDA is expected in 2H 2025. The JNDA is expected to receive priority review given the Orphan Drug Designation status granted to B-VEC in December 2023.

Respiratory

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

- In September, after initiating dosing in Cohort 2, the Company amended the protocol for its KB408 Phase 1 SERPENTINE-1 study to include mandatory bronchoscopies in this cohort in an effort to measure alpha-1 antitrypsin expression. SERPENTINE-1 is an open label, single dose escalation study in adult patients with AATD with a Pi*ZZ or a Pi*ZNull genotype. The Company is on track to report interim molecular data from the study before year end. Details about the study can be found at www.clinicaltrials.gov under NCT identifier: NCT06049082.

KB407 for the treatment of cystic fibrosis (CF)

- The Company recently activated two additional clinical sites for its KB407 Phase 1 CORAL-1 study and expects to report interim molecular data from the study in 1H 2025. CORAL-1 is a multi-center, dose escalation study evaluating KB407 in

patients with CF, regardless of their underlying genotype. Dosing of the first patient in the third and final cohort in CORAL-1 is expected before the end of the year. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT05504837.

Ophthalmology

KB803 (B-VEC formulated as an eyedrop) for ocular complications of DEB

- The Company continues to enroll patients in a 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 a registrational study evaluating KB803 effect on corneal abrasions of DEB. The KB803 registrational IOLITE study is a single arm, open-label study that is expected to commence in 1H 2025.

Pipeline expansion

- The Company is actively evaluating multiple preclinical-stage genetic medicine candidates for the treatment of diseases of the front and back of the eye.

Oncology

Inhaled KB707 for the treatment of solid tumors of the lung

- In August, the Company progressed to dose expansion in KYANITE-1, the Phase 1 open label, multi-center, monotherapy, 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.
- In May, the FDA granted Rare Pediatric Disease Designation (RPDD) for inhaled KB707 for the treatment of osteosarcoma.

Intratumoral KB707 for the treatment of injectable solid tumors

- The Company continues to enroll patients in the dose expansion cohort of OPAL-1, the Phase 1 open label, multi-center, monotherapy, 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.
- In August, the FDA granted RPDD for intratumoral KB707 for the treatment of rhabdoymyosarcoma.

The Company expects to report initial interim data for KB707 before the end of the year. In addition to being granted RPDDs, both inhaled and intratumoral KB707 have also been granted Fast Track Designations by the FDA, regulatory designations which confer multiple benefits, including more frequent FDA interactions, which may accelerate KB707 clinical development.

Aesthetics

KB301 for the treatment of aesthetic indications

- In August, Jeune Aesthetics, Inc. (“Jeune Aesthetics”), a wholly-owned subsidiary of the Company, announced positive interim safety and efficacy results for KB301 in the treatment of lateral canthal lines at rest and dynamic wrinkles of the décolleté, evaluated in Cohorts 3 and 4 of the KB301 Phase 1 study PEARL-1, respectively. Meaningful and sustained improvements in multiple skin aesthetic attributes, including wrinkles, crepiness, hydration, and radiance, were reported by the study investigators and subjects alike in both the décolleté and lateral canthal regions. Increased subject satisfaction with wrinkle appearance was also reported. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900.
- Based on the results from Cohort 3 and 4 of PEARL-1, the Company has selected treatment of the dynamic wrinkles of the décolleté for advanced clinical development and expects to initiate a Phase 2 study evaluating KB301 in this indication in 2025. The Company expects to report detailed results of PEARL-1 Cohorts 3 and 4, including redosing, at future scientific conference(s).

Dermatology

The Company is continuing preparations to enable initiation of the Phase 2 portion of its KB105 Phase 1/2 JADE-1 trial evaluating KB105 for the treatment of lamellar ichthyosis in pediatric patients in 1H 2025.

Financial Results for the Quarter Ended September 30, 2024:

- Cash, cash equivalents, and investments totaled $694.2 million as of September 30, 2024.
- Product revenue, net totaled $83.8 million and $8.6 million for the quarters ended September 30, 2024 and September 30, 2023, respectively.

- Cost of goods sold totaled $6.7 million and $223 thousand for the quarters ended September 30, 2024 and September 30, 2023, respectively.
- Research and development expenses for the quarter ended September 30, 2024 were $13.5 million, inclusive of $2.3 million of stock-based compensation, compared to $10.6 million, inclusive of stock-based compensation of $2.3 million for the quarter ended September 30, 2023.
- Selling, general, and administrative expenses for the quarter ended September 30, 2024 were $28.7 million, inclusive of stock-based compensation of $11.0 million, compared to $23.7 million, inclusive of stock-based compensation of $6.0 million, for the quarter ended September 30, 2023.
- 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). Net income for the quarter ended September 30, 2023 was $80.7 million, or $2.88 per common share (basic) and $2.79 per common share (diluted).
- For additional information on the Company's financial results for the quarter ended September 30, 2024, please refer to the Form 10-Q filed with the SEC.

Financial Results for the Nine Months Ended September 30, 2024:

- Product revenue, net totaled $199.4 million and $8.6 million for the nine months ended September 30, 2024 and September 30, 2023, respectively.
- Cost of goods sold totaled $15.1 million and $223 thousand for the nine months ended September 30, 2024 and September 30, 2023, respectively.
- Research and development expenses for the nine months ended September 30, 2024 were $40.0 million, inclusive of $6.9 million of stock-based compensation, compared to $35.1 million, inclusive of stock-based compensation of $7.7 million for the nine months ended September 30, 2023.
- Selling, general, and administrative expenses for the nine months ended September 30, 2024 were $82.4 million, inclusive of stock-based compensation of $28.9 million, compared to $73.6 million, inclusive of stock-based compensation of $22.4 million, for the nine months September 30, 2023.
- 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). Net income for the nine months ended September 30, 2023 was $2.2 million, or $0.08 per common share (basic and diluted).
- For additional information on the Company's financial results for the nine months ended September 30, 2024, please refer to the Form 10-Q filed with the SEC.

Financial Guidance

Our non-GAAP R&D and SG&A expense is now expected to be between $115 million and $125 million for the full year ending December 31, 2024. 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 2024 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. This could materially affect the calculation of forward-looking GAAP combined R&D and SG&A Expense as it is inherently uncertain. Refer to Non-GAAP Financial Measures section below for additional information.

Conference Call

The Company will host an investor webcast on November 4, 2024, at 8:30 am ET.

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

https://www.webcaster4.com/Webcast/Page/3018/51458

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.

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 Rare Pediatric Disease Designation

The FDA grants Rare Pediatric Disease Designations for serious or life-threatening diseases with manifestations in individuals aged from birth to 18 years, and that affect fewer than 200,000 people in the U.S. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application or biologics license application for a product for the prevention or treatment of a rare pediatric disease may be eligible for a voucher, which can be redeemed to obtain priority review for any subsequent marketing application, and may be sold or transferred.

About Krystal Biotech, Inc.

Krystal Biotech, Inc. (NASDAQ: KRYS) is a commercial-stage biotechnology company focused on the discovery, development and commercialization of genetic medicines to treat diseases with high unmet medical needs. VYJUVEK® is the Company's first commercial product, the first-ever redosable gene therapy, and the first medicine approved by the FDA 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 expansion opportunities for the B-VEC franchise and treating DEB patients globally and comprehensively; the commercial launch of VYJUVEK in the United States; potential marketing authorizations in Europe and Japan, including timing of filings and approvals and related commercial launches; showcasing the breadth and potential of the Company's redosable platform; timing of patient access to B-VEC in France under the AP1 program; the Company's expectations regarding reporting interim data from the Company's KB408 and KB707 studies, as well as dosing the first patient in the final cohort of its KB407 study before year end; the timing of the expected commencement of the KB803 registrational study, reporting detailed results of Cohorts 3 and 4 of the Phase 1 KB301 study, the commencement of the Phase 2 KB301 study, and the initiation of the Phase 2 portion of the KB105 Phase 1/2 study; and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; the availability or commercial potential of VYJUVEK or product candidates; and such other important factors as are set forth under the caption "Risk Factors" in the Company's annual and quarterly reports on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

Non-GAAP Financial Measures

This press release includes forward-looking combined R&D and SG&A expense guidance that is not required by, or presented in accordance with, U.S. GAAP and should not be considered as an alternative to R&D and SG&A expense or any other performance measure derived in accordance with GAAP. The Company defines non-GAAP combined R&D and SG&A expense as GAAP combined R&D and SG&A expense excluding stock-based compensation. The Company cautions investors that amounts presented in accordance with its definition of non-GAAP combined R&D and SG&A expense may not be comparable to similar measures disclosed by competitors because not all companies calculate this non-GAAP financial measure in the same manner. The Company presents this non-GAAP financial measure because it considers this measure to be an important supplemental measure and believes it is frequently used by securities analysts, investors, and other interested parties in the evaluation of companies in the

Company's industry. Management believes that investors' understanding of the Company's performance is enhanced by including this forward-looking non-GAAP financial measure as a reasonable basis for comparing the Company's ongoing results of operations. Management uses this non-GAAP financial measure for planning purposes, including the preparation of the Company's internal annual operating budget and financial projections; to evaluate the performance and effectiveness of the Company's operational strategies; and to evaluate the Company's capacity to expand its business. This non-GAAP financial measure has limitations as an analytical tool, and should not be considered in isolation, or as an alternative to, or a substitute for R&D and SG&A expense or other financial statement data presented in accordance with GAAP in the Company's consolidated financial statements. The Company has not provided a quantitative reconciliation of forecasted non-GAAP combined R&D and SG&A expense to forecasted GAAP combined R&D and SG&A expense because the Company is unable, without making unreasonable efforts, to calculate the reconciling item, stock-based compensation expenses, with confidence. This item, which could materially affect the computation of forward-looking GAAP combined R&D and SG&A expense, is inherently uncertain and depends on various factors, some of which are outside of the Company's control.

CONTACT
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Condensed Consolidated Balance Sheet Data:

(in thousands)	September 30, 2024 (unaudited)	December 31, 2023
Balance sheet data:		
Cash and cash equivalents	$ 373,966	$ 358,328
Short-term investments	214,358	173,850
Long-term investments	105,888	61,954
Total assets	982,318	818,355
Total liabilities	96,472	39,714
Total stockholders' equity	$ 885,846	$ 778,641

Condensed Consolidated Statements of Operations:

	Three Months Ended September 30,		
	2024	2023	Change
(in thousands, except per share data)	(unaudited)		
Revenue			
Product revenue, net	$ 83,841	$ 8,556	$ 75,285
Expenses			
Cost of goods sold	6,684	223	6,461
Research and development	13,511	10,629	2,882
Selling, general, and administrative	28,713	23,697	5,016
Litigation settlement	12,500	—	12,500
Total operating expenses	61,408	34,549	26,859
Income (loss) from operations	22,433	(25,993)	48,426
Other income			
Gain from Sale of Priority Review Voucher	—	100,000	(100,000)
Interest and other income, net	7,336	6,740	596
Income before income taxes	29,769	80,747	(50,978)
Income tax expense	(2,589)	—	(2,589)
Net income	$ 27,180	$ 80,747	$ (53,567)
Net income per common share:			
Basic	$ 0.95	$ 2.88	
Diluted	$ 0.91	$ 2.79	
Weighted-average common shares outstanding:			
Basic	28,716	28,042	
Diluted	29,902	28,892	

(in thousands, except per share data)	Nine Months Ended September 30, 2024 (unaudited)	2023 (unaudited)	Change
Revenue			
Product revenue, net	$ 199,376	$ 8,556	$ 190,820
Expenses			
Cost of goods sold	15,112	223	14,889
Research and development	40,050	35,061	4,989
Selling, general, and administrative	82,398	73,637	8,761
Litigation settlement	37,500	12,500	25,000
Total operating expenses	175,060	121,421	53,639
Income (loss) from operations	24,316	(112,865)	137,181
Other income			
Gain from Sale of Priority Review Voucher	—	100,000	(100,000)
Interest and other income, net	22,430	15,105	7,325
Income before income taxes	46,746	2,240	44,506
Income tax expense	(3,066)	—	(3,066)
Net income	$ 43,680	$ 2,240	$ 41,440
Net income per common share:			
Basic	$ 1.53	$ 0.08	
Diluted	$ 1.47	$ 0.08	
Weighted-average common shares outstanding:			
Basic	28,537	26,812	
Diluted	29,669	27,385	

Source: Krystal Biotech, Inc.