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

August 5, 2024

Net product revenue of $70.3 million in 2Q and $166.2 million since launch in August 2023

On track to deliver three clinical readouts in 2H 2024
Jeune Aesthetics' KB301 Phase 1 PEARL-1 study (Cohorts 3 and 4) in 3Q 2024;
KB408 Phase 1 SERPENTINE-1 study for the treatment of AATD in 4Q 2024; and
KB707 Phase 1 OPAL-1 study for the treatment of injectable solid tumors in 4Q 2024

Strong balance sheet, ending the quarter with $628.9 million in cash and investments

PITTSBURGH, Aug. 05, 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 second quarter ending June 30, 2024.

"We are pleased to report another strong quarter for Krystal, headlined by significant growth in our VYJUVEK U.S. commercial launch and steady progress across our clinical-stage pipeline," said Krish S. Krishnan, Chairman and CEO of Krystal Biotech. "The rapid growth in VYJUVEK net product revenue, up over 55% compared to the first quarter of 2024 and now totaling over $166 million since launch, is a reflection of the robust and sustained demand for VYJUVEK among the DEB patient community, the clinical benefits and correspondingly high compliance that come from a fundamentally corrective therapy, and strong execution by our commercial team. As we enter into the second year of the VYJUVEK launch, and with market authorizations in Europe and Japan either under review or planned for submission later this year, we see significant potential to drive further VYJUVEK growth both in the U.S. and overseas. At the same time, we continue to rapidly advance our deep clinical pipeline of genetic medicines and are looking forward to a wave of clinical data readouts starting later this quarter."

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

- The Company recorded $70.3 million in VYJUVEK net product revenue for the second quarter of 2024, an increase of 55.3% compared to the first quarter of 2024. Gross margin for the quarter was 91%.
- As of July, the Company has secured over 400 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 90% as of the end of the quarter.
- In May, the Company's manufacturing facility, ANCORIS, received GMP certification from the European Medicines Agency (EMA). The EMA's review of the Company's Marketing Authorization Application (MAA) for B-VEC for the treatment of DEB is ongoing and a decision on the MAA is anticipated in 2H 2024.
- The Company remains on track to file a Japan New Drug Application in 2H 2024 and anticipates a potential authorization in 2025.

Respiratory

KB407 for the treatment of cystic fibrosis (CF)

- In May, the Company cleared Cohort 2 of the Phase 1 CORAL-1 study. CORAL-1 is a multi-center, dose escalation study evaluating KB407 in patients with CF, regardless of their underlying genotype. The Company expects to initiate the third and final cohort in 2H 2024. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT05504837.
- In May, the Company presented preclinical data at the American Thoracic Society 2024 International Conference demonstrating KB407 transduction of fully differentiated, patient airway epithelial cell-derived apical out airway organoids leading to production of full-length and fully glycosylated CFTR.

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

- In May, the Company cleared Cohort 1 in the KB408 Phase 1 SERPENTINE-1 study. SERPENTINE-1 is a Phase 1 open label, single dose escalation study in adult patients with AATD with a Pi*ZZ or a Pi*ZNull genotype. Enrollment in Cohort 2 is ongoing. Details about the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier: NCT06049082. The Company is on track to report interim data from the study in 4Q 2024.
- The Company presented an overview of KB408 IND-enabling studies conducted to support the initiation of SERPENTINE-1 at the American Thoracic Society 2024 International Conference held in May.

Ophthalmology

B-VEC eyedrops for ocular complications of DEB

- In August, the Company initiated a natural history study to prospectively collect data on the frequency and severity 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 B-VEC eyedrops for ocular complications of DEB. The registrational, single arm, open-label study is expected to commence in 4Q 2024.

Pipeline expansion

- In May, the Company presented preclinical data at the Association for Research in Vision & Ophthalmology 2024 Annual Meeting highlighting the potential of the Company's HSV-1-based gene delivery platform for back of the eye gene delivery.
- 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 June, the Company cleared the first dose escalation cohort in the open label, multi-center, monotherapy, dose escalation and expansion Phase 1 KYANITE-1 clinical study in patients with locally advanced or metastatic solid tumors of the lung. Enrollment in the second dose escalation cohort is now underway. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT06228326.

Intratumoral KB707 for the treatment of injectable solid tumors

- In May, the Company cleared the third and final dose escalation cohort of the Phase 1 OPAL-1 clinical study. OPAL-1 is a Phase 1 open label, multi-center, monotherapy, dose escalation and expansion study in patients with locally advanced or metastatic solid tumor malignancies. Enrollment in the dose expansion cohort is ongoing. Details of the study can be found at www.clinicaltrials.gov under NCT identifier NCT05970497. Based on the current rate of enrollment, the Company expects to report interim data in 4Q 2024.
- In May, the FDA granted Rare Pediatric Disease Designation for intratumoral KB707 for the treatment of osteosarcoma.

Aesthetics

KB301 for the treatment of aesthetic indications

- In April, Jeune Aesthetics, Inc. ("Jeune Aesthetics"), a wholly-owned subsidiary of the Company, completed enrollment in Cohorts 3 and 4 of the Phase 1 PEARL-1 study. Cohort 3 of PEARL-1 is evaluating KB301 for the improvement of lateral canthal lines at rest. Cohort 4 of PEARL-1 is evaluating KB301 for the improvement of dynamic wrinkles of the décolleté. Details of the Phase 1 study can be found at www.clinicaltrials.gov under NCT identifier NCT04540900. Jeune Aesthetics expects to announce results from both cohorts in 3Q 2024.

Dermatology

The Company has resumed efforts in KB105 for the treatment of lamellar ichthyosis and expects to commence the Phase 2 portion of JADE-1 trial in pediatric patients in 1H 2025.

Financial Results for the Quarter Ended June 30, 2024:

- Cash, cash equivalents, and investments totaled $628.9 million as of June 30, 2024.
- Product revenue, net totaled $70.3 million for the quarter ended June 30, 2024.
- Cost of goods sold totaled $6.0 million for the quarter ended June 30, 2024. Prior to receiving FDA approval for VYJUVEK in May 2023, costs associated with the manufacturing of VYJUVEK were expensed as research and development expense.
- Research and development expenses for the quarter ended June 30, 2024 were $15.6 million, inclusive of $2.8 million of stock-based compensation, compared to $12.1 million, inclusive of stock-based compensation of $2.9 million for the quarter ended June 30, 2023.
- Selling, general, and administrative expenses for the quarter ended June 30, 2024 were $27.6 million, inclusive of stock-based compensation of $10.4 million, compared to $25.9 million, inclusive of stock-based compensation of $8.5 million, for the quarter ended June 30, 2023.
- Net income for the quarter ended June 30, 2024 was $15.6 million, or $0.54 per common share (basic) and $0.53 per common share (diluted). Net loss for the quarter ended June 30, 2023 was $(33.2) million, or $(1.25) per common share (basic and diluted).
- For additional information on the Company's financial results for the quarter ended June 30, 2024, please refer to the Form

10-Q filed with the SEC.

Financial Results for the Six Months Ended June 30, 2024:

- Product revenue, net totaled $115.5 million for the six months ended June 30, 2024.
- Cost of goods sold totaled $8.4 million for the six months ended June 30, 2024. Prior to receiving FDA approval for VYJUVEK in May 2023, costs associated with the manufacturing of VYJUVEK were expensed as research and development expense.
- Research and development expenses for the six months ended June 30, 2024 were $26.5 million, inclusive of $4.6 million of stock-based compensation, compared to $24.4 million, inclusive of stock-based compensation of $5.4 million for the six months ended June 30, 2023.
- Selling, general, and administrative expenses for the six months ended June 30, 2024 were $53.7 million, inclusive of stock-based compensation of $17.8 million, compared to $49.9 million, inclusive of stock-based compensation of $16.4 million, for the six months June 30, 2023.
- Net income for the six months ended June 30, 2024 was $16.5 million, or $0.58 per common share (basic) and $0.56 per common share (diluted). Net loss for the six months ended June 30, 2023 was $(78.5) million, or $(3.00) per common share (basic and diluted).
- For additional information on the Company's financial results for the six months ended June 30, 2024, please refer to the Form 10-Q filed with the SEC.

Financial Guidance

For the year ending December 31, 2024, we continue to anticipate approximately $150 million to $175 million of Non-GAAP Research and Development ("R&D") and Selling, General and Administrative ("SG&A") expense. 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 August 5, 2024, at 8:30 am ET.

Investors and the general public can access the live webcast at: https://www.webcaster4.com/Webcast/Page/3018/50830

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 the Company's commercial launch of VYJUVEK in the United States; the Company's beliefs about potential marketing authorizations in Europe and Japan, including timing of filings; the Company's expectation regarding the timing of initiating the third and final cohort of its CORAL-1 study evaluating KB407 in patients with cystic fibrosis; the Company's expectation that it will report interim data in 4Q 2024 from its SERPENTINE-1 clinical study evaluating KB408 for the treatment of AATD; the Company's plans to initiate its study of B-VEC eyedrops to treat ocular complications of DEB in 4Q 2024; the Company's expectation that it will report interim data in 4Q 2024 from its OPAL-1 clinical study evaluating KB707 for the treatment of injectable solid tumors; Jeune Aesthetics' plans to announce results in 3Q 2024 of Cohort 3 and Cohort 4 of its PEARL-1 clinical study to evaluate KB301; the Company's expectation that it will commence the Phase 2 portion of its JADE-1 clinical study in pediatric patients in 1H 2025 to evaluate KB105 for the treatment of lamellar ichthyosis; 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)	June 30, 2024 (unaudited)	December 31, 2023
Balance sheet data:		
Cash and cash equivalents	$ 345,786	$ 358,328
Short-term investments	213,826	173,850
Long-term investments	69,292	61,954
Total assets	917,658	818,355
Total liabilities	78,765	39,714
Total stockholders' equity	$ 838,893	$ 778,641

Condensed Consolidated Statements of Operations:

	Three Months Ended June 30,		
	2024	2023	Change
(in thousands, except per share data)	(unaudited)		
Revenue			
Product revenue, net	$ 70,284	$ —	$ 70,284
Expenses			
Cost of goods sold	6,009	—	6,009
Research and development	15,583	12,144	3,439
Selling, general, and administrative	27,626	25,904	1,722
Litigation settlement	12,500	—	12,500
Total operating expenses	61,718	38,048	23,670
Income (loss) from operations	8,566	(38,048)	46,614
Other income			
Interest and other income, net	7,479	4,838	2,641
Income (loss) before income taxes	16,045	(33,210)	49,255
Income tax expense	(477)	—	(477)
Net income (loss)	$ 15,568	$ (33,210)	$ 48,778
Net income (loss) per common share:			
Basic	$ 0.54	$ (1.25)	
Diluted	$ 0.53	$ (1.25)	
Weighted-average common shares outstanding:			
Basic	28,598	26,657	
Diluted	29,637	26,657	

	Six Months Ended June 30,		
	2024	2023	Change
(in thousands, except per share data)	(unaudited)		
Revenue			
Product revenue, net	$ 115,535	$ —	$ 115,535
Expenses			
Cost of goods sold	8,428	—	8,428
Research and development	26,539	24,432	2,107
Selling, general, and administrative	53,685	49,939	3,746
Litigation settlement	25,000	12,500	12,500
Total operating expenses	113,652	86,871	26,781
Income (loss) from operations	1,883	(86,871)	88,754
Other income			
Interest and other income, net	15,095	8,364	6,731
Income (loss) before income taxes	16,978	(78,507)	95,485
Income tax expense	(477)	—	(477)
Net income (loss)	$ 16,501	$ (78,507)	$ 95,008
Net income (loss) per common share:			

Basic	$ 0.58	$ (3.00)
Diluted	$ 0.56	$ (3.00)
Weighted-average common shares outstanding:		
Basic	28,446	26,187
Diluted	29,504	26,187

Source: Krystal Biotech, Inc.