KALA BIO Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

March 29, 2024

-- Advancing ongoing Phase 2b CHASE trial of KPI-012 for PCED; topline data targeted by year-end 2024 --
-- Exploring opportunities to expand KPI-012 into additional corneal indications --
-- Cash resources as of December 31, 2023, together with proceeds from the March 2024 private placement and anticipated funding remaining from CIRM award, expected to fund operations into 3Q 2025 --

ARLINGTON, Mass., March 29, 2024 (GLOBE NEWSWIRE) -- KALA BIO, Inc. (NASDAQ:KALA), a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the eye, today reported financial results for the fourth quarter and full year ended December 31, 2023 and provided a corporate update.

"In 2023, we focused on clinical execution, advancing our Phase 2b CHASE trial of KPI-012 for the treatment of PCED. In March 2023, we announced positive safety data from the first cohort of patients, reinforcing the promising safety and tolerability profile of high dose KPI-012, and allowing us to progress into the multicenter, randomized, double-masked efficacy cohort, which we are targeting to read out by year-end 2024," said Mark Iwicki, Chair and Chief Executive Officer of KALA BIO. "Based on its multifactorial mechanism of action, we believe KPI-012 may address a significant unmet need, potentially offering patients and physicians a highly differentiated product profile and the first therapy for PCED that addresses the multiple underlying etiologies of the disease. We look forward to topline data from the CHASE trial, as we work to establish KPI-012 as a safe, well-tolerated, easily administered and effective treatment for the nearly 100,000 patients living with PCED in the U.S."

Fourth Quarter and Recent Business Highlights:

Development-Stage Pipeline:
KALA is advancing an innovative pipeline based on its proprietary mesenchymal stem cell secretome (MSC-S) platform. KALA believes the multifactorial mechanism of action of its MSC-S platform technology may enable it to generate products for a range of ocular orphan diseases and is evaluating the potential development of this technology for multiple rare, front- and back-of-the-eye diseases.

KPI-012 combines growth factors, protease inhibitors, matrix proteins and neurotrophic factors to potentially correct the impaired corneal healing that is an underlying etiology of multiple severe ocular diseases.

KALA is initially developing KPI-012 for the treatment of persistent corneal epithelial defect (PCED), a persistent, non-healing corneal defect or wound that is refractory to conventional treatments which, if left untreated, can lead to significant complications, including infection, corneal perforation/scarring and vision loss. PCED has an estimated incidence of approximately 100,000 patients in the U.S. and represents a sizeable market opportunity; there are currently no U.S. Food and Drug Administration (FDA)-approved prescription products with a broad indication for all underlying etiologies of PCED.

- KALA is actively enrolling patients in the primary safety and efficacy portion of the CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) Phase 2b clinical trial evaluating KPI-012 for the treatment of PCED and is targeting to announce topline data by year-end 2024.
- If the results are positive, and subject to discussion with regulatory authorities, KALA believes the CHASE Phase 2b trial could serve as the first of two pivotal trials required to support the submission of a Biologics License Application (BLA) to the FDA.

KALA is also evaluating the potential of KPI-012 for additional rare, front-of-the-eye diseases, such as Limbal Stem Cell Deficiency (LSCD) and other corneal diseases that threaten vision. LSCD is characterized by the loss or deficiency of limbal epithelial stem cells, which can result in recurrent epithelial breakdown, neovascularization, conjunctivalization, inflammation and other sequalae that can lead to loss of corneal clarity and vision impairment. Like PCED, LSCD represents a substantial market opportunity, with an estimated incidence of 100,000 patients in the U.S.

KPI-014, KALA's preclinical program to evaluate the utility of its MSC-S platform for inherited retinal degenerative diseases, contains neurotrophic factors, growth factors, anti-inflammatory or immune-modulatory factors and antioxidant inhibitors with the potential to protect and preserve retinal cell function. Secretomes have demonstrated a neuroprotective effect in both *in vitro* and *in vivo* models of retinal degeneration. KALA believes KPI-014 could offer a gene-agnostic approach for the treatment of rare inherited retinal diseases and has initiated preclinical studies to evaluate the utility of KPI-014 for conditions such as Retinitis Pigmentosa and Stargardt Disease.

Corporate:
In December 2023 and March 2024, KALA announced private placement financings with an institutional investor, priced at-the-market under Nasdaq rules. Aggregate gross proceeds from the financings were approximately $2.0 million and $8.6 million, respectively.

Financial Results:

Cash Position: As of December 31, 2023, KALA had cash and cash equivalents of $50.9 million, compared to $56.1 million as of September 30, 2023. This decrease reflects cash used in operations and gross proceeds of $2.0 million received from KALA's December 2023 private placement financing. Based on its current plans, KALA anticipates that its cash resources as of December 31, 2023, together with gross proceeds of $8.6 million

received from its March 2024 private placement financing and anticipated funding under the CIRM award, will enable it to fund operations into the third quarter of 2025.

Financial Results for the Three Months Ended December 31, 2023:

- **SG&A Expenses:** For the quarter ended December 31, 2023, selling, general and administrative (SG&A) expenses were $4.6 million, compared to $5.8 million for the same period in 2022. The decrease was primarily due to the sale of KALA's commercial portfolio to Alcon Inc. (Alcon) in July 2022.
- **R&D Expenses:** For the quarter ended December 31, 2023, research and development (R&D) expenses were $4.7 million, compared to $3.3 million for the same period in 2022. The increase was primarily due to an increase in KPI-012 development costs and employee-related costs.
- **Loss on Fair Value Remeasurement of Deferred Purchase Consideration:** There was no gain or loss on fair value remeasurement of deferred purchase consideration, in connection with the acquisition of Combangio, for the quarter ended December 31, 2023 due to the settlement of the liability in March 2023. The loss on fair value remeasurement of deferred purchase consideration was $0.4 million for the same period in 2022.
- **Loss on Fair Value Remeasurement of Contingent Consideration:** For the quarter ended December 31, 2023, the loss on fair value remeasurement of continent consideration, in connection with the Combangio acquisition, was $0.3 million, compared to a loss of $0.7 million for the same period in 2022.
- **Operating Loss:** For the quarter ended December 31, 2023, loss from operations was $9.6 million, compared to $10.3 million for the same period in 2022.
- **Net Loss:** For the quarter ended December 31, 2023, net loss was $8.6 million, or $3.18 per share, compared to a net loss of $12.8 million, or $7.97 per share, for the same period in 2022. The weighted average number of shares used to calculate net loss per share was 2.7 million for the quarter ended December 31, 2023, and 1.6 million for the quarter ended December 31, 2022.

Financial Results for the Full Year Ended December 31, 2023:

- **Net Product Revenues:** KALA did not recognize product revenues in the full year ended December 31, 2023 as a result of the sale of its commercial portfolio to Alcon in July 2022. For the full year ended December 31, 2022, Kala reported net product revenues of $3.9 million.
- **Cost of Product Revenues:** KALA did not record cost of product revenues in the full year ended December 31, 2023 as a result of the sale of its commercial portfolio to Alcon in July 2022. For the full year ended December 31, 2022, cost of product revenues was $2.6 million.
- **SG&A Expenses:** For the full year ended December 31, 2023, SG&A expenses were $20.6 million, compared to $65.0 million for the same period in 2022. The decrease was primarily due to the sale of KALA's commercial portfolio to Alcon.
- **R&D Expenses:** For the full year ended December 31, 2023, R&D expenses were $18.6 million, compared to $17.7 million for the same period in 2022. The increase was primarily due to an increase in KPI-012 development costs and employee-related costs, partially offset by a decrease in other research and development costs, which primarily included preclinical studies related to KALA's former pipeline programs and facility related costs.
- **(Gain) Loss on Fair Value Remeasurement of Deferred Purchase Consideration:** For the full year ended December 31, 2023, the gain on fair value remeasurement of deferred purchase consideration, in connection with the acquisition of Combangio, was $0.2 million, compared to a loss of $0.6 million for the same period in 2022.
- **Loss (Gain) on Fair Value Remeasurement of Contingent Consideration:** For the full year ended December 31, 2023, the loss on fair value remeasurement of continent consideration,

in connection with the Combangio acquisition, was $0.7 million, compared to a gain of $0.3 million for the same period in 2022.

- **Operating Loss:** For the full year ended December 31, 2023, loss from operations was $39.7 million, compared to $81.7 million for the same period in 2022.
- **Loss on Extinguishment of Debt:** For the full year ended December 31, 2023, KALA did not report a loss on extinguishment of debt, compared to a loss of $2.6 million in the same period in 2022 as a result of a partial prepayment of outstanding principal and related fees under its loan agreement with Oxford Finance LLC in connection with the closing of the sale of its commercial business to Alcon.
- **Gain on Sale of Commercial Business:** For the full year ended December 31, 2023, KALA did not report a gain on sale of commercial business, compared to a gain of $47.0 million for the same period in 2022 related to the sale of its commercial business to Alcon.
- **Net Loss:** For the full year ended December 31, 2023, net loss was $42.2 million, or $17.35 per share, compared to a net loss of $44.8 million, or $29.48 per share, for the same period in 2022. The weighted average number of shares used to calculate net loss per share was 2.4 million for the full year ended December 31, 2023, and 1.5 million for the full year ended December 31, 2022.

About KALA BIO, Inc.

KALA is a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the eye. KALA's biologics-based investigational therapies utilize KALA's proprietary mesenchymal stem cell secretome (MSC-S) platform. KALA's lead product candidate, KPI-012, is a human MSC-S, which contains numerous human-derived biofactors, such as growth factors, protease inhibitors, matrix proteins and neurotrophic factors that can potentially correct the impaired corneal healing that is an underlying etiology of multiple severe ocular diseases. KPI-012 is currently in clinical development for the treatment of persistent corneal epithelial defect (PCED), a rare disease of impaired corneal healing, for which it has received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration. KALA is also targeting the potential development of KPI-012 for the treatment of Limbal Stem Cell Deficiency and other rare corneal diseases that threaten vision and has initiated preclinical studies to evaluate the potential utility of its MSC-S platform for retinal degenerative diseases, such as Retinitis Pigmentosa and Stargardt Disease. For more information on KALA, please visit www.kalarx.com.

Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. Any statements in this press release about KALA's future expectations, plans and prospects, including but not limited to statements about KALA's expectations with respect to potential advantages of KPI-012 and its MSC-S platform; the clinical utility of KPI-012 for PCED; anticipated timelines to report topline data for the CHASE Phase 2b clinical trial of KPI-012; KALA's belief that the Chase Phase 2b trial could serve as the first of two pivotal trials required to support the submission of a BLA to the FDA; KALA's plans to pursue research and development of KPI-012 and its MSC-S platform for other indications; expectations about the potential benefits and future operation of the CIRM award; KALA's ability to achieve the specified milestones and obtain the full funding under the CIRM award; the sufficiency of KALA's existing cash resources for the period anticipated; and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "likely," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: KALA's ability to comply with the requirements under the CIRM award; uncertainties inherent in the initiation and conduct of preclinical studies and clinical trials; uncertainties regarding availability and timing of data from clinical trials; whether results of early clinical trials or trials in different disease indications will be indicative of the results of ongoing or future trials; whether results of the Phase 1b clinical trial of KPI-012 will be indicative of results for any future clinical trials and studies of KPI-012, including the CHASE Phase 2b clinical trial; whether interim data from a clinical trial will be predictive of the results of the trial; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; KALA's ability to retain and hire key personnel; KALA's ability to comply with the covenants under its loan agreement, including the requirement that its common stock continue to be listed on The Nasdaq Stock Market; the sufficiency of cash resources and need for additional financing and other important factors, any of which could cause KALA's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of KALA's Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q and other filings KALA makes with the Securities and Exchange Commission. These forward-looking statements represent KALA's views as of the date of this press release and should not be relied upon as representing KALA's views as of any date subsequent to the date hereof. KALA does not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Financial Tables:

KALA BIO, Inc.
Balance Sheet Data
(in thousands)
(unaudited)

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 50,895	$ 70,495
Total assets	55,949	86,820
Working capital[(1)]	44,524	60,257

Long-term debt, net of discounts	34,190	37,937
Other long-term liabilities	5,909	4,224
Total stockholders' equity	7,504	18,974

(1) The Company defines working capital as current assets less current liabilities. See the Company's consolidated financial statements for further information regarding its current assets and current liabilities.

KALA BIO, Inc.
Consolidated Statement of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Product revenues, net	$ —	$ —	$ —	$ 3,892
Costs and expenses:				
Cost of product revenues	—	—	—	2,560
Selling, general and administrative	4,623	5,831	20,567	65,035
Research and development	4,718	3,323	18,586	17,653
Loss (gain) on fair value remeasurement of deferred purchase consideration	—	433	(230)	638
Loss (gain) on fair value remeasurement of contingent consideration	278	664	740	(288)
Total operating expenses	9,619	10,251	39,663	85,598
Loss from operations	(9,619)	(10,251)	(39,663)	(81,706)
Other income (expense):				
Interest income	610	354	2,711	664
Interest expense	(1,468)	(1,577)	(5,814)	(7,266)
Grant income	1,855	—	4,825	—
Loss on extinguishment of debt	—	—	—	(2,583)
Gain on sale of commercial business	—	—	—	46,995
Other income (expense), net	(5)	(1,369)	(4,258)	(926)
Total other income (expense)	992	(2,592)	(2,536)	36,884
Net loss	$ (8,627)	$ (12,843)	$ (42,199)	$ (44,822)
Net loss per share attributable to common stockholders —basic and diluted	$ (3.18)	$ (7.97)	$ (17.35)	$ (29.48)
Weighted average shares outstanding—basic and diluted	2,712,475	1,611,375	2,432,008	1,520,611

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