KALA BIO Reports First Quarter 2024 Financial Results and Provides Corporate Update

May 14, 2024

-- Patient enrollment ongoing in Phase 2b CHASE trial of KPI-012 for PCED; targeting topline data by year-end 2024 --

-- Evaluating opportunities to expand KPI-012 development into other corneal diseases, including LSCD and to explore KPI-014 in rare inherited retinal diseases --

-- Cash resources of $48.5 million as of March 31, 2024 together with anticipated funding remaining from CIRM award expected to fund operations into 3Q 2025 --

ARLINGTON, Mass., May 14, 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 first quarter ended March 31, 2024 and provided a corporate update.

"In 2024, we are acutely focused on advancing our clinical program for KPI-012 in PCED, a rare, devastating disease caused by an array of underlying etiologies, many of which cannot be treated with currently approved therapeutic options," said Mark Iwicki, Chair and Chief Executive Officer of KALA BIO. "Given its multifactorial mechanism of action and based on clinical data to-date, we believe KPI-012 has the potential to address the multiple impaired corneal healing processes that cause PCED and provide patients a well-tolerated, easily administered and effective therapy. We are targeting topline data from our ongoing Phase 2b CHASE trial by year end which, if successful, could serve as the first of two pivotal trials required to support a BLA submission."

Mr. Iwicki continued, "In parallel, we remain committed to exploring the potential of our platform technology more broadly, as we work to establish KALA as a leader in the emerging field of mesenchymal stem cell secretome therapy. We believe KPI-012 represents a pipeline-in-a-product opportunity and plan to leverage our investigational new drug-enabling activities in PCED to support follow-on indications across a range of corneal diseases, while also exploring the potential for KPI-014, our second asset, across a range of rare, inherited retinal diseases."

First Quarter and Recent Business Highlights:

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.

KALA's lead product candidate, 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 we believe 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 continues to enroll patients in the CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) Phase 2b clinical trial evaluating KPI-012 for the treatment of PCED, and are targeting the announcement of topline data by year-end 2024. Contingent on positive results and subject to discussion with regulatory authorities, the Company believes the CHASE Phase 2b trial could potentially serve as the first of two pivotal studies to support the submission of a Biologics License Application (BLA) to the FDA.
- KALA is also exploring the potential of KPI-012 for additional rare, front-of-the-eye diseases, including Limbal Stem Cell Deficiency (LSCD) and other corneal diseases. 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.

Financial Results:

Cash Position: As of March 31, 2024, KALA had cash and cash equivalents of $48.5 million, compared to $50.9 million as of December 31, 2023. This decrease reflects cash used in operations, partially offset by gross proceeds of $8.6 million received from KALA's March 2024 private placement financing. Based on its current plans, KALA anticipates that its cash resources as of March 31, 2024, together with anticipated funding under the CIRM award, will enable it to fund operations into the third quarter of 2025.

First Quarter 2024 Financial Results:

- **G&A Expenses:** For the quarter ended March 31, 2024, general and administrative (G&A) expenses were $5.4 million, compared to $6.0 million for the same period in 2023. The decrease was primarily due to a decrease in administrative and professional service fees, partially offset by an increase in stock-based compensation costs and employee related costs.
- **R&D Expenses:** For the quarter ended March 31, 2024, research and development (R&D) expenses were $6.4 million, compared to $4.0 million for the same period in 2023. The increase was primarily due to an increase in KPI-012 development costs and employee-related costs, as we advance the clinical development of KPI-012, and an increase in other research and development costs.
- **Gain on Fair Value Remeasurement of Deferred Purchase Consideration**: For the quarter ended March 31, 2024, there was no gain or loss on fair value remeasurement of deferred purchase consideration, in connection with the acquisition of Combangio. For the same period in 2023, there was a gain of $0.2 million.
- **Loss on Fair Value Remeasurement of Contingent Consideration:** For the quarter ended March 31, 2024, the loss on fair value remeasurement of continent consideration, in connection with the Combangio acquisition, was $0.2 million, compared to a loss of $1.8 million for the same period in 2023.
- **Operating Loss:** For the quarter ended March 31, 2024, loss from operations was $11.9 million, compared to $11.7 million for the same period in 2023.
- **Net Loss:** For the quarter ended March 31, 2024, net loss was $11.8 million, or $4.20 per share, compared to a net loss of $14.5 million, or $6.99 per share, for the same period in 2023. The weighted average number of shares used to calculate net loss per share was 2.8 million for the quarter ended March 31, 2024, and 2.1 million for the quarter ended March 31, 2023.

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)

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 48,478	$ 50,895
Total assets	53,033	55,949
Working capital (1)	38,208	44,524
Long-term debt, net of discounts	28,510	34,190
Other long-term liabilities	5,983	5,909
Total stockholders' equity	6,661	7,504

(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 March 31,	
	2024	2023
Costs and expenses:		
General and administrative	$ 5,422	$ 6,030
Research and development	6,351	4,036
Gain on fair value remeasurement of deferred purchase consideration	—	(230)
Loss on fair value remeasurement of contingent consideration	158	1,847
Total operating expenses	11,931	11,683
Loss from operations	(11,931)	(11,683)
Other income (expense):		
Interest income	504	675
Interest expense	(1,455)	(1,474)
Grant income	1,075	—
Other (expense) income, net	—	(1,973)
Net loss	$ (11,807)	$ (14,455)
Net loss per share attributable to common stockholders—basic and diluted	$ (4.20)	$ (6.99)
Weighted average shares outstanding—basic and diluted	2,813,210	2,069,186

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