KALA BIO Announces $10,750,000 Private Placement

December 30, 2024

ARLINGTON, Mass., Dec. 30, 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 announced that it has entered into a securities purchase agreement with a select group of institutional accredited investors for the sale, in a private placement, of shares of its common stock and shares of its Series I Convertible Non-Redeemable Preferred Stock (the "Series I Preferred Stock"), for aggregate gross proceeds of approximately $10.75 million, before deducting offering expenses.

The private placement included participation from both new and existing investors, including SR One, Cormorant Asset Management, Woodline Partners and another life sciences-focused investor.

In the private placement, KALA has agreed to sell 1,340,603 shares of its common stock at a price of $6.44 per share and 3,286 shares of its Series I Preferred Stock at a price of $644.00 per share. The private placement is expected to close on or about December 31, 2024, subject to the satisfaction of customary closing conditions.

Based on its current plans, KALA anticipates that its existing cash resources, together with the net proceeds from the private placement, will enable it to fund operations into the first quarter of 2026. KALA intends to use the net proceeds from the private placement to advance the clinical development of KPI-012 for the treatment of persistent corneal epithelial defect, as well as for general corporate purposes. KALA is actively recruiting patients for enrollment in the ongoing Phase 2b CHASE trial of KPI-012 with over 40 clinical trial sites open and enrolling. "We appreciate the support of our new and existing stockholders in this financing, which comes at an important time for our company," said Mark Iwicki, Chair and Chief Executive Officer of KALA BIO. "With over 80% of enrollment now complete in the CHASE trial, we remain on track to report topline data in the second quarter of 2025. If successful, this trial may serve as the first of two pivotal trials required to support a BLA submission."

The securities to be sold in the private placement have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or applicable state securities laws, and may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements. KALA has agreed to file a registration statement with the U.S. Securities and Exchange Commission (the "SEC") registering the resale of the shares of common stock issued in the private placement and the shares of common stock issuable upon conversion of the Series I Preferred Stock issued in the private placement no later than the 30th day after the closing of the private placement.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of securities of KALA in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction. Any offering of the securities under the resale registration statement will only be made by means of a prospectus.

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.

Cautionary Note Regarding 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 the expected closing of the private placement, the sufficiency of KALA's cash resources for the period anticipated; the anticipated use of net proceeds from the private placement; anticipated timelines to report topline data for the CHASE trial; KALA's belief that the CHASE trial could serve as the first of two pivotal trials required to support the submission of a BLA to the FDA; 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. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether the conditions for the closing of the private placement will be satisfied; market conditions; 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 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; and other factors discussed in the "Risk Factors" section of KALA's Annual Report on Form 10-K, most recently filed Quarterly Report on Form 10-Q and other filings KALA makes with the SEC. 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.

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