UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 27, 2023**

Kala Pharmaceuticals, Inc.

(Exact Name of Company as Specified in its Charter)

Delaware	**001-38150**	**27-0604595**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1167 Massachusetts Avenue
Arlington, MA 02476

(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: **(781) 996-5252**

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	KALA	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On March 27, 2023, Kala Pharmaceuticals, Inc. (the "Company") announced positive safety data from the first cohort of the CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) Phase 2b clinical trial evaluating KPI-012, a human mesenchymal stem cell secretome, for the treatment of persistent corneal epithelial defect ("PCED").

The CHASE trial includes two patient cohorts. The first cohort is an open-label study to evaluate the safety of the high dose of KPI-012 (3 U/mL) dosed topically four times per day ("QID") in two patients. Both patients in the first cohort successfully completed at least one week of dosing with no safety issues observed. The Company is now proceeding to initiate the second patient cohort.

The second cohort is a multicenter, randomized, double-masked, vehicle-controlled, parallel-group study to evaluate the safety and tolerability of two doses of KPI-012 ophthalmic solution (3 U/mL and 1 U/mL) versus vehicle dosed topically QID for 56 days in approximately 90 patients. The primary endpoint of the trial is the complete healing of the PCED as measured by corneal fluorescein staining. The Company is targeting reporting topline safety and efficacy data in the first quarter of 2024. If the results are positive, and subject to discussion with regulatory authorities, the Company believes this trial could serve as the first of two pivotal trials required to support the submission of a Biologics License Application to the U.S. Food and Drug Administration.

Forward-Looking Statements

This Form 8-K 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 Form 8-K about the Company's future expectations, plans and prospects, including but not limited to statements about the Company's expectations with respect to potential advantages of KPI-012 and its MSC-S platform; anticipated timelines to report topline data for the CHASE Phase 2b clinical trial of KPI-012; the potential regulatory pathway for KPI-012; the design of the CHASE Phase 2b clinical trial; the clinical utility of KPI-012 for PCED; plans to pursue research and development of KPI-012 and its MSC-S platform for other indications 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: 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; the Company's ability to retain and hire key personnel; the impact of extraordinary external events, such as the current pandemic health event resulting from the coronavirus (COVID-19), and their collateral consequences; the sufficiency of cash resources and need for additional financing and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K and other filings the Company makes with the Securities and Exchange Commission. These forward-looking statements represent the Company's views as of the date of this Form 8-K and should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. The Company 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KALA PHARMACEUTICALS, INC.

Date: March 27, 2023

By: /s/ Eric L. Trachtenberg
Name: Eric L. Trachtenberg
Title: General Counsel, Chief Compliance Officer & Corporate Secretary