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): **May 9, 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 2.02 Results of Operations and Financial Condition.

On May 9, 2023, Kala Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 2023 and provided a general business update. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release of Kala Pharmaceuticals, Inc. dated May 9, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

KALA PHARMACEUTICALS, INC.

Date: May 9, 2023

By: /s/ Mary Reumuth
Name: Mary Reumuth
Title: Chief Financial Officer

Kala Pharmaceuticals Reports First Quarter 2023 Financial Results and Provides Corporate Update

-- Announced positive data from initial safety portion of CHASE Phase 2b clinical trial of KPI-012; now enrolling primary safety and efficacy portion of trial, with topline data targeted in 1Q 2024 --
-- Received FDA Fast Track designation for KPI-012 for the treatment of PCED --
-- Strengthened clinical R&D team with appointment of Dr. Francis Mah as Chief Medical Advisor –
-- Awarded $15 million grant from CIRM to support the KPI-012 PCED program --

ARLINGTON, Mass., May 9, 2023 - Kala Pharmaceuticals, 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, 2023 and provided a corporate update.

"The first quarter and recent months were marked by a number of important milestones across our business. We are particularly encouraged by progress in our efforts to advance KPI-012 as the first potential treatment to address all of the underlying etiologies of PCED. We announced positive data from the initial safety portion of the CHASE Phase 2b trial of KPI-012 for PCED, enabling us to advance into the primary safety and efficacy portion of the trial. The KPI-012 PCED program was also granted Fast Track designation by the FDA, which further underscores the importance of the program and the promise of KPI-012 as a novel solution for thousands of PCED patients in need," said Mark Iwicki, Chief Executive Officer and Chairman of Kala Pharmaceuticals. "In addition, we strengthened our corporate leadership with the appointment of Dr. Francis Mah, an expert in both corneal disease and clinical trial execution, as Chief Medical Advisor, and our wholly-owned subsidiary, Combangio, Inc., was awarded a $15 million grant from the California Institute for Regenerative Medicine (CIRM). We believe the support from CIRM speaks to the potential of KPI-012 – and our MSC-S platform more broadly – as a regenerative approach to improve the treatment of rare ocular diseases. We look forward to advancing the CHASE trial toward initial data readout targeted in the first quarter of 2024, while exploring opportunities to expand our MSC-S platform into additional indications."

First Quarter and Recent Business Highlights:

Development-Stage Pipeline:
KPI-012 is a mesenchymal stem cell secretome (MSC-S), which 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.

- In April 2023, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for KPI-012 for the treatment of PCED. Fast Track is a process designed by the FDA to facilitate the development and expedite the review of drug candidates intended to treat serious conditions and for which nonclinical and/or clinical data demonstrate the potential to address unmet medical need. The purpose of this designation is to help speed development and regulatory review of new drugs, potentially making them available to the patient more quickly.
- In March 2023, Kala announced positive data from the initial safety 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, which enrolled two patients, both of whom were treated with a high dose of KPI-012 (3 U/mL) four times per day (QID). Both patients successfully completed at least one week of dosing with no safety issues observed.
- The CHASE trial is now enrolling the primary safety and efficacy portion of the trial, which 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. Kala is targeting topline safety and efficacy data in the first quarter of 2024. If the results are positive, and subject to discussion with regulatory authorities, Kala believes this 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 believes the multifactorial mechanism of action of KPI-012 makes it a platform technology and is evaluating the potential development of KPI-012 for additional rare, front-of-the-eye diseases, such as Limbal Stem Cell Deficiency and other corneal diseases that threaten vision. Kala has also initiated preclinical studies for its KPI-014 program, evaluating the utility of its MSC-S platform for inherited retinal degenerative diseases such as Retinitis Pigmentosa and Stargardt Disease.

Corporate Updates:

- In April 2023, the California Institute for Regenerative Medicine (CIRM) awarded Combangio, Inc. (Combangio), a wholly-owned subsidiary of Kala, a $15 million grant to support the ongoing KPI-012 PCED program.
- In March 2023, Kala appointed Francis Mah, M.D., as Chief Medical Advisor. In this newly established role, Dr. Mah provides support for Kala's clinical development and medical activities and plays a key role in interactions with eye care professionals. Dr. Mah is serving in this role on a part-time basis while continuing his ongoing position as Director of Cornea and External Disease and the Co-Director, Refractive Surgery at Scripps Clinic.

Financial Results:

Cash Position: As of March 31, 2023, Kala had cash and cash equivalents of $63.6 million, compared to $70.5 million as of December 31, 2022. This decrease reflects cash used in operations and a $2.5 million milestone payment to former Combangio shareholders upon the dosing of the first patient in the CHASE trial, as well as a prepayment of approximately $10 million in principal and fees under the Company's loan agreement, partially offset by $14.9 million raised under Kala's at-the-market offering program. Cash and cash equivalents as of March 31, 2023 exclude anticipated funding from the $15 million grant awarded by CIRM in April 2023. Based on its current plans, Kala anticipates that its cash resources as of March 31, 2023, together with anticipated funding under the CIRM award, will enable it to fund operations into the first quarter of 2025.

First Quarter 2023 Financial Results:

- **Net Product Revenues:** Kala did not recognize product revenues in the first quarter of 2023, as a result of the sale of its commercial portfolio to Alcon Inc. (Alcon) on July 8, 2022. For the quarter ended March 31, 2022, Kala reported net product revenues of $1.4 million.
- **Cost of Product Revenues:** Kala did not record cost of product revenues in the first quarter of 2023 as a result of the sale of its commercial portfolio to Alcon. For the quarter ended March 31, 2022, cost of product revenues was $0.8 million.
- **SG&A Expenses:** For the quarter ended March 31, 2023, selling, general and administrative (SG&A) expenses were $6.0 million, compared to $27.0 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 quarter ended March 31, 2023, research and development (R&D) expenses were $4.0 million, compared to $4.5 million for the same period in 2022. The decrease was primarily due to a decrease in R&D costs related to our former pipeline programs, partially offset by an increase in costs due to the development of KPI-012.
- **(Gain) Loss on Fair Value Remeasurement of Deferred Purchase Consideration:** For the quarter ended March 31, 2023, the gain on fair value remeasurement of deferred purchase consideration, in connection with the Combangio acquisition, was $0.2 million, compared to a loss of $1.1 million for the same period in 2022.
- **Loss (Gain) on Fair Value Remeasurement of Contingent Consideration:** For the quarter ended March 31, 2023, the loss on fair value remeasurement of continent consideration, in connection with the Combangio acquisition, was $1.8 million, compared to a gain of $1.0 million for the same period in 2022.

- **Operating Loss:** For the quarter ended March 31, 2023, loss from operations was $11.7 million, compared to $30.9 million for the same period in 2022.
- **Net Loss:** For the quarter ended March 31, 2023, net loss was $14.5 million, or $6.99 per share, compared to a net loss of $32.9 million, or $22.18 per share, for the same period in 2022. The weighted average number of shares used to calculate net loss per share was 2.1 million for the quarter ended March 31, 2023 and 1.5 million for the quarter ended March 31, 2022.

About Kala Pharmaceuticals, 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 KPI-012 as the first potential treatment to address all underlying etiologies of PCED; 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; the amount of anticipated 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," "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: 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; the impact of extraordinary external events, such as the 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 Kala's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of Kala's 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 Pharmaceuticals, Inc.
Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 63,636	$ 70,495
Total assets	72,226	86,820
Working capital [1]	61,079	60,257
Long-term debt, net of discounts	33,266	37,937
Other long-term liabilities	5,234	4,224
Total stockholders' equity	23,461	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 Pharmaceuticals, Inc.
Consolidated Statement of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Product revenues, net	$ —	$ 1,372
Costs and expenses:		
Cost of product revenues	—	775
Selling, general and administrative	6,030	26,982
Research and development	4,036	4,466
(Gain) loss on fair value remeasurement of deferred purchase consideration	(230)	1,051
Loss (gain) on fair value remeasurement of contingent consideration	1,847	(988)
Total operating expenses	11,683	32,286
Loss from operations	(11,683)	(30,914)
Other income (expense):		
Interest income	675	8
Interest expense	(1,474)	(2,035)
Other income (expense), net	(1,973)	—
Net loss	(14,455)	(32,941)
Net loss per share attributable to common stockholders—basic and diluted	$ (6.99)	$ (22.18)
Weighted average shares outstanding—basic and diluted	2,069,186	1,485,168

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