
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): **November 13, 2023**

KALA BIO, Inc.

(Exact Name of Company as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-38150
(Commission File Number)

27-0604595
(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 November 13, 2023, KALA BIO, Inc. announced its financial results for the quarter ended September 30, 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 BIO, Inc. dated November 13, 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 BIO, INC.

Date: November 13, 2023

By: /s/ Mary Reumuth

Name: Mary Reumuth

Title: Chief Financial Officer

KALA BIO Reports Third Quarter 2023 Financial Results and Provides Corporate Update

-- Enrollment ongoing in CHASE Phase 2b clinical trial of KPI-012 for PCED; topline data expected in 2H 2024 --
-- As of September 30, 2023, \$56.1 million in cash and cash equivalents; together with anticipated remaining funding from CIRM award, expected to fund operations into 2Q 2025 --

ARLINGTON, Mass., November 13, 2023 – KALA BIO, Inc. (NASDAQ:KALA), a clinical-stage biopharmaceutical company dedicated to the research and development of innovative therapies for rare and severe diseases of the eye, today reported financial results for the third quarter ended September 30, 2023 and provided a corporate update.

“We continue to execute diligently against our corporate priorities. We are actively enrolling patients in our CHASE Phase 2b trial of KPI-012 for PCED and are targeting topline safety and efficacy data in the second half of 2024,” said Mark Iwicki, Chair and Chief Executive Officer of KALA BIO. “In parallel, we are advancing our MSC-S pipeline, exploring opportunities to expand KPI-012 into additional corneal indications and evaluating KPI-014 preclinically for inherited retinal degenerative diseases and other back-of-the-eye applications. We look forward to furthering these efforts, as we aim to maximize the potential of our cell-free, regenerative approach to treating rare and severe ocular surface and retinal diseases.”

Third 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 believes the multifactorial mechanism of action of its MSC-S program makes it a platform technology and is evaluating the potential development of this technology for multiple rare, front- and back-of-the-eye diseases.

- **CHASE Phase 2b Clinical Trial.** KALA is actively enrolling patients in the primary safety and efficacy portion of the CHASE (**C**orneal **H**ealing **A**fter **S**Ecretome therapy) Phase 2b clinical trial evaluating 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 infection, corneal perforation/scarring and vision loss. KALA is targeting to announce topline data in the second half of 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 to support the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for KPI-012.
- **KPI-012 Pipeline.** KALA 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.
- **KPI-014 Pre-Clinical Program.** 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.

Financial Results:

Cash Position: As of September 30, 2023, KALA had cash and cash equivalents of \$56.1 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 the former Combangio, Inc. (Combangio) shareholders following the dosing of the first patient in the CHASE trial, as well as a prepayment of approximately \$10.0 million in principal and fees under KALA's loan agreement, partially offset by net proceeds of \$18.0 million raised under KALA's at-the-market offering program. Based on its current plans, KALA anticipates that its cash resources as of September 30, 2023, together with anticipated remaining funding under the CIRM award, will enable it to fund operations into the second quarter of 2025.

Financial Results for the Three Months Ended September 30, 2023:

- **Net Product Revenues:** KALA did not recognize product revenues in the third 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 September 30, 2022, KALA reported net product revenues of \$0.4 million, representing approximately one week of net product revenues from sales of EYSUVIS® and INVELTYS®.
- **Cost of Product Revenues:** KALA did not record cost of product revenues in the third quarter of 2023 as a result of the sale of its commercial portfolio to Alcon. For the quarter ended September 30, 2022, cost of product revenues was less than \$0.1 million representing approximately one week of cost of product revenues.
- **SG&A Expenses:** For the quarter ended September 30, 2023, selling, general and administrative (SG&A) expenses were \$5.0 million, compared to \$9.5 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 September 30, 2023, research and development (R&D) expenses were \$5.6 million, compared to \$5.4 million for the same period in 2022. The increase was primarily due to increase in employee-related costs and KPI-012 development costs, partially offset by decreases in other research and development costs, which primarily included preclinical studies related to KALA's former pipeline programs.
- **(Gain) Loss on Fair Value Remeasurement of Deferred Purchase Consideration:** For the quarter ended September 30, 2023, there was no gain or loss on fair value remeasurement of deferred purchase consideration, in connection with the acquisition of Combangio, compared to a gain of less than \$0.1 million for the same period in 2022.
- **(Gain) Loss on Fair Value Remeasurement of Contingent Consideration:** For the quarter ended September 30, 2023, the gain on fair value remeasurement of contingent consideration, in connection with the Combangio acquisition, was \$1.7 million, compared to a loss of \$0.1 million for the same period in 2022.
- **Operating Loss:** For the quarter ended September 30, 2023, loss from operations was \$8.8 million, compared to \$14.6 million for the same period in 2022.
- **Loss on Extinguishment of Debt:** For the quarter ended September 30, 2023, KALA did not report a loss on extinguishment of debt, compared to a loss of \$2.6 million for the same period in 2022 as a result of a partial prepayment of outstanding principal and related fees on the Company's loan agreement in connection with the closing of the sale of its commercial business.
- **Gain on Sale of Commercial Business:** For the quarter ended September 30, 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/Income:** For the quarter ended September 30, 2023, net loss was \$8.7 million, or \$3.41 per share, compared to a net income of \$29.1 million, or a basic net income per share of \$19.39 and \$19.25 per share on a fully diluted basis, for the same period in 2022. The weighted average number of shares used to calculate net loss/income per share was 2.6 million for the quarter ended September 30, 2023 and 1.5 million for the quarter ended September 30, 2022.

Financial Results for the Nine Months Ended September 30, 2023:

- **Net Product Revenues:** KALA did not recognize product revenues in the nine months ended September 30, 2023 as a result of the sale of its commercial portfolio to Alcon on July 8, 2022. For the nine months ended September 30, 2022, Kala reported net product revenues of \$3.9 million.
 - **Cost of Product Revenues:** KALA did not record cost of product revenues in the nine months ended September 30, 2023 as a result of the sale of its commercial portfolio to Alcon on July 8, 2022. For the nine months ended September 30, 2022, cost of product revenues was \$2.6 million.
 - **SG&A Expenses:** For the nine months ended September 30, 2023, SG&A expenses were \$15.9 million, compared to \$59.2 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 nine months ended September 30, 2023, R&D expenses were \$13.9 million, compared to \$14.3 million for the same period in 2022. The decrease was primarily due to a \$1.6 million decrease in other research and development costs, which primarily included preclinical studies related to KALA's former pipeline programs and other facility related costs, partially offset by a \$1.1 million increase in KPI-012 development costs.
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- **(Gain) Loss on Fair Value Remeasurement of Deferred Purchase Consideration:** For the nine months ended September 30, 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 \$0.2 million for the same period in 2022.
- **Loss (Gain) on Fair Value Remeasurement of Contingent Consideration:** For the nine months ended September 30, 2023, the loss on fair value remeasurement of contingent consideration, in connection with the Combangio acquisition, was \$0.5 million, compared to a gain of \$1.0 million for the same period in 2022.
- **Operating Loss:** For the nine months ended September 30, 2023, loss from operations was \$30.0 million, compared to \$71.5 million for the same period in 2022.
- **Loss on Extinguishment of Debt:** For the nine months ended September 30, 2023, KALA did not report a loss on extinguishment of debt, compared to a loss of \$2.6 million for the same period in 2022 as a result of a partial prepayment of outstanding principal and related fees on the Company's loan agreement in connection with the closing of the sale of its commercial business.
- **Gain on Sale of Commercial Business:** For the nine months ended September 30, 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 nine months ended September 30, 2023, net loss was \$33.6 million, or \$14.36 per share, compared to a net loss of \$32.0 million, or \$21.46 per share, for the same period in 2022. The weighted average number of shares used to calculate net loss per share was 2.3 million for the nine months ended September 30, 2023 and 1.5 million for the nine months ended September 30, 2022.

About KALA BIO, Inc.

KALA is a clinical-stage biopharmaceutical company dedicated to the research and development 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; 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 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)

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Cash and cash equivalents	\$ 56,063	\$ 70,495
Total assets	61,120	86,820
Working capital (1)	47,601	60,257
Long-term debt, net of discounts	33,878	37,937
Other long-term liabilities	5,718	4,224
Total stockholders' equity	11,223	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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product revenues, net	\$ -	\$ 420	\$ -	\$ 3,892
Costs and expenses:				
Cost of product revenues	-	11	-	2,560
Selling, general and administrative	4,952	9,549	15,944	59,204
Research and development	5,554	5,391	13,868	14,330
(Gain) loss on fair value remeasurement of deferred purchase consideration	-	(57)	(230)	205
(Gain) loss on fair value remeasurement of contingent consideration	(1,744)	95	462	(952)
Total costs and expenses	8,762	14,989	30,044	75,347
Loss from operations	(8,762)	(14,569)	(30,044)	(71,455)
Other income (expense):				
Interest income	708	234	2,101	310
Interest expense	(1,459)	(1,447)	(4,346)	(5,689)
Grant income	2,970	-	2,970	-
Loss on extinguishment of debt	-	(2,583)	-	(2,583)
Gain on sale of commercial business	-	46,995	-	46,995
Other (expense) income, net	(2,161)	443	(4,253)	443
Total other income (expense)	58	43,642	(3,528)	39,476
Net (loss) income	\$ (8,704)	\$ 29,073	\$ (33,572)	\$ (31,979)
Net (loss) income per share attributable to common stockholders—basic	\$ (3.41)	\$ 19.39	\$ (14.36)	\$ (21.46)
Net (loss) income per share attributable to common stockholders—diluted	\$ (3.41)	\$ 19.25	\$ (14.36)	\$ (21.46)
Weighted average shares outstanding—basic	2,550,210	1,499,001	2,337,492	1,490,159
Weighted average shares outstanding—diluted	2,550,210	1,510,421	2,337,492	1,490,159

Investor Contact:

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