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): **July 8, 2022**

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 Global Select 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 2.01. Completion of Acquisition or Disposition of Assets.

On July 8, 2022, Kala Pharmaceuticals, Inc., a Delaware corporation (the "Company") closed the transaction contemplated by the previously announced Asset Purchase Agreement, dated as of May 21, 2022 (the "Asset Purchase Agreement"), by and between the Company, Alcon Pharmaceuticals Ltd., a Swiss limited company ("Alcon Switzerland"), and Alcon Vision, LLC, a Delaware limited liability company (together, with Alcon Switzerland, the "Buyers"), pursuant to which the Buyers (1) purchased (a) the Company's rights to (i) manufacture, sell, distribute, market and commercialize EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25% and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% and (ii) develop, manufacture, market and otherwise exploit its proprietary AMPPLIFY® Drug Delivery Technology, which, among other applications, is incorporated into EYSUVIS and INVELTYS and (b) certain assets used by the Company in connection with the foregoing (collectively, the "Commercial Business") and (2) assumed certain liabilities with respect to the Commercial Business (the "Transaction").

The Buyers paid to the Company an upfront cash payment of $60.0 million upon the closing of the Transaction. In addition, pursuant to the Asset Purchase Agreement, the Company is eligible to receive from the Buyers up to four commercial-based sales milestone payments as follows: (1) $25.0 million upon the achievement of $50.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (2) $65.0 million upon the achievement of $100.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2028, (3) $75.0 million upon the achievement of $175.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029 and (4) $160.0 million upon the achievement of $250.0 million or more in aggregate worldwide net sales of EYSUVIS and INVELTYS in a calendar year from 2023 to 2029. Each milestone payment will only become payable once, if at all, upon the first time such milestone is achieved, and only one milestone payment will be paid with respect to a calendar year. In the event that more than one milestone is achieved in a calendar year, the higher milestone payment will become payable and the lower milestone payment will become payable only if the corresponding milestone is achieved again in a subsequent calendar year. Pursuant to the Asset Purchase Agreement, on July 8, 2022, the Company entered into supply and commercial agreements under which the Company agreed to supply EYSUVIS and INVELTYS to the Buyers and their affiliates and distribute EYSUVIS and INVELTYS to third-party customers of the Commercial Business on behalf of the Buyers and their affiliates for a period of six months following the closing of the Transaction, subject to early termination. In addition, the Company entered into a transition services agreement under which the Company agreed to provide agreed upon transition services to the Buyers on a cost-plus pricing arrangement for up to six months following the closing of the Transaction. Pursuant to the supply agreement, the Buyers purchased from the Company, at the closing of the Transaction, certain EYSUVIS and INVELTYS inventory on-hand at the Company.

The material terms and conditions of the Asset Purchase Agreement were described in Item 1.01 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 23, 2022 (the "Prior Report") under the heading "Asset Purchase Agreement," which description is incorporated herein by reference and is qualified in its entirety by reference to the full text of the Asset Purchase Agreement, which is attached as Exhibit 2.1 to the Prior Report.

Item 2.05. Costs Associated with Exit or Disposal Activities.

On June 16, 2022, the Board of Directors (the "Board") of the Company committed to a course of action to terminate 113 employees, consisting of the Company's entire commercial sales force and certain employees in its commercial, scientific, manufacturing, finance and administrative functions. The determination to proceed with the workforce reduction was made in the context of the anticipated closing of the Transaction and the Company's determination to focus its resources on the development of KPI-012 described in Item 8.01 of this Current Report on Form 8-K.

The Company expects this workforce reduction to result in approximately $27.6 million in reduced annualized operating expenses once the reduction is fully implemented. In addition, the Company expects to incur a charge of approximately $2.5 million primarily in the third quarter of 2022 related to the workforce reduction, consisting of severance, benefits and related costs, all of which are anticipated to be paid prior to the end of the first quarter of 2023. The Company expects to substantially complete the workforce reduction by December 31, 2022.

In addition to the reduction in operating expenses related to the workforce reduction, the Company also expects to realize additional cost savings following the closing of the Transaction by substantially eliminating development costs that are unrelated to KPI-012 and by significantly reducing external costs that were related to its Commercial Business.

Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing

On July 6, 2022, the Company received a deficiency letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market ("Nasdaq") notifying the Company that the listing of its common stock was not in compliance with Nasdaq Listing Rule 5450(b)(2)(A) (the "Minimum MVLS Requirement") for continued listing on the Nasdaq Global Select Market, as the market value of the Company's listed securities was less than $50,000,000 for the previous 30 consecutive business day. The Staff also noted in its letter that the Company is not in compliance with Nasdaq Listing Rule 5450(b)(3)(A), which requires listed companies to have total assets and total revenue of at least $50,000,000 each for the most recently completed fiscal year or for two of the three most recently completed fiscal years.

In accordance with Nasdaq Listing Rule 5810(c)(3)(C) (the "Compliance Period Rule"), the Company has been provided a period of 180 calendar days, or until January 2, 2023 (the "Compliance Date"), to regain compliance with the Minimum MVLS Requirement. If, at any time before the Compliance Date, the market value of the Company's listed securities closes at $50,000,000 or more for a minimum of 10 consecutive business days, the Staff will provide written notification to the Company that it has regained compliance with the Minimum MVLS Requirement.

If the Company does not regain compliance with the Minimum MVLS Requirement by the Compliance Date, the Company will receive written notification that its securities are subject to delisting. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Listing Qualifications Panel (the "Panel") pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. However, there can be no assurance that, if the Company receives a delisting notice and appeals the delisting determination by the Staff to the Panel, such appeal would be successful. Alternatively, if the Company does not regain compliance with the Minimum MVLS Requirement by the Compliance Date, the Company may transfer the listing of its common stock to the Nasdaq Capital Market, provided that the Company then meets the applicable requirements for continued listing on the Nasdaq Capital Market. To effect such a transfer, the Company would also need to pay an application fee to Nasdaq and submit an online transfer application.

The Company intends to monitor the market value of its listed securities and may, if appropriate, consider available options to regain compliance with the Nasdaq Listing Rules, including applying to transfer to the Nasdaq Capital Market.

Item 8.01. Other Events.

Pipeline Updates

The Company has determined to focus its research and development activities on the development of KPI-012, a mesenchymal stem cell secretome ("MSC-S"), for the treatment of persistent corneal epithelial defects ("PCED"), a rare disease of impaired corneal healing. The Company plans to submit an investigational new drug application to the U.S. Food and Drug Administration for KPI-012 and, subject to regulatory clearance, commence a Phase 2/3 clinical trial of KPI-012 for PCED in the United States in the fourth quarter of 2022. The Company also intends to evaluate KPI-012 for the treatment of Partial Limbal Stem Cell Deficiency and ocular manifestations of moderate-to-severe Sjögren's, with clinical development in at least one of these indications expected to begin in the first half of 2023. In addition, the Company plans to initiate preclinical studies to evaluate the utility of its MSC-S platform for retinal degenerative disease, such as Retinitis Pigmentosa and Stargardt Disease, in late 2022 with the goal to select a retinal indication for development in the second half of 2023.

In connection with the determination to focus its research and development efforts on KPI-012, the Company has ceased the development of its preclinical pipeline programs, including KPI-287, the Company's receptor tyrosine kinase inhibitor, and its selective glucocorticoid receptor modulators.

Cash Runway

The Company anticipates that its existing cash, cash equivalents and short-term investments, along with the upfront cash payment of $60.0 million received from the Buyers upon the closing of the Transaction and the cash purchase by the Buyers at the closing of the Transaction of EYSUVIS and INVELTYS inventory on-hand at the Company, will enable it to fund its operations, lease and debt service obligations and capital expenditure requirements into the second quarter of 2024, which is beyond the anticipated readout of the Company's planned Phase 2/3 clinical trial of KPI-012. The Company has based this estimate on assumptions that may prove to be wrong, and it could use its capital resources sooner than it currently expects.

Loan and Security Agreement

As previously disclosed, on May 21, 2022, in connection with its entry into the Asset Purchase Agreement, the Company entered into an amendment (the "Loan Amendment") with Oxford Finance LLC to the Loan and Security Agreement, dated May 4, 2021 (the "Loan Agreement"), by and among the Company, Combangio, Inc. and Oxford Finance LLC, in its capacity as lender (in such capacity, the "Lender"), and in its capacity as collateral agent (in such capacity, the "Agent"). Pursuant to the Loan Amendment, the Lender and Agent consented to the entry by the Company into the Asset Purchase Agreement and the sale of the Commercial Business to the Buyers and agreed to release its liens on the Commercial Business in consideration for the payment by the Company at the closing of the Transaction of an aggregate amount of $40,000,000 (the "Prepayment") to the Lender and Agent. The Prepayment, which represented a partial prepayment of principal in the amount of $36,697.247.71 of the $80,000,000 principal amount outstanding under the term loan advanced by the Lender under the Loan Agreement, plus a prepayment fee and a final payment fee, was paid on July 8, 2022 in connection with the closing of the Transaction.

Item 9.01. Financial Statements and Exhibits.

(b) Pro Forma Financial Information.

The Company intends to file the unaudited pro forma consolidated financial information of the Company as of and for the three months ended March 31, 2022, and for the year ended December 31, 2021 as required by Item 9.01(b) under cover of a Form 8-K/A no later than four business days after the closing of the Transaction.

Forward-looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. Any statements in this Current Report on Form 8-K about our future expectations, plans and prospects, including but not limited to statements about the Company's expectations with respect to the development of KPI-012 for PCED and additional indications; the clinical utility of KPI-012 for PCED, the Company's plans to cease the development of its preclinical pipeline programs; the conduct and timelines of clinical trials; plans for regulatory filings; the Company's potential to receive milestone payments from the Buyers pursuant to the Asset Purchase Agreement; the Company's workforce reduction and future charges expected to be incurred in connection therewith; the sufficiency of Company's existing cash resources and any other statements about future expectations, prospects, estimates and other matters that are dependent upon future events or developments, including 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 within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to realize the anticipated benefits of the Transaction; significant transaction costs, the risk of litigation and/or regulatory actions related to the Transaction; whether commercial sales-based milestones are achieved; the Company's ability to retain and hire key personnel; the uncertainties inherent in the initiation and conduct of clinical trials; 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 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; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; the sufficiency of the Company's cash resources and need for additional financing and such other important factors as are set forth under the caption "Risk Factors" in the Company's annual and quarterly reports and any other filings on file with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company's views as of the date of this Current Report on Form 8-K. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the views of the Company as of any date subsequent to the date of this Current Report on Form 8-K.

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: July 8, 2022

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