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 9, 2020**

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.)

490 Arsenal Way, Suite 120
Watertown, MA 02472
(Address of Principal Executive Offices) (Zip Code)

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

(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 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 9, 2020, Kala Pharmaceuticals, Inc. (the "Company") announced topline results from STRIDE 3, its Phase 3 clinical trial of EYSUVIS™, the Company's product candidate for the short-term treatment of dry eye disease. STRIDE 3 was a multicenter, randomized, double-masked, placebo-controlled, parallel-arm study, comparing EYSUVIS to vehicle (placebo), each dosed four times a day ("QID") for two weeks in 901 patients with dry eye disease. The intent-to-treat ("ITT") population consisted of 447 patients in the EYSUVIS treatment group and 454 patients receiving vehicle. Patients who met initial screening and inclusion/exclusion criteria then underwent a two-week run-in period with vehicle. Patients who continued to meet inclusion/exclusion criteria after the run-in were then randomized to receive either EYSUVIS or vehicle for two weeks. Ocular discomfort severity ("ODS") was graded daily by the patient over the entire course of the trial using a visual analog grading scale (measured on a scale ranging from 0 to 100 mm) recorded in a patient diary.

STRIDE 3 achieved both of its independent primary endpoints, demonstrating a statistically significant reduction in the symptom endpoint of ODS from baseline to day 15 compared to vehicle control in both the overall ITT population ($p=0.0002$) and in a pre-defined subgroup of ITT patients with more severe baseline ocular discomfort ($p=0.0007$), defined as patients who scored greater than or equal to 68 mm in baseline ocular discomfort. These data replicate the achievement of both primary symptom endpoints of STRIDE 1 ($p<0.0001$ in the overall ITT population and $p=0.0008$ in the pre-defined ITT subgroup with more severe ocular discomfort at baseline). Statistical significance was also achieved in the key secondary endpoint of conjunctival hyperemia at day 15 in the ITT population ($p<0.0001$). This result replicates the achievement of the results of STRIDE 1 and STRIDE 2, where statistical significance was demonstrated for conjunctival hyperemia at day 15 in the ITT population as a prespecified primary endpoint in each of those trials. Statistical significance was also achieved for the key secondary endpoint of ODS at day 8 in the ITT population ($p=0.0282$), which was consistent with STRIDE 1 ($p=0.0011$) and STRIDE 2 ($p=0.0408$). Significant improvement was also observed for corneal staining in the ITT population ($p=0.0042$), consistent with the result in STRIDE 2 ($p=0.0314$).

EYSUVIS was well-tolerated in this trial, consistent with prior clinical trials. The most common adverse event observed in STRIDE 3 was instillation site pain, which was reported by 2.9% in the EYSUVIS group compared to 1.5% in the vehicle group. Elevations in intraocular pressure ("IOP"), a known side effect with topical corticosteroid administration, were similar between the two groups, with no patients in either the EYSUVIS or vehicle group experiencing an increase in IOP of 5 mmHg or greater that resulted in an IOP of greater than 21 mmHg in the study eye.

If approved, the Company intends to commercialize EYSUVIS in the United States with its specialty sales force, which it plans to increase to a total of approximately 100 to 125 sales representatives, who will promote both EYSUVIS and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%.

Forward-Looking Statements

This Current Report on 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, including statements regarding INVELTYS and the Company's lead product candidate, EYSUVIS, for the temporary relief of the signs and symptoms of dry eye disease, the market potential for EYSUVIS and the Company's plans to expand its commercial sales force. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company's strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements as a result of various risks and uncertainties including, but not limited to: whether the Company will be able to successfully implement its commercialization plans for EYSUVIS, if approved; whether the market opportunity for INVELTYS and EYSUVIS is consistent with the Company's expectations and market research; whether any additional clinical trials will be initiated or required for EYSUVIS prior to approval of the NDA, or at all, and whether the NDA for EYSUVIS will be approved; the Company's ability execute on the commercial launch of EYSUVIS, if and when approved, on the timeline expected, or at all; whether the Company will be able to generate its projected net product revenue on the timeline expected, or at all; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements for the Company's expected timeline; other matters that could affect the availability or commercial potential of INVELTYS and the Company's product candidates, including EYSUVIS; 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 Current Report on 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KALA PHARMACEUTICALS, INC.

Date: March 9, 2020

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