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): **October 27, 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 2.02. Results of Operations and Financial Condition.

As described below, on October 27, 2020, Kala Pharmaceuticals, Inc. (the "Company"), issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") approved its New Drug Application ("NDA") for EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. Although the Company has not finalized its full financial results for the three and nine months ended September 30, 2020, the Company disclosed in the press release that it expects to report cash, cash equivalents and short-term investments of approximately $159.1 million as of September 30, 2020.

The estimated cash figure is preliminary and unaudited, represents management's estimate as of the date of this Form 8-K and is subject to completion of the Company's financial closing procedures. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the estimated cash figure.

The information in this Item 2.02 is furnished under 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

On October 27, 2020, the Company issued a press release announcing that the FDA approved its NDA for EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. The full text of the press release is furnished as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is furnished under Item 7.01 of Form 8-K, and shall not be deemed "filed" for purposes of Section 18 of 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On October 27, 2020, the Company announced that the FDA approved its NDA for EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

EYSUVIS™ Important Safety Information

EYSUVIS, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

The initial prescription and each renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining.

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, as well as defects in visual acuity and fields of vision. Corticosteroids should be used with caution in the presence of glaucoma. Renewal of the medication order should be made by a physician only after examination of the patient and evaluation of the IOP.

Use of corticosteroids may result in posterior subcapsular cataract formation.

Use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, corticosteroids may mask infection or enhance existing infection.

Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion must be considered in any persistent corneal ulceration where a corticosteroid has been used or is in use.

The most common adverse drug reaction following the use of EYSUVIS for two weeks was instillation site pain, which was reported in 5% of patients.

Please see full Prescribing Information at www.eysuvis.com

Cash Runway

The Company anticipates that its existing cash, cash equivalents and short-term investments, along with sales of INVELTYS, will enable it to fund its operations into at least the third quarter of 2022, with additional cash runway expected based on revenues from sales of EYSUVIS. 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.

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, including statements regarding the Company's goal of establishing EYSUVIS as the preferred, first-line prescription therapy for dry eye disease; expectations regarding potential EYSUVIS launch timing, expectations regarding the potential demand for EYSUVIS and the company's expectations regarding its use of cash, cash runway and projected revenues. All statements, other than statements of historical facts, contained in this press release, 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," "continue" "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would," 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: the impact of extraordinary external events, such as the current pandemic health event resulting from the novel coronavirus (COVID-19), and their collateral consequences, including disruption of the activities of our sales force and the market for EYSUVIS and INVELTYS; whether the Company will be able to successfully implement its commercialization plans for EYSUVIS and INVELTYS; whether the market opportunity for EYSUVIS and INVELTYS is consistent with the Company's expectations and market research; the Company's ability execute on the commercial launch of EYSUVIS 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 EYSUVIS, INVELTYS and the Company's product candidates; 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, most recently filed Quarterly Report on Form 10-Q 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1	Press Release of Kala Pharmaceuticals, Inc., dated October 27, 2020 (furnished herewith)
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: October 27, 2020

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

Exhibit 99.1

Kala Pharmaceuticals Announces FDA Approval of EYSUVIS™ for the Short-Term Treatment of the Signs and Symptoms of Dry Eye Disease

-- First Approved Prescription Therapy Specifically for Short-Term Treatment of Dry Eye Disease --
-- First Ocular Corticosteroid Indicated for Dry Eye Disease –
-- Kala to Host Conference Call Today at 8:30 a.m. ET --

WATERTOWN, Mass. – October 27, 2020 – Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye, today announced that the U.S. Food and Drug Administration (FDA) has approved EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

“The FDA approval of EYSUVIS as the first prescription therapy specifically developed to address the short-term treatment needs of people living with dry eye disease is a major accomplishment for Kala and an important moment for patients, who have been waiting for an FDA-approved, safe, effective and fast-acting therapy,” said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. “As we prepare to launch EYSUVIS, we will leverage our strong foundation of highly experienced ophthalmology marketing, sales and market access professionals with the goal of establishing EYSUVIS as the preferred, first-line prescription therapy for dry eye disease. We’d like to thank the many patients and investigators that were involved in the clinical trials that led to this important milestone.”

Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface, and can involve tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. Approximately 80 percent of people living with dry eye disease suffer from episodic flares. These flares can be caused by a wide variety of triggers and often cannot be adequately managed with current therapies.

EYSUVIS utilizes Kala’s AMPPLIFY® mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration of loteprednol etabonate (LE) into target tissue on the ocular surface. LE targets the immune responses that drive acute dry eye disease flares. Prior to EYSUVIS, there were no FDA-approved ocular corticosteroids for the treatment of dry eye disease. Kala Pharmaceuticals plans to launch EYSUVIS in the U.S. by year-end.

“The approval of EYSUVIS ushers in a new era in the treatment of dry eye disease and offers promise to the millions of dry eye patients who experience acute exacerbations, or flares, of their disease each year,” said Edward Holland, M.D., Director of Cornea Services at Cincinnati Eye Institute and Professor of Ophthalmology at the University of Cincinnati. “For the first time we will be able to offer dry eye patients a therapeutic option that provides rapid relief for both the signs and symptoms of the disease and that is safe and well tolerated.”

“Dry eye disease can significantly decrease quality-of-life among affected patients and drive decreased workplace productivity, contact lens intolerance and discontinuation, and poor cataract and refractory surgery outcomes,” said Kelly Nichols, O.D., M.P.H., Ph.D., F.A.A.O., Dean of the University of Alabama at Birmingham School of Optometry. “As the prevalence of dry eye disease increases, there is a tremendous need for new therapies to manage mild-to-moderate dry eye disease patients, many of whom currently go untreated. I am excited by the approval of EYSUVIS and confident that having access to an approved corticosteroid specifically for dry eye disease will meaningfully impact the management of patients across the U.S.”

The FDA granted approval to EYSUVIS based on results from four clinical trials, including three Phase 3 trials and one Phase 2 trial, that demonstrated significant improvements in both the signs and symptoms of dry eye disease. Specifically, statistical significance was achieved after two weeks of dosing for the sign endpoint of conjunctival hyperemia in all three Phase 3 trials. Statistical significance was observed in two of the three Phase 3 trials for the symptom endpoints of ocular discomfort severity in both the overall intent-to-treat (ITT) population and in a predefined subgroup of ITT patients with more severe ocular discomfort at baseline. EYSUVIS was well-tolerated across the four trials, with adverse events and intraocular pressure increases comparable to that observed with vehicle.

As of September 30, 2020, Kala had cash, cash equivalents and short-term investments of $159.1 million. Kala anticipates that its existing cash, cash equivalents and short-term investments, along with sales of INVELTYS®, will enable it to fund its operations into at least the third quarter of 2022, with additional cash runway expected based on revenues from sales of EYSUVIS.

EYSUVIS™ Important Safety Information

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The most common adverse drug reaction following the use of EYSUVIS for two weeks was instillation site pain, which was reported in 5% of patients.

Please see full Prescribing Information at www.eysuvis.com

Conference Call Information

Kala will hold a conference call today at 8:30 a.m. ET to discuss the approval of EYSUVIS. To access the conference call, please dial (866) 300-4091 (domestic callers) or (703) 736-7433 (international callers) five minutes prior to the start of the call and provide the conference ID: 2835104. Additionally, a live webcast and subsequent archived recording of the presentation will be available under “Events” in the “Investors” section of the Kala website at http://kalarx.com.

About EYSUVIS

EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% is approved for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. EYSUVIS utilizes Kala's AMPPLIFY mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration of loteprednol etabonate (LE) into target tissue of the ocular surface. EYSUVIS was approved by the FDA on October 26, 2020. Kala believes that EYSUVIS' broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability and safety profile and the potential to be complementary to existing therapies, offer a differentiated product profile for the management of dry eye flares. A link to the full product label can be found at: www.eysuvis.com.

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the discovery, development, and commercialization of innovative therapies for diseases of the eye. Kala has applied its AMPPLIFY® mucus penetrating particle Drug Delivery Technology to a corticosteroid, loteprednol etabonate (LE), designed for ocular applications, resulting in the January 2019 launch of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% and the October 2020 approval of EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term (up to two weeks) treatment of signs and symptoms of dry eye disease.

Forward Looking Statements

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Investors
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