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): **August 23, 2018**

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.)

100 Beaver Street, Suite 201
Waltham, MA 02453
(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 x

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. x

Item 7.01. Regulation FD Disclosure.

On August 23, 2018, Kala Pharmaceuticals, Inc. (the "Company"), issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has approved its New Drug Application ("NDA") for INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery. 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.

On August 23, 2018, the Company made available a presentation entitled "Innovation In Ophthalmology — INVELTYS™ Approval — August 2018" through the "Investors & Media" section of the Company's website (http://www.kalarx.com) under the "Events and Presentations" tab. The presentation will be available for future review for two weeks after August 23, 2018. The information contained in, or that can be accessed through, the Company's website is not a part of this filing.

The information in this Current Report on Form 8-K, 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 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, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On August 23, 2018, the Company announced that the FDA has approved its NDA for INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery. INVELTYS is the first twice-daily ocular corticosteroid approved for this indication.

INVELTYS™ Important Safety Information

INVELTYS, 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.

A prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.

Use of corticosteroids may result in posterior subcapsular cataract formation.

Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and 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 suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids 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 steroids 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 steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.

In clinical trials, the most common adverse drug reactions were eye pain (1%) and posterior capsular opacification (1%). These reactions may have been the consequence of the surgical procedure.

Please see the full prescribing information available at: www.inveltys.com

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release of Kala Pharmaceuticals, Inc., dated August 23, 2018 (furnished herewith)

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: August 23, 2018

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 INVELTYS™ for the Treatment of Post-Operative Inflammation and Pain Following Ocular Surgery

— First Twice-Daily Ocular Corticosteroid Indicated for the Treatment of Post-Operative Inflammation and Pain Following Ocular Surgery —

— Kala to Host Conference Call Today at 5:00pm (ET) —

WALTHAM, Mass.—(BUSINESS WIRE)—August 23, 2018— Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary mucus-penetrating particle (MPP) technology, today announced that the U.S. Food and Drug Administration (FDA) has approved INVELTYS™ (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery. INVELTYS is the first twice-daily (BID) ocular corticosteroid approved for this indication.

“The FDA approval of INVELTYS is a tremendous milestone for Kala,” said Kim Brazzell, Ph.D., Chief Medical Officer of Kala Pharmaceuticals. “Approximately 8 million patients undergo ocular surgeries each year. The approval of INVELTYS offers patients and their eye care professionals the first and only BID ocular corticosteroid therapy that has been shown in clinical trials to be clinically effective while maintaining a proven safety profile, which may improve compliance and prove less burdensome for patients. We believe INVELTYS will be an important addition to eye care professionals’ treatment armamentarium.”

All other ocular steroids are only approved for four-times-a-day dosing. This more frequent dosing requirement can lead to issues for both doctors and patients. Corticosteroids are the foundation of therapy for post-ocular surgery care, with the key goal of controlling inflammation and pain which is caused by surgical trauma to the eye. The use of ocular steroids post-surgery is to achieve a rapid reduction of inflammation and to promote healing of the eye. Therefore, ensuring close adherence to the steroid regimen is a critical factor for physicians in the post-surgery care of the patient and eventual overall success of the procedure.

“Today’s approval of INVELTYS is welcome news for the eye care community as it provides a clear advancement in the treatment for inflammation and pain following ocular surgery. Having access to a BID corticosteroid in a novel nanoparticle formulation with proven safety and efficacy will make a positive impact on the management of my post-operative patients,” said Terry Kim, M.D., Professor of Ophthalmology and Chief, Cornea and External Disease Division, Duke University Eye Center.

“On behalf of the Kala team, I want to thank the many patients and clinicians who participated in our clinical trials. With this approval, our ongoing commercialization preparations now advance to the next phase where we plan to hire a specialty sales force that will focus on eye care professionals in the United States. We expect to launch INVELTYS in the beginning of 2019,” said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals.

Kala also continues to advance KPI-121 0.25% for dry eye disease. Kala has initiated a third Phase 3 clinical trial, STRIDE 3 (STRIDE - Short Term Relief In Dry Eye), evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. Kala believes that the changes made to the design of STRIDE 3 will improve its probability of success. The Company expects to report top-line results for STRIDE 3 in the fourth quarter of 2019. Kala also plans to submit a New Drug Application (NDA) for KPI-121 0.25% during the second half of 2018. The NDA will include data from three clinical trials studying approximately 2,000 patients, including one Phase 2 trial and two Phase 3 efficacy and safety trials (STRIDE 1 and STRIDE 2).

INVELTYS™ Important Safety Information

INVELTYS, 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.

A prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.

Use of corticosteroids may result in posterior subcapsular cataract formation.

Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and 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 suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids 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 steroids 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 steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.

In clinical trials, the most common adverse drug reactions were eye pain (1%) and posterior capsular opacification (1%). These reactions may have been the consequence of the surgical procedure.

Please see the full prescribing information available at: www.inveltys.com

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Conference Call Information

Kala will hold a conference call today at 5:00pm (ET) to discuss the approval of INVELTYS. The dial-in numbers are (866) 300-4091 for domestic callers and (703) 736-7433 for international callers. The conference ID is 4072478. For an archived recording of the call and question and answer session, please visit the "Investors & Media" section on the Kala website at http://kalarx.com/

About Post-Operative Inflammation and Pain

Ocular inflammation and pain are common complications following ocular surgery. According to Marketscope, in 2017 there were approximately 8 million ocular surgeries in the U.S., which is projected to grow to up to approximately 10 million in 2022. More than half of the ocular surgeries performed in the U.S. are cataract surgeries. Tissue damage caused by ocular surgery leads to the production of prostaglandins, lipids that aid in recovery at the site of an injury, and an increase in blood flow to the affected area, both of which contribute to inflammation. The standard of care for post-operative inflammation and pain includes anti-inflammatory drugs such as corticosteroids, which improve patient comfort and accelerate recovery through disruption of the inflammatory cascade. The current four-times-a-day dosing regimen for corticosteroid treatment can be burdensome for patients as they are taking multiple eye drop products following surgery and is believed to reduce patient compliance. There are no other twice-daily ocular corticosteroid products currently approved in the U.S. for the treatment of post-operative inflammation and pain.

About INVELTYS™

INVELTYS (loteprednol etabonate ophthalmic suspension) 1% is a twice-a-day corticosteroid for the treatment of inflammation and pain following ocular surgery. INVELTYS utilizes Kala's proprietary Mucus-Penetrating Particle (MPP) technology to enhance penetration into target tissues of the eye. In preclinical studies, MPP technology increased delivery of LE into ocular tissues compared to current LE products. INVELTYS successfully completed two Phase 3 clinical trials and achieved statistical significance for both primary efficacy endpoints in both trials. In each of these trials, INVELTYS was well tolerated with no treatment-related serious adverse events observed. INVELTYS was approved by the FDA on August 22, 2018. Kala believes INVELTYS has a favorable profile for the treatment of inflammation and pain following ocular surgery, due to its twice-a-day dosing regimen. A link to the full product label can be found at: www.inveltys.com

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About KPI-121 0.25%

Kala is developing KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease utilizing a two-week course of therapy administered four times a day. 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. KPI-121 0.25% utilizes Kala's MPP technology to enhance penetration of LE into target tissue of the eye. Kala has completed one Phase 2 and two Phase 3 clinical trials of KPI-121 0.25%. Kala has initiated a third Phase 3 trial, STRIDE 3, for which topline results are expected in the fourth quarter of 2019. Kala believes that, if approved, KPI-121 0.25%'s broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability and safety profile and the potential to complement existing therapies, could result in a favorable profile for the management of dry eye flares and other dry eye associated conditions.

About Kala Pharmaceuticals

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary Mucus Penetrating Particle (MPP) technology, with an initial focus on the treatment of eye diseases. Kala has applied the MPP technology to a corticosteroid, LE, designed for ocular applications, resulting in the recent approval of INVELTYS for the treatment of inflammation and pain following ocular surgery. Kala plans to submit a New Drug Application for KPI-121 0.25%, for the temporary relief of the signs and symptoms of dry eye disease in the second half of 2018.

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, including statements regarding INVELTYS for the treatment of inflammation and pain following ocular surgery and the Company's lead product candidate KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, INVELTYS being an important addition to eye care professionals' treatment armamentarium, the Company's expectation to hire a specialty sales force that will cover the majority of Eye Care professionals and plans to launch INVELTYS in the beginning of 2019, ocular surgeries in the U.S. growing to up to 9.4 million in 2021, the anticipated reporting of STRIDE 3 topline results in the fourth quarter of 2019, and the Company's plans to file an NDA for KPI-121 0.25% with the FDA during the second half of 2018. 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," "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

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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 INVELTYS; whether the market opportunity for INVELTYS is consistent with the Company's expectations and market research; data from the Company's Phase 3 clinical trials of KPI-121 0.25% will warrant submission and filing of an NDA on the timeline expected, or at all; whether any additional clinical trials will be initiated or required for KPI-121 0.25% prior to submission or filing of an NDA, or at all, and whether any such NDA will be accepted for filing and/or approved; the Company's ability to initiate and complete clinical trials on the timeline expected, or at all; whether the results of clinical trials will be positive and/or replicate the results from earlier clinical development and/or preclinical studies; that post-hoc analyses are normally given less weight by regulatory authorities than pre-specified analyses; uncertainties inherent in the availability and timing of data from ongoing clinical trials; uncertainties related to the Company's ability to obtain regulatory approvals to conduct trials or to market products; the Company's ability to build a specialty sales force and prepare for commercial launch of INVELTYS 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; 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 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 release 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.

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