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): **January 5, 2018**

Kala Pharmaceuticals, Inc.
(Exact Name of Company as Specified in 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 2.02. Results of Operations and Financial Condition

On January 5, 2018, Kala Pharmaceuticals, Inc. (the "Company"), announced information about the Company's cash balance as of December 31, 2017, in the press release attached hereto as Exhibit 99.1 and more fully described in Item 7.01, below. As of December 31, 2017, the Company's preliminary, unaudited cash balance was approximately $114 million.

The information in this Item 2.02, including Exhibit 99.1, 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 7.01. Regulation FD Disclosure.

On January 5, 2018, the Company announced topline results from two Phase 3 clinical trials of KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. The press release announcing the topline results of these trials is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The Company will host a conference call to discuss the topline results of these trials on Friday, January 5, 2018 at 8:00 a.m. Eastern Time, and a live webcast of the call will be available through the investor relations section of the Company's website.

On January 5, 2018, the Company also announced its New Drug Application for INVELTYS™ has been accepted for review by the U.S. Food and Drug Administration with a target action date under the Prescription Drug User Fee Act of August 24, 2018. The press release announcing this acceptance is attached hereto as Exhibit 99.2 and incorporated herein by reference.

The information in this Item 7.01, including Exhibits 99.1 and 99.2, 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 Pharmaceuticals, Inc., dated January 5, 2018

99.2 Press Release of Kala Pharmaceuticals, Inc., dated January 5, 2018

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: January 5, 2018

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

Kala Pharmaceuticals Announces Topline Results for Two Phase 3 Trials (STRIDE 1 and STRIDE 2) of KPI-121 0.25% in Dry Eye Disease

- *Statistical significance achieved for the primary sign endpoint, conjunctival hyperemia at Day 15 in the ITT population, in STRIDE 1 (p<0.0001)*
- *Statistical significance achieved for the primary sign endpoint, conjunctival hyperemia at Day 15 in the ITT population, in STRIDE 2 (p<0.0001)*
- *Statistical significance achieved for the primary symptom endpoint, ocular discomfort severity at Day 15 in the ITT population, in STRIDE 1 (p<0.0001)*
- *Ocular discomfort severity at Day 15 in the ITT population showed improvement but did not reach statistical significance in STRIDE 2 (p=0.1298)*
- *Statistical significance for ocular discomfort severity at Day 15 in patients with more severe baseline discomfort was achieved in STRIDE 1 (p=0.0008), with a trend towards a treatment effect (p=0.0799) in STRIDE 2*
- *Positive treatment effects observed for ocular discomfort severity in the ITT population at Day 8, a key secondary endpoint in both STRIDE 1 (p=0.0011) and STRIDE 2 (p=0.0408)*
- *KPI-121 0.25% was well-tolerated with elevations in IOP similar to placebo*
- *Conference call today at 8:00 AM Eastern Time*

WALTHAM, Mass., January 5, 2018 — Kala Pharmaceuticals, Inc. (NASDAQ:KALA), today announced topline results from its two Phase 3 clinical trials, STRIDE 1 and STRIDE 2 (STRIDE - **S**hort **T**erm **R**elief **I**n **D**ry **E**ye), evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease.

In the STRIDE 1 trial, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia change from baseline to day 15 in the ITT population (p<0.0001) and the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the ITT population (p<0.0001). Statistical significance was also achieved for a second pre-specified primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in patients with more severe baseline ocular discomfort (p=0.0008). Statistical significance was not achieved for a second pre-specified primary sign endpoint, inferior corneal staining change from baseline to day 15 (p=0.1128). A positive treatment effect for ocular discomfort was also observed in the ITT population at day 8 (p=0.0011).

KPI-121 was well tolerated in this trial with the most common adverse event in STRIDE 1 being instillation site pain, which was observed in 6.1% of patients in both the KPI-121 treatment group and the placebo group. The only other adverse event reported by greater than 1% of patients was eye irritation, which was reported in 1.1% of patients on KPI-121 vs. 1.5% of patients on placebo. Elevations in IOP, a known side effect with topical corticosteroid

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administration, were similar between the two groups with 0.4% in the KPI-121 group experiencing an increase in IOP of 5 mm of mercury (mmHg) or greater resulting in an IOP of 21 mmHg or greater compared to 0.4% in the placebo group.

In the STRIDE 2 trial, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia change from baseline to day 15 in the ITT population (p<0.0001). Statistical significance was not achieved for the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the ITT population (p=0.1298), although a positive treatment effect was observed at day 8 (p=0.0408), a key secondary endpoint. A trend towards a positive treatment effect was observed for ocular discomfort severity change from baseline to day 15 in the patients with more severe baseline ocular discomfort (p=0.0799), which was a key secondary endpoint in this trial. KPI-121 was well tolerated in this trial with instillation pain being the most common adverse event In STRIDE 2 as reported by 5.7% of patients in the KPI-121 treatment group vs. 4.4% in the placebo group. The only other adverse event reported by greater than 1% of patients was blurred vision, which was reported in 0.2% of patients on KPI-121 vs. 1.3% of patients on placebo. Elevations in IOP were similar between the two groups with 1.1% in the KPI-121 group experiencing an increase in IOP of 5 mmHg or greater resulting in an IOP of 21 mmHg or greater compared to none in the placebo group.

“We are pleased with the positive topline results of STRIDE 1, in which KPI-121 demonstrated statistically significant improvements in primary sign and symptom endpoints and are encouraged with the results in STRIDE 2, which showed statistical significance for the primary sign endpoint. Although we did not achieve statistical significance for the primary symptom endpoint in STRIDE 2, we did observe a strong trend towards a positive treatment effect in symptoms in more symptomatic patients, for which we achieved statistical significance in STRIDE 1,” said Mark Iwicki, Chief Executive Officer of Kala Pharmaceuticals. “We will continue to analyze the results of both Phase 3 trials and the totality of the data from all 3 trials conducted to date and expect to discuss our clinical program with the FDA. We believe that our preliminary, unaudited December 31, 2017 cash balance of approximately $114 million puts us in a strong position as we maintain our focus on moving this program forward to serve patients with dry eye disease.”

The two Phase 3 clinical trials were each multicenter, randomized, double-masked, placebo controlled, parallel-arm studies comparing KPI-121 to placebo each dosed four times a day (QID) for 14 days. Subjects who met initial screening and inclusion/exclusion criteria underwent a 2-week run-in period with placebo dosed in each eye QID for 14 days. Subjects who continued to meet inclusion and exclusion criteria after the run-in were randomized to either KPI-121 or placebo. A total of 918 patients were randomized in STRIDE 1 and 909 patients were randomized in STRIDE 2. Ocular discomfort severity was graded daily by the patient over the entire course of the trial using a visual analog grading scale recorded in a patient diary.

Conference Call

Kala will hold a conference call on Friday, January 5, 2018 at 8:00 AM ET to discuss results of the two Phase 3 pivotal trials of KPI-121 0.25% in dry eye disease. The dial-in numbers are 1-866-300-4091 for domestic callers and 1-703-736-7433 for international callers. The conference ID is 5364789. 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/.

Presentation at the 36th Annual J.P. Morgan Healthcare Conference

Mark Iwicki, Chairman and Chief Executive Officer of Kala, will provide a corporate update on Monday, January 8, 2018 at 11:30 AM PT, followed by a question and answer session at 12:00 PM PT at the 36th Annual J.P. Morgan Healthcare Conference held at the Westin St. Francis Hotel in San Francisco, CA. For a live webcast and subsequent archived recording of the presentation and question and answer session, please visit the "Investors & Media" section on the Kala website at http://kalarx.com/.

About Dry Eye Disease

Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface that can result in tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. Dry eye disease is estimated to affect approximately 33 million people in the United States, based on an estimated prevalence of 14.5% as described in The Beaver Dam Offspring Study, a major epidemiological study published in 2014 in the American Journal of Ophthalmology. Dry eye disease can have a significant impact on quality of life and can potentially cause long-term damage to the ocular surface. In addition, the vast majority of dry eye patients experience acute exacerbations of their symptoms, which are commonly referred to as flares, at various times throughout the year. These flares can be triggered by numerous factors which cause ocular surface inflammation and impact tear production and/or tear film stability.

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 that 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 loteprednol etabonate (LE) into target tissue of the eye. In preclinical studies, MPP technology increased delivery of LE into ocular tissues more than three-fold compared to current LE products by facilitating penetration through the tear film mucus. Kala believes that KPI-121 0.25%'s broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability and safety profile and potential to be complementary to existing therapies, could result in a favorable profile for the management of dry eye flares and other dry eye associated conditions that would benefit from temporary relief of dry eye signs and symptoms.

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary mucus-penetrating particle (MPP) technology, with an initial

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focus on the treatment of eye diseases. Kala has applied the MPP technology to a corticosteroid designed for ocular applications, resulting in two lead product candidates. The product candidates are INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery, for which we have submitted a NDA, and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease.

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 the development and regulatory status of the company's product candidates, including INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. 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 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 data from our Phase 3 clinical trials of KPI-121 0.25% will warrant submission of an NDA on the timeline expected, or at all, whether any additional clinical trials will be required prior to submission of an NDA and whether any such NDA will be approved; that topline data is based on preliminary analysis of key efficacy and safety data, and such data could change following a more comprehensive review and may not accurately reflect the complete results of our clinical trials; whether our NDA for INVELTYS will be approved by its PDUFA date or at all; uncertainties inherent in the availability and timing of data from ongoing clinical trials; expectations for regulatory approvals to conduct trials or to market products; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; the risk that our audited financial results for the year ended December 31, 2017, including cash on hand, may differ materially from our estimated results for these periods as a result of the completion of year-end closing procedures, other matters that could affect the availability or commercial potential of 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.

Investor and Media Contact:
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Kala Pharmaceuticals Announces New Drug Application for INVELTYS™ (KPI-121 1%) Has Been Accepted for Review by the U.S. Food and Drug Administration

- INVELTYS expected to be the first twice-daily ocular steroid indicated for the treatment of inflammation and pain following ocular surgery, if approved -

- PDUFA target action date of August 24, 2018 -

WALTHAM, Mass., January 05, 2018 — Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a biopharmaceutical company focused on the development and commercialization of product candidates using its proprietary mucus-penetrating particle (MPP) technology, today announced that the New Drug Application (NDA) for INVELTYS™ (KPI-121 1%), a topical twice-a-day product candidate for the treatment of inflammation and pain in patients who have undergone ocular surgery, has been accepted for review by the United States Food and Drug Administration (FDA). The FDA, in its 74-day letter, indicates that the application is sufficiently complete to permit a substantive review and has set a target action date under the Prescription Drug User Fee Act (PDUFA) of August 24, 2018. If approved, INVELTYS is expected to be the first twice-daily ocular corticosteroid indicated for the treatment of post-operative ocular inflammation and pain. The brand name for KPI-121 1%, INVELTYS, has been conditionally approved by the FDA.

“All currently marketed steroids for the treatment of post-surgical inflammation and pain are approved with four-times-a-day dosing,” said Dr. Terry Kim, Professor of Ophthalmology and Chief of the Cornea and External Disease Service in the Department of Ophthalmology at Duke University Eye Center. “This regimen can be significantly burdensome for patients. Based on its efficacy and safety results, as well as its unique twice-daily dosing, I believe that if approved, INVELTYS will be an important new treatment option for patients and physicians alike.”

INVELTYS utilizes Kala’s proprietary Mucus Penetrating Particle (MPP) technology. MPPs are selectively-sized nanoparticles with proprietary coatings that Kala believes significantly enhance drug penetration and distribution in ocular tissues. In pre-clinical studies, MPPs increased delivery into ocular tissues more than three-fold by facilitating penetration through the tear film mucus.

The NDA submission for INVELTYS was supported by positive data from two Phase 3 clinical trials, in each of which INVELTYS administered twice-a-day to patients following cataract surgery achieved statistical significance for both primary efficacy endpoints of complete resolution of inflammation at day 8 maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day 8 maintained through day 15 with no need for rescue medications compared to placebo. INVELTYS was found to be well tolerated with no treatment-related serious adverse events observed during the course of either trial.

“The FDA’s acceptance of the NDA filing for INVELTYS is another significant milestone for the company towards our mission of developing innovative treatments for ocular conditions using our MPP technology,” said Kim Brazzell, Ph.D., Chief Medical Officer of Kala Pharmaceuticals.

About Post-Operative Inflammation and Pain
Ocular inflammation and pain are common complications following ocular surgery. According to Marketscope, in 2016 there were 7.7 million ocular surgeries in the U.S., which is projected to grow to up to 9.4 million in 2021. 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 twice-daily ocular corticosteroid products currently approved in the U.S. for the treatment of post-operative inflammation and pain.

About INVELTYS™ (KPI-121 1%)
INVELTYS™ (KPI-121 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 pre-clinical studies, MPP increased delivery into ocular tissues more than three-fold by facilitating penetration through the tear film mucus. INVELTYS has 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. Kala believes INVELTYS has a favorable profile compared to the standard of care for the treatment of inflammation and pain following ocular surgery, due to its twice-a-day dosing regimen and rapid onset of relief. A New Drug Application (NDA) for INVELTYS was accepted for review by the U.S. Food and Drug Administration (FDA) with a target action date of August 24, 2018.

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 designed for ocular applications, resulting in two lead product candidates. The product candidates are INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery, for which we have submitted an NDA, and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease.

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 the development and regulatory status of the company’s product candidates, including INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. All statements, other than statements of historical facts, contained in this press release, including statements regarding our 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. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our 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 our NDA for INVELTYS will be approved by its PDUFA date or at all; uncertainties inherent in the availability and timing of data from ongoing clinical trials; expectations for regulatory approvals to conduct trials or to market products; whether the Company’s cash resources will be sufficient to fund the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of 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 our Quarterly Reports on Form 10-Q and other filings we make with the Securities and Exchange Commission. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this release. We do 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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