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): **November 7, 2017**

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):

☐ 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))

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.

On November 7, 2017, Kala Pharmaceuticals Inc. (the "Company") announced its financial results for the quarter ended September 30, 2017. 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.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with 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, 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 November 7, 2017

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: November 7, 2017

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

Kala Pharmaceuticals Reports Third Quarter 2017 Financial Results And Provides Business Update

Completed Initial Public Offering Raising $103.5 million in gross proceeds

Submitted New Drug Application to U.S. Food and Drug Administration for INVELTYS™ (KPI-121 1%)

WALTHAM, Mass., November 07, 2017 – 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 reported financial results for the third quarter and nine months ended September 30, 2017 and provided an update on business progress.

"During the third quarter of 2017, Kala strengthened its financial position by closing a successful initial public offering resulting in gross proceeds of $103.5 million, which we estimate will allow us to complete clinical development, and prepare for the commercialization of INVELTYS™ (KPI-121 1%) and KPI-121 0.25%," said Mark Iwicki, Chairman and Chief Executive Officer of Kala Pharmaceuticals. "Based on the positive results of two Phase 3 clinical trials of INVELTYS for the treatment of inflammation and pain in patients who have undergone cataract surgery, we submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in October. We expect to receive topline results from the Phase 3 clinical program for KPI-121 0.25% in patients with dry eye disease by the end of 2017."

Q3 and Recent Corporate Highlights

- **Completed initial public offering** in July of 6,900,000 shares of common stock, including the underwriters' exercise in full of their option to purchase an additional 900,000 shares, at the public offering price of $15.00 per share. The exercise of the underwriters' option brought the amount of gross proceeds raised in the offering to approximately $103.5 million, or $94.1 million in net proceeds after underwriting discounts, commissions and expenses of the offering.
- **Submitted New Drug Application (NDA) for INVELTYS** in October for the treatment of inflammation and pain in patients who have undergone ocular surgery. The NDA submission is supported by positive data from two Phase 3 trials. If approved, Kala expects INVELTYS would be the first twice-daily ocular corticosteroid indicated for the treatment of post-operative ocular inflammation and pain.
- **Strengthened Board of Directors** in October with the appointment of Mr. Andrew I. Koven, who has served as President and Chief Business Officer at Aralez Pharmaceuticals Inc., since 2016 and held the same position in 2015 at POZEN Inc., where he was instrumental in negotiating a merger with Tribute Pharmaceuticals Canada Inc. to create Aralez Pharmaceuticals. Prior to joining POZEN, Mr. Koven was Chief Administrative Officer, General Counsel and Corporate Secretary at Auxilium Pharmaceuticals Inc.

Upcoming Milestones

- Top-line results from the Phase 3 clinical program for KPI-121 0.25% in patients with dry eye disease are expected by the end of 2017. KPI-121 0.25% is our product candidate for the temporary relief of the signs and symptoms of dry eye disease utilizing a two-week course of therapy. Assuming positive results from these trials, the Company anticipates submitting an NDA in the first half of 2018. If approved, KPI-121 0.25% could be the first FDA-approved product for the short-term treatment of dry eye disease.

Third Quarter 2017 Financial Results

- **Cash Position:** As of September 30, 2017, Kala had cash of $122.0 million compared to $45.5 million as of December 31, 2016. Cash as of December 31, 2016 did not include net proceeds of approximately $94.1 million from the Company's initial public offering in July 2017 or the proceeds from the draw of the Company's debt facility of $10.0 million in September 2017. Kala expects that its existing cash on hand will enable it to fund operations through the second quarter of 2019.
- **R&D Expenses:** For the quarter ended September 30, 2017, research and development expenses were $7.0 million compared to $8.3 million for the same period in 2016. The decrease in research and development expenses is primarily due to a decrease in costs associated with our two Phase 3 clinical trials of KPI-121 0.25% for the treatment of dry eye disease and the completion of our Phase 3 clinical trial of INVELTYS for the treatment of inflammation and pain following ocular surgery in the first half of 2017.
- **G&A Expenses:** General and administrative expenses for the quarter ended September 30, 2017 were $2.5 million compared to $1.5 million for the same period in 2016. The increase in G&A expenses is primarily attributable to an increase in personnel costs and professional fees associated with operating as a public company.
- **Operating Loss:** Loss from operations for the quarter ended September 30, 2017 was $9.5 million compared to $9.7 million for the same period in 2016.
- **Net Loss:** Net loss was $10.2 million, or $0.56 per share, for the three months ended September 30, 2017, compared to a net loss of $9.7 million or $8.18 per share, for the same period in 2016

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 technology increased delivery of a corticosteroid 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. Kala believes INVELTYS has a favorable treatment 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. In each of these trials, INVELTYS was well tolerated with no treatment-related serious adverse events observed.

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 result in tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. KPI-121 0.25% utilizes Kala's MPP technology to enhance penetration into target tissue of the eye. In preclinical studies, MPP technology increased delivery of a corticosteroid into ocular tissues more than three-fold 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 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. Following the achievement of successful results in a Phase 2 trial, Kala is currently evaluating KPI-121 0.25% in two Phase 3 clinical trials in patients with dry eye disease. If approved, KPI-121 0.25% could be the first FDA-approved product for the short-term treatment of dry eye disease.

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 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, currently in Phase 3 clinical development.

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. 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 our submitted NDA for INVELTYS will be accepted for filing and approved; uncertainties inherent in the availability and timing of data from ongoing clinical trials; 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, and whether any such NDA would will be approved; 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 our actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" sectionof 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.

Kala Pharmaceuticals, Inc.
Condensed Balance Sheet Data
(Unaudited)
(In thousands)

	2017	2016
	September 30,	December 31,
Cash	$ 122,049	$ 45,472
Working Capital [1]	111,751	40,080
Total Assets	123,691	46,329
Convertible Preferred Stock	-	118,391
Total Stockholders' Equity/(Deficit)	98,863	(87,762)

(1) The Company defines working capital as current assets less current liabilities. See the Company's condensed financial statements for further details regarding its current assets and current liabilities.

Kala Pharmaceuticals, Inc.
Condensed Statement of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 7,018	$ 8,256	$ 23,128	$ 18,117
General and administrative	2,516	1,491	5,607	6,356
Total operating expenses	9,534	9,747	28,735	24,473
Loss from operations	(9,534)	(9,747)	(28,735)	(24,473)
Other income (expense):				
Interest income	194	60	276	90
Interest expense	(212)	(186)	(618)	(566)
Change in fair value of warrant liability	(623)	206	(1,844)	177
Total other income (expense)	(641)	80	(2,186)	(299)
Net loss attributable to common stockholders—basic and diluted	$ (10,175)	$ (9,667)	$ (30,921)	$ (24,772)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.56)	$ (8.18)	$ (4.51)	$ (20.97)
Weighted average shares outstanding—basic and diluted	18,034,278	1,181,429	6,860,777	1,181,429

Investor and Media Contact:
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