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): **May 9, 2019**

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**

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. ☒

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

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Kala Pharmaceuticals Inc. (the "Company") announced its financial results for the quarter ended March 31, 2019 and provided a general business update. 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 May 9, 2019

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: May 9, 2019

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

Exhibit 99.1

Kala Pharmaceuticals Reports First Quarter 2019 Financial Results

–Conference Call and Webcast Today at 8:00 a.m. ET–

WATERTOWN, Mass, May 9, 2019 — Kala Pharmaceuticals, Inc. (Kala) (NASDAQ:KALA), a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary AMPPLIFY™ mucus-penetrating particle (MPP) Drug Delivery Technology, today reported financial results for the first quarter ended March 31, 2019.

"We are pleased with our results during the first quarter of 2019, particularly as it relates to the launch of INVELTYS," said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. "We have received feedback from physicians that INVELTYS has been a meaningful addition to their treatment protocols for inflammation and pain following ocular surgery. Our team has made significant progress in securing market access for INVELTYS, and initial prescription uptake has been strong. We also continue to advance KPI-121 0.25% for dry eye disease, with an August 15 Prescription Drug User Fee Act (PDUFA) target action date and topline data from STRIDE 3 expected in the fourth quarter of 2019."

First Quarter and Recent Highlights:

INVELTYS® Launch: INVELTYS was launched in January 2019 as the first and only twice-daily ocular corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery. The unique combination of safety, efficacy and twice-daily dosing of INVELTYS was developed to address a significant unmet need in this setting, and Kala believes these attributes are being viewed favorably by physicians. Since the launch of INVELTYS:

- Nearly 20,000 INVELTYS prescriptions have been filled as of April 26, 2019.

- INVELTYS has achieved approximately 5% branded new prescription market share and is now the third-most prescribed branded ocular steroid
- INVELTYS has achieved unrestricted market access in approximately 41% of all lives covered by commercial payers, for a total of approximately 70 million commercial lives.
- Medicare Part D contract negotiations are ongoing with most coverage decisions anticipated in early 2020.

KPI-121 0.25% Dry Eye Program: The U.S. Food and Drug Administration (FDA) has set a PDUFA target action date of August 15, 2019 for KPI-121 0.25%, which if approved could be the first FDA-approved product for the temporary relief of the signs and symptoms of dry eye disease. Kala's New Drug Application (NDA) filing includes data from one Phase 2 and two Phase 3 efficacy and safety trials studying over 2,000 patients with dry eye disease. Based upon the FDA's recommendation, Kala is conducting an additional Phase 3 clinical trial of KPI-121 0.25%, STRIDE 3 (STRIDE - Short Term Relief In Dry Eye). Kala believes that it has identified key factors that contributed to the differences observed in the results from STRIDE 2 compared to those of STRIDE 1 and the Phase 2 trials, and that changes made to the inclusion/exclusion criteria of STRIDE 3 based on these analyses will improve the probability of success of STRIDE 3. Enrollment continues to progress as planned, and the Company expects to receive top-line results for STRIDE 3 in the fourth quarter of 2019.

First Quarter 2019 Financial Results

The financial results below contain both GAAP and non-GAAP financial measures. The non-GAAP financial measures exclude stock compensation, depreciation and non-cash interest expense. See "Non-GAAP Financial Measures" below; for a full reconciliation of our GAAP to non-GAAP financial measures please refer to the tables at the end of this release.

- **Cash Position:** As of March 31, 2019, Kala had cash of $138.9 million compared to $170.9 million as of December 31, 2018. Kala anticipates that its existing cash on hand will enable it to fund operations through at least mid-2020, with additional cash runway expected when including INVELTYS revenue.

- **Net Product Revenue:** For the first quarter of 2019, Kala reported net product revenue of $1.4 million relating to sales of INVELTYS, which was

launched in January 2019. Kala recognizes revenue when products are delivered to distributors. Kala did not generate any revenue from product sales prior to the first quarter of 2019.

- **Cost of Product Revenues:** Cost of product revenues for the first quarter of 2019 were $0.2 million compared to $0 for the same period in 2018. Cost of product revenues for the first quarter of 2019 were favorably impacted by certain INVELTYS manufacturing costs which were expensed as R&D prior to FDA approval in August 2018**.**

- **SG&A Expenses**: For the quarter ended March 31, 2019, selling, general and administrative (SG&A) expenses were $18.2 million compared to $5.5 million for the same period in 2018. The increases in SG&A expenses for the quarter ended March 31, 2019 were primarily due to costs associated with hiring additional personnel, building our commercial organization, external costs associated with the launch of INVELTYS in January 2019, and an increase in our facility costs due to the lease of our new corporate headquarters which commenced in late 2018.

  Non-GAAP SG&A expenses were $16.3 million for the quarter ended March 31, 2019 compared to $4.2 million for the same period in 2018. For a reconciliation of GAAP to non-GAAP SG&A expenses, please see the tables provided below.

- **R&D Expenses:** For the quarter ended March 31, 2019, research and development (R&D) expenses were $7.0 million compared to $5.7 million for the same period in 2018. The increase in R&D expenses for the quarter ended March 31, 2019 was primarily due to increased clinical expenses associated with STRIDE 3, which were partially offset by a decrease in manufacturing costs related to INVELTYS which were expensed as R&D prior to FDA approval.
  Non-GAAP R&D expenses were $6.3 million for the quarter ended March 31, 2019 compared to $5.0 million for the same period in 2018. For a reconciliation of GAAP to non-GAAP R&D expenses, please see the tables provided below.
- **Operating Loss**: For the quarter ended March 31, 2019, loss from operations was $24.1 million compared to $11.1 million for the same period in 2018. Non-GAAP operating loss was $21.4 million for the quarter ended March 31, 2019 compared to $9.2 million for the same period in 2018. For a

reconciliation of GAAP to non-GAAP operating loss, please see the tables provided below.

- **Net Loss**: Net loss was $25.4 million, or $0.75 per share, for the quarter ended March 31, 2019 compared to a net loss of $11.3 million, or $0.46 per share, for the same period in 2018.

  Non-GAAP Net Loss: For the quarter ended March 31, 2019, non-GAAP net loss was $22.5 million, compared to $9.4 million for the same quarter of 2018. For a reconciliation of GAAP to non-GAAP net loss, please see the tables provided below.
  The weighted average number of shares outstanding used to calculate net loss per share was 33,878,021 for the quarter ended March 31, 2019 and 24,542,428 for the quarter ended March 31, 2018.

Conference Call Information

Kala will host a live conference call and webcast today, May 9, 2019 at 8:00 a.m. ET to review first quarter 2019 financial results. 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: 2881526.

To access a subsequent archived recording of the call, please visit the "Investors & Media" section on the Kala website at http://kalarx.com.

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary AMPPLIFY™ mucus-penetrating particle (MPP) Drug Delivery Technology, with an initial focus on the treatment of eye diseases. Kala has applied the AMPPLIFY Drug Delivery Technology to a corticosteroid, loteprednol etabonate (LE), designed for ocular applications, resulting in recently approved INVELTYS® for the treatment of inflammation and pain following ocular surgery and its lead product candidate, KPI-121 0.25%, for the temporary relief of the signs and symptoms of dry eye disease, for which a target action date under the Prescription Drug User Fee Act (PDUFA) has been set by the United States Food and Drug Administration (FDA) for August 15, 2019.

Non-GAAP Financial Measures

In this press release, the financial results of Kala are provided in accordance with accounting principles generally accepted in the United States (GAAP) and using certain non-GAAP financial measures. The items included in GAAP presentations but excluded for purposes of determining non-GAAP financial measures for the periods presented in the press release are stock-based compensation expense, non-cash interest and depreciation. Management believes this non-GAAP information is useful for investors, taken in conjunction with Kala's GAAP financial statements, because it provides greater transparency and period-over-period comparability with respect to Kala's operating performance. These measures are also used by management to assess the performance of the business. Investors should consider these non-GAAP measures only as a supplement to, not as a substitute for, or as superior to, measures of financial performance prepared in accordance with GAAP. In addition, these non-GAAP financial measures are unlikely to be comparable with non-GAAP information provided by other companies. For a reconciliation of these non-GAAP financial measures to the most comparable GAAP measures, please refer to the table at the end of this press release.

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, including progress of commercial launch, status of insurance coverage and the availability of reimbursements under Medicare Part D, the Company's lead product candidate, KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, including the Company's belief that changes made to the inclusion/exclusion criteria of STRIDE 3 will improve the probability of success and expectation to report top-line results for STRIDE 3 in the fourth quarter of 2019, the Company's expectations regarding its use of cash and cash runway. 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 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; uncertainties inherent in the availability and timing of data from ongoing clinical trials, and the results of such trials, including STRIDE 3; whether any additional clinical trials will be initiated or required for KPI-121 0.25% prior to approval of the NDA, or at all, and whether the NDA will be approved; the Company's ability execute on the 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, including KPI-121 0.25%; 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 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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Kala Pharmaceuticals, Inc.
Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2019	December 31, 2018
Cash	$ 138,944	$ 170,898
Total assets	197,016	220,966
Working capital [1]	135,847	160,018
Long-term debt, net of discounts	70,457	70,226
Other long-term liabilities	29,590	28,752
Total Stockholders' equity	82,367	104,978

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

Condensed Consolidated Statement of Operations
(In thousands, except share and per share data)
(Unaudited)

	Quarter Ended March 31,	
	2019	2018
Product revenues, net	$ 1,386	$ —
Costs and expenses:		
Cost of product revenues	241	—
Selling, general and administrative	18,236	5,482
Research and development	6,959	5,657
Total operating expenses	25,436	11,139
Loss from operations	(24,050)	(11,139)
Other income (expense):		
Interest income	756	209
Interest expense	(2,094)	(367)
Net loss	(25,388)	(11,297)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.75)	$ (0.46)
Weighted average shares outstanding—basic and diluted	33,878,021	24,542,428

Kala Pharmaceuticals, Inc.
Reconciliation of GAAP to Non-GAAP Financial Measures
(In thousands)
(Unaudited)

	Quarter Ended March 31,	
	2019	2018
Net loss (GAAP)	$ (25,388)	$ (11,297)
Add-back: stock-based compensation expense	2,473	1,861
Add-back: Non-cash interest	231	—
Add-back: depreciation	170	81
Non-GAAP Net loss	$ (22,514)	$ (9,355)
Cost of product revenues (GAAP)	$ 241	$ —
Less: stock-based compensation expense	2	—
Non-GAAP Cost of product revenues	$ 239	—
Selling, general and administrative expenses (GAAP)	$ 18,236	$ 5,482
Less: stock-based compensation expense	1,864	1,222
Less: depreciation	94	80
Non-GAAP Selling, general and administrative expenses	$ 16,278	4,180
Research and development expenses (GAAP)	$ 6,959	$ 5,657
Less: stock-based compensation expense	607	639
Less: depreciation	76	1
Non-GAAP research and development expenses	$ 6,276	5,017
Total operating loss (GAAP)	$ (24,050)	$ (11,139)
Less: stock-based compensation expense	2,473	1,861
Less: depreciation	170	81
Non-GAAP total operating loss	$ (21,407)	$ (9,197)