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 7, 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**

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 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 May 7, 2020, Kala Pharmaceuticals, Inc. announced its financial results for the quarter ended March 31, 2020 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 7, 2020

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 7, 2020

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

Exhibit 99.1

Kala Pharmaceuticals Reports First Quarter 2020 Financial Results and Provides Corporate Update

-- Announced Positive Results from STRIDE 3 Clinical Trial of EYSUVIS in March 2020, Demonstrating Statistically Significant Results for Primary and Key Secondary Endpoints --
-- EYSUVIS™ NDA Resubmitted on April 30th; Potential Approval and Launch Before Year-End --
-- Raised $146.9 Million in Gross Proceeds from Sales of Common Stock in Early 2020 --
-- 1Q 2020 INVELTYS® Revenue of $1.1 Million --
-- Conference Call and Webcast at 8:00 a.m. ET –

WATERTOWN, Mass., May 7, 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 reported financial results for the first quarter ended March 31, 2020.

"The first quarter of 2020 was marked by substantial progress across our business, even as we contended with the uncertainties and unprecedented disruptions imposed by the COVID-19 pandemic," said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. "In March, we announced positive results from our STRIDE 3 clinical trial of EYSUVIS, demonstrating statistically significant improvements in both the signs and symptoms of dry eye disease. These results replicated the positive results from prior trials, which highlight the potential of EYSUVIS to be the first prescription medicine for the short-term treatment of dry eye disease, including dry eye flares. As we announced earlier this week, we have resubmitted the NDA for EYSUVIS to the FDA incorporating the positive results from STRIDE 3 and are preparing for a potential approval and launch by year-end."

COVID-19-related restrictions on elective procedures, which include most ocular surgeries, have affected INVELTYS® prescriptions and revenue, and the impacts are expected to persist through the pandemic. Kala is continuing to support INVELTYS and is preparing for a potential EYSUVIS launch in the second half of 2020. Kala's sales force is utilizing virtual technologies to remain in contact with prescribers and, based on its interactions with eye care professionals across the United States, Kala expects that many deferred ocular surgeries will be rescheduled once conditions permit. Kala remains well-capitalized following its public offering of common stock in March 2020 and anticipates that its existing cash resources will enable it to fund its operations into at least the second quarter of 2022.

First Quarter and Recent Highlights:

EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25% Dry Eye Program: In March 2020, Kala announced positive topline results from STRIDE 3, a Phase 3 clinical trial evaluating EYSUVIS for the treatment of dry eye disease. STRIDE 3 met both of its primary efficacy endpoints, demonstrating a statistically significant improvement in the symptom endpoint of ocular discomfort severity at day 15 in the overall intent-to-treat (ITT) population and in the predefined subgroup of ITT patients with more severe ocular discomfort at baseline. Statistical significance was also achieved in conjunctival hyperemia at day 15 in the ITT population ($p<0.0001$) and ocular discomfort severity at day 8 in the ITT population ($p=0.0282$). Significant results were also observed for total corneal staining at day 15 in the ITT population ($p=0.0042$).

EYSUVIS was well tolerated, with adverse events and intraocular pressure comparable to vehicle. Read the company's press release reporting on the full topline data here.

On April 30, 2020, Kala resubmitted its New Drug Application (NDA) for EYSUVIS to the U.S. Food and Drug Administration (FDA). Kala believes this application meets the criteria of a Class 2 resubmission, with a target six-month review period under the Prescription Drug User Fee Act (PDUFA).

INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%: INVELTYS was launched in January 2019 as the first and only twice-daily post-surgical ocular corticosteroid. In the first quarter of 2020, over 42,000 INVELTYS prescriptions were reported by Symphony Health, which represents a decrease of approximately 9.5% over the fourth quarter of 2019.

Beginning in March 2020 and continuing into the second quarter of 2020, INVELTYS prescriptions and revenue have been adversely affected by the ongoing COVID-19 pandemic as federal, state and local governments implemented restrictions on elective procedures, including most ocular surgeries. Kala believes that physicians will move to reschedule many deferred procedures once conditions permit and expects INVELTYS prescriptions and revenue to return to growth, however the company is unable to project the specific timing or potential impact on future revenues given the continued uncertainty around the impact and duration of the restrictions related to COVID-19.

Additionally, while Kala has suspended substantially all in-person interactions with customers, including visits to physician offices, clinics and hospitals, Kala's sales force continues to provide support virtually through telephone and web-based technologies. Kala is following recommendations from the U.S. Centers for Disease Control and Prevention (CDC) as well as federal, state and local governments and will continue to assess when it is appropriate for employees to return to normal work practices.

Corporate:

In March 2020, Kala closed an underwritten public offering of 16,000,000 shares of common stock and, in early April 2020, sold an additional 979,371 shares of common stock resulting from the partial exercise of the underwriters' option to purchase additional shares, at a public offering price of $7.89 per share. Kala received aggregate gross proceeds of $146.9 million from these transactions and the sale of common stock in early 2020 under its at-the-market offering (ATM) program, before deducting underwriting discounts, commissions and offering expenses.

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 press release.

- **Cash Position:** As of March 31, 2020, Kala had cash of $196.5 million, compared to $85.4 million as of December 31, 2019. In April 2020, Kala received an additional $7.2 million in net proceeds as a result of the partial exercise of the underwriters' option to purchase additional shares in the March 2020 public offering. Kala anticipates that its existing cash resources will enable it to fund its operations into at least the second quarter of 2022.

- **Net Product Revenue**: For the quarter ended March 31, 2020, Kala reported net product revenue of $1.1 million relating to sales of INVELTYS, compared to $1.4 million in the first quarter of 2019, a decrease of $0.3 million. Net revenues in the first quarter of 2020 were impacted by higher reserves as compared to the same period in 2019. Kala recognizes revenue when product is shipped to distributors.

- **Cost of Product Revenues**: For the quarter ended March 31, 2020, cost of product revenues was $0.4 million, compared to $0.2 million for the same period in 2019. As Kala began capitalizing inventory costs for INVELTYS after receipt of FDA approval on August 22, 2018, cost of product revenues for the quarter ended March 31, 2019 were more favorably impacted by costs which were expensed as research and development prior to FDA approval. Non-GAAP cost of product revenues was $0.3 million for the quarter ended March 31, 2020, compared to $0.2 million for the same period in 2019.

- **SG&A Expenses:** For the quarter ended March 31, 2020, selling, general and administrative (SG&A) expenses were $15.4 million, compared to $18.2 million for the same period in 2019. The decrease was primarily due to launch-related marketing and selling expenses incurred during the quarter ended March 31, 2019 associated with the commercial launch of INVELTYS, which were not incurred during the quarter ended March 31, 2020, as well as a decrease in stock compensation costs. Non-GAAP SG&A expenses were $13.5 million for the quarter ended March 31, 2020, compared to $16.3 million for the same period in 2019.

- **R&D Expenses:** For the quarter ended March 31, 2020, research and development (R&D) expenses were $5.4 million, compared to $7.0 million for the same period in 2019. The decrease was primarily due to a $1.7 million decrease in external costs related to the STRIDE 3 dry eye clinical trial, for which Kala announced topline data in March 2020, partially offset by an increase in employee-related costs driven by manufacturing employees allocating more time to EYSUVIS research and development. Non-GAAP R&D expenses were $4.6 million for the quarter ended March 31, 2020, compared to $6.3 million for the same period in 2019.

- **Operating Loss**: For the quarter ended March 31, 2020, loss from operations was $20.1 million, compared to $24.1 million for the same period in 2019. Non-GAAP operating loss was $17.4 million for the quarter ended March 31, 2020, compared to $21.4 million for the same period in 2019.

- **Net Loss:** For the quarter ended March 31, 2020, net loss was $22.0 million, or $0.54 per share, compared to a net loss of $25.4 million, or $0.75 per share, for the same period in 2019. Non-GAAP net loss was $19.0 million for the quarter ended March 31, 2020, compared to $22.5 million for the same period in 2019. The weighted average number of shares used to calculate net loss per share was 40,761,984 for the quarter ended March 31, 2020, and 33,878,021 for the quarter ended March 31, 2019.

Conference Call Information

Kala will host a live conference call and webcast today, May 7, 2019 at 8:00 a.m. ET to review its first quarter 2020 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: 9468562.

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

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.

About Kala Pharmaceuticals:

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 its investigational product candidate, EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25%, which is being studied for the short-term treatment 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 likelihood of many deferred ocular surgeries being rescheduled once the COVID-19 pandemic subsides and INVELTYS prescriptions and

revenue returning to growth, the Company's lead product candidate, EYSUVIS, including the resubmitted NDA meeting the criteria of a Class 2 resubmission, with a target six-month FDA review period, EYSUVIS' potential to be the first prescription medicine for the short-term treatment of dry eye disease, including dry eye flares, and expectations regarding potential launch timing, 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 INVELTYS and any delay in timing of regulatory review of the NDA for EYSUVIS; whether the Company will be able to successfully implement its commercialization plans for INVELTYS and EYSUVIS, if approved; whether the market opportunity for INVELTYS and EYSUVIS is consistent with the Company's expectations and market research; whether any additional clinical trials will be initiated or required for EYSUVIS prior to approval of the NDA, or at all, and whether the NDA for EYSUVIS will be accepted for filing and/or approved on the timeline expected or at all; the Company's ability execute on the commercial launch of EYSUVIS, if and when approved, 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 INVELTYS and the Company's product candidates, including EYSUVIS; 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.

Kala Pharmaceuticals, Inc.
Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2020	December 31, 2019
Cash	$ 196,456	$ 85,449
Total assets	258,526	154,323
Working capital [(1)]	192,974	80,710
Long-term debt, net of discounts	71,438	71,184
Other long-term liabilities	28,305	28,673
Total Stockholders' equity	141,510	29,692

(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.

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

	Three Months Ended March 31,	
	2020	**2019**
Product revenues, net	$ 1,071	$ 1,386
Costs and expenses:		
Cost of product revenues	354	241
Selling, general and administrative	15,408	18,236
Research and development	5,434	6,959
Total operating expenses	21,196	25,436
Loss from operations	(20,125)	(24,050)
Other income (expense):		
Interest income	298	756
Interest expense	(2,128)	(2,094)
Net loss	(21,955)	(25,388)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.54)	$ (0.75)
Weighted average shares outstanding—basic and diluted	40,761,984	33,878,021

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

	Three Months Ended March 31,	
	2020	**2019**
Net loss (GAAP)	$ (21,955)	$ (25,388)
Add-back: stock-based compensation expense	2,497	2,473
Add-back: Non-cash interest	253	231
Add-back: depreciation	230	170
Non-GAAP Net loss	$ (18,975)	$ (22,514)
Cost of product revenues (GAAP)	$ 354	$ 241
Less: stock-based compensation expense	20	2
Less: depreciation	13	-
Non-GAAP Cost of product revenues	$ 321	239
Selling, general and administrative expenses (GAAP)	$ 15,408	$ 18,236
Less: stock-based compensation expense	1,754	1,864
Less: depreciation	150	94
Non-GAAP Selling, general and administrative expenses	$ 13,504	16,278
Research and development expenses (GAAP)	$ 5,434	$ 6,959
Less: stock-based compensation expense	723	607
Less: depreciation	67	76
Non-GAAP research and development expenses	$ 4,644	6,276
Total operating loss (GAAP)	$ (20,125)	$ (24,050)
Less: stock-based compensation expense	2,497	2,473
Less: depreciation	230	170
Non-GAAP total operating loss	$ (17,398)	$ (21,407)

Investors:
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