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): **February 12, 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 February 12, 2020, Kala Pharmaceuticals, Inc. announced its financial results for the quarter and year ended December 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 February 12, 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: February 12, 2020

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

Exhibit 99.1

Kala Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results

– Completed Last Patient Last Visit for STRIDE 3 Dry Eye Disease Trial; Topline Results on Track for First Quarter of 2020 –
– Achieved Full Year 2019 INVELTYS® Revenues of $6.1 Million –
– Conference Call and Webcast Today at 8:00 a.m. ET –

WATERTOWN, Mass. – February 12, 2020 – Kala Pharmaceuticals, Inc. (Kala) (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 fourth quarter and full year ended December 31, 2019.

“The last patient has now completed their final study visit in the STRIDE 3 Phase 3 trial,” said Mark Iwicki, Chief Executive Officer of Kala. “We are on track to report topline data in this quarter and to resubmit our New Drug Application to the U.S. Food and Drug Administration in the second quarter of 2020. If approved, we believe that EYSUVIS (KPI-121 0.25%), our product candidate for dry eye disease, could become the preferred prescription therapy for dry eye flares, which affects the vast majority of patients with dry eye disease. In 2019, we successfully launched INVELTYS, achieving steady growth in prescriptions and market share, and we continue to build a broad base of prescribing eye care professionals. This reflects the strong demand we are seeing for INVELTYS in the marketplace, as well as the execution of our commercial team. Our field sales, marketing and market access infrastructure has us well-positioned to rapidly launch EYSUVIS later this year, if approved.”

Fourth Quarter and Recent Highlights:

EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25% Dry Eye Program: In February 2020, Kala completed the last patient, last visit in STRIDE 3 (STRIDE – Short Term Relief in Dry Eye), its Phase 3 clinical trial evaluating EYSUVIS for the temporary relief of the signs and symptoms of dry eye disease. Specific modifications were made to the inclusion and exclusion criteria of STRIDE 3 relative to STRIDE 1 and STRIDE 2 to improve the probability of success of the trial. Kala expects the results of this trial to serve as the basis of its response to the complete response letter (CRL) it received in August 2019 from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for EYSUVIS. Kala is targeting to report topline results from STRIDE 3 in the first quarter of 2020 and resubmission of its NDA to the FDA in the first half of 2020. Kala believes this resubmission would be subject to a six-month review 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. Since launch:

- Over 144,000 INVELTYS prescriptions have been reported as of January 31, 2020.
- INVELTYS has achieved approximately 11.2% branded new prescription market share.
- Over 3,300 eye care professionals have prescribed INVELTYS.
- INVELTYS has achieved approximately 80% unrestricted Commercial market access, and approximately 23% unrestricted Medicare Part D market access, for an aggregate total of approximately 145 million covered lives.

In the fourth quarter, approximately 47,000 INVELTYS prescriptions were reported by Symphony Health, representing prescription growth of approximately 17% compared to the third quarter of 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 press release.

Cash Position:

- As of December 31, 2019, Kala had cash of $85.4 million, compared to $170.9 million as of December 31, 2018.
- Kala anticipates that its existing cash resources, together with projected INVELTYS revenue, will enable it to fund its operations into the second quarter of 2021.

Fourth Quarter 2019 Financial Results:

- **Net Product Revenues:** For the quarter ended December 31, 2019, Kala reported net product revenue of $1.2 million relating to sales of INVELTYS, which was launched in January 2019. Revenue is recognized when products are delivered to distributors.
- **Cost of Product Revenues:** Cost of product revenues for the quarter ended December 31, 2019 were $0.7 million, compared to $0 for the same period in 2018. Non-GAAP cost of product revenues were $0.6 million for the quarter ended December 31, 2019, compared to $0 for the same period in 2018.
- **SG&A Expenses:** For the quarter ended December 31, 2019, selling, general and administrative (SG&A) expenses were $14.5 million, compared to $14.3 million for the same period in 2018. The increase in SG&A expenses for the quarter ended December 31, 2019 was primarily due to costs associated with commercial infrastructure being in place for the entire fourth quarter of 2019 as compared to only a portion of the fourth quarter of 2018, an increase in facility-related costs, partially offset by lower pre-launch external costs incurred during the fourth quarter of 2018. Non-GAAP SG&A expenses were $12.7 million for the quarter ended December 31, 2019, consistent with the same period in 2018.
- **R&D Expenses:** For the quarter ended December 31, 2019, research and development (R&D) expenses were $6.1 million, compared to $9.2 million for the same period in 2018. The decrease in R&D expenses for the quarter ended December 31, 2019 was primarily due to the NDA filing fee for EYSUVIS of $2.6 million incurred in the fourth quarter of 2018. Non-GAAP R&D expenses were $5.5 million for the quarter ended December 31, 2019, compared to $8.6 million for the same period in 2018.
- **Operating Loss:** For the quarter ended December 31, 2019, loss from operations was $20.2 million compared to $23.6 million for the same period in 2018. Non-GAAP operating loss was $17.6 million for the quarter ended December 31, 2019, compared to $21.3 million for the same period in 2018.
- **Net Loss:** Net loss was $22.0 million, or $0.63 per share, for the quarter ended December 31, 2019, compared to a net loss of $25.2 million, or $0.76 per share, for the same period in 2018. For the quarter ended December 31, 2019, non-GAAP net loss was $19.2 million, compared to $22.7 million for the same period in 2018.

  The weighted average number of shares outstanding used to calculate net loss per share was 34.9 million for the quarter ended December 31, 2019, and 33.2 million for the quarter ended December 31, 2018.

Full Year 2019 Financial Results:

- **Net Product Revenues:** For the full year ended December 31, 2019, Kala reported net product revenues of $6.1 million relating to sales of INVELTYS, which was launched in January 2019. The Company did not recognize revenues in 2018.
- **Cost of Product Revenues:** Cost of product revenues for the full year ended December 31, 2019 was $2.0 million, compared to $0 for the same period in 2018. Non-GAAP cost of product revenues was $1.7 million for the full year ended December 31, 2019, compared to $0 for the same period in 2018.
- **SG&A Expenses:** For the full year ended December 31, 2019, SG&A expenses were $65.0 million, compared to $35.4 million for the same period in 2018. The increase in SG&A expenses for the year ended December 31, 2019 was primarily due to costs associated with hiring additional personnel, building the commercial organization to support the launch of INVELTYS, and an increase in facility-related costs. Non-GAAP SG&A expenses were $57.6 million for the full year ended December 31, 2019, compared to $29.4 million for the same period in 2018.
- **R&D Expenses:** For the full year ended December 31, 2019, R&D expenses were $27.3 million, compared to $29.3 million for the same period in 2018. The decrease in R&D expenses for the year ended December

31, 2019 was primarily due to a decrease in INVELTYS-related manufacturing and headcount costs, which in 2018 were expensed as R&D prior to FDA approval and the NDA filing fee for EYSUVIS expensed in 2018. These costs were partially offset by an increase in spending on STRIDE 3, and an increase in facility-related costs in 2019. Non-GAAP R&D expenses were $24.1 million for the full year ended December 31, 2019, compared to $26.3 million for the same period in 2018.

- **Operating Loss:** For the full year ended December 31, 2019, loss from operations were $88.2 million compared to $64.7 million for the same period in 2018. Non-GAAP operating loss was $77.4 million for the full year ended December 31, 2019, compared to $55.8 million for the same period in 2018.
- **Net Loss:** Net loss was $94.3 million, or $2.76 per share, for the full year ended December 31, 2019, compared to a net loss of $66.7 million, or $2.49 per share, for the same period in 2018. For the full year ended December 31, 2019, non-GAAP net loss was $82.6 million, compared to $57.5 million for the same period in 2018.

  The weighted average number of shares outstanding used to calculate net loss per share was 34.2 million for the year ended December 31, 2019, and 26.8 million for the year ended December 31, 2018.

Conference Call Information:

Kala will host a live conference call and webcast today, February 12, 2020 at 8:00 a.m. ET to review the fourth quarter and full year 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: 5786176. 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 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 August 2018 FDA approval 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 temporary relief of the signs and symptoms of dry eye disease.

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, including progress of commercial launch, status of insurance coverage and the availability of reimbursements for commercial and Medicare Part D patients, the Company's lead product candidate, EYSUVIS, 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 relative to STRIDE 1 and STRIDE 2 will improve the probability of success, the Company targeting topline results for STRIDE 3 in the first quarter of 2020, resubmission of its NDA to the FDA in the second quarter of 2020, expectations regarding timing of FDA review of its NDA and 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," "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 and EYSUVIS 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 EYSUVIS 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 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.

Financial Tables:

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

	December 31, 2019	December 31, 2018
Cash	$ 85,449	$ 170,898
Total assets	154,323	220,966
Working capital [(1)]	80,710	160,018
Long-term debt, net of discounts	71,184	70,226
Other long-term liabilities	28,673	28,752
Total Stockholders' equity	29,692	104,978

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

Kala Pharmaceuticals, Inc.
Consolidated Statement of Operations
(in thousands, except share and per share data)
(unaudited)

	Quarter Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Product revenues, net	$ 1,180	$ —	$ 6,074	$ —
Costs and expenses:				
Cost of product revenues	747	—	2,008	—
Selling, general and administrative	14,492	14,329	65,015	35,431
Research and development	6,138	9,239	27,275	29,290
Total operating expenses	21,377	23,568	94,298	64,721
Loss from operations	(20,197)	(23,568)	(88,224)	(64,721)
Other income (expense):				
Interest income	384	840	2,357	1,687
Interest expense	(2,145)	(2,100)	(8,480)	(3,314)
Loss on extinguishment of debt	—	(390)	—	(390)
Net loss	(21,958)	(25,218)	(94,347)	(66,738)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.63)	$ (0.76)	$ (2.76)	$ (2.49)
Weighted average shares outstanding—basic and diluted	34,899,019	33,234,169	34,209,756	26,753,906

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

	Quarter Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Net loss (GAAP)	$ (21,958)	$ (25,218)	$ (94,347)	$ (66,738)
Add-back: stock-based compensation expense	2,325	2,198	9,991	8,615
Add-back: Non-cash interest	249	197	958	273
Add-back: depreciation	229	109	843	352
Non-GAAP Net loss	$ (19,155)	$ (22,714)	$ (82,555)	$ (57,498)
Cost of product revenues (GAAP)	$ 747	$ —	$ 2,008	$ —
Less: stock-based compensation expense	167	—	268	—
Less: depreciation	1	—	3	—
Non-GAAP Cost of product revenues	$ 579	$ —	$ 1,737	$ —
Selling, general and administrative expenses (GAAP)	$ 14,492	$ 14,329	$ 65,015	$ 35,431
Less: stock-based compensation expense	1,629	1,602	6,879	5,955
Less: depreciation	146	37	522	42
Non-GAAP Selling, general and administrative expenses	$ 12,717	12,690	$ 57,614	$ 29,434
Research and development expenses (GAAP)	$ 6,138	$ 9,239	$ 27,275	$ 29,290
Less: stock-based compensation expense	529	596	2,844	2,660
Less: depreciation	82	72	318	310
Non-GAAP research and development expenses	$ 5,527	8,571	$ 24,113	$ 26,320
Total operating loss (GAAP)	$ (20,197)	$ (23,568)	$ (88,224)	$ (64,721)
Less: stock-based compensation expense	2,325	2,198	9,991	8,615
Less: depreciation	229	109	843	352
Non-GAAP total operating loss	$ (17,643)	$ (21,261)	$ (77,390)	$ (55,754)

Investors:
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