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, 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))

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 November 7, 2019, Kala Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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 November 7, 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: November 7, 2019

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

Kala Pharmaceuticals Reports Third Quarter 2019 Financial Results

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

WATERTOWN, Mass — (BUSINESS WIRE) — 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 third quarter ended September 30, 2019.

“INVELTYS demonstrated growing demand in the third quarter, with positive feedback from physicians and a continued uptick in prescriptions and market share. Additionally, we made important progress in expanding payor coverage,” said Mark Iwicki, Chief Executive Officer of Kala. “Our STRIDE 3 Phase 3 clinical trial for EYSUVIS™ (KPI-121 0.25%), our product candidate for dry eye disease, continues to enroll and we are targeting topline data in the first quarter of 2020. We expect that data from this trial will serve as the basis for our resubmission of the EYSUVIS New Drug Application to the U.S. Food and Drug Administration.”

If approved, Kala believes EYSUVIS will be the ideal prescription therapy for treating dry eye flares that affect the vast majority of dry eye patients.

Third Quarter and Recent Highlights:

INVELTYS®: INVELTYS (loteprednol etabonate ophthalmic suspension) 1% 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. Kala believes these attributes are being viewed favorably by physicians.

- Quarter-over-quarter prescription growth was 30%; approximately 40,000 INVELTYS prescriptions were reported by Symphony Health in the third quarter of 2019 compared to approximately 31,000 prescriptions reported in the second quarter of 2019. As of October 25, 2019, approximately 97,000 prescriptions of INVELTYS have been reported.
- INVELTYS continues to achieve strong market share growth and now has over 10% branded new prescription market share in just over ten months since launch. Branded new prescription market share grew by 55% in the third quarter compared to the second quarter.
- INVELTYS prescribers grew by 19% quarter-over-quarter. Launch to date, approximately 2,700 eye care professionals have prescribed INVELTYS, which represents nearly 40% of Kala’s targets.
- INVELTYS has achieved approximately 75% unrestricted Commercial market access, for a total of approximately 125 million covered commercial lives.
- INVELTYS has achieved approximately 23% Medicare Part D unrestricted market access, for a total of approximately 10 million covered Medicare Part D lives. Medicare Part D contract negotiations are ongoing with most coverage decisions anticipated in 2020.

EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25% Dry Eye Program: On August 7, Kala received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for EYSUVIS for the temporary relief of the signs and symptoms of dry eye disease. The FDA indicated that efficacy data from an additional clinical trial will be needed to support a

resubmission of the NDA. Kala is currently conducting the additional Phase 3 clinical trial, STRIDE 3 (STRIDE - Short Term Relief In Dry Eye), which Kala expects will serve as the basis of its response to the CRL. Kala 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 Kala believes that changes made to the inclusion/exclusion criteria of STRIDE 3 based on these analyses will improve the probability of success of STRIDE 3. Kala is targeting topline data from STRIDE 3 in the first quarter of 2020 and resubmission of the NDA in the first half of 2020. The Company believes this resubmission would be subject to a six-month review under the Prescription Drug User Fee Act (PDUFA).

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 September 30, 2019, Kala had cash of $97.6 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 operations through the next 18 months.

Third Quarter 2019 Financial Results

- **Net Product Revenue:** For the quarter ended September 30, 2019, Kala reported net product revenue of $1.5 million relating to sales of INVELTYS, which was launched in January 2019. Revenue is recognized when products are delivered to distributors. Included in net product revenue for the three months ended September 30, 2019, is a $0.6 million reduction of reported revenue resulting from a change in the estimate of our payor mix related to the first two quarters of 2019.
- **Cost of Product Revenues:** Cost of product revenues for the quarter ended September 30, 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 September 30, 2019 compared to $0 for the same period in 2018.
- **SG&A Expenses:** For the quarter ended September 30, 2019, selling, general and administrative (SG&A) expenses were $15.3 million compared to $8.5 million for the same period in 2018. The increase in SG&A expenses for the quarter ended September 30, 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 $13.5 million for the quarter ended September 30, 2019 compared to $6.9 million for the same period in 2018.
- **R&D Expenses:** For the quarter ended September 30, 2019, research and development (R&D) expenses were $7.1 million consistent with the same period in 2018. A decrease in INVELTYS-related R&D costs for the third quarter of 2019 was offset by an increase in facility-related costs for the same period in 2018. Non-GAAP R&D expenses were $6.1 million for the quarter ended September 30, 2019 compared to $6.3 million for the same period in 2018.
- **Operating Loss:** For the quarter ended September 30, 2019, loss from operations was $21.6 million compared to $15.5 million for the same period in 2018. Non-GAAP operating loss was $18.8 million for the quarter ended September 30, 2019 compared to $13.2 million for the same period in 2018.
- **Net Loss:** Net loss was $23.2 million, or $0.68 per share, for the quarter ended September 30, 2019 compared to a net loss of $15.6 million, or $0.63 per share, for the same period in 2018. For the quarter ended September 30, 2019, non-GAAP net loss was $20.1 million, compared to $13.2 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 quarter ended September 30, 2019 and 24.6 million for the quarter ended September 30, 2018.

Year-to-Date Financial Results

- **Net Product Revenue:** For the nine months ended September 30, 2019, Kala reported net product revenue of $4.9 million relating to sales of INVELTYS, which was launched in January 2019. The Company did not recognize revenue in the first nine months of 2018.
- **Cost of Product Revenues:** Cost of product revenues for the nine months ended September 30, 2019 were $1.3 million compared to $0 for the same period in 2018. Non-GAAP Cost of product revenues were $1.2 million for the nine months ended September 30, 2019 compared to $0 for the same period in 2018.
- **SG&A Expenses:** For the nine months ended September 30, 2019, SG&A expenses were $50.5 million compared to $21.1 million for the same period in 2018. The increase in SG&A expenses for the nine months ended September 30, 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 $44.9 million for the nine months ended September 30, 2019 compared to $16.7 million for the same period in 2018.
- **R&D Expenses:** For the nine months ended September 30, 2019, R&D expenses were $21.1 million compared to $20.0 million for the same period in 2018. The increase in R&D expenses for the nine months ended September 30, 2019 was primarily due to an increase in spending on STRIDE 3, an increase in facility-related costs in 2019, partially offset by a decrease in manufacturing costs associated with INVELTYS which were expensed as R&D prior to FDA approval. Non-GAAP R&D expenses were $18.6 million for the nine months ended September 30, 2019 compared to $17.8 million for the same period in 2018.
- **Operating Loss:** For the nine months ended September 30, 2019, loss from operations was $68.0 million compared to $41.2 million for the same period in 2018. Non-GAAP operating loss was $59.7 million for the nine months ended September 30, 2019 compared to $34.5 million for the same period in 2018.
- **Net Loss:** Net loss was $72.4 million, or $2.13 per share, for the nine months ended September 30, 2019 compared to a net loss of $ 41.5 million, or $1.69 per share, for the same period in 2018. For the nine months ended September 30, 2019, non-GAAP net loss was $63.4 million compared to $34.8 million for the same period in 2018.

  The weighted average number of shares outstanding used to calculate net loss per share was 34.0 million for the nine months ended September 30, 2019 and 24.6 million for the nine months ended September 30, 2018.

Conference Call Information

Kala will host a live conference call and webcast today, November 7, 2019 at 8:00 a.m. ET to review the third 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: 1955939. 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 the August 2018 FDA approval of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% for the treatment of inflammation and pain following ocular surgery, and its lead product candidate, EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25%, 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 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, 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 will improve the probability of success, the Company targeting topline results for STRIDE 3 in the first quarter of 2020, 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)

	September 30, 2019	December 31, 2018
Cash	$ 97,556	$ 170,898
Total assets	161,013	220,966
Working capital [(1)]	94,490	160,018
Long-term debt, net of discounts	70,935	70,226
Other long-term liabilities	29,026	28,752
Total Stockholders' equity	43,056	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.

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

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Product revenues, net	$ 1,451	$ —	$ 4,894	$ —
Costs and expenses:				
Cost of product revenues	668	—	1,261	—
Selling, general and administrative	15,280	8,469	50,523	21,102
Research and development	7,070	7,027	21,137	20,051
Total operating expenses	23,018	15,496	72,921	41,153
Loss from operations	(21,567)	(15,496)	(68,027)	(41,153)
Other income (expense):				
Interest income	571	325	1,973	848
Interest expense	(2,180)	(432)	(6,335)	(1,214)
Net loss	(23,176)	(15,603)	(72,389)	(41,519)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.68)	$ (0.63)	$ (2.13)	$ (1.69)
Weighted average shares outstanding—basic and diluted	34,168,282	24,600,080	33,977,477	24,570,081

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

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss (GAAP)	$ (23,176)	$ (15,603)	$ (72,389)	$ (41,519)
Add-back: stock-based compensation expense	2,572	2,265	7,666	6,417
Add-back: Non-cash interest	237	75	709	75
Add-back: depreciation	226	70	614	243
Non-GAAP Net loss	$ (20,141)	$ (13,193)	$ (63,400)	$ (34,784)
Cost of product revenues (GAAP)	$ 668	$ —	$ 1,261	$ —
Less: stock-based compensation expense	60	—	101	—
Less: depreciation	2	—	2	—
Non-GAAP Cost of product revenues	$ 606	$ —	$ 1,158	$ —
Selling, general and administrative expenses (GAAP)	$ 15,280	$ 8,469	$ 50,523	$ 21,102
Less: stock-based compensation expense	1,599	1,581	5,250	4,353
Less: depreciation	140	13	376	16
Non-GAAP Selling, general and administrative expenses	$ 13,541	6,875	$ 44,897	$ 16,733
Research and development expenses (GAAP)	$ 7,070	$ 7,027	$ 21,137	$ 20,051
Less: stock-based compensation expense	913	684	2,315	2,064
Less: depreciation	84	57	236	227
Non-GAAP research and development expenses	$ 6,073	6,286	$ 18,586	$ 17,760
Total operating loss (GAAP)	$ (21,567)	$ (15,496)	$ (68,027)	$ (41,153)
Less: stock-based compensation expense	2,572	2,265	7,666	6,417
Less: depreciation	226	70	614	243
Non-GAAP total operating loss	$ (18,769)	$ (13,161)	$ (59,747)	$ (34,493)

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