# 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): **March 11, 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**

(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 March 11, 2019, Kala Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2018 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 March 11, 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: March 11, 2019

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

**Exhibit 99.1**

**Kala Pharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results**

- *INVELTYS™ launched in January 2019 for the treatment of post-operative inflammation and pain following ocular surgery*
- *August 15, 2019 Prescription Drug User Fee Act (PDUFA) target action date for KPI-121 0.25% for the temporary relief of signs and symptoms of dry eye disease*
- *Topline data from STRIDE 3 trial of KPI-121 0.25% expected in 4Q19*

*–Conference Call and Webcast Today at 4:30 p.m. ET–*

**WATERTOWN, Mass, March 11, 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 fourth quarter and full year ended December 31, 2018.

**Key Highlights:**

- Launched INVELTYS™(loteprednol etabonate ophthalmic suspension) 1% in January 2019 for the treatment of post-operative inflammation and pain following ocular surgery
- Hired a highly experienced ophthalmology specialty sales organization and payer account team
- Received PDUFA target action date of August 15, 2019 for KPI-121 0.25% for the temporary relief of signs and symptoms of dry eye disease
- Enrollment for STRIDE 3 trial of KPI-121 0.25% continues to progress as planned. Topline data expected in 4Q19
- Strengthened balance sheet with successful debt and equity financings during 4Q18 with aggregate net proceeds of $123.6 million

“The past year was a landmark period for Kala with the approval and launch of INVELTYS, the first and only twice-daily ocular corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery,” said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. “Since approval, we completed the buildout of our commercial infrastructure for INVELTYS, including on-boarding a highly experienced ophthalmology specialty sales organization and payer account team. The physician feedback in the first few weeks of launch has been positive, and we are pleased with the uptake in prescription volume along with the progress made in gaining market access.”

**Fourth Quarter and Recent Highlights:**

**INVELTYS Launch Progress:** 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. In preparation for the launch, Kala hired an experienced specialty ophthalmology sales organization, which is actively calling on customers. In the first few weeks of launch:

- More than 4,000 INVELTYS prescriptions have been filled since launch in January
- INVELTYS has achieved unrestricted market access in approximately one-third of all lives covered by commercial payers
- Medicare Part D contract negotiations are ongoing with most coverage anticipated to begin in 2020; already approximately 20% of INVELTYS prescriptions launch-to-date have been successfully reimbursed through Medicare Part D health plans
- More than 3,000 patients have utilized the co-pay assistance program to have immediate access to INVELTYS

**Continued Advancement of KPI-121 0.25% Dry Eye Program:** In December 2018, the U.S. Food and Drug Administration (FDA) accepted for review Kala's New Drug Application (NDA) 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. The FDA has set a PDUFA target action date of August 15, 2019.

- The NDA 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 initiated an additional Phase 3 clinical trial in July 2018, STRIDE 3, evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. 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 the trial.
- STRIDE 3 enrollment continues to progress as planned. The Company expects to receive top-line results for STRIDE 3 in the fourth quarter of 2019.

**Fourth Quarter and Full Year 2018 Financial Results**

- **Cash Position:** As of December 31, 2018, Kala had cash of $170.9 million compared to $114.6 million as of December 31, 2017. 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 Loss**: Net loss was $25.2 million, or $0.76 per share, for the quarter ended December 31, 2018 compared to a net loss of $11.3 million, or $0.46 per share, for the same period in 2017. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 33,234,169 for the quarter ended December 31, 2018 and 24,518,415 for the same period in 2017. Net loss for the full year ended December 31, 2018 was $66.7 million, or $2.49 per share, compared to a net loss of $42.2 million, or $3.71 per share, for the same period in 2017. The weighted average number of shares outstanding utilized in the calculation of net loss per share was 26,753,906 for the full year ended December 31, 2018 and 11,375,000 shares for the same period in 2017.

- **Non-GAAP Net Loss:** For the quarter ended December 31, 2018, non-GAAP net loss was $22.7 million, compared to $9.6 million for the same quarter of 2017. For the year ended December 31, 2018, non-GAAP net loss was $57.5 million compared to $36.4 million for the same period of 2017. Non-GAAP net loss excludes the impact of stock-based compensation, depreciation, non-cash interest expense and the change in fair value of its warrants. See "Non-GAAP Financial Measures" below for a description of non-GAAP financial measures. For a full reconciliation of GAAP to non-GAAP financial measures appearing in this release, please see the tables provided below.

  **R&D Expenses:** For the quarter ended December 31, 2018, research and development (R&D) expenses were $9.2 million compared to $5.9 million for the same period in 2017. The increase in R&D expenses for the fourth quarter was primarily due to the initiation of STRIDE 3 as well as increased headcount and costs in anticipation of the INVELTYS launch.

  R&D expenses for the full year ended December 31, 2018 were $29.3 million compared to $29.0 million for the year ended December 31, 2017. External costs associated with STRIDE 1 and 2 decreased during 2018 and were offset by costs associated with STRIDE 3, as well as an increase in headcount and costs in anticipation of the INVELTYS launch, stock-based compensation expense, and the PDUFA fee paid in connection with our NDA for KPI-121 0.25%.

  Non-GAAP R&D expenses were $8.6 million for the quarter ended December 31, 2018 compared to $5.3 million for the same period in 2017. For the full year ended December 31, 2018, non-GAAP R&D expenses were $26.3 million compared to $27.5 million for the same period in 2017. For a reconciliation of GAAP to non-GAAP R&D expenses please see the tables provided below.

- **SG&A Expenses**: For the quarter ended December 31, 2018, selling, general and administrative (SG&A) expenses were $14.3 million compared to $5.3 million for the same period in 2017. SG&A expenses for the full year ended December 31, 2018 were $35.4 million compared to $10.9 million for the year ended December 31, 2017.

The increases in SG&A expenses for the quarter ended December 31, 2018 were primarily due to costs associated with hiring additional personnel, building our commercial organization and external costs in advance of the launch of INVELTYS in January 2019, and an increase in our facility costs due to the commencement of the lease of our new corporate headquarters.

For the year ended December 31, 2018 compared to the same period in 2017, the increase in costs was a result of stock compensation expense associated with stock options granted during the year and external costs associated with operating as a public company for a full year, in addition to the items which resulted in an increase in SG&A expenses for the quarter ended December 31, 2018 compared to the same period in 2017.

Non-GAAP SG&A expenses were $12.7 million for the quarter ended December 31, 2018 compared to $4.3 million for the same period in 2017. For the full year ended December 31, 2018, non-GAAP SG&A expenses were $29.4 million compared to $8.6 million for the same period in 2017. For a reconciliation of GAAP to non-GAAP SG&A expenses please see the tables provided below.

- **Operating Loss:** For the quarter ended December 31, 2018, operating loss was $23.6 million compared to $11.1 million for the same period in 2017. Operating loss for the full year ended December 31, 2018 was $64.7 million compared to $39.9 million for the year ended December 31, 2017. Non-GAAP operating loss was $21.2 million for the quarter ended December 31, 2018 compared to $9.6 million for the same period in 2017. For the full year ended December 31, 2018, non-GAAP operating loss was $55.8 million compared to $36.0 million for the same period in 2017. For a reconciliation of GAAP to non-GAAP operating loss please see the tables provided below.

**Conference Call Information**

Kala will host a live conference call and webcast today, March 11, 2019 at 4:30 p.m. ET to review the launch of INVELTYS, as well as fourth quarter and year end 2018 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: 9581138.

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 New Drug Application (NDA) was accepted for review with the United States Food and Drug Administration (FDA) and a target action date under the Prescription Drug User Fee Act (PDUFA) has been set 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, depreciation and the change in fair value of its warrant liability. 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. 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," "sh
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 filing or 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.

**Investor Contact:**
Michael Schaffzin
michael@sternir.com
212-362-1200

**Media Contact:**
Kari Watson
kwatson@macbiocom.com
781-235-3060

**Kala Pharmaceuticals, Inc.**

**Balance Sheet Data**

**(In thousands)**

**(Unaudited)**

| | December 31, | |
|---|---|---|
| | **2018** | **2017** |
| Cash | $170,898 | $114,565 |
| Total Assets | 220,966 | 116,546 |
| Working Capital [1] | 160,018 | 100,341 |
| Long-term debt—less current portion | 70,226 | 11,987 |
| Other long-term liabilities | 28,752 | 8 |
| Total Stockholders' Equity | 104,987 | 89,679 |

(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 STATEMENTS OF OPERATIONS**

**(In thousands, except share and per share data)**

**(Unaudited)**

| | Quarter Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Operating expenses: | | | | |
| Research and development | $ 9,239 | $ 5,880 | $ 29,290 | $ 29,008 |
| Selling, General and administrative | 14,329 | 5,260 | 35,431 | 10,867 |
| Total operating expenses | 23,568 | 11,140 | 64,721 | 39,875 |
| Loss from operations | (23,568) | (11,140) | (64,721) | (39,875) |
| Other income (expense): | | | | |
| Interest income | 840 | 250 | 1,687 | 527 |
| Interest expense | (2,100) | (401) | (3,314) | (1,019) |
| Loss on extinguishment of debt | (390) | — | (390) | — |
| Change in fair value of warrant liability | — | — | — | (1,844) |
| Net loss | (25,218) | (11,291) | (66,738) | (42,211) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (0.76) | $ (0.46) | $ (2.49) | $ (3.71) |
| Weighted average shares outstanding—basic and diluted | 33,234,169 | 24,518,415 | 26,753,906 | 11,375,000 |

**Kala Pharmaceuticals, Inc.**

**Reconciliation of GAAP to Non-GAAP Financial Measures**

**(In thousands)**

**(Unaudited)**

| | Quarter Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net loss (GAAP) | $ (25,218) | $ (11,291) | $ (66,738) | $ (42,211) |
| Add-back: stock-based compensation expense | 2,198 | 1,501 | 8,615 | 3,571 |
| Add-back: Non-cash interest | 197 | 70 | 273 | 156 |
| Add-back: depreciation | 109 | 74 | 352 | 287 |
| Add back: change in fair value of warrants | — | — | — | 1,844 |
| Non-GAAP Net loss | $ (22,714) | (9,646) | (57,498) | (36,353) |
| | | | | |
| Research and development expenses (GAAP) | $ 9,239 | $ 5,880 | $ 29,290 | $ 29,008 |
| Less: stock-based compensation expense | 596 | 518 | 2,660 | 1,267 |
| Less: depreciation | 72 | 73 | 310 | 284 |
| Non-GAAP research and development expenses | $ 8,571 | 5,289 | 26,320 | 27,457 |
| | | | | |
| Selling, general and administrative expenses (GAAP) | $ 14,329 | $ 5,260 | $ 35,431 | $ 10,867 |
| Less: stock-based compensation expense | 1,602 | 983 | 5,955 | 2,304 |
| Less: depreciation | 37 | 1 | 42 | 3 |
| Non-GAAP Selling, general and administrative expenses | $ 12,690 | $ 4,276 | $ 29,434 | $ 8,560 |
| | | | | |
| Total operating expenses (GAAP) | $ 23,568 | $ 11,140 | $ 64,721 | $ 39,875 |
| Less: stock-based compensation expense | 2,198 | 1,501 | 8,615 | 3,571 |
| Less: depreciation | 109 | 74 | 352 | 287 |
| Non-GAAP total operating expenses | $ 21,261 | $ 9,565 | $ 55,754 | $ 36,017 |