# 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): **August 6, 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 August 6, 2020, Kala Pharmaceuticals, Inc. announced its financial results for the quarter ended June 30, 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 August 6, 2020 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**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: August 6, 2020

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

**Exhibit 99.1**

**Kala Pharmaceuticals Reports Second Quarter 2020 Financial Results and Provides Corporate Update**

*– EYSUVIS™ NDA Accepted by FDA; Assigned PDUFA Goal Date of October 30, 2020 –*
*– 2Q 2020 INVELTYS® Revenue of $0.8 Million –*
*– Conference Call and Webcast at 8:00 a.m. ET –*

**WATERTOWN, Mass., August 6, 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 second quarter ended June 30, 2020.

"We are very pleased with our progress in the second quarter," said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. "In May, the FDA accepted our NDA resubmission for EYSUVIS, bringing us closer to potentially delivering the first prescription medicine for the short-term treatment of dry eye disease, including dry eye flares, which affects approximately 33 million people in the United States. We have now turned our attention toward a potential U.S. launch before year-end. Given our established relationships with eye care professionals across the United States and our experience with INVELTYS, we believe we are well-positioned for a successful launch of EYSUVIS, if approved."

**Second Quarter and Recent Highlights:**

**EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25% Dry Eye Program:** In May 2020, Kala announced that the U.S. Food and Drug Administration (FDA) accepted the Company's New Drug Application (NDA) resubmission for EYSUVIS. The FDA stated that the NDA resubmission is a complete, Class 2 response to the Complete Response Letter (CRL) issued in August 2019, and set a Prescription Drug User Fee Act (PDUFA) goal date of October 30, 2020 for the completion of its six-month review of the NDA.

If approved, Kala intends to commercialize EYSUVIS in the United States with its specialty sales force, which it plans to increase, pending the status of the COVID-19 pandemic, to a total of approximately 100 to 125 sales representatives, who will promote both EYSUVIS and INVELTYS.

**INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%:** In the second quarter of 2020, cataract procedures were down 50% compared to the second quarter of 2019, due to the deferral of ocular surgeries as a result of the COVID-19 pandemic.

Similarly, approximately 21,000 INVELTYS prescriptions were reported by Symphony Health in the second quarter of 2020, which represented a decrease of approximately 51% compared to the first quarter of 2020. Beginning in March 2020 and continuing through most of the second quarter of 2020, INVELTYS prescriptions and revenue were adversely affected by the ongoing COVID-19 pandemic as federal, state and local governments implemented restrictions on elective procedures, including most ocular surgeries. INVELTYS prescriptions subsequently achieved strong growth as states started relaxing restrictions on elective procedures late in the second quarter, resulting in total INVELTYS prescriptions growing from 544 during the week ended April 17th to over 3,000 prescriptions during the week ended July 24th. Based on the speed with which ocular surgeries were rescheduled as restrictions on elective procedures were initially lifted, Kala believes INVELTYS prescriptions and revenue will return to growth over time. 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.

While in-person interactions with customers, including visits to physician offices, clinics and hospitals, were suspended for a significant portion of the second quarter, Kala's entire sales force is now back in the field and calling on customers. In addition, the sales force continues to provide support virtually through telephone and web-based technologies to those eye care professionals they are unable to meet with face-to-face.

**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 June 30, 2020, Kala had cash, cash equivalents and short-term investments of $184.6 million, compared to $85.4 million as of December 31, 2019. This increase reflects aggregate gross proceeds of approximately $146.9 million received from its follow-on underwritten public offering of common stock in March 2020 and sales of common stock under its at-the-market (ATM) offering program in the first quarter of 2020, partially offset by cash used in operating activities. Kala anticipates that its existing cash, cash equivalents and short-term investments will enable it to fund its operations into at least the second quarter of 2022.

**Second Quarter 2020 Financial Results**

- **Net Product Revenue**: For the quarter ended June 30, 2020, Kala reported net product revenue of $0.8 million relating to sales of INVELTYS, compared to $2.1 million in the second quarter of 2019, a decrease of $1.3 million. Net revenues in the second quarter of 2020 were impacted by a reduction in ocular surgeries due to restrictions related to COVID-19 when compared to the same period in 2019. Kala recognizes revenue when product is shipped to distributors.

- **Cost of Product Revenues**: For the quarter ended June 30, 2020, cost of product revenues was $0.8 million, compared to $0.4 million for the same period in 2019. Included in cost of product revenues for the second quarter of 2020, and due to COVID-19, was a reserve of $0.5 million for excess inventory. Non-GAAP cost of product revenues was $0.7 million for the quarter ended June 30, 2020, compared to $0.3 million for the same period in 2019.

- **SG&A Expenses:** For the quarter ended June 30, 2020, selling, general and administrative (SG&A) expenses were $15.3 million, compared to $17.0 million for the same period in 2019. The decrease was primarily due to lower travel and external spending due to COVID-19 as well as INVELTYS launch-related spending incurred during the second quarter of 2019 which was not incurred during the same quarter in 2020. Non-GAAP SG&A expenses were $13.2 million for the quarter ended June 30, 2020, compared to $15.1 million for the same period in 2019.

- **R&D Expenses:** For the quarter ended June 30, 2020, research and development (R&D) expenses were $6.1 million, compared to $7.1 million for the same period in 2019. The decrease was primarily due to lower spending on STRIDE 3, our recently completed Phase 3 trial of EYSUVIS, partially offset by manufacturing of EYSUVIS which has been expensed as R&D. Non-GAAP R&D expenses were $5.4 million for the quarter ended June 30, 2020, compared to $6.2 million for the same period in 2019.

- **Operating Loss**: For the quarter ended June 30, 2020, loss from operations was $21.3 million, compared to $22.4 million for the same period in 2019. Non-GAAP operating loss was $18.6 million for the quarter ended June 30, 2020, compared to $19.6 million for the same period in 2019.

- **Net Loss:** For the quarter ended June 30, 2020, net loss was $23.3 million, or $0.42 per share, compared to a net loss of $23.8 million, or $0.70 per share, for the same period in 2019. Non-GAAP net loss was $20.1 million for the quarter ended June 30, 2020, compared to $20.7 million for the same period in 2019. The weighted average number of shares used to calculate net loss per share was 55,703,882 for the quarter ended June 30, 2020, and 33,882,939 for the quarter ended June 30, 2019.

**Financial Results for the Six Months Ended June 30, 2020**

- **Net Product Revenue**: For the six months ended June 30, 2020, Kala reported net product revenue of $1.9 million relating to sales of INVELTYS, compared to $3.4 million for the same period in 2019, a decrease of $1.5 million. Net revenues in the first six months of 2020 were impacted by a reduction in ocular surgeries due to restrictions related to COVID-19 as compared to the same period in 2019. Kala recognizes revenue when product is shipped to distributors.

- **Cost of Product Revenues**: For the six months ended June 30, 2020, cost of product revenues was $1.1 million, compared to $0.6 million for the same period in 2019. Included in cost of product revenues for the second quarter of 2020, was a reserve of $0.5 million for excess inventory. Non-GAAP cost of product revenues was $1.1 million for the six months ended June 30, 2020, compared to $0.6 million for the same period in 2019.

- **SG&A Expenses:** For the six months ended June 30, 2020, SG&A expenses were $30.7 million, compared to $35.2 million for the same period in 2019. The decrease was primarily due to lower travel and external spending due to COVID-19 as well as INVELTYS launch-related spending incurred during the first six months of 2019 which was not incurred during the same six month period in 2020. Non-GAAP SG&A expenses were $26.7 million for the six months ended June 30, 2020, compared to $31.4 million for the same period in 2019.

- **R&D Expenses:** For the six months ended June 30, 2020, R&D expenses were $11.5 million, compared to $14.1 million for the same period in 2019. The decrease was primarily due to lower spending on STRIDE 3, partially offset by manufacturing of EYSUVIS which had been expensed as R&D. Non-GAAP R&D expenses were $10.1 million for the six months ended June 30, 2020, compared to $12.5 million for the same period in 2019.

- **Operating Loss**: For the six months ended June 30, 2020, loss from operations was $41.4 million, compared to $46.5 million for the same period in 2019. Non-GAAP operating loss was $36.0 million for the six months ended June 30, 2020, compared to $41.0 million for the same period in 2019.

- **Net Loss:** For the six months ended June 30, 2020, net loss was $45.3 million, or $0.94 per share, compared to a net loss of $49.2 million, or $1.45 per share, for the same period in 2019. Non-GAAP net loss was $39.3 million for the six months ended June 30, 2020, compared to $43.3 million for the same period in 2019. The weighted average number of shares used to calculate net loss per share was 48,232,933 for the six months ended June 30, 2020, and 33,880,494 for the six months ended June 30, 2019.

**Conference Call Information**

Kala will host a live conference call and webcast today, August 6, 2020 at 8:00 a.m. ET to review its second 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: 6999350.

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%, for which a New Drug Application (NDA) is under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) goal date set for October 30, 2020.

**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 company potentially delivering the first prescription medicine for the short-term treatment of dry eye disease, including dry eye flares, plans to increase the number of sales representatives to a total of approximately 100 to 125, INVELTYS prescriptions and revenue returning to growth over time, expectations regarding potential EYSUVIS 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 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)**

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 184,559 | $ 85,449 |
| Total assets | 245,510 | 154,323 |
| Working capital [(1)] | 180,084 | 80,710 |
| Long-term debt, net of discounts | 71,697 | 71,184 |
| Other long-term liabilities | 27,930 | 28,673 |
| Total Stockholders' equity | 128,943 | 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Product revenues, net | $ 833 | $ 2,057 | $ 1,904 | $ 3,443 |
| Costs and expenses: | | | | |
| Cost of product revenues | 759 | 352 | 1,113 | 593 |
| Selling, general and administrative | 15,301 | 17,007 | 30,709 | 35,243 |
| Research and development | 6,053 | 7,108 | 11,487 | 14,067 |
| Total operating expenses | 22,113 | 24,467 | 43,309 | 49,903 |
| Loss from operations | (21,280) | (22,410) | (41,405) | (46,460) |
| Other income (expense): | | | | |
| Interest income | 102 | 646 | 400 | 1,402 |
| Interest expense | (2,134) | (2,061) | (4,262) | (4,155) |
| Net loss | (23,312) | (23,825) | (45,267) | (49,213) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (0.42) | $ (0.70) | $ (0.94) | $ (1.45) |
| Weighted average shares outstanding—basic and diluted | 55,703,882 | 33,882,939 | 48,232,933 | 33,880,494 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Net loss(GAAP) | $ (23,312) | $ (23,825) | $ (45,267) | $ (49,213) |
| Add-back: stock-based compensation expense | 2,493 | 2,621 | 4,988 | 5,094 |
| Add-back: Non-cash interest | 513 | 240 | 513 | 472 |
| Add-back: depreciation | 224 | 218 | 454 | 388 |
| Non-GAAP Net loss | $ (20,082) | $ (20,746) | $ (39,312) | $ (43,259) |
| | | | | |
| Cost of product revenues (GAAP) | $ 759 | $ 352 | $ 1,113 | $ 593 |
| Less: stock-based compensation expense | 9 | 39 | 28 | 41 |
| Less: depreciation | 13 | — | 26 | — |
| Non-GAAP Cost of product revenues | $ 737 | $ 313 | $ 1,059 | $ 552 |
| | | | | |
| Selling, general and administrative expenses (GAAP) | $ 15,301 | $ 17,007 | $ 30,709 | $ 35,243 |
| Less: stock-based compensation expense | 1,933 | 1,787 | 3,686 | 3,651 |
| Less: depreciation | 150 | 142 | 300 | 236 |
| Non-GAAP Selling, general and administrative expenses | $ 13,218 | $ 15,078 | $ 26,723 | $ 31,356 |
| | | | | |
| Research and development expenses (GAAP) | $ 6,053 | $ 7,108 | $ 11,487 | $ 14,067 |
| Less: stock-based compensation expense | 551 | 795 | 1,274 | 1,402 |
| Less: depreciation | 61 | 76 | 128 | 152 |
| Non-GAAP research and development expenses | $ 5,441 | $ 6,237 | $ 10,085 | $ 12,513 |
| | | | | |
| Total operating loss (GAAP) | $ (21,280) | $ (22,410) | $ (41,405) | $ (46,460) |
| Less: stock-based compensation expense | 2,493 | 2,621 | 4,988 | 5,094 |
| Less: depreciation | 224 | 218 | 454 | 388 |
| Non-GAAP total operating loss | $ (18,563) | $ (19,571) | $ (35,963) | $ (40,978) |

**Investors:**
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