# Kala Pharmaceuticals Reports Third Quarter 2018 Financial Results

November 8, 2018

*– INVELTYS ™Launch on Track for Early 2019 –*

*– Strengthened Cash Position; Runway Extends At Least Through Early 2020 –*

*– KPI-121 0.25% NDA Filed for Dry Eye Disease –*

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 8, 2018-- 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, 2018.

"We have made substantial progress over the past few months. In addition to receiving U.S. Food and Drug Administration (FDA) approval for INVELTYS™, we filed a New Drug Application (NDA) for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease and extended our cash runway to include upcoming key milestones," said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. "We remain focused on preparing for commercialization and building our sales force in anticipation of the INVELTYS launch in early 2019. In addition, the STRIDE 3 trial for dye eye disease is enrolling, and we are on track to report topline data in Q4 2019."

**Third Quarter and Recent Highlights:**

**INVELTYS Approved; Launch Targeted for Early 2019:** INVELTYS (loteprednol etabonate ophthalmic suspension) 1% was approved by the FDA on August 22, 2018 as the first twice-daily ocular corticosteroid indicated for the treatment of post-operative inflammation and pain following ocular surgery. All other ocular steroids are approved for four-times-a-day dosing. The Company believes that there is a significant unmet need for an improved regimen that could foster close adherence to the steroid regimen. This is a critical factor for physicians in the post-surgery care of the patient and eventual overall success of the procedure. Kala's market research with ophthalmologists indicates that INVELTYS offers a compelling combination of efficacy, safety and dosing, and that they believe INVELTYS will be an important addition to their treatment options for post-ocular surgery. Kala is preparing for launch and building its commercial team, including hiring a specialty sales force that will focus on eye care professionals in the United States. Kala expects to launch INVELTYS in early 2019.

**NDA Submitted For Dry Eye Disease; STRIDE 3 Study Ongoing:** Following a productive meeting with the FDA, Kala announced its strategy 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.

- In October 2018, Kala submitted an NDA to the FDA, which includes data from one Phase 2 and two Phase 3 efficacy and safety trials studying over 2,000 patients with dry eye disease.
- In addition, based upon the FDA's recommendation, Kala initiated an additional Phase 3 clinical trial in July 2018, STRIDE 3 (STRIDE - Short Term Relief In Dry Eye), 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 study, and that changes made to the inclusion/exclusion criteria of STRIDE 3 based on these analyses will improve the probability of success. The Company expects to report top-line results for STRIDE 3 in the fourth quarter of 2019.

**Completed Financing Transactions to Strengthen Balance Sheet:** In October 2018, Kala strengthened its balance sheet by completing multiple financing transactions. The Company expects these financings will support its efforts to achieve significant milestones including the launch of INVELTYS and top-line data from its ongoing STRIDE 3 trial of KPI-121 0.25%.

- Closed a $110M credit facility from Athyrium Capital Management, LP, a leading healthcare-focused investment firm. The initial $75 million tranche was funded immediately and an additional $35 million of funding will be available upon reaching certain future milestones. A portion of the initial tranche was used to repay in full the Company's prior debt facility.
- Closed an underwritten public offering of 8,625,000 shares of its common stock, including the underwriters' option to purchase additional shares, at a public offering price of $8.25 per share, before offering discounts. The offering resulted in aggregate net proceeds of approximately $66.4 million to Kala.

**Third Quarter 2018 Financial Results**

- Cash Position: As of September 30, 2018, Kala had cash of $74.9 million compared to $114.6 million as of December 31, 2017. The Company believes that the existing cash as of September 30, 2018 combined with the proceeds from the October 2018 financings will extend through at least early 2020.
- R&D Expenses: For the quarter ended September 30, 2018, research and development expenses were $7.0 million compared to $7.0 million for the same period in 2017. A decrease in external costs as a result of the completion of our Phase 3 clinical trials of INVELTYS and KPI-121 0.25% STRIDE 1 and 2 was offset by an increase in costs associated with the KPI-121 0.25% STRIDE 3 trial and an increase in employee-related costs due to the hiring of additional personnel

and stock compensation expense associated with stock options granted in 2018, resulting in a net change of $0.

- G&A Expenses: For the quarter ended September 30, 2018, general and administrative expenses were $8.5 million compared to $2.5 million for the same period in 2017. The increase in general and administrative expenses is primarily attributable to an increase in commercial-related costs as the Company builds its commercial infrastructure in anticipation of the launch of INVELTYS in early 2019, an increase in employee-related costs due to an increase in general and administrative employee headcount to support public company operations and a commercial organization and stock compensation expense associated with stock options granted in 2018.
- Operating Loss: Loss from operations for the quarter ended September 30, 2018 was $15.5 million compared to $9.5 million for the same period in 2017.
- Net Loss: Net loss was $15.6 million, or $0.63 per share, for the quarter ended September 30, 2018, compared to a net loss of $10.2 million, or $0.56 per share, for the same period in 2017.

**About INVELTYS™**

INVELTYS (loteprednol etabonate ophthalmic suspension) 1% is a twice-a-day corticosteroid for the treatment of post-operative inflammation and pain following ocular surgery. INVELTYS utilizes Kala's proprietary AMPPLIFY™ mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration into target tissues of the eye. In preclinical studies, the AMPPLIFY Drug Delivery Technology increased delivery of loteprednol etabonate (LE) into ocular tissues more than three-fold compared to current LE products by facilitating penetration through the tear film mucus. INVELTYS was approved by the FDA on August 22, 2018. Kala believes INVELTYS has a favorable profile for the treatment of inflammation and pain following ocular surgery, due to its twice-a-day dosing regimen. A link to the full product label can be found at: www.inveltys.com.

**About KPI-121 0.25%**

Kala is developing KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease utilizing a two-week course of therapy administered four times a day. Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface and can involve tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. KPI-121 0.25% utilizes Kala's AMPPLIFY mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration of loteprednol etabonate (LE) into target tissue of the eye. In preclinical studies, the AMPPLIFY Drug Delivery Technology increased delivery of LE into ocular tissues more than three-fold compared to current LE products by facilitating penetration through the tear film mucus. Kala has completed one Phase 2 and two Phase 3 clinical trials of KPI-121 0.25%. Kala believes that KPI-121 0.25%'s broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability and safety profile and the potential to be complementary to existing therapies, could result in a favorable profile for the management of dry eye flares and other dry eye associated conditions.

**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.

**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 timing of commercial launch, 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 and its cash runway and the Company's ability to access the second tranche under its credit facility with Athyrium. 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 is consistent with the Company's expectations and market research; whether the FDA will accept the NDA for filing; 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 any such NDA will be approved; the Company's ability to build a specialty sales force and prepare for 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.

**Kala Pharmaceuticals, Inc.**
**Condensed Consolidated Balance Sheets**
**(In thousands)**

**(Unaudited)**

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Cash | $ 74,910 | $ 114,565 |
| Working Capital[(1)] | 67,770 | 100,341 |
| Total Assets | 84,075 | 116,546 |
| Total Stockholders' Equity | 54,934 | 89,679 |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Operating expenses: | | | | |
| Research and development | $ 7,027 | $ 7,018 | $ 20,051 | $ 23,128 |
| General and administrative | 8,469 | 2,516 | 21,102 | 5,607 |
| Total operating expenses | 15,496 | 9,534 | 41,153 | 28,735 |
| Loss from operations | (15,496) | (9,534) | (41,153) | (28,735) |
| Other income (expense): | | | | |
| Interest income | 325 | 194 | 848 | 276 |
| Interest expense | (432) | (212) | (1,214) | (618) |
| Change in fair value of warrant liability | — | (623) | — | (1,844) |
| Total other income (expense) | (107) | (641) | (366) | (2,186) |
| Net loss | $ (15,603) | $ (10,175) | $ (41,519) | $ (30,921) |
| Net loss per share—basic and diluted | $ (0.63) | $ (0.56) | $ (1.69) | $ (4.51) |
| Weighted average shares outstanding—basic and diluted | 24,600,080 | 18,034,278 | 24,570,081 | 6,860,777 |

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