Kala Pharmaceuticals Reports Second Quarter 2018 Financial Results

August 9, 2018

– PDUFA Target Action Date for INVELTYS™ is August 24, 2018 –

– Defined Strategy for KPI-121 0.25% in Dry Eye Disease –

– Strengthened Commercial Team in Preparation for INVELTYS Launch –

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 9, 2018-- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a biopharmaceutical company focused on the development and commercialization of therapies using its proprietary mucus-penetrating particle (MPP) technology with an initial focus on the treatment of eye diseases, today reported financial results for the second quarter ended June 30, 2018.

"Since our last update we have made excellent progress," said Mark Iwicki, Chairman and Chief Executive Officer. "We have defined our strategy for KPI-121 0.25% in dry eye disease and have initiated the STRIDE 3 trial incorporating changes to the design that we believe will improve the probability of success. We have also continued to strengthen our commercial team in preparation for the potential approval and commercialization of INVELTYS, our twice-daily corticosteroid candidate for the treatment of post-operative ocular inflammation and pain."

Recent Highlights

PDUFA Date for INVELTYS of August 24th: The U.S. Food and Drug Administration (FDA) has given INVELTYS a target action date under the Prescription Drug User Fee Act (PDUFA) of August 24, 2018. If approved, INVELTYS could be the first FDA-approved twice-daily ocular corticosteroid indicated for the treatment of post-operative ocular inflammation and pain. INVELTYS utilizes Kala's proprietary MPP technology to enhance penetration into target tissues of the eye, resulting in a favorable treatment profile with a unique twice-daily dosing regimen designed to help maximize patient compliance.

Defined Path for KPI-121 0.25% in Dry Eye Disease: 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 short-term treatment of dry eye disease.

- Kala plans to submit a New Drug Application (NDA) during the second half of 2018 including data from one Phase 2 and two Phase 3 efficacy and safety trials.
- In addition, based upon the FDA's recommendation, Kala has initiated an additional Phase 3 clinical trial, 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 the changes made to the design of STRIDE 3 will improve the probability of success. The Company expects to report top-line results for STRIDE 3 in the fourth quarter of 2019.

Strengthened Commercial Organization: Kala continues to strengthen its commercial team in anticipation of the potential launch of INVELTYS. During the second quarter, Kala hired five seasoned industry leaders for key roles. Kala plans to continue growing its commercial organization in preparation for the potential launch of INVELTYS, including beginning to hire its own specialty ophthalmology sales force.

Second Quarter 2018 Financial Results

- Cash Position: As of June 30, 2018, Kala had cash of $91.2 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 the next twelve months.
- R&D Expenses: For the quarter ended June 30, 2018, research and development expenses were $7.4 million compared to $8.1 million for the same period in 2017. The decrease in research and development expenses is primarily due to a $1.9 million decrease in external costs associated with the completion of our Phase 3 clinical trials of INVELTYS for the treatment of inflammation and pain following cataract surgery and KPI-121 0.25% for the short-term treatment of dry eye disease. This decrease was offset by a $1.4 million increase in employee-related costs due to the additional hiring of clinical and regulatory personnel, overall merit increases and an increase in stock compensation expense related to stock option grants.
- G&A Expenses: For the quarter ended June 30, 2018, general and administrative expenses were $7.2 million compared to $1.6 million for the same period in 2017. The increase in general and administrative expenses is attributable to a $2.5 million increase in employee-related costs, consisting of a $1.3 million increase in general and administrative employee headcount expense and merit increases and a $1.2 million increase in stock compensation expenses related to stock options granted during 2018. In addition, the Company incurred a $1.2 million increase in costs associated with legal, accounting and finance activities, primarily as a result of operating as a public company, and a $1.9 million increase in commercial-related costs as the Company advances its product candidates toward regulatory approval.
- Operating Loss: Loss from operations for the quarter ended June 30, 2018 was $14.5 million compared to $9.6 million for the same period in 2017.
- Net Loss: Net loss was $14.6 million, or $0.60 per share, for the quarter ended June 30, 2018, compared to a net loss of

$11.0 million, or $9.30 per share, for the same period in 2017.

About INVELTYS™

INVELTYS™ (KPI-121 1%) is a twice-a-day corticosteroid for the treatment of inflammation and pain following ocular surgery. INVELTYS utilizes Kala's proprietary mucus-penetrating particle (MPP) technology to enhance penetration into target tissues of the eye. In preclinical studies, MPP increased delivery of the active ingredient, loteprednol etabonate (LE), into ocular tissues more than three-fold by facilitating penetration through the tear film mucus. Two Phase 3 clinical trials have been successfully completed for INVELTYS and statistical significance was achieved for both primary efficacy endpoints in both trials. In each of these trials, INVELTYS was well tolerated with no treatment-related serious adverse events observed. Kala believes INVELTYS has a favorable profile for the treatment of inflammation and pain following ocular surgery. The NDA for INVELTYS was accepted for review by the FDA in January 2018 and given a target action date under the Prescription Drug User Fee Act (PDUFA) of August 24, 2018. The brand name for KPI-121 1%, INVELTYS, has been conditionally approved by the FDA.

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 mucus-penetrating particle (MPP) technology to enhance penetration of the active ingredient, loteprednol etabonate (LE), into target tissue of the eye. In preclinical studies, MPP 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 complement existing therapies, could result in a favorable profile for the management of dry eye flares and other dry eye associated conditions.

About Kala

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary mucus-penetrating particle (MPP) technology, with an initial focus on the treatment of eye diseases. Kala has applied the MPP technology to a corticosteroid designed for ocular applications, resulting in two lead product candidates. Kala’s product candidates are INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery, for which an NDA has been accepted for review by the FDA with a target PDUFA date of August 24, 2018, and 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 the Company's product candidates including INVELTYS (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, INVELTYS being well-received by physicians and patients as a twice-daily ocular corticosteroid, the target action date under the PDUFA of August 24, 2018 for INVELTYS, the Company’s belief that the changes made to the design of STRIDE 3 will improve the probability of success for the trial, the Company’s existing cash on hand enabling it to fund operations through at least the next twelve months, the anticipated reporting of STRIDE 3 topline results in the fourth quarter of 2019, and the Company’s plans to file an NDA for KPI-121 0.25% with the FDA during the second half of 2018. 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 data from the Company’s Phase 3 clinical trials of KPI-121 0.25% will warrant submission and filing of an NDA on the timeline expected, or at all; whether any additional clinical trials will be initiated or required for KPI-121 0.25% prior to submission or filing of an NDA, or at all, and whether any such NDA will be accepted for filing and/or approved; the Company’s ability to initiate and complete clinical trials on the timeline expected, or at all; whether the results of clinical trials will be positive and/or replicate the results from earlier clinical development and/or preclinical studies; that post-hoc analyses are normally given less weight by regulatory authorities than pre-specified analyses; whether the Company’s NDA for INVELTYS will be approved by its PDUFA date, or at all; uncertainties inherent in the availability and timing of data from ongoing clinical trials; uncertainties related to the Company’s ability to obtain regulatory approvals to conduct trials or to market products; the Company’s ability to build a sales force and prepare for commercial launch 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 the Company's product candidates; 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 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)

	June 30, 2018	December 31, 2017

Cash	$ 91,205	$ 114,565
Working Capital[(1)]	82,539	100,341
Total Assets	95,590	116,546
Total Stockholders' Equity	68,093	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.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 7,368	$ 8,071	$ 13,024	$ 16,110
General and administrative	7,151	1,559	12,633	3,091
Total operating expenses	14,519	9,630	25,657	19,201
Loss from operations	(14,519)	(9,630)	(25,657)	(19,201)
Other income (expense):				
Interest income	313	37	522	83
Interest expense	(414)	(208)	(781)	(406)
Change in fair value of warrant liability	-	(1,185)	-	(1,221)
Total other income (expense)	(101)	(1,356)	(259)	(1,544)
Net loss	$ (14,620)	$ (10,986)	$ (25,916)	$ (20,745)
Net loss per share—basic and diluted	$ (0.60)	$ (9.30)	$ (1.06)	$ (17.56)
Weighted average shares outstanding—basic and diluted	24,567,103	1,181,429	24,554,834	1,181,429

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