Kala Pharmaceuticals Reports Third Quarter 2020 Financial Results and Provides Corporate Update

November 5, 2020

-- Obtained FDA Approval for EYSUVIS™, First Prescription Therapy Approved Specifically for the Short-Term Treatment of the Signs and Symptoms of Dry Eye Disease --
-- EYSUVIS Expected to Begin Shipping to Wholesalers by End of 2020 --
-- 3Q 2020 INVELTYS® Net Revenue of $2.2 Million --
-- Cash Position and INVELTYS Revenue Expected to Provide Runway Into at Least 3Q 2022
EYSUVIS Revenue Expected to Provide Additional Runway --
-- Conference Call and Webcast at 8:00 a.m. ET --

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 5, 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 third quarter ended September 30, 2020 and provided a corporate update.

"We are pleased with our third quarter results and the fourth quarter of 2020 is off to a strong start following the recent FDA approval of EYSUVIS, which we plan to launch by year end as the first prescription therapy specifically designed to address the short-term treatment needs of people living with dry eye disease," said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. "EYSUVIS, which is enabled by Kala's proprietary AMPPLIFY technology, is well-suited to address a significant unmet need for eye care professionals and patients who want an FDA-approved, safe, effective and fast-acting therapy for dry eye disease. We are in a strong financial position to commercialize EYSUVIS along with INVELTYS and we look forward to ensuring that patients and eye care professionals have access to these innovative therapies."

Third Quarter and Recent Highlights:

EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25%: On October 26, 2020, the U.S. Food and Drug Administration (FDA) approved EYSUVIS for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease (DED). The FDA granted approval for EYSUVIS based on results from four clinical trials that enrolled over 2800 patients and demonstrated rapid and significant improvements in both the signs and symptoms of dry eye disease. EYSUVIS was well-tolerated across the four trials, with adverse events and intraocular pressure increases comparable to that observed with vehicle (placebo).

Kala estimates that DED impacts approximately 38 million people in the U.S. and that approximately 17 million people have been diagnosed with DED and are under the care of an eye care professional. Based on Kala's research, 75% of patients have never tried a prescription therapy and only approximately 10% of patients are currently on a prescription dry eye medication. Kala estimates that approximately 80 percent of dry eye patients experience episodic symptoms (flares) and EYSUVIS is the first FDA-approved therapeutic with a clinical profile well-suited for providing fast-acting relief from these dry eye flares.

For the EYSUVIS launch, Kala will leverage its experienced and established ophthalmic team that successfully launched INVELTYS in January 2019. Kala will target ophthalmologists and optometrists who treat the majority of dry eye patients and are responsible for over 85% of market prescriptions. The Company plans to expand its sales force to 90 sales representatives by year-end, with additional expansion to approximately 125 sales representatives planned in 2021, pending the status of the COVID-19 pandemic. Launch efforts are underway and EYSUVIS has received strong positive feedback from eye care professionals as a first-line prescription therapy for their patients with dry eye disease. Kala expects to begin shipping EYSUVIS to wholesalers in the U.S. by the end of 2020 and for the full promotional launch to begin in January of 2021.

INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%: Approximately 38,000 INVELTYS prescriptions were reported by Symphony Health in the third quarter of 2020, which represents an increase of approximately 84% compared to the second quarter of 2020. Relatedly, cataract procedures increased in the third quarter compared to the second quarter of 2020, reflecting the resumption of ocular surgeries as COVID-19-related restrictions on elective procedures began to relax late in the second quarter.

Based on the speed with which ocular surgeries have continued to be rescheduled, Kala continues to believe that INVELTYS prescriptions and revenue will continue to grow over time. However, the Company is unable to project the specific timing or quantify the specific potential impact on future revenues given the continued uncertainty around the impact and duration of the restrictions related to COVID-19. Kala expects that net revenues will be negatively impacted for the full year 2020 and could continue to be negatively impacted into 2021.

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 Kala's GAAP to non-GAAP financial measures, please refer to the tables at the end of this press release.

- **Cash Position:** As of September 30, 2020, Kala had cash, cash equivalents and short-term investments of $159.1 million, compared to $85.4 million as of December 31, 2019. This increase reflects aggregate gross proceeds of approximately $146.9 million received from Kala's 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 operations. Kala anticipates that its existing cash, cash equivalents and short-term investments, along with anticipated sales of INVELTYS, will enable it to fund its operations into at least the third quarter of 2022. Kala expects revenue anticipated to be generated from sales of EYSUVIS will provide additional cash runway.

Third Quarter 2020 Financial Results

- **Net Product Revenue**: For the quarter ended September 30, 2020, Kala reported net product revenue of $2.2 million relating to sales of INVELTYS, compared to $1.5 million in the third quarter of 2019, an increase of $0.7 million.
- **Cost of Product Revenues**: For the quarter ended September 30, 2020, cost of product revenues was $0.7 million, consistent with the same period in 2019. Non-GAAP cost of product revenues was $0.7 million for the quarter ended September 30, 2020, compared to $0.6 million for the same period in 2019.
- **SG&A Expenses:** For the quarter ended September 30, 2020, selling, general and administrative (SG&A) expenses were $23.9 million, compared to $15.3 million for the same period in 2019. The increase was primarily due to an increase in external sales and marketing costs related to preparation for the launch of EYSUVIS and increased stock-based compensation costs. Non-GAAP SG&A expenses were $20.5 million for the quarter ended September 30, 2020, compared to $13.5 million for the same period in 2019.
- **R&D Expenses:** For the quarter ended September 30, 2020, research and development (R&D) expenses were $3.5 million, compared to $7.1 million for the same period in 2019. The decrease was primarily due to a decrease in external spend on STRIDE 3, Kala's Phase 3 clinical trial of EYSUVIS. Non-GAAP R&D expenses were $2.4 million for the quarter ended September 30, 2020, compared to $6.1 million for the same period in 2019.
- **Operating Loss**: For the quarter ended September 30, 2020, loss from operations was $25.8 million, compared to $21.6 million for the same period in 2019. Non-GAAP operating loss was $21.4 million for the quarter ended September 30, 2020, compared to $18.8 million for the same period in 2019.
- **Net Loss:** For the quarter ended September 30, 2020, net loss was $27.9 million, or $0.50 per share, compared to a net loss of $23.2 million, or $0.68 per share, for the same period in 2019. Non-GAAP net loss was $23.2 million for the quarter ended September 30, 2020, compared to $20.1 million for the same period in 2019. The weighted average number of shares used to calculate net loss per share was 56,030,717 for the quarter ended September 30, 2020, and 34,168,282 for the quarter ended September 30, 2019.

Nine Months Ended September 30, 2020 Financial Results

- **Net Product Revenue**: For the nine months ended September 30, 2020, Kala reported net product revenue of $4.1 million relating to sales of INVELTYS, compared to $4.9 million for the same period in 2019, a decrease of $0.8 million. Net revenues in the first nine 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.
- **Cost of Product Revenues**: For the nine months ended September 30, 2020, cost of product revenues was $1.8 million, compared to $1.3 million for the same period in 2019. Included in cost of product revenues for the nine months ended September 30, 2020, and due to COVID-19, was a reserve of $0.5 million for excess inventory. Non-GAAP cost of product revenues was $1.7 million for the nine months ended September 30, 2020, compared to $1.2 million for the same period in 2019.
- **SG&A Expenses:** For the nine months ended September 30, 2020, SG&A expenses were $54.6 million, compared to $50.5 million for the same period in 2019. The increase was primarily due to an increase in external sales and marketing costs related to preparation for the launch of EYSUVIS, increased administrative and professional fees and increased stock-based compensation costs, partially offset by lower travel due to COVID-19. Non-GAAP SG&A expenses were $47.2 million for the nine months ended September 30, 2020, compared to $44.9 million for the same period in 2019.
- **R&D Expenses:** For the nine months ended September 30, 2020, R&D expenses were $15.0 million, compared to $21.1 million for the same period in 2019. The decrease was primarily due to a decrease in external spend on STRIDE 3, Kala's Phase 3 clinical trial of EYSUVIS. Non-GAAP R&D expenses were $12.5 million for the nine months ended September 30, 2020, compared to $18.6 million for the same period in 2019.
- **Operating Loss**: For the nine months ended September 30, 2020, loss from operations was $67.2 million, compared to $68.0 million for the same period in 2019. Non-GAAP operating loss was $57.3 million for the nine months ended September 30, 2020, compared to $59.7 million for the same period in 2019.
- **Net Loss:** For the nine months ended September 30, 2020, net loss was $73.2 million, or $1.44 per share, compared to a net loss of $72.4 million, or $2.13 per share, for the same period in 2019. Non-GAAP net loss was $62.5 million for the nine months ended September 30, 2020, compared to $63.4 million for the same period in 2019. The weighted average number of shares used to calculate net loss per share was 50,851,167 for the nine months ended September 30, 2020, and 33,977,477 for the nine months ended September 30, 2019.

Conference Call Information:
Kala will host a live conference call and webcast today, November 5, 2020 at 8:00 a.m. ET to review its third 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: 9199546. 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 EYSUVIS:
EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% is approved for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. EYSUVIS utilizes Kala's AMPPLIFY mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration of loteprednol etabonate (LE) into target tissue of the ocular surface. EYSUVIS was approved by the FDA on October 26, 2020. Kala believes that EYSUVIS' 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, offer a differentiated product profile for the short-term treatment of dry eye disease, including the management of dry eye flares.

EYSUVIS, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. The initial prescription and each renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, as well as defects in visual acuity and fields of vision. Corticosteroids should be used with caution in the presence of glaucoma. Renewal of the medication order should be made by a physician only after examination of the patient and evaluation of the IOP. Use of corticosteroids may result in posterior subcapsular cataract formation. Use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, corticosteroids may mask infection or enhance existing infection. Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion must be considered in any persistent corneal ulceration where a corticosteroid has been used or is in use. The most common adverse drug reaction following the use of EYSUVIS for two weeks was instillation site pain, which was reported in 5% of patients.

Please see full Prescribing Information at www.eysuvis.com.

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 of loteprednol etabonate (LE) into target tissues 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 mucins. 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.

INVELTYS, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. A prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored. Use of corticosteroids may result in posterior subcapsular cataract formation. Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining. Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. In clinical trials, the most common adverse drug reactions were eye pain (1%) and posterior capsular opacification (1%). These reactions may have been the consequence of the surgical procedure.

Please see the full Prescribing Information available at: www.inveltys.com.

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 October 2020 approval of EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term (up to two weeks) treatment of signs and symptoms of dry eye disease and the January 2019 launch of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery.

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 expectation to begin shipping EYSUVIS to wholesalers in the U.S. by the end of 2020 and for the full promotional launch to begin in January of 2021, the Company having approximately 90 sales professionals in place by year-end and growing to 125 sales representatives in 2021, pending the status of the COVID-19 pandemic, to support the launch of EYSUVIS, INVELTYS prescriptions and revenue returning to growth over time, the commercial opportunity for EYSUVIS and INVELTYS, 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 EYSUVIS and INVELTYS; whether the Company will be able to successfully implement its commercialization plans for EYSUVIS and INVELTYS; whether the market opportunity for EYSUVIS and INVELTYS is consistent with the Company’s expectations and market research; the Company’s ability execute on the commercial launch of EYSUVIS 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 EYSUVIS, INVELTYS and 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 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)

	September 30, 2020	**December 31, 2019**
Cash, cash equivalents and short-term investments	$ 159,120	$ 85,449
Total assets	225,096	154,323
Working capital [(1)]	158,606	80,710
Long-term debt, net of discounts	71,967	71,184
Other long-term liabilities	27,549	28,673
Total Stockholders’ equity	106,030	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	**Nine Months Ended**

	September 30,		September 30,	
	2020	2019	2020	2019
Product revenues, net	$ 2,220	$ 1,451	$ 4,124	$ 4,894
Costs and expenses:				
Cost of product revenues	701	668	1,814	1,261
Selling, general and administrative	23,893	15,280	54,602	50,523
Research and development	3,468	7,070	14,955	21,137
Total operating expenses	28,062	23,018	71,371	72,921
Loss from operations	(25,842)	(21,567)	(67,247)	(68,027)
Other income (expense):				
Interest income	51	571	451	1,973
Interest expense	(2,157)	(2,180)	(6,419)	(6,335)
Net loss	(27,948)	(23,176)	(73,215)	(72,389)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.50)	$ (0.68)	$ (1.44)	$ (2.13)
Weighted average shares outstanding—basic and diluted	56,030,717	34,168,282	50,851,167	33,977,477

Kala Pharmaceuticals, Inc.

Reconciliation of GAAP to Non-GAAP Financial Measures

(In thousands)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Net loss (GAAP)	$ (27,948)	$ (23,176)	$ (73,215)	$ (72,389)
Add-back: stock-based compensation expense	4,261	2,572	9,249	7,666

Add-back: Non-cash interest	269	237	782	709
Add-back: depreciation	220	226	674	614
Non-GAAP Net loss	$ (23,198)	$ (20,141)	$ (62,510)	$ (63,400)
Cost of product revenues (GAAP)	$ 701	$ 668	$ 1,814	$ 1,261
Less: stock-based compensation expense	32	60	60	101
Less: depreciation	13	2	39	2
Non-GAAP Cost of product revenues	$ 656	$ 606	$ 1,715	$ 1,158
Selling, general and administrative expenses (GAAP)	$ 23,893	$ 15,280	$ 54,602	$ 50,523
Less: stock-based compensation expense	3,244	1,599	6,930	5,250
Less: depreciation	150	140	450	376
Non-GAAP Selling, general and administrative expenses	$ 20,499	$ 13,541	$ 47,222	$ 44,897
Research and development expenses (GAAP)	$ 3,468	$ 7,070	$ 14,955	$ 21,137
Less: stock-based compensation expense	985	913	2,259	2,315
Less: depreciation	57	84	185	236
Non-GAAP research and development expenses	$ 2,426	$ 6,073	$ 12,511	$ 18,586
Total operating loss (GAAP)	$ (25,842)	$ (21,567)	$ (67,247)	$ (68,027)
Less: stock-based compensation expense	4,261	2,572	9,249	7,666
Less: depreciation	220	226	674	614
Non-GAAP total operating loss	$ (21,361)	$ (18,769)	$ (57,324)	$ (59,747)

View source version on businesswire.com: https://www.businesswire.com/news/home/20201105005262/en/

Investors:
Hannah Deresiewicz
hannah.deresiewicz@sternir.com
212-362-1200

Source: Kala Pharmaceuticals, Inc.