Kala Pharmaceuticals Reports First Quarter 2021 Financial Results and Provides Corporate Update

May 5, 2021

-- Achieved $3.3 Million in Net Revenue in First Quarter --

-- Launched EYSUVIS® and Expanded Commercial Coverage to More than 69 Million Commercial Lives --

-- New Credit Facility Provides up to $125M --

-- Cash Runway Projected for at Least Two Years --

-- Conference Call and Webcast at 8:00 a.m. ET --

WATERTOWN, Mass.--(BUSINESS WIRE)--May 5, 2021-- 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 first quarter ended March 31, 2021 and provided a corporate update.

“We are early in the launch of EYSUVIS and encouraged by our progress to establish the product as the first and only prescription therapy specifically for the short-term treatment of dry eye disease. We have secured market access for approximately 43 percent of all commercial lives and are pleased with the early launch metrics and feedback from eye care professionals who view EYSUVIS as a first-line treatment option for a range of patients suffering from dry eye flares,” said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. “The new credit facility announced today helps extend our projected cash runway to at least two years, strengthening our financial position to invest across our business as we build on early EYSUVIS momentum, continue to promote INVELTYS and advance our pipeline of new chemical entities targeted to address front and back of the eye diseases.”

First Quarter and Recent Business Highlights:

EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25%: EYSUVIS became commercially available in January 2021 as the first and only FDA-approved medicine for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. Data from Symphony Health and the EYSUVIS patient hub indicate that more than 11,600 EYSUVIS prescriptions were filled between early January 2021 and April 23, 2021. Data also indicates that more than 2,000 unique prescribers have written prescriptions for EYSUVIS for the same time period. Kala currently has a sales force of 91 ophthalmic sales professionals. Kala plans to expand this sales force to approximately 105 by the start of the third quarter of 2021, with a subsequent expansion to 125 expected by year-end, pending continued growth in payer coverage and the status of the COVID-19 pandemic.

To date, Kala has secured coverage for more than 69 million commercial lives, which represents approximately 43 percent of all commercially insured lives. In February 2021, EYSUVIS was added to Express Scripts’ National Preferred, Basic and High Performance Formularies and, effective May 15, 2021, EYSUVIS will be added to the Cigna commercial formulary. Kala continues to engage in contract discussions with other commercial health plans and expects to further expand formulary coverage in the coming months.

INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%: Approximately 37,000 INVELTYS prescriptions were reported by Symphony Health in the first quarter of 2021, compared to 41,000 prescriptions reported in the fourth quarter of 2020. Kala continues to believe that INVELTYS prescriptions and revenues will 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 COVID-19 pandemic on elective procedures, which includes ocular surgeries.

Development-Stage Pipeline: Kala is progressing a pipeline of preclinical development programs targeted to address front and back of the eye diseases. These programs, all of which are new chemical entities (NCEs), include selective glucocorticoid receptor modulators (SEGRMs), which are a novel class of therapies designed to modify the downstream activity of the glucocorticoid receptor to exhibit the anti-inflammatory and immunomodulatory properties of corticosteroids while potentially avoiding the typical safety concerns of steroids; and a receptor Tyrosine Kinase Inhibitor program (rTKI) for the treatment of retinal diseases, including wet age-related macular degeneration (wet AMD). Kala owns all intellectual property and worldwide rights to these pipeline candidates.

New Credit Facility: On May 4, 2021, Kala entered into an agreement with Oxford Finance that provides it with a credit facility totaling up to $125 million and replaces the previous $75 million facility. The new credit facility includes an initial $80 million tranche that was funded immediately and Kala has two additional tranches available upon meeting certain revenue targets. Under the agreement, Kala will begin principal payments in December 2024 at the earliest, which is more than two years beyond Kala’s previous credit facility. Additional information regarding the new credit facility is available in the Form 8-K filed by Kala this morning.

Morgan Stanley & Co. LLC acted as the sole placement agent on the transaction.

Financial Results:

The financial results below contain both GAAP and non-GAAP financial measures. The non-GAAP financial measures exclude stock-based compensation expense and non-cash interest expense and depreciation and amortization. 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 March 31, 2021, Kala had cash, cash equivalents and short-term investments of $156.0 million, compared to $153.5 million as of December 31, 2020. This increase primarily reflects net proceeds of $34.7 million received from sales of common stock under

Kala's at-the-market (ATM) offering program in the three months ended March 31, 2021, partially offset by cash used in operations. Kala anticipates that its cash resources as of March 31, 2021, together with anticipated revenue from EYSUVIS and INVELTYS, will enable it to fund its operations for at least two years.

First Quarter 2021 Financial Results

- **Net Product Revenues**: For the quarter ended March 31, 2021, Kala reported net product revenues of $3.3 million, consisting of $1.63 million of net revenue from INVELTYS sales and $1.64 million of net revenue from EYSUVIS sales, compared to $1.1 million from INVELTYS sales for the same period in 2020.

- **Cost of Product Revenues**: For the quarter ended March 31, 2021, cost of product revenues was $0.8 million, compared to $0.4 million for the same period in 2020. The increase was primarily due to units of EYSUVIS sold as well as the increase in total INVELTYS units sold during the three months ended March 31, 2021 compared to the three months ended March 31, 2020. Non-GAAP cost of product revenues was $0.7 million for the quarter ended March 31, 2021, compared to $0.3 million for the same period in 2020.

- **SG&A Expenses:** For the quarter ended March 31, 2021, selling, general and administrative (SG&A) expenses were $27.7 million, compared to $15.4 million for the same period in 2020. The increase was primarily due to an increase in costs as a result of the launch of EYSUVIS, including expansion of the sales force, and stock-based compensation costs. Non-GAAP SG&A expenses were $23.8 million for the quarter ended March 31, 2021, compared to $13.5 million for the same period in 2020.

- **R&D Expenses:** For the quarter ended March 31, 2021, research and development (R&D) expenses were $3.1 million, compared to $5.4 million for the same period in 2020. 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 $2.1 million for the quarter ended March 31, 2021, compared to $4.6 million for the same period in 2020.

- **Operating Loss**: For the quarter ended March 31, 2021, loss from operations was $28.3 million, compared to $20.1 million for the same period in 2020. Non-GAAP operating loss was $23.4 million for the quarter ended March 31, 2021, compared to $17.4 million for the same period in 2020.

- **Net Loss:** For the quarter ended March 31, 2021, net loss was $30.4 million, or $0.49 per share, compared to a net loss of $22.0 million, or $0.54 per share, for the same period in 2020. Non-GAAP net loss was $25.2 million for the quarter ended March 31, 2021, compared to $19.0 million for the same period in 2020. The weighted average number of shares used to calculate net loss per share was 61.7 million for the quarter ended March 31, 2021, and 40.8 million for the quarter ended March 31, 2020.

Conference Call Information:

Kala will host a live conference call and webcast today, May 5, 2021 at 8:00 a.m. ET to review its first quarter 2021 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: 2777865.

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 expense and depreciation and amortization. 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. In preclinical studies, the AMPPLIFY Drug Delivery Technology increased delivery of LE into target ocular tissues more than three-fold compared to an active LE comparator by facilitating penetration through the tear film mucins. 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 target ocular tissues more than three-fold compared to an active LE comparator 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 full Prescribing Information 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 (MPP) Drug Delivery Technology to two ocular therapies, 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 INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery. The Company also has a pipeline of pre-clinical development programs targeted to address unmet medical needs, including both front and back of the eye diseases. For more information on Kala, please visit www.kalarx.com.

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 building on early EYSUVIS momentum, the Company's plans to expand its sales force to approximately 105 ophthalmic sales professionals by the start of the third quarter of 2021, with a subsequent expansion to 125 expected by year-end, pending continued growth in payer coverage and the status of the COVID-19 pandemic, the Company's belief that INVELTYS prescriptions and revenues will grow over time, the Company progressing its pipeline of preclinical development programs targeted to address front and back of the eye diseases, and the Company's expectations regarding its use of cash, cash runway and anticipated 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 the Company's 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, including obtaining Commercial and Medicare Part D payor coverage; 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 and INVELTYS; 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)

	March 31, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 155,985	$ 153,540
Total assets	229,827	221,606
Working capital [1]	159,076	149,154
Long-term debt, net of discounts	72,521	72,243
Other long-term liabilities	27,525	27,143
Total stockholders' equity	109,792	99,995

(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.

	Three Months Ended March 31, 2021	2020
Product revenues, net	$ 3,266	$ 1,071
Costs and expenses:		
Cost of product revenues	755	354
Selling, general and administrative	27,699	15,408
Research and development	3,126	5,434
Total operating expenses	31,580	21,196
Loss from operations	(28,314)	(20,125)
Other income (expense):		
Interest income	43	298
Interest expense	(2,141)	(2,128)
Net loss	(30,412)	(21,955)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.49)	$ (0.54)
Weighted average shares outstanding—basic and diluted	61,655,867	40,761,984

	Three Months Ended March 31, 2021	2020
Net loss (GAAP)	$ (30,412)	$ (21,955)
Add-back: stock-based compensation expense	4,702	2,497
Add-back: non-cash interest	278	253
Add-back: depreciation and amortization	248	230
Non-GAAP net loss	$ (25,184)	$ (18,975)
Cost of product revenues (GAAP)	$ 755	$ 354
Less: stock-based compensation expense	34	20
Less: depreciation and amortization	13	13
Non-GAAP cost of product revenues	$ 708	$ 321
Selling, general and administrative expenses (GAAP)	$ 27,699	$ 15,408
Less: stock-based compensation expense	3,702	1,754
Less: depreciation and amortization	181	150
Non-GAAP selling, general and administrative expenses	$ 23,816	$ 13,504
Research and development expenses (GAAP)	$ 3,126	$ 5,434
Less: stock-based compensation expense	966	723

Less: depreciation and amortization	54	67
Non-GAAP research and development expenses	$ 2,106	$ 4,644
Total operating loss (GAAP)	$ (28,314)	$ (20,125)
Add-back: stock-based compensation expense	4,702	2,497
Add-back: depreciation and amortization	248	230
Non-GAAP total operating loss	$ (23,364)	$ (17,398)

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Investors:
Niranjan Kameswaran
niranjan.kameswaran@kalarx.com

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

Source: Kala Pharmaceuticals, Inc.