



Kala Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

February 25, 2021

-- Launched EYSUVIS™, First and Only Prescription Therapy Approved Specifically for Short-Term Treatment of the Signs and Symptoms of Dry Eye Disease --

-- Progressing Pipeline Programs to Address Front and Back of Eye Diseases --

-- Cash Position and INVELTYS Revenue Expected to Provide Runway Into at Least 4Q 2022; EYSUVIS Revenue Expected to Provide Additional Runway --

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

WATERTOWN, Mass.--(BUSINESS WIRE)--Feb. 25, 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 fourth quarter and full year ended December 31, 2020 and provided a corporate update.

"2020 was a pivotal year for Kala, highlighted by U.S. Food and Drug Administration (FDA) approval of EYSUVIS, the first and only prescription therapy specifically for the short-term treatment of dry eye disease and our second product approval in as many years. Now, with launch activities underway, we are seeing prescription growth and pleased to have secured formulary access with Express Scripts as we continue to broaden our managed care coverage," said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. "As we begin the new year, we are operating from a position of strength. We believe we are well-funded, with sufficient resources to support our commercial efforts and investments in our pipeline, which includes several preclinical programs with the potential to address multiple front and back of the eye diseases."

Fourth Quarter and Recent 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. EYSUVIS is now available through national and regional U.S. pharmaceutical distribution centers, as well as local pharmacies and for home delivery. Kala's ophthalmic sales force, which was expanded during the fourth quarter of 2020 and now consists of 91 sales professionals, is actively calling on eye care professionals, including both ophthalmologists and optometrists.

As of February 12, which marked six weeks of full promotional launch, an aggregate of more than 2,200 EYSUVIS prescriptions were filled by over 550 unique prescribers. These figures reflect data from both Symphony Health and the EYSUVIS I-Save program, Kala's patient hub. Additionally, in February 2021, EYSUVIS was added to Express Scripts' National Preferred, Basic and High Performance Formularies. Kala continues to engage in contract discussions with other commercial and Medicare Part D health plans and expects to further expand formulary coverage in the coming weeks and months.

INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%: Approximately 41,000 INVELTYS prescriptions were reported by Symphony Health in the fourth quarter of 2020, which represents an increase of approximately eight percent compared to the third quarter of 2020. For the full year 2020, INVELTYS prescriptions grew approximately 11% over the full year 2019.

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. Kala expects that net revenues could continue to be negatively impacted in 2021.

Preclinical Development Program 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: (1) 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; (2) a receptor Tyrosine Kinase Inhibitor program (rTKI) for the treatment of retinal diseases, including wet age-related macular degeneration (wet AMD); and (3) novel steroids designed to target the ocular surface and thus have the potential to have fewer side effects compared to traditional topical steroids. Kala owns all intellectual property and worldwide rights to these pipeline candidates.

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 December 31, 2020, Kala had cash, cash equivalents and short-term investments of \$153.5 million, compared to \$85.4 million as of December 31, 2019. This increase reflects net proceeds of approximately \$158.6 million received from Kala's underwritten public offering of common stock in March 2020 and sales of common stock under its at-the-market (ATM) offering program in 2020, partially offset by cash used in operations. Kala anticipates that its cash resources as of December 31, 2020, together with anticipated INVELTYS revenue and the \$18.2 million in net proceeds raised in January 2021 under the Company's ATM offering program, will enable it to fund its operations into at least the fourth quarter of 2022. Kala expects anticipated revenue generated from sales of EYSUVIS to provide additional cash runway.

Fourth Quarter 2020 Financial Results

- **Net Product Revenues:** For the quarter ended December 31, 2020, Kala reported net product revenues of \$2.2 million, consisting of \$1.9 million of net revenue from INVELTYS sales and \$0.3 million from EYSUVIS sales, which we began shipping in late December 2020, compared to \$1.2 million from INVELTYS for the same period in 2019, an increase of \$1.0 million.

- **Cost of Product Revenues:** For the quarter ended December 31, 2020, cost of product revenues was \$1.4 million, compared to \$0.7 million for the same period in 2019. Included in cost of product revenues and due to COVID-19, was a reserve of \$0.5 million for excess inventory of INVELTYS. Non-GAAP cost of product revenues was \$1.3 million for the quarter ended December 31, 2020, compared to \$0.6 million for the same period in 2019.

- **SG&A Expenses:** For the quarter ended December 31, 2020, selling, general and administrative (SG&A) expenses were \$26.5 million, compared to \$14.5 million for the same period in 2019. The increase was primarily due to an increase in costs related to preparation for the launch of EYSUVIS, including expansion of the sales force, and stock-based compensation costs. Non-GAAP SG&A expenses were \$23.1 million for the quarter ended December 31, 2020, compared to \$12.7 million for the same period in 2019.

- **R&D Expenses:** For the quarter ended December 31, 2020, research and development (R&D) expenses were \$3.4 million, compared to \$6.1 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 \$2.5 million for the quarter ended December 31, 2020, compared to \$5.5 million for the same period in 2019.

- **Operating Loss:** For the quarter ended December 31, 2020, loss from operations was \$29.0 million, compared to \$20.2 million for the same period in 2019. Non-GAAP operating loss was \$24.7 million for the quarter ended December 31, 2020, compared to \$17.6 million for the same period in 2019.

- **Net Loss:** For the quarter ended December 31, 2020, net loss was \$31.1 million, or \$0.55 per share, compared to a net loss of \$22.0 million, or \$0.63 per share, for the same period in 2019. Non-GAAP net loss was \$26.5 million for the quarter ended December 31, 2020, compared to \$19.2 million for the same period in 2019. The weighted average number of shares used to calculate net loss per share was 56.9 million for the quarter ended December 31, 2020, and 34.9 million for the quarter ended December 31, 2019.

Full Year Ended December 31, 2020 Financial Results

- **Net Product Revenues:** For the full year ended December 31, 2020, Kala reported net product revenues of \$6.4 million, consisting of \$6.1 million in net revenue from INVELTYS sales and \$0.3 million in net revenue from EYSUVIS sales, compared to \$6.1 million from INVELTYS sales for the same period in 2019, an increase of \$0.3 million.

- **Cost of Product Revenues:** For the full year ended December 31, 2020, cost of product revenues was \$3.2 million, compared to \$2.0 million for the same period in 2019. Included in cost of product revenues for the full year ended December 31, 2020, and due to COVID-19, was a reserve of \$1.0 million for excess inventory of INVELTYS. Non-GAAP cost of product revenues was \$3.0 million for the full year ended December 31, 2020, compared to \$1.7 million for the same period in 2019.

- **SG&A Expenses:** For the full year ended December 31, 2020, SG&A expenses were \$81.1 million, compared to \$65.0 million for the same period in 2019. The increase was primarily due to an increase in costs related to preparation for the launch of EYSUVIS, including expansion of the sales force and stock-based compensation costs. Non-GAAP SG&A expenses were \$70.3 million for the full year ended December 31, 2020, compared to \$57.6 million for the same period in 2019.

- **R&D Expenses:** For the full year ended December 31, 2020, R&D expenses were \$18.4 million, compared to \$27.3 million for the same period in 2019. The decrease was primarily due to a decrease in external spend on STRIDE 3. Non-GAAP R&D expenses were \$15.0 million for the full year ended December 31, 2020, compared to \$24.1 million for the same period in 2019.

- **Operating Loss:** For the full year ended December 31, 2020, loss from operations was \$96.2 million, compared to \$88.2 million for the same period in 2019. Non-GAAP operating loss was \$82.0 million for the full year ended December 31, 2020, compared to \$77.4 million for the same period in 2019.

- **Net Loss:** For the full year ended December 31, 2020, net loss was \$104.3 million, or \$1.99 per share, compared to a net loss of \$94.3 million, or \$2.76 per share, for the same period in 2019. Non-GAAP net loss was \$89.0 million for the full year ended December 31, 2020, compared to \$82.6 million for the same period in 2019. The weighted average number of shares used to calculate net loss per share was 52.4 million for the full year ended December 31, 2020, and 34.2 million for the full year ended December 31, 2019.

Conference Call Information:

Kala will host a live conference call and webcast today, February 25, 2021 at 8:00 a.m. ET to review its fourth quarter and full year 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: 5865513.

To access a subsequent archived recording of the call, please visit the "Investors" 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 preclinical 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 engaging in contract discussions with commercial and Medicare Part D health plans and its expectation to further expand formulary coverage in the coming weeks and months; the Company's belief that INVELTYS prescriptions and revenues will grow over time; the Company's plans to advance its preclinical pipeline of programs and the potential benefits of such programs; 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.

Financial Tables

Kala Pharmaceuticals, Inc. Balance Sheet Data (in thousands) (unaudited)

	December 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	\$ 153,540	\$ 85,449
Total assets	221,606	154,323
Working capital ⁽¹⁾	149,154	80,710
Long-term debt, net of discounts	72,243	71,184
Other long-term liabilities	27,143	28,673
Total stockholders' equity	99,995	29,692

(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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Product revenues, net	\$ 2,238	\$ 1,180	\$ 6,362	\$ 6,074
Costs and expenses:				
Cost of product revenues	1,359	747	3,173	2,008
Selling, general and administrative	26,466	14,492	81,068	65,015
Research and development	3,397	6,138	18,352	27,275
Total operating expenses	31,222	21,377	102,593	94,298
Loss from operations	(28,984)	(20,197)	(96,231)	(88,224)
Other income (expense):				
Interest income	42	384	493	2,357
Interest expense	(2,170)	(2,145)	(8,589)	(8,480)
Net loss	(31,112)	(21,958)	(104,327)	(94,347)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.55)	\$ (0.63)	\$ (1.99)	\$ (2.76)
Weighted average shares outstanding—basic and diluted	56,923,421	34,899,019	52,377,526	34,209,756

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Net loss (GAAP)	\$ (31,112)	\$ (21,958)	\$ (104,327)	\$ (94,347)
Add-back: stock-based compensation expense	4,063	2,325	13,312	9,991
Add-back: non-cash interest	277	249	1,059	958
Add-back: depreciation and amortization	238	229	912	843
Non-GAAP net loss	\$ (26,534)	\$ (19,155)	\$ (89,044)	\$ (82,555)
Cost of product revenues (GAAP)	\$ 1,359	\$ 747	\$ 3,173	\$ 2,008
Less: stock-based compensation expense	32	167	92	268
Less: depreciation and amortization	13	1	52	3
Non-GAAP cost of product revenues	\$ 1,314	\$ 579	\$ 3,029	\$ 1,737
Selling, general and administrative expenses (GAAP)	\$ 26,466	\$ 14,492	\$ 81,068	\$ 65,015
Less: stock-based compensation expense	3,207	1,629	10,137	6,879
Less: depreciation and amortization	171	146	621	522
Non-GAAP selling, general and administrative expenses	\$ 23,088	\$ 12,717	\$ 70,310	\$ 57,614
Research and development expenses (GAAP)	\$ 3,397	\$ 6,138	\$ 18,352	\$ 27,275
Less: stock-based compensation expense	824	529	3,083	2,844
Less: depreciation and amortization	54	82	239	318
Non-GAAP research and development expenses	\$ 2,519	\$ 5,527	\$ 15,030	\$ 24,113
Total operating loss (GAAP)	\$ (28,984)	\$ (20,197)	\$ (96,231)	\$ (88,224)
Add-back: stock-based compensation expense	4,063	2,325	13,312	9,991
Add-back: depreciation and amortization	238	229	912	843
Non-GAAP total operating loss	\$ (24,683)	\$ (17,643)	\$ (82,007)	\$ (77,390)

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