



Kala Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 16, 2022

- Expanded Coverage for EYSUVIS® to 92% of Total Commercial Lives and 30% of All Medicare Lives -

- Achieved 18% EYSUVIS Prescription Growth in 1Q 2022 -

- Presented KPI-012 Phase 1b Clinical Data at ARVO; Initiation of Phase 2/3 Clinical Trial in PCED Expected 4Q 2022 -

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

ARLINGTON, Mass., May 16, 2022 (GLOBE NEWSWIRE) -- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a commercial-stage 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, 2022 and provided a corporate update.

"Since our founding, we have been committed to developing innovative medicines that can better treat diseases of the front and back of the eye and we have advanced two products to market, which address significant unmet needs in dry eye disease and post-ocular surgery," said Mark Iwicki, Chief Executive Officer and Chairman of Kala. "Securing broad market access so prescriptions can be filled at reasonable costs is of paramount importance in the success of any commercial launch. I'm very pleased that in recent months, we have made meaningful progress toward our goal of increasing payer coverage for EYSUVIS. We recently expanded EYSUVIS coverage to more than 90% of commercial lives and 30% of Medicare lives, which we believe will enable more prescriptions to be filled and support long-term revenue growth. As we have been working to expand market access, we have used patient assistance programs to help ensure prescriptions are filled and have seen increased usage in the first quarter of 2022, representing an increased demand for EYSUVIS but also negatively impacting our net revenues. With the recent expansion in payor coverage, we expect our patient assistance programs to have less of an impact on average selling price, and thus net revenue, in the future."

Kala continues to progress the development of KPI-012, and believes it has broad potential to change the standard of care in persistent corneal epithelial defect (PCED), as well as other rare and severe ocular diseases. The Company expects to initiate a Phase 2/3 clinical trial of KPI-012 for PCED later this year, subject to regulatory clearance, and plans to provide updates on its indication expansion strategy in the months ahead.

First Quarter and Recent Business Highlights:

Commercial Portfolio:

EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25%: Data from Symphony Health indicate that 26,518 EYSUVIS prescriptions were filled in the first quarter of 2022, representing quarter-over-quarter growth of 18%. EYSUVIS prescription growth has continued in the second quarter of 2022. As of the week ended May 6, 2022, 103,514 prescriptions of EYSUVIS, including over 17,955 refill prescriptions, written by more than 8,200 unique prescribers, have been filled since the product launched in January 2021.

In May 2022, Kala announced that the largest Pharmacy Benefit Manager in the United States added EYSUVIS as a covered brand on its commercial formularies, effective May 2, 2022. In addition, effective June 1, 2022, Humana, one of the largest Medicare health plans in the United States, will include EYSUVIS as a "preferred brand" on its Medicare formularies. With these additions, Kala has secured coverage for 155.3 million commercial lives, representing approximately 92% of all commercially insured lives, and 14.1 million Medicare lives, representing approximately 30% of all Medicare-insured lives. Kala expects this expanded payor coverage to substantially reduce reliance on co-pay assistance programs and, as a result, significantly improve the Company's gross-to-net adjustments. Kala continues to engage in contract discussions with other health plans and expects to further expand formulary coverage in 2022.

INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%: 34,691 INVELTYS prescriptions were reported by Symphony Health in the first quarter of 2022, compared to 36,695 prescriptions reported in the fourth quarter of 2021. INVELTYS prescriptions were impacted by the reduction in ocular surgeries due to the pandemic but the amount of ocular surgeries has since returned to pre-pandemic levels. Despite this trend, the market for the treatment of post-operative inflammation and pain following ocular surgery has become more generic causing the branded market to decline. Kala believes that INVELTYS prescriptions and revenues will grow as Medicare Part D coverage for the product increases.

Development-Stage Pipeline:

Kala is progressing a pipeline of clinical and preclinical programs addressing important unmet needs in ophthalmology:

KPI-012: KPI-012 is a novel cell-free secretome therapy containing biomolecules secreted by human bone marrow derived mesenchymal stem cells that has the potential for multiple therapeutic applications. The combination of growth factors, protease inhibitors, matrix proteins and neurotrophic factors in KPI-012 has the potential to correct the impaired corneal healing that is an underlying etiology of diseases such as PCED, the first indication that Kala is pursuing for KPI-012, and other severe ocular diseases driven by impaired corneal healing.

At the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in May 2022, Kala presented data from a Phase 1b clinical trial of KPI-012. The single arm trial enrolled patients with PCED of various etiologies, who were treated with KPI-012 twice daily for up to four weeks and followed for up to 12 weeks. Of the eight patients who were evaluable for efficacy, six achieved complete healing after four weeks of treatment, including four who were healed by the end of one week of treatment and one who was healed by the end of the second week of treatment. All six healed patients remained healed through the end of the follow-up period. In addition, an improvement in PCED lesion size was observed in both patients who did not experience full wound healing. KPI-012 was generally well-tolerated in the trial.

Kala plans to submit an investigational new drug application to the U.S. Food and Drug Administration for KPI-012 and, subject to regulatory clearance, initiate a Phase 2/3 clinical trial in patients suffering from PCED in the fourth quarter of 2022. Kala believes this trial could serve as the first of two required pivotal trials needed for securing a potential PCED indication in the U.S. and potentially in other countries.

In addition, Kala believes KPI-012 represents a platform technology due to its multifactorial mechanism of action and is evaluating KPI-012 for potential expansion to other ocular indications. Based on existing pre-clinical and clinical data, Kala believes that KPI-012 has the potential to treat multiple corneal diseases characterized by severe ocular surface damage driven by impaired healing. Additionally, mesenchymal stem cell secretomes are known to contain constituents with therapeutic potential for diseases of the back of the eye. The Company is currently conducting an in-depth analysis to identify potential additional front and back of the eye indications for future development.

Financial Results:

The financial results below contain both GAAP and non-GAAP financial measures. The non-GAAP financial measures exclude stock-based compensation expense, non-cash interest expense, depreciation and amortization and gain or loss on fair value remeasurement of deferred purchase and contingent consideration. 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, 2022, Kala had cash, cash equivalents and short-term investments of \$70.2 million, compared to \$92.1 million of cash and cash equivalents as of December 31, 2021. This decrease reflects cash used in operations. Based on its current plans, Kala anticipates that its cash resources as of March 31, 2022, together with anticipated revenue from EYSUVIS and INVELTYS, will enable it to fund its operations into the second quarter of 2023.

First Quarter 2022 Financial Results:

- **Net Product Revenues:** For the quarter ended March 31, 2022, Kala reported net product revenues of \$1.4 million, consisting of \$1.0 million of net revenue from EYSUVIS sales and \$0.4 million of net revenue from INVELTYS sales, compared to net product revenues of \$3.3 million for the same period in 2021, consisting of \$1.6 million of net revenues from EYSUVIS sales and \$1.6 million of net reviews from INVELTYS sales.
- **Cost of Product Revenues:** For the quarter ended March 31, 2022, cost of product revenues was \$0.8 million, consistent with the same period in 2021. Non-GAAP cost of product revenues was \$0.7 million for the quarter ended March 31, 2022, consistent with the same period in 2021.
- **SG&A Expenses:** For the quarter ended March 31, 2022, selling, general and administrative (SG&A) expenses were \$27.0 million, compared to \$27.7 million for the same period in 2021. The decrease was primarily due to decreases in stock-based compensation and facility related costs. Non-GAAP SG&A expenses were \$24.7 million for the quarter ended March 31, 2022, compared to \$23.8 million for the same period in 2021.
- **R&D Expenses:** For the quarter ended March 31, 2022, research and development (R&D) expenses were \$4.5 million, compared to \$3.1 million for the same period in 2021. The increase was primarily due to increased spending on pipeline programs, including development costs for KPI-012, in the quarter ended March 31, 2022, as compared to the same period in 2021. Non-GAAP R&D expenses were \$3.9 million for the quarter ended March 31, 2022, compared to \$2.1 million for the same period in 2021.
- **Loss on Fair Value Remeasurement of Deferred Purchase Consideration:** For the quarter ended March 31, 2022, the loss on fair value remeasurement of deferred purchase consideration, in connection with the Combangio acquisition, was \$1.1 million. There was no gain or loss on fair value remeasurement of deferred purchase consideration for the same period in 2021. Non-GAAP operating loss and non-GAAP net loss exclude the loss on fair value remeasurement of deferred purchase consideration.
- **Gain on Fair Value Remeasurement of Contingent Consideration:** For the quarter ended March 31, 2022, the gain on fair value remeasurement of contingent consideration, in connection with the Combangio acquisition, was \$1.0 million. There was no gain or loss on fair value remeasurement of contingent consideration for the same period in 2021. Non-GAAP operating loss and non-GAAP net loss exclude the gain on fair value remeasurement of contingent consideration.
- **Operating Loss:** For the quarter ended March 31, 2022, loss from operations was \$30.9 million, compared to \$28.3 million for the same period in 2021. Non-GAAP operating loss was \$27.9 million for the quarter ended March 31, 2022, compared to \$23.4 million for the same period in 2021.
- **Net Loss:** For the quarter ended March 31, 2022, net loss was \$32.9 million, or \$0.45 per share, compared to a net loss of \$30.4 million, or \$0.49 per share, for the same period in 2021. Non-GAAP net loss was \$29.5 million for the quarter ended March 31, 2022, compared to \$25.2 million for the same period in 2021. The weighted average number of shares used to calculate net loss per share was 73.6 million for the quarter ended March 31, 2022, and 61.7 million for the quarter ended March 31, 2021.

Conference Call Information:

Kala will host a live conference call and webcast today, May 16, 2022 at 8:00 a.m. ET to review its first quarter 2022 financial results. To access the live 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: 6384677. To access the live webcast and subsequent archived recording of the call, please visit the "Investor" 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 this press release are stock-based compensation expense, non-cash interest expense, depreciation and amortization and gain or loss on fair value remeasurement of deferred purchase and contingent consideration. 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, Inc.

Kala is a commercial-stage 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% and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%. The Company also has a pipeline of development programs including a clinical-stage secretome product candidate, KPI-012, initially targeting persistent corneal epithelial defects (PCED) and multiple proprietary new chemical entity (NCE) 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. Any statements in this press release about Kala's future expectations, plans and prospects, including but not limited to statements about Kala's expectations with respect to potential advantages of KPI-012, the future development or commercialization of

KPI-012, conduct and timelines of clinical trials, the clinical utility of KPI-012 for PCEDs, plans for regulatory filings and discussions with regulatory authorities, the market opportunity for KPI-012 for PCEDs and other indications, plans to pursue research and development of KPI-012 for other indications, expectations regarding the growth in EYSUVIS and INVELTYS prescriptions and revenue over time, expectations regarding the expansion of Commercial and Medicare Part D payor coverage, estimates regarding anticipated product revenue, Kala's plans to progress its pipeline of preclinical development programs targeted to address front and back of the eye diseases, the sufficiency of Kala's existing cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: 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 Kala's sales force and the market for EYSUVIS and INVELTYS; whether Kala will be able to successfully implement its commercialization plans for EYSUVIS and INVELTYS; whether the market opportunity for EYSUVIS and INVELTYS is consistent with Kala's expectations and market research; Kala's ability execute on the commercial launch of EYSUVIS on the timeline expected, or at all, including obtaining and increasing Commercial and Medicare Part D payor coverage; whether Kala will be able to generate its projected net product revenue on the timeline expected, or at all; the uncertainties inherent in the initiation and conduct of preclinical studies and clinical trials; availability and timing of data from clinical trials; whether results of early clinical trials or trials in different disease indications will be indicative of the results of ongoing or future trials; whether results of the Phase 1b clinical trial of KPI-012 will be indicative of results for any future clinical trials and studies of KPI-012; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; whether regulatory or commercial milestones are achieved; Kala's ability to successfully integrate Combangio's business into its business; Kala's ability to retain and hire key personnel; the risk that disruption resulting from the acquisition of Combangio may adversely affect its business and business relationships, including with employees and suppliers; the sufficiency of cash resources and need for additional financing and other important factors, any of which could cause the Kala's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of Kala's Annual Report on Form 10-K, most recently filed Quarterly Report on Form 10-Q and other filings Kala 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 Kala's views as of any date subsequent to the date hereof. Kala 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.

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Financial Tables:

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

	<u>March 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Cash, cash equivalents and short-term investments	\$ 70,162	\$ 92,136
Total assets	111,574	139,427
Working capital ⁽¹⁾	65,497	86,944
Long-term debt, net of discounts	79,361	78,929
Other long-term liabilities	4,739	6,272
Total stockholders' (deficit) equity	(5,284)	16,804

(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)

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2022</u>	<u>2021</u>
Product revenues, net	\$ 1,372	\$ 3,266
Costs and expenses:		
Cost of product revenues	775	755

Selling, general and administrative	26,982	27,699
Research and development	4,466	3,126
Loss on fair value remeasurement of deferred purchase consideration	1,051	—
Gain on fair value remeasurement of contingent consideration	(988)	—
Total operating expenses	32,286	31,580
Loss from operations	(30,914)	(28,314)
Other income (expense):		
Interest income	8	43
Interest expense	(2,035)	(2,141)
Net loss	(32,941)	(30,412)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.45)	\$ (0.49)
Weighted average shares outstanding—basic and diluted	73,640,830	61,655,867

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

Three Months Ended
March 31,

	2022	2021
Net loss (GAAP)	\$ (32,941)	\$ (30,412)
Add-back: stock-based compensation expense	2,805	4,702
Add-back: non-cash interest	432	278
Add-back: depreciation and amortization	157	248
Add-back: loss on fair value remeasurement of deferred purchase consideration	1,051	—
Less: gain on fair value remeasurement of contingent consideration	(988)	—
Non-GAAP net loss	\$ (29,484)	\$ (25,184)
Cost of product revenues (GAAP)	\$ 775	\$ 755
Less: stock-based compensation expense	48	34
Less: depreciation and amortization	13	13
Non-GAAP cost of product revenues	\$ 714	\$ 708
Selling, general and administrative expenses (GAAP)	\$ 26,982	\$ 27,699
Less: stock-based compensation expense	2,232	3,702
Less: depreciation and amortization	89	181
Non-GAAP selling, general and administrative expenses	\$ 24,661	\$ 23,816
Research and development expenses (GAAP)	\$ 4,466	\$ 3,126
Less: stock-based compensation expense	525	966
Less: depreciation and amortization	55	54
Non-GAAP research and development expenses	\$ 3,886	\$ 2,106
Loss on fair value remeasurement of deferred purchase consideration (GAAP)	\$ 1,051	\$ —
Less: loss on fair value remeasurement of deferred purchase consideration	1,051	—
Non-GAAP loss on fair value remeasurement of deferred purchase consideration	\$ —	\$ —

Gain on fair value remeasurement of contingent consideration (GAAP)	\$ (988)	\$ —
Less: gain on fair value remeasurement of contingent consideration	(988)	—
Non-GAAP gain on fair value remeasurement of contingent consideration	\$ —	\$ —
Total operating loss (GAAP)	\$ (30,914)	\$ (28,314)
Add-back: stock-based compensation expense	2,805	4,702
Add-back: depreciation and amortization	157	248
Add-back: loss on fair value remeasurement of deferred purchase consideration	1,051	—
Less: gain on fair value remeasurement of contingent consideration	(988)	—
Non-GAAP total operating loss	\$ (27,889)	\$ (23,364)