
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 29, 2022**

Kala Pharmaceuticals, Inc.

(Exact Name of Company as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-38150
(Commission File Number)

27-0604595
(IRS Employer Identification No.)

1167 Massachusetts Avenue
Arlington, MA 02476
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: **(781) 996-5252**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading symbol(s) | Name of each exchange on which registered |
|---|--------------------------|--|
| Common Stock, \$0.001 par value per share | KALA | The Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 29, 2022, Kala Pharmaceuticals, Inc. announced its financial results for the quarter and year ended December 31, 2021 and provided a general business update. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

- 99.1 [Press Release of Kala Pharmaceuticals, Inc. dated March 29, 2022](#)
 - 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KALA PHARMACEUTICALS, INC.

Date: March 29, 2022

By: /s/ Mary Reumuth

Name: Mary Reumuth

Title: Chief Financial Officer

Kala Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

-- Achieved \$11.2 Million in Net Revenue in 2021 --

-- Expanded Coverage for EYSUVIS® to 118 Million Commercial Lives and 7.1 Million Medicare Lives --
 -- KPI-012 Phase 1b Clinical Data Accepted for Presentation at ARVO; Initiation of Phase 2/3 Clinical Trial of KPI-012 expected in 4Q 2022 --

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

ARLINGTON, Mass., March 29, 2022 – 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 fourth quarter and full year ended December 31, 2021 and provided a corporate update.

“In recent months, we have made meaningful progress toward our goal of establishing EYSUVIS as the preferred first line prescription therapy for mild or moderate dry eye disease, and we are pleased to report a 21% increase in prescriptions for the fourth quarter of 2021 relative to the prior quarter,” said Mark Iwicki, Chairman and Chief Executive Officer of Kala. “We believe this prescription growth is a positive indicator and will be enhanced by our recently launched direct-to-consumer marketing campaign, as well as expanded commercial and Medicare coverage, which together now account for over 125 million total lives.”

Mr. Iwicki continued, “In parallel, we continue to progress our portfolio of innovative medicines for diseases of the front and back of the eye, including KPI-012, our novel investigational secretome therapy, and KPI-287, our potent and selective tyrosine kinase inhibitor candidate. We look forward to sharing data from the completed Phase 1b clinical trial of KPI-012 at the ARVO Annual Meeting in the second quarter and expect to initiate our Phase 2/3 development program in the fourth quarter of 2022, as we advance KPI-012 to address the unmet needs in persistent corneal epithelial defect (PCED) and additional indications.”

Fourth Quarter and Recent Business Highlights:

Commercial Portfolio:

EYSUVIS® (loteprednol etabonate ophthalmic suspension) 0.25%: EYSUVIS became commercially available in January 2021 as the first and only U.S. Food and Drug Administrative (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 indicate that 22,460 EYSUVIS prescriptions were filled in the fourth quarter of 2021, representing quarter-over-quarter growth of 21%. EYSUVIS prescription growth has continued in the first quarter of 2022. As of the week ended March 18, 2022, 86,969 prescriptions of EYSUVIS, including over 14,533 refill prescriptions, written by more than 7,400 unique prescribers, have been filled since the product launched in January 2021.

Kala has secured coverage for more than 118 million commercial lives, which represents approximately 70% of all commercially insured lives. This includes coverage under UnitedHealthcare, one of the largest commercial health care plans in the United States, which became effective in March 2022. In addition, Kala has secured coverage for 7.1 million Medicare lives, which represents approximately 15% of all Medicare-insured lives. This includes coverage under Cigna Medicare, which added EYSUVIS as a preferred brand in February 2022. Kala continues to engage in contract discussions with other health plans and expects to further expand formulary coverage in the first half of 2022.

INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%: 36,695 INVELTYS prescriptions were reported by Symphony Health in the fourth quarter of 2021, compared to 37,410 prescriptions reported in the third quarter of 2021. Kala believes that INVELTYS prescriptions and revenues will return to growth as the number of ocular surgeries return to pre-COVID levels and 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 persistent corneal epithelial defect (PCED), the first indication that Kala is pursuing, and other severe ocular diseases driven by impaired healing. A Phase 1b clinical trial in PCED patients demonstrated significant improvement in seven of the eight PCED patients treated and complete healing in six of eight of the patients, in most cases within 1-2 weeks of initiation of twice-daily (BID) dosing. Kala plans to submit an investigational new drug (IND) application to the FDA for KPI-012 and, subject to regulatory clearance, initiate a Phase 2/3 clinical trial of KPI-012 in PCED patients in the fourth quarter of 2022. Kala believes the multifactorial mechanism of action of KPI-012 also makes it a platform technology and is evaluating KPI-012 for potential expansion to indications for rare front of the eye diseases, such as limbal stem cell deficiency, chemical burns and Sjogren's Syndrome, as well as select rare back of the eye diseases, such as retinitis pigmentosa and optic neuritis.

A poster presentation detailing the results of the previously completed Phase 1b clinical trial of KPI-012 in patients with PCED has been accepted for presentation at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, which will be held from May 1-4, 2022 in Denver, Colorado and virtually from May 11-12, 2022.

KPI-287: KPI-287 is a suprachoroidal tyrosine kinase inhibitor (TKI) candidate for the treatment of retinal diseases such as wet age-related macular degeneration and diabetic macular edema. Preclinical studies are ongoing to evaluate pharmacokinetics and efficacy over six months to evaluate the potential for sustained delivery and inhibition of VEGF-induced pathology. Kala plans to provide updates on this program throughout 2022.

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, loss on extinguishment of debt, acquired in-process research and development, gain on fair value remeasurement of deferred purchase consideration, transaction costs related to the acquisition of Combangio, and the impact of the termination of the lease for the Company's former corporate headquarters. 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, 2021, Kala had cash and cash equivalents of \$92.1 million, compared to \$124.5 million of cash, cash equivalents and short-term investments as of September 30, 2021. This decrease primarily reflects cash used in operations, as well as the \$5 million paid as upfront consideration for the acquisition of Combangio, which closed in the fourth quarter of 2021. Based on its current plans, Kala anticipates that its cash resources as of December 31, 2021, together with anticipated revenue from EYSUVIS and INVELTYS, will enable it to fund its operations into the second quarter of 2023.
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Fourth Quarter 2021 Financial Results:

Net Product Revenues: For the quarter ended December 31, 2021, Kala reported net product revenues of \$1.9 million, consisting of \$1.2 million of net revenues from EYSUVIS sales and \$0.7 million of net revenues from INVETYS sales, compared to net product revenues of \$2.2 million, consisting of \$0.3 million of net revenues from EYSUVIS sales and \$1.9 million of net revenues from INVETYS sales, for the same period in 2020. The increase of \$0.9 million in net revenue from the sales of EYSUVIS in the fourth quarter of 2021 compared to the same period in 2020 is due to the commencement of the full commercial launch of EYSUVIS beginning in January 2021. The decrease of \$1.2 million in net revenue from sales of INVETYS for the fourth quarter of 2021 compared to the fourth quarter of 2020 is primarily the result of increased product returns.

- **Cost of Product Revenues:** For the quarter ended December 31, 2021, cost of product revenues was \$1.4 million, consistent with the same period in 2020. Non-GAAP cost of product revenues was \$1.3 million for the quarter ended December 31, 2021, consistent with the same period in 2020.
 - **SG&A Expenses:** For the quarter ended December 31, 2021, selling, general and administrative (SG&A) expenses were \$24.0 million, compared to \$26.5 million for the same period in 2020. The decrease was primarily due to decreases in professional service fees, external sales and marketing costs and stock compensation. Non-GAAP SG&A expenses were \$21.5 million for the quarter ended December 31, 2021, compared to \$23.1 million for the same period in 2020.
 - **R&D Expenses:** For the quarter ended December 31, 2021, research and development (R&D) expenses were \$2.4 million, compared to \$3.4 million for the same period in 2020. The decrease was primarily due to decreased employee-related costs, such as stock compensation expense, in the quarter ended December 31, 2021 as compared to the same period in 2020, partially offset by increased spending on pipeline programs. Non-GAAP R&D expenses were \$2.0 million for the quarter ended December 31, 2021, compared to \$2.5 million for the same period in 2020.
 - **Acquired IPR&D Expenses:** For the quarter ended December 31, 2021, acquired in-process R&D expenses (IPR&D) were \$26.6 million. Acquired IPR&D for the quarter ended December 31, 2021 are costs associated with the acquisition of acquired IPR&D assets from Combangio. There were no acquired IPR&D expenses for the same period in 2020. Non-GAAP operating loss and net loss exclude acquired IPR&D expenses.
 - **Gain on Fair Value Remeasurement of Deferred Purchase Consideration:** For the quarter ended December 31, 2021, the gain on fair value remeasurement of deferred purchase consideration, in connection with the Combangio acquisition, was \$5.8 million. There was no gain or loss on fair value remeasurement of deferred purchase consideration for the same period in 2020. Non-GAAP operating loss and net loss exclude the gain on fair value remeasurement of deferred purchase consideration.
 - **Operating Loss:** For the quarter ended December 31, 2021, loss from operations was \$46.8 million, compared to \$29.0 million for the same period in 2020. Non-GAAP operating loss was \$23.0 million for the quarter ended December 31, 2021, compared to \$24.7 million for the same period in 2020.
 - **Net Loss:** For the quarter ended December 31, 2021, net loss was \$47.6 million, or \$0.68 per share, compared to a net loss of \$31.1 million, or \$0.55 per share, for the same period in 2020. Non-GAAP net loss was \$24.6 million for the quarter ended December 31, 2021, compared to \$26.5 million for the same period in 2020. The weighted average number of shares used to calculate net loss per share was 69.5 million for the quarter ended December 31, 2021 and 56.9 million for the quarter ended December 31, 2020.
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Financial Results for the Full Year Ended December 31, 2021:

- **Net Product Revenues:** For the full year ended December 31, 2021, Kala reported net product revenues of \$11.2 million, consisting of \$6.3 million of net revenues from EYSUVIS sales and \$4.9 million of net revenues from INVELTYS sales, compared to net product revenues of \$6.4 million, consisting of \$0.3 million of net revenues from EYSUVIS sales and \$6.1 million of net revenues from INVELTYS sales, for the same period in 2020. The increase of \$6.0 million in net revenue from the sales of EYSUVIS for the year ended December 31, 2021 compared to the same period in 2020 is due to the commencement of the full commercial launch of EYSUVIS beginning in January 2021. The decrease of \$1.2 million in net revenue from sales of INVELTYS for the year ended December 31, 2021 compared to the same period in 2020 is primarily the result of increased product returns.
 - **Cost of Product Revenues:** For the full year ended December 31, 2021, cost of product revenues was \$4.1 million, compared to \$3.2 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 year ended December 31, 2021, compared to the same period in 2020. Partially offsetting these increases was an additional reserve for excess or obsolete inventory of \$0.5 million recorded during the year ended December 31, 2020, as compared to the year ended December 31, 2021. Non-GAAP cost of product revenues was \$3.9 million for the full year ended December 31, 2021, compared to \$3.0 million for the same period in 2020.
 - **SG&A Expenses:** For the full year ended December 31, 2021, SG&A expenses were \$105.1 million, compared to \$81.1 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 Kala's field sales force and stock-based compensation costs. Non-GAAP SG&A expenses were \$91.6 million for the full year ended December 31, 2021, compared to \$70.3 million for the same period in 2020.
 - **R&D Expenses:** For the full year ended December 31, 2021, R&D expenses were \$11.5 million, compared to \$18.4 million for the same period in 2020. The decrease was primarily due to costs incurred for STRIDE 3, Kala's Phase 3 clinical trial of EYSUVIS, during the year ended December 31, 2020, which were not incurred during the same period in 2021, partially offset by increased spending on pipeline programs. Non-GAAP R&D expenses were \$8.1 million for the full year ended December 31, 2021, compared to \$15.0 million for the same period in 2020.
 - **Acquired IPR&D Expenses:** For the full year ended December 31, 2021, acquired IPR&D were \$26.6 million. Acquired IPR&D for the year ended December 31, 2021 are costs associated with the acquisition of acquired IPR&D assets from Combangio. There were no acquired IPR&D expenses for the same period in 2020. Non-GAAP operating loss and net loss exclude the acquired IPR&D expenses.
 - **Gain on Fair Value Remeasurement of Deferred Purchase Consideration:** For the full year ended December 31, 2021, the gain on fair value remeasurement of deferred purchase consideration, in connection with the Combangio acquisition, was \$5.8 million. There was no gain or loss on fair value remeasurement of deferred purchase consideration for the same period in 2020. Non-GAAP operating loss and net loss exclude the gain on fair value remeasurement of deferred purchase consideration.
 - **Operating Loss:** For the full year ended December 31, 2021, loss from operations was \$130.2 million, compared to \$96.2 million for the same period in 2020. Non-GAAP operating loss was \$92.3 million for the full year ended December 31, 2021, compared to \$82.0 million for the same period in 2020.
 - **Net Loss:** For the full year ended December 31, 2021, net loss was \$142.6 million, or \$2.19 per share, compared to a net loss of \$104.3 million, or \$1.99 per share, for the same period in 2020. Non-GAAP net loss was \$99.1 million for the full year ended December 31, 2021, compared to \$89.0 million for the same period in 2020. The weighted average number of shares used to calculate net loss per share was 65.2 million for the full year ended December 31, 2021, and 52.4 million for the full year ended December 31, 2020.
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Conference Call Information:

Kala will host a live conference call and webcast today, March 29, 2022 at 8:00 a.m. ET to review its fourth quarter and full year 2021 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: 7368936. 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, loss on extinguishment of debt, acquired in-process research and development expense, gain on fair value remeasurement of deferred purchase consideration, transaction costs related to the acquisition of Combangio, and the impact of the termination of the lease for the Company's former corporate headquarters. 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.eyesuvis.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 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; Kala's ability to realize the anticipated benefits of the acquisition of Combangio, including the possibility that the expected benefits, synergies and growth prospects from the acquisition of Combangio will not be realized or will not be realized within the expected time period 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.

Investors:

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Financial Tables:

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

| | <u>December 31,</u> <u>2021</u> | <u>December 31,</u> <u>2020</u> |
|---|------------------------------------|------------------------------------|
| Cash, cash equivalents and short-term investments | \$ 92,136 | \$ 153,540 |
| Total assets | 139,427 | 221,606 |
| Working capital (1) | 86,944 | 149,154 |
| Long-term debt, net of discounts | 78,929 | 72,243 |
| Other long-term liabilities | 6,272 | 27,143 |
| Total stockholders' equity | 16,804 | 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.

| | <u>Three Months Ended</u> <u>December 31,</u> | | <u>Year Ended</u> <u>December 31,</u> | |
|--|--|-------------|--|-------------|
| | <u>2021</u> | <u>2020</u> | <u>2021</u> | <u>2020</u> |
| Product revenues, net | \$ 1,856 | \$ 2,238 | \$ 11,240 | \$ 6,362 |
| Costs and expenses: | | | | |
| Cost of product revenues | 1,418 | 1,359 | 4,097 | 3,173 |
| Selling, general and administrative | 24,027 | 26,466 | 105,061 | 81,068 |
| Research and development | 2,414 | 3,397 | 11,515 | 18,352 |
| Acquired in-process research and development | 26,617 | — | 26,617 | — |
| Gain on fair value remeasurement of deferred purchase consideration | (5,805) | — | (5,805) | — |
| Total operating expenses | 48,671 | 31,222 | 141,485 | 102,593 |
| Loss from operations | (46,815) | (28,984) | (130,245) | (96,231) |
| Other income (expense): | | | | |
| Interest income | 12 | 42 | 104 | 493 |
| Interest expense | (2,076) | (2,170) | (8,380) | (8,589) |
| Loss on extinguishment of debt | — | — | (5,395) | — |
| Gain on lease modification | 1,311 | — | 1,311 | — |
| Net loss | (47,568) | (31,112) | (142,605) | (104,327) |
| Net loss per share attributable to common stockholders—basic and diluted | \$ (0.68) | \$ (0.55) | \$ (2.19) | \$ (1.99) |
| Weighted average shares outstanding—basic and diluted | 69,466,320 | 56,923,421 | 65,202,832 | 52,377,526 |

| | Three Months Ended December 31, | | Year Ended December 31, | |
|--|------------------------------------|--------------------|----------------------------|---------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Net loss (GAAP) | <u>\$ (47,568)</u> | <u>\$ (31,112)</u> | <u>\$ (142,605)</u> | <u>\$ (104,327)</u> |
| Add-back: stock-based compensation expense | 2,748 | 4,063 | 16,088 | 13,312 |
| Add-back: non-cash interest | 439 | 277 | 1,519 | 1,059 |
| Add-back: depreciation and amortization | 212 | 238 | 975 | 912 |
| Add-back: loss on extinguishment of debt | — | — | 5,395 | — |
| Add-back: acquired in-process research and development | 26,617 | — | 26,617 | — |
| Less: gain on fair value remeasurement of deferred purchase consideration | (5,805) | — | (5,805) | — |
| Add-back: transaction costs related to acquisition of Combangio, Inc. | 1,179 | — | 1,179 | — |
| Less: impact of lease modification | (2,467) | — | (2,467) | — |
| Non-GAAP net loss | <u>\$ (24,645)</u> | <u>\$ (26,534)</u> | <u>\$ (99,104)</u> | <u>\$ (89,044)</u> |
| Cost of product revenues (GAAP) | <u>\$ 1,418</u> | <u>\$ 1,359</u> | <u>\$ 4,097</u> | <u>\$ 3,173</u> |
| Less: stock-based compensation expense | 60 | 32 | 169 | 92 |
| Less: depreciation and amortization | 13 | 13 | 52 | 52 |
| Non-GAAP cost of product revenues | <u>\$ 1,345</u> | <u>\$ 1,314</u> | <u>\$ 3,876</u> | <u>\$ 3,029</u> |
| Selling, general and administrative expenses (GAAP) | <u>\$ 24,027</u> | <u>\$ 26,466</u> | <u>\$ 105,061</u> | <u>\$ 81,068</u> |
| Less: stock-based compensation expense | 2,364 | 3,207 | 12,774 | 10,137 |
| Less: depreciation and amortization | 140 | 171 | 693 | 621 |
| Less: transaction costs related to acquisition of Combangio, Inc. | 1,179 | — | 1,179 | — |
| Less: impact of lease modification | (1,156) | — | (1,156) | — |
| Non-GAAP selling, general and administrative expenses | <u>\$ 21,500</u> | <u>\$ 23,088</u> | <u>\$ 91,571</u> | <u>\$ 70,310</u> |
| Research and development expenses (GAAP) | <u>\$ 2,414</u> | <u>\$ 3,397</u> | <u>\$ 11,515</u> | <u>\$ 18,352</u> |
| Less: stock-based compensation expense | 324 | 824 | 3,145 | 3,083 |
| Less: depreciation and amortization | 59 | 54 | 230 | 239 |
| Non-GAAP research and development expenses | <u>\$ 2,031</u> | <u>\$ 2,519</u> | <u>\$ 8,140</u> | <u>\$ 15,030</u> |
| Acquired in-process research and development expenses (GAAP) | <u>\$ 26,617</u> | <u>\$ —</u> | <u>\$ 26,617</u> | <u>\$ —</u> |
| Less: acquired in-process research and development expenses | 26,617 | — | 26,617 | — |
| Non-GAAP acquired in-process research and development expenses | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> |
| Gain on fair value remeasurement of deferred purchase consideration (GAAP) | <u>\$ (5,805)</u> | <u>\$ —</u> | <u>\$ (5,805)</u> | <u>\$ —</u> |
| Less: gain on fair value remeasurement of deferred purchase consideration | (5,805) | — | (5,805) | — |
| Non-GAAP gain on fair value remeasurement of deferred purchase consideration | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ —</u> |
| Total operating loss (GAAP) | <u>\$ (46,815)</u> | <u>\$ (28,984)</u> | <u>\$ (130,245)</u> | <u>\$ (96,231)</u> |
| Add-back: stock-based compensation expense | 2,748 | 4,063 | 16,088 | 13,312 |
| Add-back: depreciation and amortization | 212 | 238 | 975 | 912 |
| Add-back: acquired in-process research and development | 26,617 | — | 26,617 | — |
| Less: gain on fair value remeasurement of deferred purchase consideration | (5,805) | — | (5,805) | — |
| Add back: transaction costs related to acquisition of Combangio, Inc. | 1,179 | — | 1,179 | — |
| Less: impact of lease modification | (1,156) | — | (1,156) | — |
| Non-GAAP total operating loss | <u>\$ (23,020)</u> | <u>\$ (24,683)</u> | <u>\$ (92,347)</u> | <u>\$ (82,007)</u> |