



Kala Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

March 3, 2023

-- Enrolled first patient in CHASE Phase 2b clinical trial evaluating KPI-012 for PCED; Top-line data targeted for 1Q 2024 --

-- Closed \$31.0 million private placement financing, extending cash runway into 1Q 2025 --

ARLINGTON, Mass., March 03, 2023 (GLOBE NEWSWIRE) -- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the eye, today reported financial results for the fourth quarter and full year ended December 31, 2022 and provided a corporate update.

"2022 was a transformational year for Kala. In the third quarter, we completed the sale of EYSUVIS® and INVELTYS® to Alcon Inc., enabling us to devote our full attention to developing innovative therapies, including KPI-012, for rare and severe eye diseases," said Mark Iwicki, Chief Executive Officer and Chairman of Kala Pharmaceuticals. "In the months since, we made great progress advancing KPI-012 for the treatment of persistent corneal epithelial defect (PCED), a rare and debilitating ocular condition. We recently enrolled the first patient in our CHASE Phase 2b clinical trial of KPI-012, potentially the first of two pivotal studies required to support an application for marketing approval in the United States, and we are targeting top-line safety and efficacy data in the first quarter of 2024. In addition, following the completion of our \$31.0 million private placement financing in the fourth quarter of 2022 and coupled with our streamlined corporate structure, we are operating from a position of financial strength, with capital well beyond the anticipated readout from the CHASE trial."

Fourth Quarter and Recent Business Highlights:

Development-Stage Pipeline:

In February 2023, Kala dosed the first patient in its CHASE (**C**orneal **H**ealing **A**fter **S**Ecretome therapy) Phase 2b clinical trial evaluating KPI-012 for PCED in the United States. The CHASE Phase 2b clinical trial is a multicenter, randomized, double-masked, vehicle-controlled, parallel-group study to evaluate the safety and efficacy of two doses of KPI-012 ophthalmic solution (3 U/mL and 1 U/mL) compared to vehicle when dosed topically four times per day (QID) for 56 days. After the first cohort with two initial patients to evaluate the safety of the high dose, patients in the second cohort will be randomized to treatment with either KPI-012 or vehicle. The trial is expected to enroll approximately 90 adult patients with PCED, and the primary endpoint of the trial is the complete healing of the PCED as measured by corneal fluorescein staining. Kala is targeting top-line safety and efficacy data from the CHASE Phase 2b clinical trial in the first quarter of 2024. If the results are positive, and subject to discussions with regulatory authorities, Kala believes this trial could serve as the first of two pivotal trials required to support the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). Kala has received Orphan Drug Designation from the FDA for KPI-012 for the treatment of PCED.

Kala believes the multifactorial mechanism of action of KPI-012 makes it a platform technology and is evaluating the potential development of KPI-012 for additional rare, front-of-the-eye diseases, such as Limbal Stem Cell Deficiency and ocular manifestations of moderate-to-severe Sjögren's. Kala has also initiated preclinical studies for its KPI-014 program, evaluating the utility of its mesenchymal stem cell secretome (MSC-S) platform for inherited retinal degenerative diseases such as Retinitis Pigmentosa and Stargardt Disease.

Corporate Updates:

In December 2022, Kala closed a private placement financing, raising aggregate gross proceeds of \$31.0 million. Under the terms of the private placement, Kala sold an aggregate of 76,813 shares of its common stock at a price of \$5.75 per share and an aggregate of 53,144 shares of its Series E Convertible Non-Redeemable Preferred Stock at a price of \$575.00 per share to a life sciences-focused investor.

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, acquired in-process research and development (IPR&D) expense, transaction costs related to the Alcon, Inc. (Alcon) and Combango, Inc. (Combango) transactions, gain or loss on fair value remeasurement of deferred purchase and contingent consideration, gain on sale of the commercial business, loss on extinguishment of debt, the impact of the termination of the lease for the Company's former corporate headquarters and other non-cash expenses. 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, 2022, Kala had cash and cash equivalents of \$70.5 million, compared to \$52.4 million as of September 30, 2022. This increase reflects the gross proceeds of \$31.0 million received from Kala's private placement financing, which closed in December 31, 2022, partially offset by cash used in operations. In January 2023, Kala raised net proceeds of \$11.4 million under its at-the-market (ATM) offering program and used approximately \$10 million to prepay a portion of the principal on its debt facility. Based on its current plans, Kala anticipates that its cash resources as of December 31, 2022 will enable it to fund operations into the first quarter of 2025.

Fourth Quarter 2022 Financial Results:

- **Net Product Revenues:** Kala did not recognize product revenues in the fourth quarter of 2022, following the sale of its commercial portfolio to Alcon on July 8, 2022. For the quarter ended December 31, 2021, Kala reported net product revenues of \$1.9 million.

- **Cost of Product Revenues:** Kala did not record cost of product revenues in the fourth quarter of 2022 following the sale of its commercial portfolio to Alcon on July 8, 2022. For the quarter ended December 31, 2021, cost of product revenues was \$1.4 million. Non-GAAP cost of product revenues were \$1.3 million for the quarter ended December 31, 2021.
- **SG&A Expenses:** For the quarter ended December 31, 2022, selling, general and administrative (SG&A) expenses were \$5.8 million, compared to \$24.0 million for the same period in 2021. The decrease was primarily due to the sale of Kala's commercial portfolio to Alcon, which closed on July 8, 2022, and related workforce reduction. Non-GAAP SG&A expenses were \$5.0 million for the quarter ended December 31, 2022, compared to \$21.5 million for the same period in 2021.
- **R&D Expenses:** For the quarter ended December 31, 2022, research and development (R&D) expenses were \$3.3 million, compared to \$2.4 million for the same period in 2021. The increase was primarily due to the increase in development costs for KPI-012. Non-GAAP R&D expenses were \$3.1 million for the quarter ended December 31, 2022, compared to \$2.0 million for the same period in 2021.
- **Acquired IPR&D Expenses:** There were no acquired IPR&D expenses for the quarter ended December 31, 2022. For the quarter ended December 31, 2021, acquired IPR&D expenses were \$26.6 million and were costs associated with the acquisition of acquired IPR&D assets from Combangio in November 2021. Non-GAAP operating loss and net loss exclude acquired IPR&D expenses.
- **Loss (Gain) on Fair Value Remeasurement of Deferred Purchase Consideration:** For the quarter ended December 31, 2022, the loss on fair value remeasurement of deferred purchase consideration, in connection with the acquisition of Combangio, was \$0.4 million. For the quarter ended December 31, 2021, the gain on fair value remeasurement of deferred purchase consideration was \$5.8 million. Non-GAAP operating loss and non-GAAP net loss exclude the loss (gain) on fair value remeasurement of deferred purchase consideration.
- **Loss on Fair Value Remeasurement of Contingent Consideration:** For the quarter ended December 31, 2022, the loss on fair value remeasurement of contingent consideration, in connection with the Combangio acquisition, was \$0.7 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 loss on fair value remeasurement of contingent consideration.
- **Operating Loss:** For the quarter ended December 31, 2022, loss from operations was \$10.3 million, compared to \$46.8 million for the same period in 2021. Non-GAAP operating loss was \$8.1 million for the quarter ended December 31, 2022, compared to \$23.0 million for the same period in 2021.
- **Net Loss:** For the quarter ended December 31, 2022, Kala reported a net loss of \$12.8 million, or a basic and diluted net loss per share of \$7.97, compared to a net loss of \$47.6 million, or \$33.94 per share on a basic and diluted basis, for the same period in 2021. Non-GAAP net loss was \$10.4 million for the quarter ended December 31, 2022, compared to \$24.6 million for the same period in 2021. The weighted average number of shares used to calculate net loss per share was 1.6 million for the quarter ended December, 2022, and 1.4 million for the quarter ended December 31, 2021. On October 20, 2022, Kala effected a reverse stock split of its outstanding common stock at a ratio of 1 post-split share for every 50 pre-split shares. Proportional adjustments were also made to the number of shares of Kala's common stock issuable upon exercise or conversion of Kala's equity awards and warrants, as well as the applicable exercise prices. The weighted average number of shares used to calculate net loss has been retroactively adjusted for all periods presented in this press release to reflect the reverse stock split.

Financial Results for Full Year ended December 31, 2022:

- **Net Product Revenues:** For the full year ended December 31, 2022, Kala reported net product revenues of \$3.9 million, which is reflective of the closing of the sale of Kala's commercial portfolio to Alcon on July 8, 2022. For the same period in 2021, Kala reported net product revenues of \$11.2 million.
- **Cost of Product Revenues:** For the full year ended December 31, 2022, cost of product revenues was \$2.6 million, compared to \$4.1 million for the same period in 2021. Non-GAAP cost of product revenues was \$2.4 million for the full year ended December 31, 2022, compared to \$3.9 million for the same period in 2021.
- **SG&A Expenses:** For the full year ended December 31, 2022, SG&A expenses were \$65.0 million, compared to \$105.1 million for the same period in 2021. The decrease was primarily due to the sale of Kala's commercial portfolio to Alcon, which closed on July 8, 2022. Non-GAAP SG&A expenses were \$58.4 million for the full year ended December 31, 2022, compared to \$91.6 million for the same period in 2021.
- **R&D Expenses:** For the full year ended December 31, 2022, R&D expenses were \$17.7 million, compared to \$11.5 million for the same period in 2021. The increase was primarily due to development costs for KPI-012. Non-GAAP R&D expenses were \$16.2 million for the full year ended December 31, 2022, compared to \$8.1 million for the same period in 2021.
- **Acquired IPR&D Expenses:** There were no acquired IPR&D expenses for the full year ended December 31, 2022. For the full year ended December 31, 2021, acquired IPR&D were \$26.6 million and were costs associated with the acquisition of acquired IPR&D assets from Combangio. Non-GAAP operating loss and net loss exclude acquired IPR&D expenses.
- **Loss (Gain) on Fair Value Remeasurement of Deferred Purchase Consideration:** For the full year ended December 31, 2022, the loss on fair value remeasurement of deferred purchase consideration, in connection with the acquisition of Combangio, was \$0.6 million. For the full year ended December 31, 2021, the gain on fair value remeasurement of

deferred purchase consideration was \$5.8 million. Non-GAAP operating loss and non-GAAP net loss exclude the gain or loss on fair value remeasurement of deferred purchase consideration.

- **Gain on Fair Value Remeasurement of Contingent Consideration:** For the full year ended December 31, 2022, the gain on fair value remeasurement of contingent consideration, in connection with the Combangio acquisition, was \$0.3 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 full year ended December 31, 2022, loss from operations was \$81.7 million, compared to \$130.2 million for the same period in 2021. Non-GAAP operating loss was \$73.1 million for the full year ended December 31, 2022, compared to \$92.3 million for the same period in 2021.
- **Loss on Extinguishment of Debt:** For the full year ended December 31, 2022, Kala reported a loss on extinguishment of debt of \$2.6 million as a result of a partial prepayment of outstanding principal and related fees on its loan agreement with Oxford Finance LLC in connection with the closing of the sale of its commercial business to Alcon. For the full year ended December 31, 2021, Kala reported a loss on extinguishment of debt of \$5.4 million as a result of the repayment in full of all amounts owed under the credit agreement with Athyrium Opportunities III Acquisition LP in May 2021.
- **Gain on Sale of Commercial Business:** For the full year ended December 31, 2022, Kala reported a gain on the sale of its commercial business to Alcon of \$47.0 million. There was no gain on sale of commercial business for the same period in 2021.
- **Net Loss:** For the full year ended December 31, 2022, net loss was \$44.8 million, or \$29.48 per share, compared to a net loss of \$142.6 million, or \$108.32 per share, for the same period in 2021. Non-GAAP net loss was \$79.1 million for the full year ended December 31, 2022, compared to \$99.1 million for the same period in 2021. The weighted average number of shares used to calculate net loss per share was 1.5 million for the full year ended December 31, 2022, and 1.3 million for the full year ended December 31, 2021. On October 20, 2022, Kala effected a reverse stock split of its outstanding common stock at a ratio of 1 post-split share for every 50 pre-split shares. Proportional adjustments were also made to the number of shares of Kala's common stock issuable upon exercise or conversion of Kala's equity awards and warrants, as well as the applicable exercise price. The weighted average number of shares used to calculate net loss has been retroactively adjusted for all periods presented in this press release to reflect the reverse stock split.

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, acquired in-process research and development expense, transaction costs related to the Alcon and Combangio transactions, gain or loss on fair value remeasurement of deferred purchase consideration and contingent consideration, gain on sale of the commercial business, loss on extinguishment of debt, the impact of the termination of the lease for the Company's former corporate headquarters and other non-cash expenses. 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 Kala Pharmaceuticals, Inc.

Kala is a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the eye. Kala's biologics-based investigational therapies utilize Kala's proprietary mesenchymal stem cell secretome (MSC-S) platform. Kala's lead product candidate, KPI-012, is a human MSC-S, which contains numerous human-derived biofactors, such as growth factors, protease inhibitors, matrix proteins and neurotrophic factors that can potentially correct the impaired corneal healing that is an underlying etiology of multiple severe ocular diseases. KPI-012 is currently in clinical development for the treatment of persistent corneal epithelial defect (PCED), a rare disease of impaired corneal healing, for which it has received orphan drug designation from the U.S. Food and Drug Administration. Kala is also targeting the potential development of KPI-012 for the treatment of Limbal Stem Cell Deficiency and ocular manifestations of moderate-to-severe Sjögren's and has initiated preclinical studies to evaluate the potential utility of its MSC-S platform for inherited retinal degenerative diseases, such as Retinitis Pigmentosa and Stargardt Disease. 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 and its MSC-S platform; anticipated timelines to report topline data for the CHASE Phase 2b clinical trial of KPI-012; the design of the CHASE Phase 2b clinical trial; Kala's belief that the Chase Phase 2b trial could serve as the first of two pivotal trials required to support the submission of a BLA to the FDA; the clinical utility of KPI-012 for PCED; Kala's plans to pursue research and development of KPI-012 and its MSC-S platform for other indications and to apply for RMAT designation; the sufficiency of Kala's existing cash resources for the period anticipated; 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: uncertainties inherent in the initiation and conduct of preclinical studies and clinical trials; uncertainties regarding 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, including the planned Phase 2b clinical trial; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; Kala's ability to retain and hire key personnel; the impact of extraordinary external events, such as the current pandemic health event resulting from the coronavirus (COVID-19), and their collateral consequences; 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 Kala's views as of the date of this press release and should not be relied upon as representing 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)

	December 31,		December 31,	
	2022		2021	
Cash and cash equivalents	\$	70,495	\$	92,136
Total assets		86,820		139,427
Working capital ⁽¹⁾		60,257		86,944
Longterm debt, net of discounts		37,937		78,929
Other long-term liabilities		4,224		6,272
Total stockholders' equity		18,974		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)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Product revenues, net	\$ —	\$ 1,856	\$ 3,892	\$ 11,240
Costs and expenses:				
Cost of product revenues	—	1,418	2,560	4,097
Selling, general and administrative	5,831	24,027	65,035	105,061
Research and development	3,323	2,414	17,653	11,515
Acquired in-process research and development	—	26,617	—	26,617
Loss (gain) on fair value remeasurement of deferred purchase consideration	433	(5,805)	638	(5,805)
Loss (gain) on fair value remeasurement of contingent consideration	664	—	(288)	—
Total operating expenses	10,251	48,671	85,598	141,485
Loss from operations	(10,251)	(46,815)	(81,706)	(130,245)
Other income (expense):				
Interest income	354	12	664	104
Interest expense	(1,577)	(2,076)	(7,266)	(8,380)
Loss on extinguishment of debt	—	—	(2,583)	(5,395)
Gain on sale of Commercial Business	—	—	46,995	—
Gain on lease modification	—	1,311	—	1,311
Other income (expense), net	(1,369)	—	(926)	—

Net loss	\$ (12,843)	\$ (47,568)	\$ (44,822)	\$ (142,605)
Net loss per share attributable to common stockholders—basic and diluted	\$ (7.97)	\$ (33.94)	\$ (29.48)	\$ (108.32)
Weighted average shares outstanding—basic and diluted	1,611,375	1,401,729	1,520,611	1,316,495

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Net loss (GAAP)	\$ (12,843)	\$ (47,568)	\$ (44,822)	\$ (142,605)
Add-back: stock-based compensation expense	960	2,748	7,008	16,088
Add-back: non-cash interest	295	439	1,425	1,519
Add-back: depreciation and amortization	80	212	537	975
Add-back: acquired in-process research and development	—	26,617	—	26,617
Add-back: transaction costs related to the Alcon transaction	—	—	758	—
Add back: transaction costs related to acquisition of Combangio, Inc.	—	1,179	—	1,179
Add loss (gain) on fair value remeasurement of deferred purchase consideration	433	(5,805)	638	(5,805)
Add: loss (gain) on fair value remeasurement of contingent consideration	664	—	(288)	—
Add-back: gain on sale of Commercial Business	—	—	(46,995)	—
Add-back: loss on debt extinguishment	—	—	2,583	5,395
Add-back: impact of lease modification	—	(2,467)	—	(2,467)
Add-back: other (income) expense	(4)	—	90	—
non-GAAP net loss	\$ (10,415)	\$ (24,645)	\$ (79,066)	\$ (99,104)
Cost of product revenues (GAAP)	\$ —	\$ 1,418	\$ 2,560	\$ 4,097
Less: stock-based compensation expense	—	60	166	169
Less: depreciation and amortization	—	13	33	52
non-GAAP cost of product revenues	\$ —	\$ 1,345	\$ 2,361	\$ 3,876
Selling, general and administrative expenses (GAAP)	\$ 5,831	\$ 24,027	\$ 65,035	\$ 105,061
Less: stock-based compensation expense	753	2,364	5,550	12,774
Less: depreciation and amortization	59	140	332	693
Less: transaction costs related to the Alcon transaction	—	—	758	—
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	\$ 5,019	\$ 21,500	\$ 58,395	\$ 91,571
Research and development expenses (GAAP)	\$ 3,323	\$ 2,414	\$ 17,653	\$ 11,515
Less: stock-based compensation expense	207	324	1,292	3,145
Less: depreciation and amortization	21	59	172	230
non-GAAP research and development expenses	\$ 3,095	\$ 2,031	\$ 16,189	\$ 8,140
Acquired in-process research and development expenses (GAAP)	\$ —	\$ 26,617	\$ —	\$ 26,617
Less: acquired in-process research and development expenses	—	26,617	—	26,617

non-GAAP acquired in-process research and development expenses	\$	—	\$	—	\$	—	\$	—
Loss (gain) on fair value remeasurement of deferred purchase consideration	\$	433	\$	(5,805)	\$	638	\$	(5,805)
Less: loss (gain) on fair value remeasurement of deferred purchase consideration		433		(5,805)		638		(5,805)
non-GAAP gain or loss on fair value remeasurement of deferred purchase consideration	\$	—	\$	—	\$	—	\$	—
Loss (gain) on fair value remeasurement of contingent consideration	\$	664	\$	—	\$	(288)	\$	—
Less: loss (gain) on fair value remeasurement of contingent consideration		664		—		(288)		—
non-GAAP gain or loss on fair value remeasurement of contingent consideration	\$	—	\$	—	\$	—	\$	—
Total operating loss (GAAP)	\$	(10,251)	\$	(46,815)	\$	(81,706)	\$	(130,245)
Add-back: stock-based compensation expense		960		2,748		7,008		16,088
Add-back: depreciation and amortization		80		212		537		975
Add-back: acquired in-process research and development				26,617		—		26,617
Add-back: transaction costs related to the Alcon transaction		—		—		758		—
Add-back: transaction costs related to acquisition of Combangio, Inc.		—		1,179		—		1,179
Add: loss (gain) on fair value remeasurement of deferred purchase consideration		433		(5,805)		638		(5,805)
Add: loss (gain) on fair value remeasurement of contingent consideration		664		—		(288)		—
Add-back: impact of lease modification		—		(1,156)		—		(1,156)
non-GAAP total operating loss	\$	(8,114)	\$	(23,020)	\$	(73,053)	\$	(92,347)