

May 10, 2024



Kiora Pharmaceuticals Reports First Quarter Results; Update on Pipeline of Drugs Targeting Retinal Disease

Phase 2 trial for KIO-301 for the treatment of retinitis pigmentosa, in partnership with Théa Open Innovation, expected to be initiated in Q4 2024

Phase 2 clinical trial for KIO-104 for retinal inflammation expected to begin in 2025

Ended Q1 2024 with \$31.3 million in cash and cash equivalents, providing an expected runway of more than two years

Encinitas, California--(Newsfile Corp. - May 10, 2024) -[Kiora Pharmaceuticals, Inc.](#) (NASDAQ: KPRX) ("Kiora" or the "Company") announces first quarter 2024 financial results and updates on its development pipeline of treatments for retinal disease.

"Our balance sheet and strategic partnership with Théa Open Innovation (TOI) put us in a strong position to advance our two retinal programs, KIO-301 and KIO-104, into mid-stage clinical trials," said Brian M. Strem, Ph.D., chief executive officer of Kiora. "Both compounds, given their mechanisms of action, have the potential to address multiple diseases; KIO-301 for the treatment of inherited retinal disorders, and KIO-104 for the treatment of retinal inflammatory diseases. Our upcoming Phase 2 ABACUS-2 trial of KIO-301 for the treatment of retinitis pigmentosa, is a multi-center double-masked, randomized, controlled, multiple-dose study performed in collaboration with TOI.

"As part of our partnership, TOI will fund the remaining clinical development of KIO-301 across multiple indications, allowing us to efficiently invest our capital in the development of KIO-104 to treat retinal inflammatory diseases. KIO-104 may address the established need for eye treatments that spare the complications of chronic steroid use and/or systemic anti-inflammatory drugs. Clinical proof-of-concept for KIO-104 in the treatment of non-infectious uveitis, a rare retinal inflammatory condition, has been established with recently published results from [a Phase 1/2a study](#). Prior to initiating a Phase 2 trial, we are conducting additional investigational new drug (IND) enabling work. Beyond non-infectious uveitis, the mechanism of action of KIO-104 could apply to other retinal conditions, such as macular edema, and proliferative vitreoretinopathy (PVR), a serious complication following retinal detachment repair."

Business Highlights		
Innovative Modalities	KIO-301	Molecular photoswitch
	KIO-104	Anti-inflammatory DHODH inhibitor
Market Need for Rare Diseases	KIO-301	100K patients in US with RP and other IRDs
	KIO-104	400k patients in US with non-infectious uveitis
Commercial Rights & Partners	KIO-301	<ul style="list-style-type: none"> Théa reimburses and/or funds development through Phase 3 \$285 MM in development, regulatory, and commercial milestones Tiered royalties can exceed 20% Pursuing partnership for Asia rights
	KIO-104	Kiora controls worldwide rights
Balance Sheet (March 2024)	<ul style="list-style-type: none"> KIO-301 R&D reimbursed quarterly \$30+ MM in cash; Funds operations through 2026 	

To view an enhanced version of this graphic, please visit:

https://images.newsfilecorp.com/files/8481/208569_691494d424a0f97a_001full.jpg

"In the first quarter, we executed a strategic partnership with TOI, which included a \$16 million upfront payment, and raised \$15 million from an equity offering," added Melissa Tosca, EVP Finance. "These developments substantially strengthened our cash position, allowing us to advance our two exciting programs while maintaining G&A expenses, and provides a runway of greater than two years. The TOI upfront payment was recognized entirely in the first quarter as collaboration revenue and we expect future development and regulatory milestone payments to be treated similarly."

Milestones achieved in the first quarter and year-to-date 2024 include the following:

KIO-301

- Entered a strategic partnership granting TOI exclusive worldwide co-development and commercialization rights, excluding Asia, to KIO-301 for the treatment of retinal degenerative diseases. Under the terms of the agreement, Kiora received an upfront payment of \$16 million, recognized as collaboration revenue, and is eligible to receive up to an additional \$285 million in development, regulatory, and commercial milestones; tiered royalties of up to low 20 percent on net sales; and full reimbursement of future KIO-301 research and development expenses.
- Reported quantitative functional MRI results at the Association of Research in Vision and Ophthalmology (ARVO) annual conference from ABACUS-1, showing a statistically significant increase in neural activity over baseline specifically within the brain's visual processing center. This increase in observed brain activity was time-dependent and concordant with previously reported improvements in visual field, visual acuity, and functional vision.

KIO-104

- Publication of results from a Phase 1 double-masked study of KIO-101 in the medical journal *Pharmaceutics*, documenting a 12-day treatment of KIO-101 topically at multiple doses was well tolerated in healthy volunteers and patients with inflammation

of the eye. There was a significant decrease in conjunctival hyperemia in the treatment group compared to placebo.

- Initiated Investigational New Drug enabling preclinical work in support of planned phase 2 retinal inflammation clinical trial.

Kiora anticipates achieving the following clinical and regulatory milestones:

KIO-301

- Type D meeting with the FDA for functional vision endpoint 1H 2024
- Initiate ABACUS-2 clinical trial 2H 2024
- Begin design of additional inherited retinal disease studies 1H 2025

KIO-104

- Complete non-clinical package 2H 2024
- Initiate Phase 2 clinical trial 1H 2025

Financial Results Highlights

Kiora ended the first quarter of 2024 with \$31.3 million in cash and cash equivalents plus \$1.8 million in research and development incentive tax credits and \$0.2 million in collaboration receivables from TOI.

Revenue was \$16.0 million for the first quarter of 2024, compared to no revenue in the first quarter of 2023. The revenue comes from collaboration revenue as part of an upfront payment from TOI connected to the strategic development and commercialization partnership.

Research and development expenses were \$1.5 million, net of \$0.2 million in offsetting credits related to expenses for KIO-301 which will be reimbursed by TOI, for the first quarter of 2024, compared to \$0.4 million, net of \$0.3 million in offsetting tax credits, for the first quarter of 2023. The increase was primarily due to a one-time licensing payment made to the University of California related to a sublicense fee of \$0.7 million, and a decrease of \$0.3 million in R&D tax credits due to reduced credit-eligible expenses given the KIO-301 expenses are now being reimbursed by TOI.

General and administrative expenses were \$1.3 million for the first quarter of 2024, compared to \$1.3 million for the first quarter of 2023.

Net income was \$13.5 million for the first quarter of 2024 compared to a net loss of \$1.9 million for the first quarter of 2023. The change in income is attributable to the recognition of \$16 million in collaboration revenue.

About Kiora Pharmaceuticals

Kiora Pharmaceuticals is a clinical-stage biotechnology company developing and commercializing products for the treatment of orphan retinal diseases. KIO-301 is being developed for the treatment of retinitis pigmentosa, choroideremia, and Stargardt disease. It is a molecular photoswitch that has the potential to restore vision in patients with inherited and/or age-related retinal degeneration. KIO-104 is being developed for the treatment of

posterior non-infectious uveitis. It is a next-generation, non-steroidal, immuno-modulatory, and small-molecule inhibitor of dihydroorotate dehydrogenase. In addition to news releases and SEC filings, we expect to post information on our website, www.kiorapharma.com, and social media accounts that could be relevant to investors. We encourage investors to follow us on Twitter and LinkedIn as well as to visit our website and/or subscribe to email alerts.

Forward-Looking Statements

Some of the statements in this press release are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These "forward-looking" statements include statements relating to, among other things, Kiora's ability to execute on development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora's development-stage products, including KIO-104, KIO-301, KIO-201 and KIO-101, as well as the success thereof, with such approvals or success may not be obtained or achieved on a timely basis or at all, the sufficiency of existing cash on hand to fund operations for specific periods, the projected cash runway, the ability to timely complete planned initiatives for 2024, including phase 2 clinical development of KIO-301 and KIO-104, the potential for KIO-301 to be the first treatment options for patients with inherited degenerative diseases like RP, Kiora's plans to further fund development of KIO-104, the potential for KIO-104 to reduce inflammation, the timing of topline results from a Phase 2b trial of KIO-104, the potential for KIO-104 to apply to other retinal inflammatory diseases, and expected trends for research and development and general and administrative spending in 2024. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release, including, among other things, the ability to satisfy the closing conditions related to the offering, the ability to conduct clinical trials on a timely basis, market and other conditions and certain risk factors described under the heading "Risk Factors" contained in Kiora's Annual Report on Form 10-K filed with the SEC on March 25, 2024 or described in Kiora's other public filings including on Form 10-Q filed with the SEC on May 10, 2024. Kiora's results may also be affected by factors of which Kiora is not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. Kiora expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions, or circumstances on which any such statement is based, except as required by law.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2024 (unaudited)	December 31, 2023
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$ 31,276,330	\$ 2,454,684
	206,671	233,382
Prepaid Expenses and Other Current Assets		
Collaboration Receivables	189,905	—
Tax Receivables	1,808,787	2,049,965

Total Current Assets	33,481,693	4,738,031
Non-Current Assets:		
Property and Equipment, Net	12,918	8,065
Restricted Cash	4,084	4,267
Intangible Assets and In-Process R&D, Net	8,807,600	8,813,850
Operating Lease Assets with Right-of-Use	94,298	106,890
Other Assets	39,414	40,767
Total Assets	<u>\$ 42,440,007</u>	<u>\$ 13,711,870</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 323,062	\$ 206,260
Accrued Expenses	1,222,078	1,380,666
Operating Lease Liabilities	47,851	47,069
Total Current Liabilities	<u>1,592,991</u>	<u>1,633,995</u>
Non-Current Liabilities:		
Contingent Consideration	5,116,765	5,128,959
Deferred Tax Liability	779,440	779,440
Operating Lease Liabilities	46,448	59,822
Total Non-Current Liabilities	<u>5,942,653</u>	<u>5,968,221</u>
Total Liabilities	<u>7,535,644</u>	<u>7,602,216</u>
Commitments and Contingencies (Note 8)		
Stockholders' Equity:		
Preferred Stock, \$0.01 Par Value: 10,000,000 shares authorized; 3,750 designated Series A, 0 shares issued and outstanding; 10,000 designated Series B, 0 shares issued and outstanding; 10,000 shares designated Series C, 0 shares issued and outstanding; 20,000 shares designated Series D, 7 shares issued and outstanding; 1,280 shares designated Series E, 0 shares issued and outstanding; 3,908 shares designated Series F, 420 issued and outstanding at March 31, 2024 and December 31, 2023, respectively	4	4
Common Stock, \$0.01 Par Value: 50,000,000 shares authorized; 26,256,197 and 7,705,640 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	262,584	77,078
Additional Paid-In Capital	168,429,797	153,192,228
Accumulated Deficit	(133,523,648)	(146,976,855)
Accumulated Other Comprehensive Loss	(264,374)	(182,801)
Total Stockholders' Equity	<u>34,904,363</u>	<u>6,109,654</u>
Total Liabilities and Stockholders' Equity	<u>\$ 42,440,007</u>	<u>\$ 13,711,870</u>

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND
COMPREHENSIVE INCOME (LOSS)**
(unaudited)

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Collaboration Revenue	\$ 16,000,000	\$ —
Total Revenue	16,000,000	—
Operating Expenses:		
General and Administrative	1,296,441	1,269,458
Research and Development	1,493,659	438,283
Change in Fair Value of Contingent Consideration	(12,194)	208,926
Total Operating Expenses	2,777,906	1,916,667
Operating Income (Loss)	13,222,094	(1,916,667)
Other Income, Net:		
Interest Income, Net	223,047	33,465
Other Income, Net	8,066	14,666
Total Other Income, Net	231,113	48,131
Net Income (Loss)	<u>\$ 13,453,207</u>	<u>\$ (1,868,536)</u>
Net Income (Loss) per Common Share - Basic	<u>\$ 0.52</u>	<u>\$ (1.00)</u>
	25,936,163	1,863,466
Weighted Average Shares Outstanding - Basic	<u>25,936,163</u>	<u>1,863,466</u>
Net Income (Loss) per Common Share - Diluted	<u>\$ 0.38</u>	<u>\$ (1.00)</u>
Weighted Average Shares Outstanding - Diluted	<u>35,025,494</u>	<u>1,863,466</u>
Other Comprehensive Income (Loss):		
Net Income (Loss)	\$ 13,453,207	\$ (1,868,536)
Foreign Currency Translation Adjustments	(81,573)	(32,671)
Comprehensive Income (Loss)	<u>\$ 13,371,634</u>	<u>\$ (1,901,207)</u>



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