# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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): November 8, 2024

# KIORA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36672 (Commission File Number) 98-0443284
(IRS Employer Identification No.)

332 Encinitas Blvd. Suite 102 Encinitas, CA 92024

(858) 224-9600

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

	(* 55								
Che	ck the appropriate box below if the Form 8-K filing is intended to sim-	ultaneously satisfy the filing obligation of the	registrant under any of the following provisions:						
	Written communications pursuant to Rule 425 under the Securities	s 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))								
Seci	urities 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, \$0.01 par value	KPRX	NASDAQ						
	tate by check mark whether the registrant is an emerging growth collange Act of 1934 (§240.12b-2 of this chapter).	mpany as defined in Rule 405 of the Securiti	ies Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities						
Eme	rging growth company □								
	emerging growth company, indicate by check mark if the registrar dards provided pursuant to Section 13(a) of the Exchange Act. $\Box$	nt has elected not to use the extended trans	sition period for complying with any new or revised financial accounting						

### Item 2.02. Results of Operations and Financial Conditions.

On November 8, 2024, Kiora Pharmaceuticals, Inc. (the "Company") issued a press release announcing financial results for the quarter ended September 30, 2024 and an update on clinical development progress. A copy of the release is attached as Exhibit 99.1.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, is not deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section. This information will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates them by reference.

#### Item 9.01. Financial Statements and Exhibits.

#### (d) Exhibits.

Exhibit Number	Title
99.1	Press Release of Kiora Pharmaceuticals, Inc., dated as of November 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

<sup>\*</sup>Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

# **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 thereunto duly authorized.

# KIORA PHARMACEUTICALS, INC.

By: /s/ Melissa Tosca

Melissa Tosca Executive Vice President and Chief Financial Officer (Principal financial and accounting officer)

Date: November 8, 2024

## Kiora Pharmaceuticals Reports Third Quarter Results; Retinal Disease Pipeline Advancing Two Phase 2 Studies

Encinitas, California – November 8, 2024 - <u>Kiora Pharmaceuticals, Inc.</u> (NASDAQ: KPRX) ("Kiora" or the "Company") today announced third quarter 2024 financial results and provided an update on its pipeline of therapeutics for the treatment of retinal diseases. Key third quarter and recent corporate highlights include:

- Investigational new drug application approval to initiate ABACUS-2, the Phase 2 study of KIO-301, a novel molecular photoswitch, for the treatment of retinitis pigmentosa.
- Finalized the design of the Phase 2 KLARITY trial of KIO-104, a small molecule targeting the treatment of multiple retinal inflammatory diseases, with submission for trial approval on track for Q4 2024.
- Ended the quarter with \$29.0 million in cash, cash equivalents and short-term investments plus \$1.8 million in collaboration receivables related to the Company's Théa Open Innovation (TOI or Théa) partnership.
- Expected runway into 2027, excluding any potential partnership milestones.

"Kiora remains in a strong position with two compelling and innovative drug candidates entering Phase 2 clinical trials and a strong balance sheet to fund development and operations beyond anticipated readouts for both studies," said Brian M. Strem, Ph.D., President & Chief Executive Officer of Kiora. "During the third quarter, we worked diligently to prepare for these trials, which will increase their likelihood of success.

"Regarding KIO-301, we recently received approval to initiate ABACUS-2, a 36-patient, multi-center, double-masked, randomized, controlled, multi-dose study in patients with ultra-low vision or no light perception due to retinitis pigmentosa. Based on KIO-301's differentiated mechanism of action as a small molecule, we will enroll patients with any of the known 150-plus underlying gene mutations associated with retinitis pigmentosa. Dosing of the first patient with KIO-301 will begin next year following the completion of the ongoing validation work around functional vision endpoints.

"Following multiple interactions with the FDA and European regulators, retinal specialists, and patient advocacy groups, it's clear that demonstrating improvement in functional vision is essential for marketing authorization as well as reimbursement. Thus, throughout the third quarter and continuing into the fourth, we've invested time to validate functional vision endpoints, increasing the probability of success of ABACUS-2 and a potential Phase 3 study in the US and Europe. This validation work is being performed in collaboration with our partner Théa, with additional support from the Choroideremia Research Foundation.

"Our other active program is KIO-104, a potent, locally delivered small molecule that we are developing to treat inflammatory retinal diseases. The goal is to offer patients and providers an alternative to chronic steroid use or systemic anti-inflammatory drugs, both of which often lead to complications. KIO-104 acts by suppressing specific types of T cells and their resulting biomolecules (cytokines) that underlie damaging inflammation. Following a previously successful first-in-man study, we now plan to initiate KLARITY in the first half of next year. This study will be a Phase 2 clinical trial to explore multiple doses of KIO-104 in patients with inflammatory retinal diseases, including posterior non-infectious uveitis and diabetic macular edema. Findings in the study will inform a dose expansion trial in one or more specific indications."

Kiora's Chief Financial Officer, Melissa Tosca, added, "We continue to efficiently manage our cash while creating value by investing in our pipeline. Our Théa partnership enables our overall pipeline progress through their reimbursement of our KIO-301 R&D activities, allowing us to invest further in KIO-104. Going forward, we anticipate R&D expenses will increase as we begin patient enrollment in the KLARITY trial. However, we maintain a cash runway into 2027, before any potential partnership milestones, and beyond the expected data readouts from ABACUS-2 and KLARITY."

#### Third Quarter Financial Highlights

Kiora ended the third quarter of 2024 with \$29.0 million in cash and cash equivalents and short-term investments. In addition, the Company recorded \$1.8 million in collaboration receivables from TOI for reimbursed R&D expenses and \$0.4 million R&D incentive tax credits. The increase in cash position from the prior quarter was due primarily to the receipt of \$1.5 million in R&D incentive tax credits.

Research and development expenses for the third quarter of 2024 were \$2.2 million, before recognizing \$0.9 million in reimbursement from Théa. This resulted in net research and development expenses for the third quarter of 2024 of \$1.3 million compared to \$1.1 million in R&D expenses in the third quarter of 2023, during which time there were no partnership-related reimbursement credits. The year-over-year increase was primarily due to research activities related to KIO-301 and KIO-104.

General and administrative expenses were \$1.4 million for the third quarter of 2024, no change from the \$1.4 million spent in the third quarter of 2023.

Net loss was \$3.4 million for the third guarter of 2024 compared to a net loss of \$5.8 million for the third guarter of 2023. The decrease in net loss is primarily attributed to a non-cash component, the change in fair value of contingent consideration, of -\$1.1 million in the third quarter of 2024 related to the strategic decision to focus on KIO-301 and KIO-104 and halt any continuing development and licensing activities for KIO-201.

#### **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 retinal inflammation. It is a nextgeneration, 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**

investors@kiorapharma.com

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 and KIO-301, 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.

development of KiO-301 and KiO-104, the potential for KiO-301 to be the first fleatment options for patients with inherited degenerative diseases like Kr,
Kiora's plans to further fund development of KIO-104, the potential for KIO-104 to reduce inflammation, the timing of topline results from clinical trials of KIO-
104, the potential for KIO-104 to apply to other retinal inflammatory diseases, the anticipated readout dates for Kiora's clinical trials and their likelihood of
success, 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 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 November 8, 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.
Contact:

Financial Tables Follow

# KIORA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2024 (unaudited)		De	December 31, 2023	
ASSETS		, ,		·	
Current Assets:					
Cash and Cash Equivalents	\$	5,637,019	\$	2,454,684	
Short-Term Investments		23,398,016		_	
Prepaid Expenses and Other Current Assets		470,424		233,382	
Collaboration Receivables		1,783,472		_	
Tax and Other Receivables		363,706		2,049,965	
Total Current Assets		31,652,637		4,738,031	
Non-Current Assets:					
Property and Equipment, Net		62,609		8,065	
Restricted Cash		4,520		4,267	
Intangible Assets and In-Process R&D, Net		6,687,100		8,813,850	
Operating Lease Assets with Right-of-Use		72,637		106,890	
Other Assets		29,851		40,767	
Total Assets	\$	38,509,354	\$	13,711,870	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current Liabilities:					
Accounts Payable	\$	660,415	\$	206,260	
Accrued Expenses		1,714,211		1,380,666	
Accrued Collaboration Credit		1,119,591		_	
Operating Lease Liabilities		33,447		47,069	
Contingent Consideration, short-term		_		_	
Total Current Liabilities		3,527,664		1,633,995	
Non-Current Liabilities:					
Contingent Consideration		4,133,008		5,128,959	
Deferred Tax Liability		779,440		779,440	
Operating Lease Liabilities		39,190		59,822	
Total Non-Current Liabilities		4,951,638		5,968,221	
Total Liabilities		8,479,302		7,602,216	
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 as; 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 September 30, 2024 and December 31, 2023, respectively		4		4	
Common Stock, \$0.01 Par Value: 150,000,000 and 50,000,000 shares authorized and 3,000,788 and 856,182 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively		267,679		77,078	
Additional Paid-In Capital		168,996,195		153,192,228	
Accumulated Deficit		(139,158,620)		(146,976,855)	
Accumulated Other Comprehensive Loss		(75,206)		(182,801)	
Total Stockholders' Equity		30,030,052		6,109,654	
Total Liabilities and Stockholders' Equity	\$	38,509,354	\$	13,711,870	

# KIORA PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (unaudited)

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2024		2023		2024		2023
Revenue:								
Collaboration Revenue	\$	_	\$	_	\$	16,000,000	\$	_
Grant Revenue	-					20,000		_
Total Revenue		_		_		16,020,000		_
Operating Expenses:								
General and Administrative		1,380,997		1,415,844		4,215,411		3,782,596
Research and Development		1,317,231		1,085,010		3,717,570		2,915,392
Executive Severance		_		_		_		_
Change in Fair Value of Contingent Consideration		(1,103,991)		1,513,400		(995,951)		1,865,945
Total Operating Expenses		3,602,237	_	5,918,568		8,945,030		10,468,247
Change in Fair Value of Warranty Liability		_		_		_		_
Interest Income, Net		248,840		49,912		813,989		128,464
Other Income (Expense), Net		(59,929)		105,715		(70,724)		94,493
Total Other Income, Net		188,911		155,627		743,265		222,957
Net Income (Loss)	\$	(3,413,326)	\$	(5,762,941)	\$	7,818,235	\$	(10,245,290)
Deemed Dividends from Warrant Reset Provision				(530,985)				(530,985)
Net Loss Attributable to Common Shareholders	\$	(3,413,326)	\$	(6,293,926)	\$	7,818,235	\$	(10,776,275)
Net Income (Loss) per Common Share - Basic	\$	(0.81)	\$	(7.30)	\$	2.08	\$	(23.35)
Weighted Average Shares Outstanding - Basic		4,214,950		789,656		3,757,467		438,687
Net Income (Loss) per Common Share - Diluted	\$	(0.81)	\$	(7.30)	\$	1.91	\$	(23.35)
Weighted Average Shares Outstanding - Diluted		4,214,950		789,656		4,092,880		438,687
Other Comprehensive Income (Loss):								
Net Income (Loss)	\$	(3,413,326)	\$	(5,762,941)	\$	7,818,235	\$	(10,245,290)
Unrealized Gain on Marketable Securities		76,435		_		73,607		_
Foreign Currency Translation Adjustments		94,094		(40,310)		33,988		(83,430)
Comprehensive Income (Loss)	\$	(3,242,797)	\$	(5,803,251)	\$	7,925,830	\$	(10,328,720)