

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): **March 25, 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)

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:

- ☐ 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, \$0.01 par value	KPRX	NASDAQ

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 Conditions.**

On March 25, 2024, Kiora Pharmaceuticals, Inc. (the “Company”) issued a press release announcing financial results for the year ended December 31, 2023 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
<a href="#">99.1</a>	<a href="#">Press Release of Kiora Pharmaceuticals, Inc., dated as of March 25, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

\*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.

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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 thereunto duly authorized.

### **KIORA PHARMACEUTICALS, INC.**

By: /s/ Melissa Tosca  
Melissa Tosca  
Executive Vice President of Finance  
(Principal financial and accounting officer)

Date: March 25, 2024

**Kiora Pharmaceuticals Reports 2023 Results; Continues to Advance Pipeline of Treatments for Rare Retinal Diseases; Recent Strategic Partnership and Financing Expected to Fund Operations Through 2026**

Encinitas, California -- March 25, 2024 - Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX) ("Kiora" or the "Company") today announced its 2023 financial results and provided an update on its retinal disease development pipeline. The Company's major initiatives planned for 2024 are to initiate Phase 2 clinical development of KIO-301, a small molecule photoswitch, for the treatment of inherited retinal diseases, starting with retinitis pigmentosa (RP); and further development of KIO-104, an intravitreal, anti-inflammatory for treatment of non-infectious uveitis. The \$16 million upfront payment from Kiora's development and commercialization partnership with Théa Open Innovation (TOI) for KIO-301 and its \$15 million private placement are expected to be sufficient to fund the Company through 2026, excluding any potential partnership milestones or warrant exercises.

"Our greatest priorities this year are to advance KIO-301 and KIO-104 to assess their further potential to benefit patients," said Brian M. Strem, Ph.D., chief executive officer of Kiora. "Both products are clinically validated drug candidates based on proprietary and innovative small molecules targeting rare retinal diseases with large unmet needs.



"KIO-301 could potentially become the first vision restoring option for patients with inherited retinal degenerative diseases like RP. Ongoing development will be collaboratively guided and fully funded by our partner, TOI. Should KIO-301 gain marketing authorization, it would provide Kiora with meaningful commercial milestones and royalties up to the low 20's with a partner who has a proven track-record of leadership in the eye space. Working with TOI, we are finalizing details of the randomized, double-masked, controlled, dose-ascending Phase 2 trial in RP and look forward to providing more specifics on expected enrollment and results timelines.

"The balance sheet provides us financial ability to fund the further development of KIO-104 for the treatment of posterior non-infectious uveitis. Because non-infectious uveitis can be sight threatening, there is a strong market appetite for new, steroid sparing therapeutic approaches. The active compound in KIO-104 is a highly potent, disease modifying anti-inflammatory agent belonging to a class of drugs helping hundreds of thousands of patients with systemic autoimmune diseases including multiple sclerosis and rheumatoid arthritis. By delivering KIO-104 directly to the eye, we believe we can reduce the negative effects of retinal inflammation without the associated potential side effects of systemic anti-inflammatory drugs or chronic steroid exposure. Beyond non-infectious uveitis, the mechanism of action of KIO-104 could apply to other retinal conditions, such as proliferative vitreoretinopathy (PVR), a complication following retinal detachment repair, where nonclinical work is ongoing."

"Orphan indications involve efficient, cost-effective paths to market," added Melissa Tosca, EVP Finance. "For 2024, we expect to increase our R&D spend, with expenses for KIO-301 offset by quarterly reimbursement from TOI. Further, we anticipate G&A expenses to remain relatively flat for the year. We believe this balances our

desire to accelerate meaningful development while maintaining a strong cash position expected to fund operations through 2026.”



## Achieved and Upcoming Milestones:

*Notable milestones that Kiora achieved in 2023 and year-to-date 2024 include the following:*

### **KIO-301**

- Entered a strategic partnership granting TOI exclusive worldwide development and commercialization rights, excluding Asia, to KIO-301 for the treatment of retinal degenerative diseases. Under the terms of the deal, Kiora received an upfront payment of \$16 million and is eligible to receive up to an additional \$285 million in development, regulatory, and commercial milestones; tiered royalties of up to low 20's on net sales; and reimbursement of KIO-301 research and development expenses.
- Completed enrollment and reported topline results from ABACUS-1 study. Results demonstrated KIO-301 was safe and tolerable and demonstrated improvements consistent across multiple measures, including improved visual field, visual acuity, and functional vision (navigating in real-world simulations). In addition, functional MRI measures showed reactivation of the specific regions of the brain responsible for vision.
- Held a Type B, pre-IND meeting with the US FDA regarding Kiora's proposed clinical development plans and received feedback on trial design, including approvable endpoints, details for the control group, and outstanding non-clinical requirements, all consistent with Kiora's current plans and timelines.

### **KIO-100 Family (KIO-104, KIO-101)**

- The publication of results from 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 the placebo group.
- Granted US and European patents covering local ocular delivery of the KIO-100 family of non-steroidal, anti-inflammatory small molecules.

*Kiora anticipates achieving the following clinical and regulatory milestones:*

### **KIO-301**

- Report additional ABACUS-1 data, including quantitative functional MRI measures showing reactivated brain activity in the visual cortex in a time-dependent manner.
- Complete comprehensive design, under the joint Kiora-TOI steering committee, of a randomized, controlled, multicenter, double-masked, dose-ascending Phase 2 study of KIO-301 in retinitis pigmentosa with initiation expected as early as the fourth quarter of 2024.

- Pursue Orphan Drug Designations for KIO-301 for choroideremia and Stargardt disease in the US and EU.

#### **KIO-104**

- Initiate supportive non-clinical research to inform and optimize Phase 2 and registration studies in 2024.
- Plan a multicenter, randomized, double-masked, dose-ascending Phase 2 study of KIO-104 for the treatment of non-infectious uveitis.
- Perform additional pre-clinical proof-of-concept studies of KIO-104 in proliferative vitreoretinopathy, a rare but serious complication of retinal reattachment procedures beginning in 2024.

#### **Financial Results**

Kiora ended the year with \$2.5 million in cash and cash equivalents and \$2.0 million in tax receivables. In February of 2024, Kiora received an additional \$16 million for an upfront payment from TOI and raised \$13.8 million in net proceeds from a private placement offering. The Company's cash and cash equivalents as of March 24, 2024, exceeds \$30 million and the Company believes this will fund operations through 2026.

In 2023, research and development expenses were \$4.0 million, net of \$1.7 million in offsetting tax credits, compared to \$3.5 million, net of \$1.5 million in offsetting tax credits, for 2022. Research and development expenses for the fourth quarter of 2023 were \$1.1 million, net of \$0.5 million in offsetting tax credits, compared to \$0.8 million, net of \$0.4 million in offsetting tax credits for the fourth quarter of 2022. The increase in R&D in 2023 was primarily due to greater investment in clinical trial-related activities for KIO-301 and personnel-related expenses for the R&D team. Kiora anticipates R&D expenses will increase as it begins planning and enrollment of patients in Phase 2 clinical trials, with trial-related expenses for KIO-301 offset by reimbursement from TOI.

General and administrative expenses for 2023 were \$4.7 million compared to \$8.3 million for 2022. General and administrative expenses for the fourth quarter of 2023 were \$0.9 million, compared to \$2.8 million in the fourth quarter of 2022. The reduction in general and administrative expenses for the full year and fourth quarter of 2023 were primarily related to lower professional service fees, driven by reduced external accounting and auditing services. Kiora expects that general and administrative expenses will remain relatively consistent for the near future.

Net loss was \$12.5 million for 2023 compared to \$13.6 million for 2022. Net loss was \$2.3 million for the fourth quarter of 2023 compared to \$2.5 million for the fourth quarter of 2022.

#### **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](http://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 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. 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.

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