

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 9, 2023**

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 November 9, 2023, Kiora Pharmaceuticals, Inc. (the “Company”) issued a press release announcing financial results for the first quarter ended September 30, 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
99.1	Press Release of Kiora Pharmaceuticals, Inc., dated as of November 9, 2023
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.

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: November 8, 2023

Kiora Pharmaceuticals Reports Q3 2023 Results; Expanding Clinical Development of KIO-301 for Inherited Retinal Diseases Based on Encouraging Results of ABACUS-1 Study in Retinitis Pigmentosa

Encinitas, California -- November 9, 2023 -- Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX) ("Kiora" or the "Company") today announced its third quarter 2023 financial results and is providing an update on its plans to advance clinical development of KIO-301 for other inherited retinal diseases.

On November 4, 2023, Kiora reported results from the ABACUS-1 study, a Phase 1b first-in-human clinical trial of the Company's molecular photoswitch, KIO-301, in patients with late-stage retinitis pigmentosa (RP). The key findings from ABACUS-1 demonstrated that KIO-301 is safe & tolerable in this population and further showed significant improvements in visual field and a concordance of trended improvements in visual acuity and functional vision. Functional MRI demonstrated increased brain activity in visual cortex.

Based on these findings, the Company will expand clinical development of KIO-301 for multiple inherited retinal diseases. This includes the initiation of a Phase 2 controlled, double-masked, randomized, ascending-dose trial in up to 20 patients with RP dosed monthly over 90 days (ABACUS-2). In addition, Kiora plans to initiate two additional Phase 2 studies, one for Choroideremia (CHM) and another Stargardt disease, being able to leverage synergies for efficient trial execution. CHM and Stargardt disease are inherited retinal diseases with a similar pathology to RP and may qualify of Orphan Drug Designation.

"Based on our internal assessment and input from our scientific and medical advisors, we will initiate ABACUS-2 in the first half of 2024, with the goal of confirming both efficacy and safety in a multi-dose, double-masked, controlled clinical trial," said Brian M. Strem, Ph.D., chief executive officer of Kiora. "Ahead of this trial, we have plans to meet with the FDA in Q4 2023 to ensure alignment on study designs, endpoints and additional requirements to perform studies in the US and Europe for RP as well as other inherited retinal diseases like CHM and Stargardt disease. This strategy represents a cost-effective and expedited path to bring a potential new treatment for multiple inherited retinal diseases for which there are currently no available therapies."

Achieved and Upcoming Milestones:

The milestones that Kiora achieved in the first half of 2023 include the following:

- KIO-301: Reported encouraging topline results from ABACUS-1 at the American Academy of Ophthalmology 2023 Annual Meeting on November 4, 2023
- KIO-301: Received Investigational New Drug Application approval in Australia to enroll additional patients in an ABACUS-1 study expansion to evaluate KIO-301 in patients with late-stage CHM
- KIO-301: Entered a partnership with the Choroideremia Research Foundation to support strategic clinical development of KIO-301 in Choroideremia
- KIO-201: Reported results from a Phase 2 Persistent Corneal Epithelial Defect study at the ARVO Annual Meeting in Q2 2023
- KIO-100 family: granted U.S. and European Patents covering local ocular delivery of the KIO-100 family of non-steroidal, anti-inflammatory small molecules.
- Business: Raised \$6.3 million in funding to extend runway into May 2024
- Business: Received \$1.2 million of research tax incentives from Australia and Austria
- Business: Appointed Praveen Tyle, PhD as its Chairman of the Board of Directors.

The Company anticipates achieving the following clinical and regulatory milestones:

- KIO-301: Discuss the development path for KIO-301 in RP with the FDA in a type B pre-IND meeting in Q4 2023
- KIO-301: Initiate the ABACUS-2 phase 2 trial of KIO-301 in RP
- KIO-301: Initiate a Phase 2 trial for Choroideremia
- KIO-301: Initiate a Phase 2 trial for Stargardt disease

- KIO-301: Pursue Orphan Drug Designations for KIO-301 for Choroideremia and Stargardt Disease in the USA and EU
- KIO-104: Pursue Orphan Drug Designation for KIO-104 for Posterior Non-Infectious Uveitis in the USA

Financial Results

In the first nine months of 2023, research and development expenses were \$4.1 million, exclusive of \$1.2 million in offsetting tax credits, compared to \$3.8 million, exclusive of \$1.2 million in offsetting tax credits, for the first nine months of 2022. Research and development expenses for the third quarter of 2023 were \$1.6 million, exclusive of \$0.5 million in offsetting tax credits, compared to \$2.4 million, exclusive of \$1.1 million in offsetting tax credits for the third quarter of 2022. In the third quarter of 2022, a year-to-date catch-up for the 2022 research tax credit was recorded, resulting in an additional \$0.7 million in out-of-period expense. The increase for the first nine months was primarily due to clinical trial-related expenses while the decline in the third quarter was primarily due to the completion of the ABACUS study.

General and administrative expenses for the first nine months of 2023 were \$3.8 million compared to \$5.5 million for the first nine months of 2022. General and administrative expenses for the third quarter of 2023 were \$1.4 million, compared to \$2.0 million in the third quarter of 2022. The reduction is attributable to reduced consulting fees, lower facilities cost due to the consolidation of offices, and lower personnel costs due to staffing optimization and benefit cost savings.

Net loss was \$10.2 million for the first nine months of 2023 compared to \$11.1 million for the first nine months of 2022. Net loss was \$5.8 million for the third quarter of 2023 compared to \$5.1 million for the third quarter of 2022. This increase in the first nine months and third quarter of 2023 compared to the same periods in 2022 was primarily due to a non-cash impairment of in-process R&D, related to the strategic decision to stop internal development activities leading to commercialization for KIO-101 and KIO-201. The Company is seeking partnership opportunities for the continued development of these programs. The decrease in net loss before the non-cash impairment in the nine and three months ended Sept 30, 2023, compared to the same periods in 2022 was primarily due to lower personnel, consulting and facilities expenses.

Kiora ended the quarter with \$5.4 million in cash and cash equivalents and \$1.3 million in tax receivables. Additionally, Kiora may in the future draw on a \$10 million equity line of credit (subject to certain limitations), of which there is up to approximately \$9.6 million available.

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, the development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora's development-stage products, including KIO-301 and KIO-104, 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 ability of KIO-301 to improve vision in everyday activities, the potential to expand KIO-301 to other indications including choroideremia and Stargardt disease, Kiora's ability to expand clinical development into the U.S. and the EU, and the timing of results of the ABACUS study and design of the ABACUS II study. 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 conduct clinical trials on a timely basis, the ability to obtain any required regulatory approvals, whether future trials of KIO-301 will yield similar

results for participants, 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 23, 2023, 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.