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): **May 9, 2023**

KIORA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-36672	**98-0443284**
(Commission File Number)	(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. o

Item 2.02. Results of Operations and Financial Conditions.

On May 9, 2023, Kiora Pharmaceuticals, Inc. (the "Company") issued a press release announcing financial results for the first quarter ended March 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
99.1	Press Release of Kiora Pharmaceuticals, Inc., dated as of May 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: May 9, 2023

Exhibit 99.1

Kiora Pharmaceuticals Reports First Quarter Results; Positive Clinical Data Driving Significant Progress Advancing Pipeline of Eye Disease Treatments

Encinitas, CA -- May 9, 2023 -- Kiora Pharmaceuticals (NASDAQ: KPRX) announced its first quarter 2023 results, during which time it significantly advanced its ocular drug development pipeline of clinical-stage candidates for the treatment of Retinitis Pigmentosa (RP), Persistent Corneal Epithelial Defects (PCEDs), and the Ocular Presentation of Rheumatoid Arthritis (OPRA).

CEO Commentary

“This has been a pivotal quarter for our business resulting in several recently reported clinical development milestones,” said Brian M. Strem, Ph.D., president and CEO of Kiora. “Last month we reported preliminary results from our open-label study of KIO-301, our flagship asset, demonstrating profound improvements in light perception in a blind patient with RP. Importantly, the patient reported functional improvements consistent with objective functional MRI imaging results, showing elevated activity in regions of the brain activated by vision. Predictably, this activity diminished over time, consistent with our preclinical models, where the effect increases after dosing, continues to peak, and returns to baseline as the drug is eliminated. We are extremely encouraged by the early results from the low dose of 7.5µg. Additionally, we have fully enrolled the study and look forward to completing dosing in the higher dose groups of 25µ g and 50µg and reporting topline results on the full study by the end of this year.

“Continuing the progress, we reported favorable and statistically significant outcomes from our Phase 2 clinical trial of KIO-201, evaluating its ability to accelerate wound healing after four weeks of therapy in patients with chronic, non-healing wounds on the ocular surface. If left untreated, these wounds can lead to infection, scarring, and vision loss. Notably, five out of eight patients achieved the primary endpoint at four weeks. The adverse event profile was also favorable to the advancement of this therapeutic candidate. These results, consistent with the five previous clinical trials evaluating KIO-201 in other corneal wounds, lay the foundation for planning and initiating a registration study in the U.S.

“Lastly, in mid-April we enrolled the first patient in our Phase 2 trial of KIO-101. This indication focuses on a narrowly defined population of patients who suffer from ocular surface disease attributed to an underlying autoimmune condition. Current standard of care for these patients typically has little to no effect. With KIO-101, we believe by addressing the underlying condition locally with an eyedrop, we can help the millions of patients who suffer from the pain and discomfort associated with this condition.

“We continue to execute on our plan and achieve milestones on or ahead of schedule. The remainder of 2023 will build on our success as we plan to continue enrollment in the Phase 2 trial for KIO-101 in OPRA, begin planning a registration study of KIO-201, and expect to report topline results from the ABACUS trial in patients with RP.”

Achieved and Upcoming Milestones:

The clinical development milestones that Kiora has achieved year to date include the following:

- KIO-301: Reported initial results from ABACUS at ARVO in Q2 2023
- KIO-201: Reported initial results from Phase 2 PCED study at ARVO in Q2 2023
- KIO-101: Initiated enrollment in Phase 2 trial for KIO-101 in Q2 2023

The Company anticipates achieving the following clinical milestones:

- KIO-301: Complete dosing all patients in ABACUS by end of Q3 2023
- KIO-301: Report topline results of the ABACUS study by year-end 2023
- KIO-201: Receive Orphan Drug Designation PCED in 2023
- KIO-201: Design and potentially initiate registration study following FDA guidance

Financial Results

In the first quarter of 2023, research and development expenses were $0.4 million compared to $0.7 million last year. The decrease was primarily due to an increase of $0.3 million for credits expected from Australian and Austrian government programs related to research and development activities. General and administrative expenses for the first quarter were $1.3 million, compared to $1.7 million in the same period last year. The reduction is attributable to reduced consulting fees, lower facilities costs due to the consolidation of offices, and lower personnel costs due to staffing optimization and benefit cost savings.

Net loss was $1.9 million for the first quarter of 2023 compared to $3.6 million for the first quarter of 2022. This decrease was primarily due to executive severance of $1.0 million that was incurred in the first quarter of 2022 and the reduction of general and administrative expenses as summarized.

Kiora ended the quarter with $3.4 million in cash and cash equivalents as well as $1.7 million in tax receivables related to Austrian and Australian research and development tax credit incentive programs. Additionally, Kiora can draw on a $10 million equity line of credit (subject to certain limitations), of which there is approximately $9.6 million available.

About Kiora Pharmaceuticals

Kiora Pharmaceuticals is a clinical-stage biotechnology company developing and commercializing products for the treatment of ophthalmic diseases. KIO-301 is being developed for the treatment of retinitis pigmentosa. It is a molecular photoswitch that has the potential to restore vision in patients with inherited and/or age-related retinal degeneration. KIO-101 is being developed for the treatment of the Ocular Presentation of Rheumatoid Arthritis (OPRA). It is a next-generation, non-steroidal, immuno-modulatory and small molecule inhibitor of Dihydroorotate Dehydrogenase (DHODH) with what Kiora believes is best-in-class picomolar potency and a validated immune modulating mechanism (blocks T cell proliferation and proinflammatory cytokine release) designed to overcome the off-target side effects and safety issues associated with commercially available DHODH inhibitors. In addition, Kiora is developing KIO-201, a chemically cross-linked form of the natural polymer hyaluronic acid, designed to accelerate corneal wound healing.

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-101, KIO-201 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 potential ability of KIO-301 to restore vision in patients with RP, the expecting timing of the ABACUS study, Kiora's ability to draw on its equity line of credit, the potential of KIO-201 to receive an orphan indication, and Kiora's ability to achieve the specific milestones described herein. 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, 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.

Investor Contact

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