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 23, 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

(781) 788-9043
(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 March 23, 2023, Kiora Pharmaceuticals, Inc. (the "Company") issued a press release announcing financial results for the fiscal year and fourth quarter ended December 31, 2022 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 March 23, 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: March 23, 2023

Exhibit 99.1

Kiora Pharmaceuticals Reports 2022 Financial Results; Provides Update on Clinical Development Progress

March 23, 2023 -- Encinitas, CA -- Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX), ("Kiora" or the "Company") today is providing a business update and reporting financial results for the year ended December 31, 2022.

CEO Commentary:

“In 2022, we advanced our pipeline of three differentiated assets across rare orphan and underserved eye disease indications,” said Brian M. Strem, Ph.D., President and Chief Executive Officer of Kiora. “Enrollment is ongoing in our Phase 1b study of KIO-301 in patients with Retinitis Pigmentosa (RP); we initiated a Phase 2 study of KIO-101 in patients whose autoimmune disease manifests on the ocular surface; and we recently completed a Phase 2 study of KIO-201 in patients suffering from Persistent Corneal Epithelial Defects (PCEDs).

“KIO-301, our flagship asset, is targeting a tremendous need in patients with RP, namely vision restoration. Unfortunately, there are no approved therapies to help patients who have this orphan disease, and based on this as well as our operational efficiencies, we are able to pursue an accelerated clinical development path for this program. Our phase 1b trial (termed “ABACUS ”) began dosing patients late last year. Enrollment is on track to enable full trial results expected before the end of 2023. In addition to safety, tolerability and visual efficacy assessments, we are incorporating novel and rigorous imaging and analysis protocols to ensure the trial is as informative as possible. This includes the use of functional MRI to assess visual activity in the brain. As a confirmatory measure, and being an open label study, we reviewed preliminary observations from the first two patients treated. Thus far, there have been no reported adverse events, including ocular adverse events, and patient-reported outcomes indicate an improvement in the ability to perceive light, delineate contrast between light and dark and improvement in overall vision function following KIO-301 injection. Based on these observations and more, we are continuing enrollment and look forward to reporting additional early results on April 27, 2023, at the Association for Research in Vision and Ophthalmology (ARVO) annual conference in New Orleans. Beyond development of KIO-301 as a potential vision restoring treatment for RP, we are exploring this small molecule ‘photoswitch’ for additional therapeutic applications, including other inherited and age-related retinal degenerative diseases, namely geographic atrophy and late-stage wet AMD.”

“With respect to our anterior segment programs, we recently completed a Phase 2 study of KIO-201 in patients suffering from PCEDs. This rare ocular surface condition is characterized by non-healing wounds on the eye’s surface. Topline results were accepted for presentation at the ARVO meeting on April 25, 2023. Patients treated with KIO-201 achieved a 90.0% mean reduction in defect size four weeks after treatment ($p<0.003$), while 5 of 8 patients (62.5%) achieved the primary endpoint of healing over the 4-week period. KIO-201 was safe and well tolerated, with no drug related adverse events. Based on these results, we will be seeking input from the FDA to guide the design of a registration study in PCED.

“KIO-101 is targeting an underserved subset of patients whose autoimmune disease manifests on their ocular surface. Moreover, the development of a non-steroidal drug to mitigate ocular inflammation is an important development in the field. The initial focus is patients with Rheumatoid Arthritis (RA), psoriatic disease, lupus and fibromyalgia, which we refer to as Ocular Presentations of RA (OPRA+). In the US alone, the total addressable market is estimated to be approximately 3.43 million people. Specifically in RA, it is one of the most common extra-articular complaints among patients. Results from two previous ocular inflammation studies were reported last year demonstrating additional clinical proof-of-concept of KIO-101 as a safe and effective non-steroidal ocular immune modulator when applied locally. We recently received approval to begin our next stage of development and anticipate enrolling the first patient in a Phase 2 trial in the first half of this year.”

Upcoming milestones:

Key upcoming milestones Kiora expects to achieve include the following:

KIO-301:

- Report initial results from ABACUS at ARVO in Q2 2023
- Report topline results of the ABACUS study by year-end 2023

KIO-201

- Receive Orphan Drug Designation PCED in 2023
- Report initial results from Phase 2 PCED study at ARVO in Q2 2023
- Design and initiate registration study following FDA guidance

KIO-101

- Initiate enrollment in Phase 2 trial for KIO-101 in Q2 2023

Financial Results

“For 2023, our goal is to attract the required capital to invest across three planned clinical trials for KIO-301, KIO-201 and KIO-101,” said Melissa Tosca, Executive VP Finance. “This will result in an expected increase in R&D spend while our budget calls for a decrease in G&A now that we have implemented several operational and financial efficiencies.”

Research and development expenses were $3.4 million for the year ended December 31, 2022, compared to $5.3 million for the year ended December 31, 2021. The year over year decrease of $1.9 million was primarily due to reduced development costs for KIO-101 and KIO-201 of $1.1 million, decreased personnel costs of approximately $1.0 million, and the Company’s ability to claim an Australian research and development tax credit in 2022 of approximately $1.0 million which is a reduction against the research and development expenses. This was partially offset by increased activities related to the commencement of patient dosing in the ABACUS study totaling approximately $1.3 million. Research and development expenses in the fourth quarter of 2022 were $0.8 million, a decrease of $0.2 million compared to the fourth quarter of 2021 of $1.0 million. This decrease was primarily due to an increase in clinical spend of $0.3 million related to KIO-301, partially offset by decreased personnel costs of $0.2 million.

General and administrative expenses were $8.3 million for the year ended December 31, 2022, compared to $5.3 million for the year ended December 31, 2021. This increase was primarily due to an increase in audit and consulting fees of $1.5 million, executive severance of $1.0 million, increased travel and other office and corporate expenses of $0.8 million. This was partially offset by a decrease in personnel-related expenses of $0.3 million. General and administrative expenses in the fourth quarter of 2022 were $2.7 million, an increase of $1.8 million compared to the fourth quarter of 2021 of $1.4 million. This increase was primarily due to increased professional fees of $0.3 million and corporate and other office expenses of $0.2 million, partially offset by lower personnel costs of $0.1 million.

Net loss was $13.6 million for the year ended December 31, 2022, compared to $13.8 million for the year ended December 31, 2021. In the third quarter of 2022, there was a non-cash expense of $1.4 million due to a change in fair value of warrant liability. This was due to the reclassification of warrant liabilities to equity and the

resulting fair value impact between issuance and reclassification. The warrants are now equity-classified and are considered permanent equity, so there will not be ongoing fair value adjustments. Net loss was $2.5 million for the fourth quarter of 2022, decrease of $3.7 million compared to the fourth quarter of 2021 of $6.2 million. This decrease was primarily due to an impairment of goodwill in the fourth quarter of 2021 for $4 million.

Net cash used in operating activities was $10.4 million in 2022 compared to $10.7 million in 2021. Net cash used in operating activities was $2.1 million in Q4 2022 compared to $2.9 million in 2021.

Cash and cash equivalents were $6.0 million as of December 31, 2022, with an additional $1.4 million in tax receivables related to Austrian and Australian research and development tax credit incentive programs.

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 anticipated use of the net proceeds of the offering, 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, the potential of KIO-301 to be used in combination with gene therapies and to address other inherited forms of blindness and retinal degenerative diseases, trends in research and development and general and administrative expenses for the fiscal year ending December 31, 2023, 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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