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): **February 7, 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. ☐

Item 8.01. Other Events.

On February 7, 2023, Kiora Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it has received investigational new drug application approval for a Phase 2 study of KIO-101 for the treatment of the Ocular Presentation of Rheumatoid Arthritis or other autoimmune diseases (OPRA+). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein 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 February 7, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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/ Brian M. Strem, Ph.D.
Brian M. Strem, Ph.D.
President and Chief Executive Officer

Date: February 7, 2023

Exhibit 99.1

Kiora Pharmaceuticals Receives Approval for Phase 2 Study of KIO-101 for Treatment of Ocular Presentation of Autoimmune Diseases

Encinitas, California — February 07, 2023 -- Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX), ("Kiora" or the "Company") today announced it has received investigational new drug application approval for a Phase 2 study of KIO-101 for the treatment of the Ocular Presentation of Rheumatoid Arthritis and other autoimmune diseases (OPRA+). This study will enroll approximately 120 patients in a multi-center, controlled, randomized, double-masked trial assessing the safety and efficacy of KIO-101 eye drops in patients living with autoimmune disease who have signs and symptoms of ocular surface disease. The study is expected to begin enrolling patients in Australia in the first half of 2023.

“Ocular surface disease is the most common non-joint manifestation of patients living with Rheumatoid Arthritis (RA) as well as other common autoimmune diseases,” said Eric Daniels, M.D., Chief Development Officer of Kiora. “While the systemic treatment of underlying autoimmune diseases has advanced dramatically in the past decade, these agents commonly do not address local ocular disease. This unfortunately leaves affected autoimmune patients with few available eye drug options that only offer limited relief in addressing the moderate to severe ocular dryness, pain and discomfort associated with these diseases. KIO-101 is a topical, patient-friendly eye drop with a proven mechanism of action in autoimmune diseases. Proof-of-concept has been established in previous ocular inflammation clinical studies for KIO-101. This drug has the potential to finally close the wide gap of untreated ocular disease in patients with common autoimmune diseases."

KIO-101 is part of a class of non-steroidal autoimmune disease drugs called DHODH inhibitors, which reduce T-cell proliferation and ongoing proinflammatory cytokine release. Approved systemic drugs in this class, which target systemic disease, generate about $2B in annual revenue. KIO-101 has the potential to affect the local immune response in the eye responsible for the ophthalmic signs and symptoms of these autoimmune diseases. Of the autoimmune diseases that KIO-101 is targeting, the ocular manifestations are found in approximately 3.43M patients in the U.S.

The Phase 2 study of KIO-101 is a multicenter, randomized, controlled, double-masked clinical trial in up to 120 patients with ocular signs and symptoms and diagnosed autoimmune diseases, including RA, psoriatic disease, systemic lupus erythematosus, or fibromyalgia. The study will evaluate two concentrations of KIO-101, 0.15 % and 0.30 %. The efficacy endpoints will evaluate a number of established ocular signs and symptoms, including but not limited to corneal staining and changes in the Schirmer's test score at 12 weeks. The study will also evaluate several safety and tolerability measures.

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 modified 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 but are not limited to statements relating to, among other things, results from the planned study or studies of KIO-101 that could support Kiora's efforts to advance KIO-101 to more advanced stages of clinical development, gaining regulatory approvals and commercialization, as well as the success thereof, with such approvals. Success may not be obtained or achieved on a

timely basis or at all. 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, market and other conditions and certain risk factors described under the heading "Risk Factors" contained in Kiora's Amendment No. 1 to Annual Report on Form 10-K/A filed with the SEC on July 7, 2022 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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