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): **December 14, 2021**

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.)
1371 East 2100 South **Suite 200** **Salt Lake City, Utah 84105**	**84105**
(Address of principal executive offices)	(Zip Code)

(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	The Nasdaq Capital Market

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 December 14, 2021, Kiora Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the Company hasreceived topline data from its vehicle-controlled, randomized safety study of KIO-101 eyedrops in 24 healthy subjects and 21 patients diagnosed with ocular surface inflammation.

The press release is filed as Exhibit 99.1 and investors should read the press release in its entirety, including the cautionary statements regarding forward looking statements therein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby files or furnishes, as applicable, the following exhibits:

99.1	Press Release of the Company, dated as of December 14, 2021
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: December 14, 2021

Kiora Reports KIO-101 is Safe and Tolerable; Topline Data Supports Advancing KIO-101 to a Phase 2 Study in Patients with Dry Eye Disease

SALT LAKE CITY, UT, Dec 14, 2021 – Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX), ("Kiora" or the "Company") announced topline data from its vehicle-controlled, randomized safety study of KIO-101 eyedrops. The study evaluated 24 healthy subjects and 21 patients diagnosed with ocular surface inflammation, a key driver of dry eye disease. The results demonstrated favorable safety and tolerability of KIO-101 as well as statistically significant improvements in conjunctival hyperemia, a key inclusion criterion for the 21 patients enrolled with ocular surface inflammation and a recognized clinical sign in patients with ocular surface inflammation and associated dry eye. These results warrant advancing KIO-101 into Phase 2 studies of longer duration. KIO-101 is a small molecule DHODH inhibitor representing a novel approach to addressing ocular inflammation and dry eye disease. Previous generations of DHODH inhibitors are currently approved to treat patients with the systemic autoimmune diseases, multiple sclerosis and rheumatoid arthritis.

"As an exploratory study, our predetermined analysis plan was limited to only formal comparisons between groups for pharmacokinetics, safety and tolerability. A post-hoc analysis on predefined secondary efficacy outcomes showed a meaningful reduction in conjunctival hyperemia, consistent with inhibition of both T-cell proliferation and proinflammatory cytokine release that we would expect from an immune modulating DHODH inhibitor," said Eric J Daniels, MD, Chief Development Officer of Kiora. "These early signs of a drug-related effect on clinical outcomes are encouraging and support KIO-101's continued development for patients with ocular surface inflammation associated with dry eye disease."

The topline results and observations include the following:

- KIO-101 had a favorable safety and tolerability profile with no systemic serious adverse events (SAE) or ocular SAEs in any subjects tested.
- Pharmacokinetic analysis demonstrated no detectable levels of KIO-101 in the plasma in the majority of subjects, consistent with the design of Kiora's ophthalmic formulation.
- Treatment with KIO-101 resulted in a statistically significant and clinically meaningful reduction in conjunctival hyperemia, an FDA accepted pivotal study "sign endpoint" for dry eye disease.
    - Results showed at day 13, 100% of patients treated with KIO-101 (14/14) saw a reduction≥1 from baseline, measured on the Efron scale (0-5), versus only 42.8% with vehicle control (3/7) ($p < 0.006$).
    - The mean reduction in conjunctival hyperemia score from baseline to day 13 demonstrated statistical significance in active vs. vehicle control (-1.055 vs. -0.604; $p = 0.0316$).
    - This apparent drug effect on conjunctival hyperemia was lost when patients were assessed at the Day 20 post-treatment follow-up, 8 days after the last dose was administered.
- There was a numerical trend favoring KIO-101 in ocular surface disease index (OSDI), but no statistically significant differences were observed in tear break up time (TBUT), corneal staining, conjunctival staining nor other exploratory endpoints. A larger sample size and dosing period longer than two weeks is necessary to effectively evaluate a statistical drug effect on these efficacy endpoints.
- Additional data will be submitted for presentation at an upcoming scientific/medical conference.

Trial Design

The randomized, double-masked, vehicle-controlled, single site study was conducted in Vienna, Austria and led by Principal Investigator Gerhard Garhöfer, MD, Associate Professor, Medical University of Vienna. The trial was designed to evaluate the safety and tolerability of KIO-101 in patients with ocular surface inflammation. A total of 21 patients were treated BID for 12 days with 0.15% of KIO-101 (n=14) or vehicle (n=7). The key inclusion criteria were conjunctival hyperemia score ≥2 and an OSDI of > 22. Primary endpoints included safety and tolerability. Secondary and exploratory endpoints included pharmacokinetics of KIO-101 as well as OSDI, conjunctival hyperemia, TBUT, corneal staining (Fluorescein), and conjunctival staining (Lissamine Green), ocular discomfort, lid edema, lid erythema.

This followed the Phase 1 dose-ascending portion of the study in healthy volunteers, in which a total of 24 subjects were randomized to receive KIO-101 (0.05%, 0.15%, and 0.30%) or vehicle. Key endpoints assessed were safety, tolerability and plasma pharmacokinetics of KIO-101 following 1 day (single dose) and 12 days (48 doses).

About Kiora

Kiora is a clinical-stage biotechnology company developing and commercializing products for treating ophthalmic diseases. KIO-301 is a molecular photoswitch that has the potential to restore light perception in patients with inherited and/or age-related retinal degeneration. KIO-101 is a next-generation, non-steroidal, immuno-modulatory and small molecule inhibitor of Dihydroorotate Dehydrogenase ("DHODH") with 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 other DHODH inhibitors. In addition, Kiora is developing KIO-201, a modified form of the natural polymer hyaluronic acid, designed to accelerate corneal wound healing. For more information, please visit www.kiorapharma.com.

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 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. 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, 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, 2021 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

Francina Agosti, PhD
(617) 546-0742
fagosti@reportablenews.com
