

**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): **July 30, 2024**

**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 8.01. Other Events.**

On July 30, 2024, Kiora Pharmaceuticals, Inc. (the "Company") issued a press release announcing that it has received European Orphan Medicinal Product Designation for KIO-301 for the treatment of inherited retinal dystrophies. 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
<a href="#">99.1</a>	<a href="#">Press Release of Kiora Pharmaceuticals, Inc. dated July 30, 2024.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**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 and Chief Financial Officer  
(Principal financial and accounting officer)

Date: July 30, 2024

## **Kiora Pharmaceuticals Receives European Orphan Medicinal Product Designation for KIO-301 for the Treatment of Inherited Retinal Dystrophies**

Encinitas, CA – July 30, 2024 – [Kiora Pharmaceuticals](#) (NASDAQ: KPRX) (“Kiora” or the “Company”) today announced it has received [Orphan Medicinal Product Designation](#) from the European Medicines Agency (EMA) for the treatment of a group of inherited retinal diseases (IRDs) that include retinitis pigmentosa (RP), choroideremia and more. The broad designation covers KIO-301, a small molecule photoswitch, for the treatment of non-syndromic rod-dominant retinal dystrophies. This classification of dystrophies, in simplified terms, refers to rare diseases from underlying genetic mutations resulting in predominantly and primarily the degeneration of rod photoreceptors, the cells responsible almost entirely for night vision as well as peripheral and non-color vision. In RP, which today has no approved therapeutics, rods degenerate first followed by degeneration of cone photoreceptors, the cells responsible for color and central vision. This degenerative process causes partial or severe loss of vision and may result in complete blindness. There are approximately 92 million rods in the human eye compared to approximately 6 million cones.

“This designation provides Kiora and our development and commercialization partner, Théa Open Innovation, with at least ten years of market exclusivity, exclusive of patent protection, in Europe. This is in addition to other regulatory and market access benefits,” said Eric Daniels, M.D., Chief Development Officer of Kiora Pharmaceuticals. “With Orphan Drug Designation already granted in the U.S., KIO-301 is well positioned for expedited regulatory guidance, review, and market exclusivity in two major marketplaces. We are finalizing the design and planning to initiate the Phase 2 trial of KIO-301 (ABACUS-2) later this year.”

In addition to market exclusivity, additional benefits of Orphan Medicinal Product Designation includes:

- A centralized process for EU market approval;
- Reduced or waived fees for regulatory activities; and
- EMA scientific advice and protocol assistance to optimize trial design.

The European Union provides Orphan Medicinal Product Designation to incentivize drug developers to bring products for rare diseases to market that may otherwise not be developed. The designation is granted after a critical review and only if a drug candidate meets specific criteria, which includes but is not limited to the following:

- The investigational therapy is medically plausible and intended to treat a serious or life-threatening disease; and
- The condition affects no more than 5 in 10,000 people in the EU.

Kiora’s upcoming ABACUS-2 trial of KIO-301 for vision restoration in individuals with RP, will be a multi-center, double-masked, randomized, controlled, multiple-dose study. KIO-301 is a small molecule photoswitch designed to selectively confer light-sensing capabilities to retinal ganglion cells following the degeneration of photoreceptors in inherited retinal diseases like retinitis pigmentosa. This represents a novel, gene-mutation agnostic, non-cell or gene therapy approach to addressing vision loss in IRDs.

In January 2024, Kiora, along with Théa Open Innovation (TOI), a sister company of the global ophthalmic specialty company Laboratoires Théa (Théa), agreed to an exclusive worldwide co-development and commercialization agreement, excluding Asia, for KIO-301 in the treatment of retinal diseases.

### **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.

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In addition to news releases and SEC filings, we expect to post information on our website ( [www.kiorapharma.com](http://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, Kiora's ability to execute on development and commercialization efforts and other regulatory or marketing approval efforts pertaining to Kiora's development-stage products, including KIO-104 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 sufficiency of existing cash on hand to fund operations for specific periods, the projected cash runway, and Kiora's plans to further fund development of KIO-104. 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 satisfy the closing conditions related to the offering, 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 Annual Report on Form 10-K filed with the SEC on March 25, 2024 or described in Kiora's other public filings including on Form 10-Q filed with the SEC on May 10, 2024. 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.

#### **Contacts:**

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