August 9, 2024

Kiora Pharmaceuticals Reports Second Quarter Results; Retinal Disease Drug Development Pipeline Advancing Toward Two Phase 2 Studies

Encinitas, California--(Newsfile Corp. - August 9, 2024) - Kiora Pharmaceuticals, Inc. (NASDAQ: KPRX) ("Kiora" or the "Company") announces second quarter 2024 financial results and provides an update on its pipeline of therapeutics for the treatment of retinal diseases. During the quarter, Kiora finalized the trial design for the Phase 2 study (ABACUS-2) of KIO-301, a novel molecular photoswitch, for the treatment of retinitis pigmentosa through our partnership with Théa Open Innovation (TOI). In parallel, the Company is planning its Phase 2 clinical trial (CLARITY) of KIO-104, a small molecule targeting the treatment of multiple retinal inflammatory diseases. Kiora ended the quarter with $27.8 million in cash, cash equivalents and short-term investments. Additionally, the Company has near-term receivables from R&D reimbursements from TOI and research incentive tax credits totaling an additional $3.7 million. This provides Kiora with an expected runway into 2027, before any potential partnership milestones.

"We are advancing two exciting and potential first-in-class small molecules toward Phase 2 trials," said Brian M. Strem, Ph.D., President & Chief Executive Officer of Kiora. "Our cash position allows us to invest time upfront to design and implement robust studies, which can reduce time to market and increase our chances for approval and commercial success.

"KIO-301 is our small molecule photoswitch for the treatment of inherited retinal diseases, such as retinitis pigmentosa (RP). Under our development and commercialization partnership with TOI, we are responsible for conducting the Phase 2 clinical trial. Strategic benefits from this partnership include reimbursement for KIO-301 R&D as well as potential milestone payments when pre-defined clinical development triggers are met.

"A key initiative in the second quarter was to gain clarity on details of the approvable endpoints for KIO-301. Through multiple interactions with the FDA and European regulators, functional vision testing, such as navigation course and object identification, remains the path to approval. While we deployed functional vision testing in our ABACUS-1 trial, we sought to further refine the assessments being used, and have begun clinical validation of these improvements prior to our planned initiation of our Phase 2 ABACUS-2 trial later this year. The goal of the clinical validation, supported in part by a grant from the Choroideremia Research Foundation (CRF), is to finalize endpoints to be used for the ABACUS-2 trial and become a standard measure for clinical trials of vision restoring therapeutics. ABACUS-2 follows on the positive data reported in ABACUS-1, reported at the most recent American Academy of Ophthalmology and the Association for Research in Vision and Ophthalmology annual conferences.

"KIO-104 is a potent, locally delivered small molecule we are developing to treat several inflammatory retinal diseases. The goal is to offer patients and providers the hope of an alternative to chronic steroid use or systemic anti-inflammatory drugs, both of which can lead to complications. KIO-104 acts by suppressing the number and function of specific T cells causing damaging levels of inflammation. Early next year we plan to initiate a Phase 2 trial, building on positive Phase 1b results, where we will explore multiple doses and enroll patients with several forms of inflammatory retinal disease, such as non-infectious uveitis, diabetic macular edema and retinal vein occlusion. Findings in the study will inform a dose expansion trial in one or more specific indications. Additional non-clinical work is currently underway to support final trial design and we anticipate initiating the clinical trial early next year."

Chief Financial Officer, Melissa Tosca, added, "We maintained our strong cash position, ending the second quarter with effectively $31.5 million and a cash runway of more than two years, excluding any potential milestone payments or warrant exercise accelerators. This provides us the financial resources to implement, complete and report data on two robust Phase 2 studies."

Milestones achieved during and after the end of the second quarter of 2024 include:

KIO-301

- 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, choroideremia and more.
- Reported quantitative functional MRI results at the Association of Research in Vision and Ophthalmology (ARVO) annual conference from ABACUS-1, showing a statistically significant increase in neural activity over baseline specifically within the brain's visual processing center. This increase in observed brain activity was time-dependent and concordant with previously reported improvements in visual field, visual acuity, and functional vision improvements.
- Received grant funding from the CRF in support of validating functional vision assessments for patients with profound blindness to be used in ABACUS-2 and other inherited retinal disease clinical trials.

KIO-104

- Initiated Investigational New Drug enabling preclinical work in support of planned phase 2 retinal inflammation clinical trial.
- Developed framework of Phase 2 clinical trial (CLARITY) design for KIO-104 in the treatment of retinal inflammatory diseases.

Corporate

- Promoted Melissa Tosca to Chief Financial Officer.
- Appointed Lisa Walters-Hoffert as an independent member to the Company's Board of Directors.

Kiora anticipates achieving the following clinical and regulatory milestones:

KIO-301

- 2H 2024: Complete clinical validation of functional vision endpoints for ABACUS-2

- 2H 2024: Receive approval to initiate Phase 2 ABACUS-2 study

KIO-104

- 2H 2024: Complete non-clinical, Phase 2 enabling package
- 1H 2025: Initiate Phase 2 CLARITY study

Second Quarter Financial Highlights

Kiora ended the second quarter of 2024 with $27.8 million in cash and cash equivalents and short-term investments. In addition, the Company recorded $1.3 million in collaboration receivables from TOI for reimbursed R&D expenses and $2.3 million R&D incentive tax credits.

Revenue was $20,000 for the second quarter of 2024, compared to no revenue in the second quarter of 2023. The revenue was recognized as part of the grant received from Choroideremia Research Foundation in support of validating functional vision assessments for patients with profound blindness.

Kiora spent $2.0 million on research and development in the second quarter of 2024. After $1.1 million in offsetting expense reimbursement credits related to the strategic development and commercialization agreement with TOI, Kiora is recording net research and development expenses of $0.9 million, compared to $1.4 million for the second quarter of 2023.

General and administrative expenses were $1.5 million for the second quarter of 2024, compared to $1.1 million for the second quarter of 2023. The increase is due in part to technical accounting advisory services related to the strategic development and commercialization agreement with TOI, a benchmarking survey, and legal and other advisory services related to the reverse stock split.

Net loss was $2.2 million for the second quarter of 2024 compared to a net loss of $2.6 million for the second quarter of 2023. The decrease in net loss is primarily attributed to offsetting KIO-301 expense credits of $1.1 million dollars related to the strategic development and commercialization agreement of KIO-301 with TOI.

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. 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.

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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, KIO-301, KIO-201 and KIO-101, 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, the ability to timely complete planned initiatives for 2024, including phase 2 clinical development of KIO-301 and KIO-104, the potential for KIO-301 to be the first treatment options for patients with inherited degenerative diseases like RP, Kiora's plans to further fund development of KIO-104, the potential for KIO-104 to reduce inflammation, the timing of topline results from a Phase 2b trial of KIO-104, the potential for KIO-104 to apply to other retinal inflammatory diseases, and expected trends for research and development and general and administrative spending in 2024. 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 August 9, 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.

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CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 6,575,394	$ 2,454,684
Short-Term Investments	21,242,671	—
Prepaid Expenses and Other Current Assets	339,646	233,382
Collaboration Receivables	1,341,297	—
Tax and Other Receivables	2,331,797	2,049,965
Total Current Assets	31,830,805	4,738,031
Non-Current Assets:		
Property and Equipment, Net	63,487	8,065
Restricted Cash	4,179	4,267
Intangible Assets and In-Process R&D, Net	8,801,350	8,813,850

Operating Lease Assets with Right-of-Use	82,322	106,890
Other Assets	32,122	40,767
Total Assets	$ 40,814,265	$ 13,711,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 268,638	$ 206,260
Accrued Expenses	1,345,192	1,380,666
Operating Lease Liabilities	42,126	47,069
Total Current Liabilities	1,655,956	1,633,995
Non-Current Liabilities:		
Contingent Consideration	5,236,999	5,128,959
Deferred Tax Liability	779,440	779,440
Operating Lease Liabilities	40,197	59,822
Total Non-Current Liabilities	6,056,636	5,968,221
Total Liabilities	7,712,592	7,602,216
Commitments and Contingencies (Note 8)		
Stockholders' Equity:		
Preferred Stock, $0.01 Par Value: 10,000,000 shares authorized; 3,750 designated Series A, 0 shares issued and outstanding; 10,000 designated Series B, 0 shares issued and outstanding; 10,000 shares designated Series C, 0 shares issued and outstanding; 20,000 shares designated Series D, 7 shares issued and outstanding; 1,280 shares designated Series E, 0 shares issued and outstanding; 3,908 shares designated Series F, 420 issued and outstanding at June 30, 2024 and December 31, 2023, respectively	4	4
Common Stock, $0.01 Par Value: 150,000,000 and 50,000,000 shares authorized; 2,970,545 and 856,182 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	267,373	77,078
Additional Paid-In Capital	168,825,325	153,192,228
Accumulated Deficit	(135,745,294)	(146,976,855)
Accumulated Other Comprehensive Loss	(245,875)	(182,801)
Total Stockholders' Equity	33,101,673	6,109,654
Total Liabilities and Stockholders' Equity	$ 40,814,265	$ 13,711,870

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(unaudited)

	Three Months Ended June 30,		Six Months Ended, June 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration Revenue	$ —	$ —	$ 16,000,000	$ —
Grant Revenue	20,000	—	20,000	—
Total Revenue	20,000	—	16,020,000	—
Operating Expenses:				
General and Administrative	1,537,973	1,097,294	2,834,414	2,366,752
Research and Development	906,680	1,392,099	2,400,339	1,830,382
Change in Fair Value of Contingent Consideration	120,234	143,619	108,040	352,545
Total Operating Expenses	2,564,887	2,633,012	5,342,793	4,549,679
Operating Income (Loss)	(2,544,887)	(2,633,012)	10,677,207	(4,549,679)
Other Income, Net:				
Interest Income, Net	342,102	45,087	565,149	78,552
Other Income, Net	(18,861)	(25,888)	(10,795)	(11,222)
Total Other Income, Net	323,241	19,199	554,354	67,330
Net Income (Loss)	$ (2,221,646)	$ (2,613,813)	$ 11,231,561	$ (4,482,349)
Net Income (Loss) per Common Share - Basic	$ (0.53)	$ (7.15)	$ 3.19	$ (15.63)
Weighted Average Shares Outstanding - Basic	4,170,627	365,530	3,526,211	286,729
Net Income (Loss) per Common Share - Diluted	$ (0.53)	$ (7.15)	$ 2.79	$ (15.63)
Weighted Average Shares Outstanding - Diluted	4,170,627	365,530	4,031,174	286,729
Other Comprehensive Income (Loss):				
Net Income (Loss)	$ (2,221,646)	$ (2,613,813)	$ 11,231,561	$ (4,482,349)
Unrealized Loss on Marketable Securities	(2,828)	—	(2,828)	—
Foreign Currency Translation Adjustments	21,467	(10,449)	(60,246)	(43,120)
Comprehensive Income (Loss)	$ (2,203,007)	$ (2,624,262)	$ 11,168,627	$ (4,525,469)



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