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Zacks Small-Cap Research

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Elizabeth Senko, CFA
312-265-9484
esenko@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Kiora Pharmaceuticals (NASDAQ:KPRX)

KPRX: What a difference a year makes!

Our $1.16 valuation for KPRX is based on a risk-adjusted sum-of-the-products NPV, less R&D and corporate overhead, and a 15% discount rate. Our model assumes KPRX carries all R&D and overhead costs through approval (~ $80 million), out-licenses production, and retains marketing/ sales. Potential upside could come from R&D cost sharing, milestones and other cash inflows.

OUTLOOK

We are updating our model and valuation for Kiora Pharmaceuticals, a clinical stage company developing new approaches to treating ophthalmic conditions. The past 18 months have been full of change at Kiora - the pipeline expanded from one to three candidates (with multiple possible indications), the Company raised over $20 million in funding, and added key clinical and management hires. We expect a series of clinical milestones over the next 12-18 months to help refocus attention on an underappreciated company.

Current Price (08/12/22)	$0.16
Valuation	**$1.16**

SUMMARY DATA

52-Week High	**$2.25**
52-Week Low	**$0.15**
One-Year Return (%)	**-90.03**
Beta	**0.43**
Average Daily Volume (sh)	**5,575,652**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$6**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**30**
Insider Ownership (%)	**0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**-0.2**
P/E using 2023 Estimate	**0.5**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2022	0.0 A	0.0 A			0.0 E
2023					0.0 E
2024					0.0 E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.27 A	-$0.35 A	-$0.29 A	-$0.42 A	-$1.33 A
2022	-$0.27 A	-$0.18 A			-$0.43 E
2023					-$0.30 E
2024					$0.28 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

INVESTMENT SUMMARY

COMPANY DESCRIPTION. We are updating our model and valuation for Kiora Pharmaceuticals (formerly EyeGate Pharmaceuticals), a clinical stage company developing new approaches to treating ophthalmic conditions. The past 18-months have been full of change at Kiora - the pipeline expanded from one to three candidates (with multiple possible indications), the Company raised over $20 million in funding, and added key clinical and management hires. We expect a series of clinical milestones over the next 12-18 months to help refocus attention on an underappreciated company.

VALUATION. Our $1.16 valuation for KPRX is based on a risk-adjusted sum-of-the-products NPV, less R&D and corporate overhead, and a 15% discount rate. Our model assumes KPRX carries all R&D and overhead through approval (estimated at $80 million), out-licenses production, and retains sales/ marketing. Several factors provide upside to our valuation including: pre-approval partnership that provides milestones and/or R&D cost sharing, potential for sales in other geographies, and approval of other indications (e.g., KIO-301 in AMD) or molecules.

FINANCIALS. We forecast ~$80 million in development and overhead costs for KPRX to get its three pipeline candidates approved and to the market. If all goes to plan, we KIO-101 and KIO-301 to begin sales in 2028, with $41 million in revenue. We also forecast that Kiora will be GAAP profitable during 2028.

In 2021, R&D expenses totaled $5.4 million, compared to $3.6 million in 2020. The increase was primarily due to development costs for KIO-101 in DED, as well as personnel-related costs from the Panoptes acquisition in December 2020. These increases were partially offset by lower development costs related to KIO-201 (ocular bandage gel). General and administrative expenses rose 14% to $5.3 million from $4.6 million in 2020. Higher personnel costs and professional service use drove the increase.

On July 7, 2022, Kiora Pharmaceuticals filed restated financial statements for 2020 and 2021, to correct misstatements related to contingent consideration, goodwill and in-process R&D valuation for three acquisitions. In our view, the restatements primarily affect how previously-acquired assets are carried on the balance sheet, not cash, and do not represent a meaningful change to our outlook for these pipeline assets. On July 26, Kiora closed a public offering of common stock and warrants, of $6.0 million in gross proceeds.

SENSITIVITIES. In our view, Kiora Pharmaceuticals has several promising compounds in its development pipeline. While the Company's shift to earlier-stage, differentiated drug development, extends its commercialization timeline, we believe it is de-risked somewhat by creating potentially more compelling collaborative opportunities with pharmaceutical partners. We see financing/partnership access and development risk as the primary factors that could affect our forecasts and valuation.

COMPANY DESCRIPTION

Kiora Pharmaceuticals is developing multiple assets in the ophthalmic medicine space: KIO-101 in dry eye disease, KIO-201 in photorefractive keratectomy (PRK) surgery recovery, and KIO-301 in retinitis pigmentosa (RP). We see Kiora Pharmaceuticals as uniquely situated within ophthalmology therapeutics for several reasons:

First, the company has already generated strong clinical data in two indications. In 2019, completed a pivotal study in which OBG demonstrated superiority over the standard-of-care (bandage contact lens) for wound healing following photorefractive keratectomy (PRK) surgery. Importantly, Kiora has previously demonstrated success on the endpoint (central corneal staining improvement) versus a positive control in two pilot studies. Although the company has recently elected to pursue regulatory clearance of OBG as a drug, which will lengthen the timeline to commercialization, we think it is likely they can study the compound versus vehicle, making approval more likely, in our view. In addition, approval by the FDA's CDER (Center for Drug Evaluation and Research) division would allow for Medicare Part D reimbursement, a decision we would expect commercial insurers to follow, which we see as expanding the covered population and potentially enabling more favorable pricing.

Second, we are intrigued by KIO-101, Kiora's potential first-in-class therapy for ocular presentation of rheumatoid arthritis (OPRA). KIO-101 is a dihydroorotate dehydrogenase (DHODH) inhibitor. First-generation DHODH inhibitors (e.g., Sanofi) are blockbusters despite carrying block box warnings from the FDA, and we expect KIO-101 to have a much "cleaner" safety profile. The RA market is large with ~3.3 million patients in the US. Just as RA causes inflammation in the joints, it creates inflammation throughout the body, including the eye, in up to 30% of patients. Ocular manifestations generally affect the area between the inside corneal surface and the iris. Generally, ocular manifestations present in longstanding RA patients, however, if may also be an early symptom of the disease. OTC eye drops mitigate discomfort for the 10% of patients with mild symptoms, but for the remaining 90% of patients with moderate to severe symptoms, symptoms are managed with systemic therapies (e.g., DHODH inhibitors, IL-6). There is a need for targeted, effective therapies.

Third, Kiora's newest asset, KIO-301, could be a game changer in ophthalmology, if the research proves out. KIO-301, acquired from Bayon Therapeutics in 2021. KIO-301, a small-molecule "photoswitch" is being studied to for its ability to restore vision in patients with certain degenerative retinal diseases. The molecule is designed to act on retinal ganglion cells, enabling them to sense the presence or absence of light, and transmit the information to the brain.

Kiora Pharmaceuticals (formerly EyeGate Pharmaceuticals), has changed strategy and faced setbacks in recent years, leaving investors somewhat skeptical as to whether the Company can deliver on its goals. A new management team, financial restatement, and the CFO's recent departure have provided additional fuel for skeptics. Clearly, the current team needs to deliver successfully, and consistently, on its long to-do list over the five years.

We continue to believe that science and study design at Kiora is solid. In the past, the Company has emphasized a shorter runway to profitability, but potentially at the expense of leading with "me too" products (e.g., KIO-201 in the broader dry eye disease market). Kiora's current focus on differentiated pipeline candidates and indications, comes with a longer timeline, and more development risk. However, in our view, it is much better matched to market opportunities and management expertise.

Exhibit 1. Kiora Pharmaceuticals pipeline

	Indication	Product Formulation	Development Stage				Anticipated Near-Term Milestones
			Pre-clinical	Phase 1	Phase 2	Phase 3	
Posterior Segment	Retinitis Pigmentosa (Mutation Agnostic)	KIO-301 IVT	*Granted Orphan Drug Designation – March 2022*				Expect to initiate Phase 1b in Q3 2022
Anterior Segment	Ocular Presentation of Rheumatoid Arthritis	KIO-101 Eye Drop					Expect to initiate Phase 2 in H2 2022
	Persistent Corneal Epithelial Defects	KIO-201 Eye Drop					Initiated Phase 2 in Q2 2022 Expect Orphan Drug Designation in Q3 2022
	Corneal Surgical Wounds	KIO-201 Eye Drop					Expect to initiate Phase 3b in 2023

Source. Kiora Pharmaceuticals.

Pipeline and catalysts.

KIO-201. KIO-201 is a modified form of hyaluronic acid eye drop being developed as an alternative to the bandage contact lens, used to protect the ocular surface following photorefractive keratectomy (PRK) surgery. KIO-201 has been studied in five clinical trials. In 2019, a phase III study demonstrated that it may accelerate ocular surface wound healing, reducing healing time from 7-10 days, to 3-4 days. Kiora initially sought FDA regulatory approval under the medical device pathway, however, in 2020, changes in regulatory rules reclassified it as a drug. As a result, Kiora would need to conduct a phase IIIb study prior to filing for approval; however, the drug classification (vs. device) opens up a larger market of potential patients through Medicare Part D (drug) coverage.

KIO-101. KIO-101 is a small molecule inhibitor of dihydroorotate dehydrogenase (DHODH) being studied for the treatment of moderate-to-severe dry eye disease (DED). DHODH inhibitors are currently approved for treatment of rheumatoid arthritis (RA) and other inflammatory conditions. The downside to systemic use of DHODH inhibitors, it increased risk of liver toxicity. Kiora hopes to demonstrate that this risk is mitigated as a localized treatment, and studies to date support this hypothesis. The next step is a phase IIb study, expected in 2H22.

KIO-301. KIO-301, is a first-in-class small molecule 'photoswitch' being developed as a treatment to reactive vision in patients with retinitis pigmentosa (RP), a rare, inherited genetic eye disease that causes degeneration of the retinal photoreceptors, leaving to severe loss of functional vision. The FDA granted KIO-301 Orphan Drug designation in late March, and gave Kiora approval to initial a first-in-human clinical trial in late June. The ABACUS study is a Phase 1b open label, single ascending dose clinical trial for people living with Retinitis Pigmentosa. This single-site study will be conducted at The Royal Adelaide Hospital (RAH) in Adelaide, South Australia and is expected to start enrollment in 3Q22. Kiora also plans to study KIO-301 for geographic atrophy associated with age-related macular degeneration (AMD).

SENSITIVITIES

In our view, Kiora Pharmaceuticals has several promising compounds in its development pipeline. While the Company's shift to earlier-stage, differentiated drug development, extends its commercialization timeline, we believe it is derisked somewhat by creating potentially more compelling collaborative opportunities with pharmaceutical partners.

Financing and partnership risk. Our model calls for ~$80 million of non-cash expenses (e.g., R&D, corporate overhead), over the next five years. To date, Kiora has primarily raised funds through private placements (usually common stock and options/warrants), and we anticipate that this will be the primary financing avenue, at least through 2024. If KIO-201 is approved as we anticipate in late 2023-early 2024, that would likely offset some of Kiora's funding needs. More likely, in our view, would be development/ licensing partnerships for KIO-301 or KIO-101 after phase II or early phase-III trials. Such collaboration s might include upfront cost-sharing, milestone payments and/or royalties, which are not built into our current assumptions.

Commercialization. Kiora's management plans to outsource production to a CMO, and build an in-house sales/marketing effort, as two of its three pipeline products are expected to launch with orphan drug/specialized indications. Previously, we modeled that Kiora would outsource both production and sales/marketing, in exchange for a royalty stream. With the Company's new focus on differentiated, higher-value indications, we believe the rationale for building an in-house sales team is solid. An in-house team will likely have more specialized expertise than an outsourced team, and will not be distracted by the need to sell a large portfolio of products to a wider range of ophthalmologists.

Development risk. Both KIO-101 and KIO-301 are in early clinical development. KIO-101 has demonstrated efficacy in inflammatory conditions, as well as safety and tolerability in a small human trial; however, it will require several larger studies prior to filing for regulatory approval. KIO-301 is conducting its FIH trial in 2022, and as a first-in-class agent, there is higher risk of clinical trial failure, but at this point we don't believe the risk profile is markedly different than early-stage drugs as a whole.

Dilution and milestone payments. Unlike many development stage companies, we aren't overly concerned with shareholder dilution from convertible shares and options. A longer-term consideration for shareholders is potential milestone payments up to $7.1 million related to Kiora's acquisition of Bayon Therapeutics. However, these payments can be made in either cash or common stock, so while there is potential dilution risk to shareholders, the payment itself would be unlikely to trigger a liquidity issue.

VALUATION

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Exhibit 2. Sum-of-the parts NPV valuation

Valuation by NPV sum-of-the-parts					
Product	**Indication**	**Launch**	**NPV ($M)**	**Probability**	**rNPV ($M)**
KIO-201	Ocular bandage	2026	21	***90%***	19
KIO-101	DED	2028	1,842	***40%***	737
KIO-301	Retinitis pigmentosa	2028	875	***20%***	262
Total Products					
Corporate overhead			(982)	***100%***	(982)
Net Cash			9	***100%***	9
Firm Value			**1,765**		**45**
Basic shares outstanding (millions)					39
Value per basic share ($)					**1.16**

Source. Zacks Investment Research estimates.

FINANCIALS

Profit and loss

In 2021, R&D expenses totaled $5.4 million, compared to $3.6 million in 2020. The increase was primarily due to development costs for KIO-101 in DED, as well as personnel-related costs from the Panoptes acquisition in December 2020. These increases were partially offset by lower development costs related to KIO-201 (ocular bandage gel). General and administrative expenses rose 14% to $5.3 million from $4.6 million in 2020. Higher personnel costs and professional service use drove the increase.

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Cash flow

As a pre-revenue company, Kiora, is not cash flow positive; its current burn rate is ~$1 million per month. Our model forecasts a need to raise $12 million - $16 million annually through 2027 at least; however, we believe a sizeable portion of these funds will come from external R&D partnerships, particularly as we move past 2024, reducing Kiora's need to access the capital markets.

Balance sheet

At the end of December 2021, cash and cash equivalents were $7.9 million as of compared to $1.2 million at the end of 2020. The increase in cash and cash equivalents was mainly due to net proceeds of $8.0 million received from the completion of a private placement in January 2021, as well as net proceeds of $9.8 million from the completion of a registered direct offering in August 2021. On July 26, Kiora closed a public offering of common stock and warrants, of $6.0 million in gross proceeds.

Exhibit 3. Financial Summary

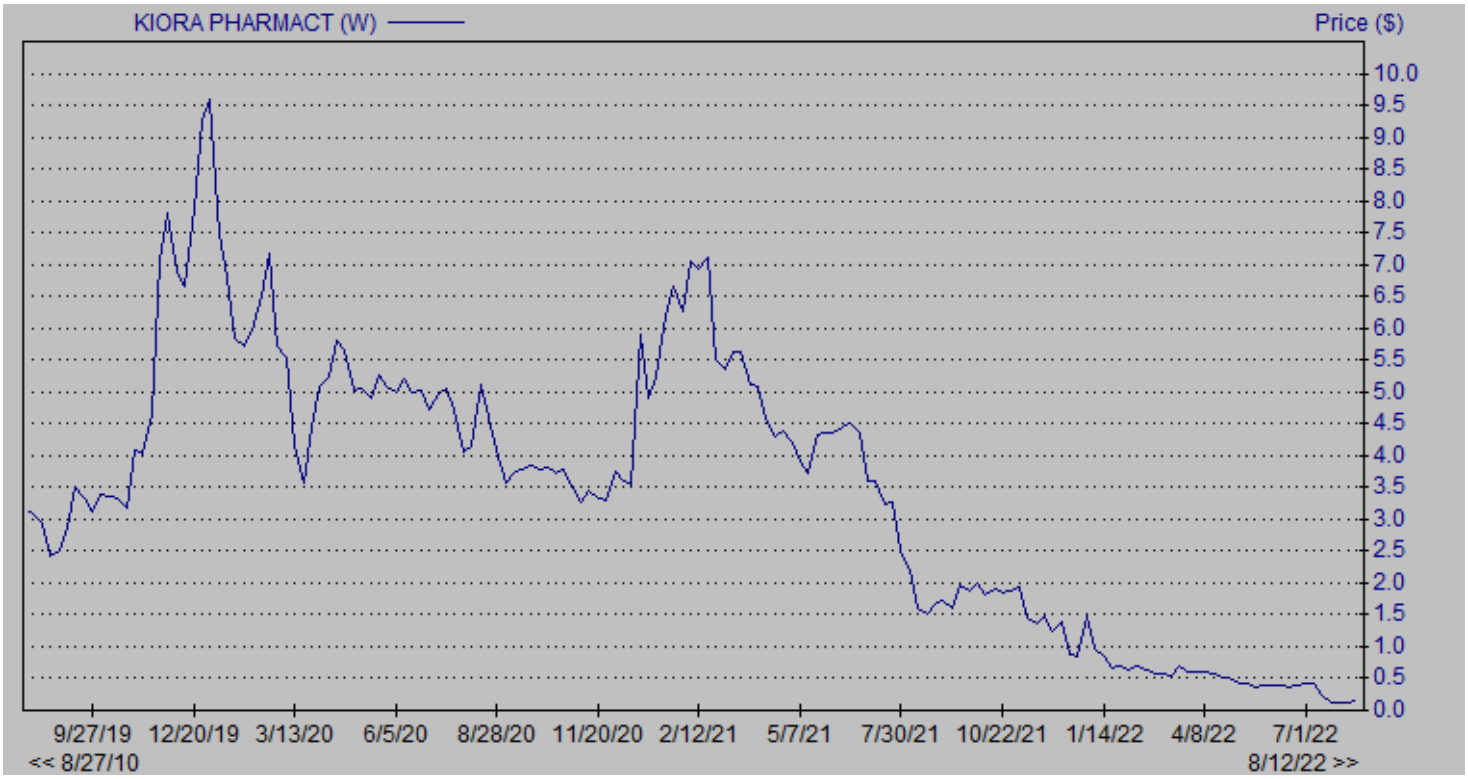
INCOME STATEMENT ($M)								
Fiscal year (Dec)	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E
Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.2**	**1.3**
Cost of sales	0.0	0.0	0.0	0.0	0.0	0.0	(0.0)	(0.1)
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.2	1.2
Research and development	(3.6)	(5.4)	(6.4)	(7.7)	(9.2)	(11.1)	(13.1)	(15.3)
Sales and marketing	0.0	0.0	0.0	0.0	0.0	0.0	(0.0)	(0.2)
General & administrative	(4.7)	(5.3)	(6.1)	(6.8)	(7.5)	(8.1)	(8.7)	(9.3)
Operating profit (EBIT)	**(6.9)**	**(14.2)**	**(13.7)**	**(14.5)**	**(16.7)**	**(19.2)**	**(21.6)**	**(23.6)**
Total other income/(expense)	0	0	0	0	0	0	0	0
Pretax profit	**(6.8)**	**(14.0)**	**(13.7)**	**(14.5)**	**(16.7)**	**(19.2)**	**(21.6)**	**(23.6)**
Taxes	(0.0)	0.2	0.0	0.0	0.0	0.0	0.0	0.0
Net income	**(6.9)**	**(13.8)**	**(13.7)**	**(14.5)**	**(16.7)**	**(19.2)**	**(21.6)**	**(23.6)**
Basic shares outstanding (M)	4.6	9.6	32.1	47.7	54.9	68.5	80.5	93.7
Diluted shares outstanding (M)	4.6	9.6	32.1	47.7	54.9	68.5	80.5	93.7
Basic EPS	**($1.49)**	**($1.43)**	**($0.43)**	**($0.30)**	**($0.30)**	**($0.28)**	**($0.27)**	**($0.25)**
Diluted EPS	**($1.49)**	**($1.43)**	**($0.43)**	**($0.30)**	**($0.30)**	**($0.28)**	**($0.27)**	**($0.25)**

BALANCE SHEET								
Fiscal year	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E
Cash & equivalents	1.2	7.9	10.4	9.2	5.8	(0.2)	(8.6)	(13.0)
Accounts receivable	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.3
Total current assets	**1.7**	**9.0**	**11.2**	**9.7**	**6.1**	**0.1**	**(8.2)**	**(12.4)**
Property plant and equipment	0.0	0.1	0.1	0.1	0.2	0.2	0.3	0.3
Total Assets	**15.3**	**20.1**	**22.4**	**20.9**	**17.3**	**11.3**	**3.0**	**(1.2)**
Accounts payable	0.4	0.2	0.3	0.3	0.3	0.4	0.4	0.5
Total current liabilities	**2.0**	**1.6**	**1.7**	**1.7**	**1.8**	**1.8**	**1.9**	**1.9**
Total liabilities	**5.6**	**5.6**	**5.6**	**5.7**	**5.7**	**5.8**	**5.8**	**5.9**
Common stock / APIC	116.8	135.4	0.0	0.0	0.0	0.0	0.0	0.0
Retained earnings / accumulated defici	(107.1)	(120.9)	(134.6)	(149.1)	(165.9)	(185.1)	(206.6)	(230.2)
Other comprehensive income / (loss)	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Total equity	**9.7**	**14.6**	**16.8**	**15.2**	**11.5**	**5.5**	**(2.8)**	**(7.0)**
Total liabilities and equity	**15.3**	**20.1**	**22.4**	**20.9**	**17.3**	**11.3**	**3.0**	**(1.2)**

CASH FLOW STATEMENT								
Fiscal year	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E
Cash from operating activities	**(7.3)**	**(10.7)**	**(12.4)**	**(13.2)**	**(15.4)**	**(18.0)**	**(20.3)**	**(22.3)**
Capital expenditures	(0.1)	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0
Cash from investing activities	**(0.2)**	**(0.2)**	**(0.1)**	**(0.1)**	**(0.1)**	**(0.1)**	**(0.1)**	**(0.1)**
Cash from financing activities	**5.0**	**17.6**	**15.0**	**12.0**	**12.0**	**12.0**	**12.0**	**18.0**
Net change in cash during period	**(2.6)**	**6.7**	**2.6**	**(1.2)**	**(3.4)**	**(6.0)**	**(8.3)**	**(4.4)**

Source. Company filings, Zacks Investment Research estimates.

HISTORICAL STOCK PRICE



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