

# **Eyenovia Reports First Quarter 2024 Financial Results and Provides Updates on its Myopia Phase III Program and its Two FDA Approved Commercial Products, Mydcombi and Clobetasol**

*Remains on track towards accelerating development of its late-stage product candidate in the multi-billion-dollar pediatric progressive myopia market, MicroPine*

*Preparing for a 3Q 2024 launch of the first new ophthalmic steroid in 15 years, clobetasol propionate ophthalmic suspension 0.05%, for the treatment of inflammation and pain following ocular surgery*

*Company to host conference call and webcast today, May 15<sup>th</sup>, at 4:30 pm ET*

NEW YORK, May 15, 2024 (GLOBE NEWSWIRE) -- [Eyenovia, Inc.](#) (NASDAQ: EYEN), a commercial-stage ophthalmic company with two FDA-approved products and a late-stage asset in pediatric progressive myopia, today announced its financial and operating results for the first quarter ended March 31, 2024.

## **First Quarter 2024 and Recent Business Developments**

- Announced updated plans to accelerate development of its late-stage product candidate for pediatric progressive myopia, MicroPine. These plans include a protocol amendment to allow for a Data Monitoring Committee to review the Phase 3 CHAPERONE study data early in the fourth quarter. External sources have valued the pediatric progressive myopia market at over \$3.0 billion annually in the U.S. and China.
- Announced FDA approval of clobetasol propionate ophthalmic suspension 0.05% for the treatment of inflammation and pain following ocular surgery. Eyenovia is planning a launch of this product in the third quarter of 2024. Clobetasol has a desirable clinical profile as compared to other topical ocular steroids with twice-a-day dosing, a high level of efficacy and with adverse events occurring in fewer than 2% of patients.
- Reported training and shipping product to 50 new Mydcombi-using offices by its initial five Key Account Managers since sales promotion started in April 2024. Additionally, formulary agreements with Vision Source and the University of California have been executed.
- Reduced the Company's anticipated cash-based expenses by approximately \$0.8 million per quarter from first quarter 2024 actual levels.

Michael Rowe, Chief Executive Officer, commented, "During the first quarter of 2024, we took tangible steps to increase the inherent value of our company, which currently includes

our novel Optejet technology, two FDA-approved products, and a third in late Phase 3 development. With highly differentiated and desirable products such as Mydcombi for mydriasis and clobetasol for post-surgical pain and inflammation, we look forward to meaningful sales growth over the next 18 months that we anticipate will lead us towards profitability. And our crown jewel, MicroPine for progressive myopia, if approved, would add significant value to the company by addressing a key unmet medical need of the approximately five million at-risk children in the U.S. alone.”

“We believe the progress that we continue to make toward optimizing our platform technology has laid a strong foundation towards transforming Eyenovia into a leader in the development and commercialization of topical ophthalmic products and medications. We are committed to demonstrating the value of our existing and near-term products as well as future product candidates in ophthalmic markets with high unmet needs.”

“At the same time, we completed the build-out of our manufacturing capabilities, with FDA approval of our Redwood City location in addition to our Reno facility and Coastline International as our contract manufacturer. With all three facilities online, we are currently producing commercial supply of Mydcombi while at the same time supporting both current and future development partnerships as well as our transition from the Gen-1 to Gen-2 Optejet dispenser. To that end, we recently requested a meeting with the FDA to discuss our validation of the Gen-2 dispenser, which we anticipate will occur this summer,” Mr. Rowe concluded.

### **First Quarter 2024 Financial Review**

For the first quarter of 2024, net loss was approximately \$10.9 million, or \$0.23 per share, as compared to a net loss of \$5.7 million, or \$0.15 per share, for the first quarter of 2023. The first quarter 2024 net loss includes \$2.5 million of expense, or \$0.05 loss per share, associated with the reacquisition of the license rights from Bausch for MicroPine and the write off of related clinical trial inventory.

Research and development expenses totaled approximately \$4.4 million for the first quarter of 2024, compared to \$2.5 million for the first quarter of 2023, an increase of approximately 75.7%.

For the first quarter of 2024, general and administrative expenses were approximately \$3.8 million, compared to \$2.9 million for the first quarter of 2023, an increase of approximately 30.6%.

Total operating expenses for the first quarter of 2024 were approximately \$10.3 million, including the previously referenced \$2.5 million of expenses associated with the Bausch transaction, compared to approximately \$5.5 million for the first quarter of 2023. This represents an increase of approximately 88.1%. The first quarter 2024 operating expense figure includes approximately \$1.5 million of non-cash expenses.

As of March 31, 2024, the Company’s unrestricted cash and cash equivalents were approximately \$8.0 million, not including \$2.2 million in additional capital the Company raised in April 2024.

### **Conference Call and Webcast**

The conference call is scheduled to begin at 4:30 pm ET today, May 15<sup>th</sup>. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international), and reference conference ID 13746269.

To access the Call me™ feature, which avoids having to wait for an operator, click [here](#).

A live webcast of the conference call will also be available [here](#) and on the investor relations page of the Company's corporate website at [www.eyenovia.com](http://www.eyenovia.com). After the live webcast, the event will be archived on Eyenovia's website for one year.

**PLEASE GO TO [MYDCOMBI.COM](#) FOR IMPORTANT SAFETY INFORMATION for  
MYDCOMBI™ (tropicamide and phenylephrine hydrochloride ophthalmic spray)  
1%/2.5%**

**PLEASE GO TO [CLOBETASOLBID.COM](#) FOR IMPORTANT SAFETY INFORMATION for  
Clobetasol Propionate Ophthalmic Suspension 0.05%**

### **About Eyenovia, Inc.**

Eyenovia, Inc. (NASDAQ: EYEN) is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its Optejet platform. Eyenovia is currently focused on the commercialization of Mydcombi (tropicamide+phenylephrine ophthalmic spray) for mydriasis, as well as clobetasol propionate ophthalmic nanosuspension 0.05% to reduce pain and inflammation following ocular surgery, which was approved by the FDA on March 4, 2024.

Eyenovia is also advancing late-stage development of medications in the Optejet device for presbyopia (Apersure) and myopia progression (MicroPine, partnered with Arctic Vision in China and South Korea).

For more information, visit [Eyenovia.com](http://Eyenovia.com).

The Eyenovia Corporate Information slide deck may be found at [ir.eyenovia.com/events-and-presentations](http://ir.eyenovia.com/events-and-presentations).

### **Forward-Looking Statements**

Except for historical information, all of the statements, expectations and assumptions contained in this press release are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our products, product candidates and platform technology. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements. In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment, timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential impacts of any disruptions on

our supply chain, including the availability of sufficient components and materials used in our products and product candidates; the potential advantages of our products, product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our products and product candidates; our estimates regarding the potential market opportunity for our products and product candidates; reliance on third parties to develop and commercialize our products and product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our products and product candidates; the risk of defects in, or returns of, our products; intellectual property risks; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; our competitive position; and other risks described from time to time in the "Risk Factors" section of our filings with the U.S. Securities and Exchange Commission, including those described in our Annual Report on Form 10-K as well as our Quarterly Reports on Form 10-Q, and supplemented from time to time by our Current Reports on Form 8-K. Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.

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**EYENOVIA, INC.**

**Condensed Balance Sheet**

	<b>March 31, 2024</b>	<b>December 31, 2023</b>
		<b>(unaudited)</b>

**Assets**

**Current Assets**

Cash and cash equivalents	\$ 7,976,106	\$ 14,849,057
Inventories	3,513,860	109,798

Deferred clinical supply costs	846,301	4,256,793
License fee and expense reimbursements receivable	88,045	123,833
Security deposits, current	1,506	1,506
Prepaid expenses and other current assets	2,025,267	1,365,731
 Total Current Assets	 14,451,085	 20,706,718
Property and equipment, net	3,155,710	3,374,384
Security deposits, non-current	197,168	197,168
Intangible assets	6,122,945	2,122,945
Operating lease right-of-use asset	1,538,814	1,666,718
Equipment deposits	711,441	711,441
 Total Assets	 \$ 26,177,163	 \$ 28,779,374

## **Liabilities and Stockholders' Equity**

### **Current Liabilities:**

Accounts payable	\$ 2,145,272	\$ 1,753,172
Accrued compensation	828,286	1,658,613
Accrued expenses and other current liabilities	4,751,755	287,928
Operating lease liabilities - current portion	579,585	501,250
Notes payable - current portion, net of debt discount of \$621,712 and \$503,914 as of March 31, 2024 and December 31, 2023, respectively	8,155,025	5,329,419
 Total Current Liabilities	 16,459,923	 9,530,382
Operating lease liabilities - non-current portion	1,140,231	1,292,667
Notes payable - non-current portion, net of debt discount of \$200,711 and \$448,367 as of March 31, 2024 and December 31, 2023, respectively	2,103,456	4,355,800
Convertible notes payable - net of debt discount of \$344,219 and \$398,569 as of March 31, 2024 and December 31, 2023, respectively	4,655,781	4,601,431
 Total Liabilities	 24,359,391	 19,780,280

### **Stockholders' Equity:**

Preferred stock, \$0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023		
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 47,386,349 and 45,553,026 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	4,738	4,555
Additional paid-in capital	158,226,694	154,486,098

Accumulated deficit	<u>(156,413,660)</u>	<u>(145,491,559)</u>
Total Stockholders' Equity	<u>1,817,772</u>	<u>8,999,094</u>
Total Liabilities and Stockholders' Equity	<u>\$ 26,177,163</u>	<u>\$ 28,779,374</u>

### EYENOVIA, INC.

#### Condensed Statements of Operations (unaudited)

	For the Three Months Ended March 31,	
	2024	2023
<b>Operating Income</b>		
Revenue	\$ 4,993	\$ -
Cost of revenue	<u>(4,993)</u>	<u>-</u>
Gross Profit	-	-
<b>Operating Expenses:</b>		
Research and development	4,431,601	2,521,950
General and administrative	3,835,223	2,936,886
Reacquisition of license rights	<u>2,000,000</u>	<u>-</u>
Total Operating Expenses	<u>10,266,824</u>	<u>5,458,836</u>
Loss From Operations	<u>(10,266,824)</u>	<u>(5,458,836)</u>
<b>Other Income (Expense):</b>		
Other (expense) income, net	(97,558)	70,993
Interest expense	(678,658)	(454,003)
Interest income	120,939	102,480
Total Other Expense	<u>(655,277)</u>	<u>(280,530)</u>
<b>Net Loss</b>	<b><u>\$(10,922,101)</u></b>	<b><u>\$ (5,739,366)</u></b>
Net Loss Per Share - Basic and Diluted	\$ (0.23)	\$ (0.15)
Shares Outstanding - Basic and Diluted	46,606,790	37,410,587



Source: Eyenovia, Inc.