March 18, 2024

Eyenovia Reports Fourth Quarter and Full-Year 2023 Financial Results and Provides Business Update

Announced FDA approval of clobetasol propionate ophthalmic suspension 0.05% for post-operative pain and inflammation following ocular surgery

Reacquired development and commercialization rights to MicroPine for progressive pediatric myopia in the U.S. and Canada

Continued to advance commercial operations with launch of Mydcombi™, FDA approval of manufacturing facility, onboarding of sales organization and signing of copromotion agreement

Company to host conference call and webcast today, March 18th, at 4:30 pm ET

NEW YORK, March 18, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company, today announced its financial and operating results for the fourth quarter and full-year ended December 31, 2023.

Fourth Quarter 2023 and Recent Business Developments

- Announced FDA approval of clobetasol propionate ophthalmic suspension 0.05% ("clobetasol") for the treatment of post-operative pain and inflammation following ocular surgery, which the company in-licensed from Formosa Pharmaceuticals for the U.S. With the transfer of the clobetasol NDA for this product to Eyenovia, the company is planning to launch in the second half of 2024 with its existing 10-person sales force.
- Reacquired the development and commercialization rights to MicroPine in the U.S. and Canada. MicroPine is currently being evaluated in the Phase 3 "CHAPERONE" clinical trial for pediatric progressive myopia. External sources have estimated the value of this market at over $1 billion dollars in the U.S., and of a similar size in China.
- Announced FDA approval for the Redwood City manufacturing facility. Along with approval of Coastline International in Mexico and Eyenovia's facility in Reno, Nevada, the company is now the manufacturer of the finished Mydcombi product for commercial distribution.
- Hired, trained and deployed half of its planned 10-person field sales force, with the remainder set to join in the coming weeks.
- Signed an agreement with Vision Source, a large buying group consisting of optometrists throughout North America, to offer Mydcombi as an approved product to its member offices.
- Announced a co-promotion agreement with NovaBay whereby NovaBay will promote clobetasol through its sales channels, and Eyenovia will promote NovaBay's prescription Avenova Antimicrobial Lid & Lash Solution through its field sales force.

Michael Rowe, Chief Executive Officer, commented, “During the fourth quarter and subsequent period, we continued to execute on our corporate strategy that we initiated just a few quarters ago. FDA approval of clobetasol propionate ophthalmic suspension 0.05% gives us access to a large-market indication that is complementary to Mydcombi and allows us to add additional value to eye doctors using our existing field sales force. Additionally, our recent decision to reacquire the development and commercialization rights to MicroPine expands our pipeline with a potential blockbuster drug, if approved. With the CHAPERONE study in our hands, we plan to engage with FDA later this year to explore ways to expedite its development.

“At the same time, we made significant progress building out our manufacturing capabilities, with FDA approval of both our Redwood City facility as well as our contract manufacturer, Coastline International. These capabilities, together with our facility in Reno, provide us the capacity to manufacture 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, beginning with Mydcombi later this year.

“We also continue to work on ways to increase uptake of Mydcombi including acceptance of our product by Vision Source, a leading group buying organization supporting optometrists throughout the United States, as well as with formulary wins at ophthalmic surgical institutions. And looking longer term, we see many opportunities to leverage the Optejet through additional collaboration and co-development agreements in high-value indications, including dry eye, which we estimate to be a three-billion-dollar annual market opportunity in the U.S. alone.

“Overall, I am extremely pleased with our progress and our current momentum as we successfully transition to a commercial-stage, revenue generating leader in topical ophthalmic medications,” Mr. Rowe concluded.

Fourth Quarter and Full-Year 2023 Financial Review

For the fourth quarter of 2023, net loss was approximately $8.0 million, or $0.18 per share. This includes a $0.02 per share loss related to a one-time event for the repatriation of the rights to MicroPine. In 2022, our net loss was $6.1 million, or $0.17 per share, for the fourth quarter of 2022. For the full-year 2023, net loss was approximately $27.3 million, or $0.66 per share on approximately 41.0 million shares outstanding, and this compares to a net loss of $28.0 million, or $0.83 per share, on approximately 33.6 million weighted average shares outstanding, for the full year 2022.

Research and development expenses totaled approximately $4.1 million for the fourth quarter of 2023, compared to $2.2 million for the fourth quarter of 2022, an increase of approximately 84.6%. For the full-year 2023, research and development expenses were $13.0 million, a decrease of 3.0% as compared to $13.4 million for the full-year 2022. The decrease was driven primarily by lower direct clinical and non-clinical expenses, as well as deferral of costs related to future delivery of clinical supply to our partners.

For the fourth quarter of 2023, general and administrative expenses were approximately $3.4 million, compared to $3.2 million for the fourth quarter of 2022, an increase of approximately 7.3%. For the full-year 2023, general and administrative expenses were $12.4 million, a decrease of 8.1% as compared to $13.5 million for the full-year 2022. The full year decrease was driven by reduction in legal expenses and executive recruitment cost year over year.

Total operating expenses for the fourth quarter of 2023 were approximately $7.5 million, compared to approximately $5.4 million for the fourth quarter of 2022. This represents an increase of approximately 39.0%. Total operating expenses for the full-year 2023 were $25.4 million, representing a decrease of 5.6% versus $26.9 million for the full-year 2022.

As of December 31, 2023, the Company's unrestricted cash and cash equivalents were approximately $14.8 million, as compared to $22.9 million in unrestricted and restricted cash as of December 31, 2022.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, March 18th. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international), and reference conference ID 13744365.

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. 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.

The Eyenovia Corporate Information slide deck may be found at 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.
Balance Sheets

	December 31,

	2023 (unaudited)	2022
Assets		
Current Assets		
Cash and cash equivalents	$ 14,849,057	$ 22,863,520
Inventories	109,798	-
Deferred clinical supply costs	4,256,793	2,284,931
License fee and expense reimbursements receivable	123,833	1,183,786
Security deposits, current	1,506	119,550
Prepaid expenses and other current assets	1,365,731	1,190,719
Total Current Assets	20,706,718	27,642,506
Property and equipment, net	3,374,384	1,295,115
Security deposits, non-current	197,168	80,874
Intangible assets	2,122,945	-
Operating lease right-of-use asset	1,666,718	1,291,592
Equipment deposits	711,441	726,326
Total Assets	$ 28,779,374	$ 31,036,413
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,753,172	$ 1,428,283
Accrued compensation	1,658,613	1,747,191
Accrued expenses and other current liabilities	287,928	503,076
Operating lease liabilities - current portion	501,250	484,882
Notes payable - current portion, net of debt discount of $503,914 and $33,885 as of December 31, 2023 and 2022, respectively	5,329,419	174,448
Convertible notes payable - current portion, net of debt discount of $0 and $33,885 as of December 31, 2023 and 2022, respectively	-	174,448
Total Current Liabilities	9,530,382	4,512,328
Operating lease liabilities - non-current portion	1,292,667	907,644
Notes payable - non-current portion, net of debt discount of $448,367 and $813,229 as of December 31, 2023 and 2022, respectively	4,355,800	4,190,938
Convertible notes payable - non-current portion, net of debt discount of $398,569 and $813,229 as of December 31, 2023 and 2022, respectively	4,601,431	4,190,938

Total Liabilities	19,780,280	13,801,848
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2023 and 2022		
Common stock, $0.0001 par value, 90,000,000 shares authorized; 45,553,026 and 36,668,980 shares issued and outstanding as of December 31, 2023 and 2022, respectively	4,555	3,667
Additional paid-in capital	154,486,098	135,461,361
Accumulated deficit	(145,491,559)	(118,230,463)
Total Stockholders' Equity	8,999,094	17,234,565
Total Liabilities and Stockholders' Equity	$ 28,779,374	$ 31,036,413

EYENOVIA, INC.
Statements of Operations

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2023 (unaudited)	**2022 (unaudited)**	**2023 (unaudited)**	**2022**
Operating Income				
Revenue	$ 2,589	$ -	$ 3,787	$ -
Cost of revenue	(2,589)	-	(3,787)	-
Gross Profit	-	-	-	-
Operating Expenses:				
Research and development	4,064,708	2,202,354	12,975,832	13,378,680
General and administrative	3,401,846	3,169,928	12,430,614	13,532,835
Total Operating Expenses	7,466,554	5,372,282	25,406,446	26,911,515
Loss From Operations	(7,466,554)	(5,372,282)	(25,406,446)	(26,911,515)
Other (Expense) Income:				
Other (expense) income , net	(18,628)	100,510	(176,411)	197,090
Interest expense	(680,623)	(904,247)	(2,371,851)	(1,380,058)
Interest income	198,668	52,623	693,612	83,326
Total Other Expense	(500,583)	(751,114)	(1,854,650)	(1,099,642)
Net Loss	$ (7,967,137)	$ (6,123,396)	$(27,261,096)	$(28,011,157)

Net Loss Per Share - Basic and Diluted	$ (0.18)	$ (0.17)	$ (0.66)	$ (0.83)
Shares Outstanding - Basic and Diluted	45,402,034	35,900,850	41,032,970	33,649,747

Source: Eyenovia, Inc.