Eyenovia Reports Fourth Quarter 2022 Financial Results and Provides Business Update

March 30, 2023

Announced FDA acceptance of Mydcombi New Drug Application (NDA) and PDUFA action date of May 8, 2023

Announced positive results from Microline Phase 3 program as a potential treatment for presbyopia and received feedback from the FDA outlining a clear path forward for the program

Entered into co-development agreement with Formosa Pharmaceuticals

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

NEW YORK, March 30, 2023 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (Nasdaq: EYEN), a pre-commercial ophthalmic technology company developing the Optejet® delivery system for use both in combination with its own drug-device therapeutic programs for mydriasis, presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced its financial and operating results for the fourth quarter and full-year ended December 31, 2022.

Fourth Quarter 2022 and Recent Business Developments

- Announced U.S. Food and Drug Administration (FDA) acceptance of the Mydcombi NDA and Prescription Drug User Fee Act (PDUFA) action target date of May 8th, 2023.
- Announced positive results from Microline Phase 3 program as a potential treatment for presbyopia and received encouraging feedback from FDA outlining a clear path forward for the program.
- Entered into a development collaboration agreement with Formosa Pharmaceuticals to combine Eyenovia's Optejet® dispensing technology with Formosa's APNT nanoparticle formulation platform for the potential development of new topical therapeutics in high-value ophthalmic indications with significant unmet medical needs.
- Manufacturing facility in Redwood City is operational and producing clinical supply; legacy Reno facility is currently being inspected by the FDA as part of the Mydcombi review process; second facility in Reno anticipated to come online during the third quarter 2023.
- Development partner Arctic Vision continues to enroll patients in its Phase 3 study of Microline (ARVN003) as a potential treatment for presbyopia in China.
- Ended the fourth quarter of 2022 with approximately $22.9 million in total cash and cash equivalents.

Michael Rowe, Chief Executive Officer, commented, "We continue to make significant progress with our two lead programs, Mydcombi and Microline. Specifically, we are preparing for our May 8th PDUFA date for Mydcombi which, if approved, would validate the Optejet dispensing technology that is core to all of our proprietary and partnered programs, and would transition us to a commercial stage company. We are in the middle of a FDA inspection of our manufacturing facility as part of that review process."

"Regarding Microline, having completed our VISION 2 study, we recently received feedback from the FDA which outlines a clear path forward for the program. Importantly, the feedback is in line with our expectations, and our development timeline for the program remains unchanged. Presbyopia represents a very significant market opportunity for our company, and the agency's feedback is very encouraging."

"Finally, our co-development agreement with Formosa represents an opportunity to significantly expand our pipeline and will serve as a model for any future partnerships. We are in advanced discussions with additional potential partners to leverage the Optejet in high-value indications, and we are optimistic that we will sign one or more partnership agreements this year."

Fourth Quarter and Full Year 2022 Financial Review

For the fourth quarter of 2022, net loss was approximately $[6.1] million, or $[0.17] per share compared to a net income of approximately $3.0 million, or $0.11 per share, for the fourth quarter of 2021. For the full-year 2022, net loss was approximately $[28.0] million, or $[0.83] per share on approximately 33.6 million weighted average shares outstanding, and this compares to a net loss of approximately $[12.8] million, or $[0.49] per share, for the full year 2021 on approximately 26.3 million weighted average shares outstanding.

Research and development expenses totaled approximately $2.2 million for the fourth quarter of 2022 as compared to $3.3 million for the fourth quarter of 2021, a decrease of approximately 33%. For the full-year 2022, research and development expenses decreased approximately 10% to $13.4 million, versus $14.9 million for the full-year 2021. 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 2022, general and administrative expenses were approximately $3.2 million, compared to $3.7 million for the fourth quarter of 2021, a decrease of approximately 13.3%. For the full-year 2022, general and administrative expenses were $13.5 million, an increase of 28% as

compared to $10.6 million for the full-year 2021. The full year increase was driven by staff additions, higher professional fees, and an increase in stock-based compensation.

Total operating expenses for the fourth quarter of 2022 were approximately $5.4 million compared to $6.9 million for the fourth quarter of 2021. This represents a decrease of approximately 22.7%. Total operating expenses for the full-year 2022 were $26.9 million, representing an increase of 6% versus $25.4 million for the full-year 2021.

As of December 31, 2022, the Company's unrestricted cash and cash equivalents were approximately $22.9 million, as compared to $27.3 million in unrestricted and restricted cash as of December 31, 2021.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, March 30th. Participants should dial 1-877-407-9039 or 1-201-689-8470. 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.

About the VISION Trials

The VISION trials are Phase 3, double-masked, placebo-controlled, cross-over superiority trials that enroll participants with presbyopia. The primary endpoint is improvement in high-contrast binocular distance corrected near visual acuity in low light conditions. Microline is intended for the "on demand" improvement of near vision in people with presbyopia.

About Microline for Presbyopia

Microline (pilocarpine ophthalmic spray) is Eyenovia's investigational pharmacologic treatment for presbyopia. Presbyopia, or farsightedness, is the non-preventable, age-related hardening of the lens, which causes a gradual loss of the eye's ability to focus on nearby objects and is estimated to affect nearly 113 million Americans. Pilocarpine ophthalmic solution is known to constrict the pupil and improve near-distance vision by creating an extended depth of focus through its small aperture effect. Eyenovia believes that its administration of pilocarpine using the Company's high precision microdosing technology could provide a meaningful improvement in near vision while enhancing tolerability and usability. Microline has been licensed to Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

About MicroPine for Progressive Myopia

MicroPine (atropine ophthalmic spray) is Eyenovia's investigational, potentially first-in-class topical treatment for the reduction of pediatric myopia progression, also known as nearsightedness, in children ages 3-12. It has been developed for comfort and ease-of-use in children, and its microdose administration is designed to potentially result in low systemic and ocular drug exposure. MicroPine has been licensed to Bausch+Lomb, Inc. in the United States and Canada, and Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

About Mydcombi™ for Mydriasis

Mydcombi is Eyenovia's investigational, first-in-class fixed-dose-combination product (tropicamide 1% and phenylephrine 2.5% ophthalmic spray) for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 100 million office-based comprehensive eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. Developed as a micro-formulation for use without anesthetic, Eyenovia believes Mydcombi will help improve the efficacy, tolerability, and efficiency of pharmacologic mydriasis. Mydcombi has been licensed to Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

About Optejet® and Microdose Array Print (MAP™) Therapeutics

Eyenovia's Optejet microdose formulation and delivery platform for ocular therapeutics uses high-precision piezo-print technology to deliver ~8 µL of drug, consistent with the capacity of the tear film of the eye. We estimate the volume of ophthalmic solution administered with the Optejet is less than 20% of that delivered using conventional eyedroppers, thus reducing overdosing and exposure to drug and preservatives. Eyenovia's patented microfluidic ejection technology is designed for fast and gentle ocular surface delivery. Successful use of the Optejet has been demonstrated more than 85% of the time after basic training in a variety of clinical settings compared to 40 – 50% historically seen with conventional eyedroppers. Additionally, future versions with smart electronics and mobile e-health technology are being designed to track and enhance patient compliance.

About Eyenovia, Inc.

Eyenovia, Inc. (Nasdaq: EYEN) is an pre-commercial ophthalmic technology company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for mydriasis, presbyopia and myopia progression. 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 the statements, expectations and assumptions contained in this presentation 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 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 due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission.

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 advantages of our product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; intellectual property risks; changes in legal, regulatory, legislative and geopolitical environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and our competitive position.

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, 2022 (unaudited)	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 22,863,520	$ 19,461,850
Deferred clinical supply costs	2,284,931	-
License fee and expense reimbursements receivable	1,183,786	1,805,065
Security deposits, current	119,550	-
Prepaid expenses and other current assets	1,190,719	734,942
Total Current Assets	27,642,506	22,001,857
Restricted cash	-	7,875,000
Property and equipment, net	1,295,115	1,271,225
Security deposits, non-current	80,874	119,035
Operating lease right-of-use asset	1,291,592	-
Equipment deposits	726,326	391,941
Total Assets	$ 31,036,413	$ 31,659,058
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,428,283	$ 1,614,104
Accrued compensation	1,747,191	1,543,618
Accrued expenses and other current liabilities	503,076	845,719
Deferred rent - current portion	-	18,685
Operating lease liabilities - current portion	484,882	-
Notes payable - current portion, net of debt discount of		

$33,885 and $349,632 as of December 31, 2022 and 2021, respectively	174,448	7,150,368
Convertible notes payable - current portion, net of debt discount of $33,885 and $0 as of December 31, 2022 and 2021, respectively	174,448	-
Total Current Liabilities	4,512,328	11,172,494
Deferred rent - non-current portion	-	19,949
Operating lease liabilities - non-current portion	907,644	-
Notes payable - non-current portion, net of debt discount of $813,229 and $0 as of December 31, 2022 and 2021, respectively	4,190,938	-
Convertible notes payable - non-current portion, net of debt discount of $813,229 and $0 as of December 31, 2022 and 2021, respectively	4,190,938	-
Total Liabilities	13,801,848	11,192,443
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2022 and 2021, respectively	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 36,668,980 and 28,426,616 shares issued and outstanding as of December 31, 2022 and 2021, respectively	3,667	2,844
Additional paid-in capital	135,461,361	110,683,077
Accumulated deficit	(118,230,463)	(90,219,306)
Total Stockholders' Equity	17,234,565	20,466,615
Total Liabilities and Stockholders' Equity	$ 31,036,413	$ 31,659,058

EYENOVIA, INC.
Statements of Operations

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2022 (unaudited)	**2021 (unaudited)**	**2022 (unaudited)**	**2021**
Operating Income				
Revenue	$ -	$ 10,000,000	$ -	$ 14,000,000
Cost of revenue	-	-	-	(1,600,000)
Gross Profit	-	10,000,000	-	12,400,000
Operating Expenses:				
Research and development	2,202,354	3,291,510	13,378,680	14,850,874
General and administrative	3,169,928	3,655,172	13,532,835	10,569,653
Total Operating Expenses	5,372,282	6,946,682	26,911,515	25,420,527
Loss From Operations	(5,372,282)	3,053,318	(26,911,515)	(13,020,527)
Other Income (Expense):				
Extinguishment of PPP 7(a) loan	-	-	-	463,353
Other income, net	100,510	115,147	197,090	164,027
Interest expense	(904,247)	(185,349)	(1,380,058)	(387,756)
Interest income	52,623	162	83,326	2,516
		-		
Net Loss	$ (6,123,396)	$ 2,983,278	$ (28,011,157)	$ (12,778,387)

Net Loss Per Share - Basic				
Basic	$ (0.17)	$ 0.11	$ (0.83)	$ (0.49)
Diluted	$ (0.17)	$ 0.10	$ (0.83)	$ (0.49)
Weighted Average Number of Common Shares Outstanding				
Basic	36,701,880	27,959,123	33,649,747	26,324,081
Diluted	36,701,880	30,019,966	33,649,747	26,324,081

Source: Eyenovia, Inc.