August 10, 2022

Eyenovia Reports Second Quarter 2022 Financial Results

Announced appointment of Michael Rowe as Chief Executive Officer and Board member

Mydcombi™ NDA resubmission on track for the fourth quarter of 2022

Phase 3 VISION-2 study evaluating MicroLine as an on-demand treatment for improving near vision (presbyopia) progressing as planned; topline data expected in the third quarter of 2022

Company to host conference call and webcast today, August 10, at 4:30 pm ET

NEW YORK, Aug. 10, 2022 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (Nasdaq: EYEN), a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on its proprietary microdose array print (MAP™) platform technology, today announced its financial and operating results for the second quarter ended June 30, 2022.

Second Quarter 2022 and Recent Business Developments

- Announced the appointment of Eyenovia's former Chief Operating Officer, Michael Rowe, as the company's new Chief Executive Officer, replacing Dr. Sean Ianchulev, who has transitioned to Chairman of the Board of Directors. Mr. Rowe was also appointed as a director to Eyenovia's Board of Directors.
- Global supply chain issues impacting the production of Mydcombi™ validation units have been resolved and the New Drug Application ("NDA") resubmission is now expected in the fourth quarter of 2022.
- VISION-2 Phase 3 trial evaluating MicroLine as a potential, on-demand treatment for presbyopia progressing as planned, with topline data anticipated in the third quarter of 2022. If successful, the Company plans to start production of registration batches as a requirement towards filing a new drug/device combination application to the U.S. Food and Drug Administration ("FDA")
- Announced that the Company's new manufacturing facility in Redwood City, CA is now operational, and also announced the appointment of Bren Kern as Senior Vice President of Manufacturing and Operations.
- Appointed Dr. Ellen Strahlman and Dr. Ram Palanki as directors to the Board of Directors. Together, they bring decades of medical technology, clinical development, product launch and commercialization experience, much of it specific to ophthalmology.
- Announced that the Company's strategic partner, Arctic Vision, enrolled the first patient in its Phase 3 clinical trial of ARVN003 (MicroLine) for presbyopia in China.
- Ended the second quarter of 2022 with approximately $29.4 million in total cash and cash equivalents, including $7.9 million of restricted cash.

Dr. Sean Ianchulev, Chairman of the Board of Directors, commented, “We achieved significant progress during the second quarter and subsequent period across both our Mydcombi and MicroLine programs, and we are very fortunate to have concluded our CEO search with the appointment of Michael Rowe who we believe is the ideal candidate to sustain our current momentum. His appointment maintains continuity while bringing significant ophthalmic operations and commercialization expertise to the role ahead of significant regulatory and clinical milestones. These include the pending resubmission of our Mydcombi New Drug Application and near completion of our second Phase 3 presbyopia trial, each of which moves us a step further to transitioning to a commercial stage company.”

Michael Rowe, Chief Executive Officer, commented, “We are nearing completion of the additional Optejet device validation testing requested by the FDA when Mydcombi was reclassified as a drug-device combination product. Global supply chain issues that have impacted most high technology manufacturers and delayed the production of our validation units have now been resolved. As a result, we now anticipate resubmitting our NDA to the FDA during the fourth quarter of 2022. If approved next year, Mydcombi for mydriasis would be the first commercial product to leverage our Optejet dispensing technology, a significant achievement for our Company. With our presbyopia program also progressing, and our Redwood City manufacturing operations up and running, this is indeed a transformational time for our Company. I am pleased with the progress made addressing these challenges during the second quarter and look forward to a productive back half of the year.”

Second Quarter 2022 Financial Review

For the second quarter of 2022, net loss was approximately $(7.2) million, or $(0.22) per share compared to a net loss of approximately $(4.8) million, or $(0.19) per share, for the second quarter of 2021.

Total license revenue was $0.0 million for the second quarter of 2022 as compared to $2.0 million for the second quarter of 2021.

Research and development expenses totaled approximately $3.6 million for the second quarter of 2022 as compared to $3.7 million for the second quarter of 2021, a decrease of approximately (2.7%).

For the second quarter of 2022, general and administrative expenses were approximately $3.5 million, compared to $2.3 million for the second quarter of 2021, an increase of approximately 53.8%.

Total operating expenses for the second quarter of 2022 were approximately $7.1 million compared to $6.0 million for the second quarter of 2021. This represents an increase of approximately 19.0%.

As of June 30, 2022, the Company’s cash and cash equivalents were approximately $29.4 million, including $7.9 million of restricted cash, as compared to $27.3 million as of December 31, 2021.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, August 10. Participants should dial 877-407-9039 (domestic) or 201-689-8470 (international) with the conference code 13731733. A live webcast of the conference call will also be available 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 6-8 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, where solution is dispensed to the ocular surface in approximately 80 milliseconds, beating the ocular blink

reflex. 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, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

About Eyenovia, Inc.

Eyenovia, Inc. (Nasdaq: EYEN) is an ophthalmic pharmaceutical 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 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 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 (which could still be adversely impacted by COVID-19), 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 COVID-19 and related economic disruptions on our supply chain, including the availability of sufficient components and materials used in 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 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 Sheets

	June 30, 2022 (unaudited)	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 21,506,582	$ 19,461,850
Deferred clinical supply costs	1,538,380	-
License fee and expense reimbursements receivable	709,234	1,805,065
Prepaid expenses and other current assets	1,858,530	721,438
Total Current Assets	25,612,726	21,988,353
Restricted cash	7,875,000	7,875,000
Property and equipment, net	1,406,666	1,271,225
Security deposits	201,407	132,539
Equipment deposits	510,239	391,941
Total Assets	$ 35,606,038	$ 31,659,058
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,686,794	$ 1,614,104
Accrued compensation	1,014,084	1,543,618
Accrued expenses and other current liabilities	824,302	845,719
Deferred rent - current portion	27,462	18,685
Notes payable	7,429,131	7,150,368

Total Current Liabilities	11,981,773	11,172,494
Deferred rent - non-current portion	13,528	19,949
Total Liabilities	11,995,301	11,192,443
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2022 and December 31, 2021	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 33,623,053 and 28,426,616 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	3,363	2,844
Additional paid-in capital	128,405,445	110,683,077
Accumulated deficit	(104,798,071)	(90,219,306)
Total Stockholders' Equity	23,610,737	20,466,615
Total Liabilities and Stockholders' Equity	$ 35,606,038	$ 31,659,058

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating Income				
Revenue	$ -	$ 2,000,000	$ -	$ 4,000,000
Cost of revenue	-	(800,000)	-	(1,600,000)
Gross Profit	-	1,200,000	-	2,400,000
Operating Expenses:				
Research and development	3,586,866	3,684,647	7,299,450	8,007,296
General and administrative	3,534,590	2,297,492	7,009,555	4,541,482
Total Operating Expenses	7,121,456	5,982,139	14,309,005	12,548,778

Loss From Operations	(7,121,456)	(4,782,139)	(14,309,005)	(10,148,778)
Other Income (Expense):				
Other income, net	33,376	18,567	26,303	37,152
Interest expense	(153,436)	(78,047)	(298,673)	(83,195)
Interest income	2,416	220	2,610	1,754
Net Loss	$ (7,239,100)	$ (4,841,399)	$(14,578,765)	$(10,193,067)
Net Loss Per Share - Basic and Diluted	$ (0.22)	$ (0.19)	$ (0.46)	$ (0.40)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	33,644,867	25,927,303	31,836,582	25,630,572

Source: Eyenovia, Inc.