Eyenovia Reports Third Quarter 2021 Financial Results

November 10, 2021

On track with VISION-2 phase 3 presbyopia trial and expedited resubmission of MydCombi™ New Drug Application as a drug/device combination in early 2022

Current cash resources anticipated to be sufficient to cover MydCombi NDA resubmission, completion of Phase 3 MicroLine program, and completion of manufacturing facility

Company to host conference call and webcast tomorrow, November 11, at 5:00pm ET

NEW YORK, Nov. 10, 2021 (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 results for the third quarter ended September 30, 2021.

Third Quarter 2021 and Recent Business Developments

- Announced that the first patient has been enrolled in VISION-2, a second Phase 3 trial of MicroLine, the Company's proprietary investigational pilocarpine spray for the treatment of presbyopia, with topline data expected in mid-2022.
- Announced that Dr. Fred Eshelman, who has served as Chairman of the Eyenovia Board since 2014, will step down by the end of 2021 to pursue other professional interests.
- On July 22, 2021, Eyenovia provided an update on the Company's MicroLine program at Eyecelerator, a joint venture between the American Academy of Ophthalmology (AAO) and the American Society of Cataract and Refractive Surgery (ASCRS).
- On September 14, 2021, Arctic Vision and Eyenovia expanded an existing licensing agreement to include MydCombi. All three of Eyenovia's current programs have now been out licensed to Arctic Vision for the greater China and Korean markets.
- On October 25, 2021, Eyenovia announced that it had received notice from the U.S. Food and Drug Administration (FDA) in the form of a Complete Response Letter (CRL) that MydCombi has been reclassified as a drug-device combination product as part of the agency's review of the MydCombi New Drug Application (NDA).
    - The Company is working to furnish additional information to the FDA for expedited resubmission of the NDA in early 2022 and continues to believe that, if approved, MydCombi represents a significant advancement for mydriasis (pupil dilation).
- Granted additional international patents related to the Optejet® dispenser. Eyenovia now has a total of 13 patents for the technology in the United States and over 80 international patents.

Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia, commented, "Over the past weeks we have made excellent progress preparing the additional information requested by the FDA pertaining to our MydCombi NDA. As noted previously, throughout development of MydCombi, we had taken actions to minimize the potential impact of a reclassification of MydCombi to a drug-device combination. These efforts are now proving to be invaluable and, importantly, the additional information we are now submitting related to our Optejet dispenser should streamline regulatory review of our other late-stage development programs, MicroLine and MicroPine, that also leverage this technology. We remain confident in our ability to resubmit the MydCombi NDA in early 2022."

"In parallel, we remain acutely focused on completing enrollment in our recently initiated second Phase 3 trial of MicroLine for presbyopia, VISION-2. If positive, the VISION program will support submission of a MicroLine NDA, giving us potential line-of-sight to two approved products in the relative near-term, should both applications be successful."

"We are also announcing the departure of our friend and supporter, Dr. Fred Eshelman, from our Board. On behalf of the entire Company, I would like to thank Dr. Eshelman for his years of distinguished service and many contributions. The Company intends to engage in a thorough search process to recruit one or more new members to its Board, with particular emphasis on medical, ophthalmological and drug development expertise, prior public company Board experience, corporate governance and capital markets credentials and/or diversity."

"As of today, we believe we are sufficiently capitalized with approximately $30 million in unrestricted and restricted cash to cover the Company's planned expenses for Mydcombi, MicroLine and MicroPine throughout 2022. In addition, we look forward to delivering potentially value creating milestones in 2022 and into 2023," Dr. Ianchulev concluded.

Third Quarter 2021 Financial Review

For the third quarter of 2021, net loss was approximately $5.6 million, or $(0.21) per share, compared to a net loss of approximately $5.1 million,

or $(0.23) per share, for the third quarter of 2020.

Research and development expenses for the three months ended September 30, 2021 totaled $3.5 million, an increase of 3.2%, as compared to $3.4 million recorded for the three months ended September 30, 2020.

For the third quarter of 2021, general and administrative expenses for the three months ended September 30, 2021 totaled $2.4 million, an increase of 40.1%, as compared to $1.7 million recorded for the three months ended September 30, 2020.

Total operating expenses for the third quarter of 2021 were approximately $5.9 million, compared to total operating expenses of approximately $5.1 million for the same period in 2020, an increase of approximately 16%.

As of September 30, 2021, the Company's unrestricted and restricted cash balance was approximately $21.4 million.

Conference Call and Webcast

The conference call is scheduled to begin at 5:00pm ET on Thursday, November 11, 2021. Participants should dial 877-407-9039 (domestic) or 201-689-8470 (international) with the conference code 13724626. 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 solution) 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. Treatment options are typically device-based, such as reading glasses and contact lenses. 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 solution) 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 Health Companies, Inc. in the United States and Canada, and Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

About MyCombi™ for Mydriasis

MydCombi is Eyenovia's investigational, first-in-class fixed-dose-combination product (tropicamide 1% and phenylephrine 2.5% ophthalmic solution) 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 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 (which could still be adversely impacted by COVID-19 and resulting social distancing), 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 on our supply chain; 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; 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.
Condensed Balance Sheets

	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 13,500,871	$ 28,371,828
Restricted cash	7,875,000	-
Deferred license costs	-	1,600,000
License fee and expense reimbursements receivables	960,180	2,966,039
Prepaid expenses and other current assets	1,123,289	453,478
Total Current Assets	23,459,340	33,391,345
Property and equipment, net	1,413,201	396,380
Security deposit	119,035	119,035
Total Assets	$ 24,991,576	$ 33,906,760
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,684,733	$ 1,461,665
Accrued compensation	1,184,236	1,150,672
Accrued expenses and other current liabilities	552,336	1,480,692
Deferred rent - current portion	16,037	7,809
Deferred license fee	10,000,000	14,000,000
Notes payable - current portion	7,282,037	97,539
Total Current Liabilities	20,719,379	18,198,377
Deferred rent - non-current portion	26,059	38,684

Notes payable - non-current portion	-	365,814
Total Liabilities	20,745,438	18,602,875
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 25,963,185 and 24,978,585 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	2,597	2,498
Additional paid-in capital	97,446,125	92,742,306
Accumulated deficit	(93,202,584)	(77,440,919)
Total Stockholders' Equity	4,246,138	15,303,885
Total Liabilities and Stockholders' Equity	$ 24,991,576	$ 33,906,760

EYENOVIA, INC.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating Income				
Revenue	$ -	$ -	$ 4,000,000	**$ -**
Cost of revenue	-	-	(1,600,000)	**-**
Gross Profit	-	-	2,400,000	-
Operating Expenses:				
Research and development	3,470,188	3,363,759	11,334,296	9,913,296
General and administrative	2,435,141	1,728,366	7,082,659	5,669,311
Total Operating Expenses	5,905,329	5,092,125	18,416,955	15,582,607
Loss From Operations	(5,905,329)	(5,092,125)	(16,016,955)	(15,582,607)
Other Income (Expense):				
Small Business Administration Economic Injury Disaster Grant	-	-	-	10,000
Extinguishment of PPP 7(a) loan	463,353	-	463,353	-
Other expense	(8,010)	-	(8,010)	-
Interest expense	(119,212)	(4,945)	(202,407)	(14,977)
Interest income	600	540	2,354	24,579
		-		
Net Loss	$ (5,568,598)	$ (5,096,530)	$ (15,761,665)	$ (15,563,005)
Net Loss Per Share - Basic and Diluted	$ (0.21)	$ (0.23)	$ (0.61)	$ (0.79)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	26,053,532	22,206,195	25,773,098	19,802,999

Source: Eyenovia, Inc.