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Eyenovia Reports First Quarter 2020 Financial Results

NEW YORK, May 13, 2020 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose therapeutics utilizing its patented piezo-print delivery technology, today announced its financial results for the first quarter ended March 31, 2020.

First Quarter 2020 and Recent Business Highlights

- Successfully completed a private placement of units comprised of common stock and warrants with aggregate net proceeds to the Company of approximately $5.4 million in March 2020;
- Amended its Exclusive License Agreement with Senju Pharmaceutical Co., Ltd. allowing Eyenovia to license certain of its products in China (including, Hong Kong, Macao and Taiwan) and South Korea; and
- Experiencing delays in initiation of MicroLine Phase III studies for presbyopia and completion of enrollment of MicroPine Phase III study for progressive myopia due to global COVID-19 pandemic.

“In the first quarter of 2020, we successfully strengthened our balance sheet with our private placement, which should fund the Company’s operations into 2021. Looking ahead, we are preparing to submit our New Drug Application for MicroStat to the FDA this year, as well as anticipate initiating our Phase III trials for MicroLine when the environment becomes safe to do so. We also look forward to re-initiating enrollment of our MicroPine Phase III trial, and in the interim, will continue to supply cartridges of MicroPine by mail and work with our clinical partners to follow-up virtually with previously enrolled study participants,” commented Dr. Sean Ianchulev, Eyenovia’s Chief Executive Officer and Chief Medical Officer. “Our priority remains the health and safety of our employees, patients, and partners as well as the communities they serve. We believe that our fearless Eyenovia spirit of ingenuity and resilience will help ensure that we persevere through this period of uncertainty.”

First Quarter 2020 Financial Review

For the first quarter of 2020, net loss was approximately $5.5 million, or $(0.31) per share, compared to a net loss of approximately $5.9 million, or $(0.50) per share for the first quarter of 2019.

Research and development expenses totaled approximately $3.6 million for the first quarter of 2020, compared to approximately $4.0 million for the same period in 2019, a decrease of approximately 9.3%.

For the first quarter of 2020, general and administrative expenses were approximately $1.8 million compared to approximately $1.9 million for the first quarter of 2019, a decrease of approximately 5.5%.

Total operating expenses for the first quarter of 2020 were approximately $5.5 million, compared to total operating expenses of approximately $6.0 million for the same period in 2019, a decrease of approximately 8.1%.

As of March 31, 2020, the Company's cash balance was approximately $13.7 million. This includes approximately $5.4 million of net proceeds from Eyenovia's private placement, which closed in March 2020.

Conference Call and Webcast

The conference call is scheduled to begin at 4:45pm ET on Wednesday, May 13, 2020. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 4397339. 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. In addition, a telephonic replay of the call will be available until May 20, 2020. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 4397339.

About Eyenovia
Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose therapeutics utilizing its patented piezo-print delivery technology. Eyenovia's pipeline is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more Information please visit www.eyenovia.com.

About MicroLine for Presbyopia
MicroLine is Eyenovia's pharmacologic treatment for presbyopia. Presbyopia 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. Current 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.

About MicroPine for Progressive Myopia
MicroPine (atropine ophthalmic solution) is Eyenovia's first-in-class topical treatment for progressive myopia, a back-of-the-eye condition commonly known as nearsightedness. Progressive myopia is estimated to affect close to 5 million children in the United States who suffer from uncontrolled axial elongation of the sclera leading to increasing levels of myopia and in some cases major pathologic changes such as retinal atrophy, macular staphylomas, retinal detachment and visual impairment. MicroPine has been developed for comfort and ease-of-use in children. Microdose administration of MicroPine is anticipated to result in low systemic and ocular drug exposure. A recent therapeutic evidence assessment and review by the American Academy of Ophthalmology indicates Level 1 (highest) evidence of efficacy for the role of low dose atropine for progressive myopia (Ophthalmology 2017;124:1857-1866; Ophthalmology 2016; 123(2) 391:399).

Feasibility Dose-finding Atropine Studies: ATOM 1; ATOM 2; LAMP (Independent Collaborative Group Trials)

About MicroStat for Mydriasis
MicroStat is Eyenovia's first-in-class fixed-combination micro-formulation product (phenylephrine 2.5% -tropicamide 1%) candidate for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 80 million office-based comprehensive and diabetic eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. Developed for use without anesthetic, we are developing MicroStat to improve the efficacy and tolerability of pharmacologic mydriasis.

About Optejet™ and MicroRx Ocular 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 believe the volume of ophthalmic solution administered with the Optejet is less than 75% 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% with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

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 in the United States for our product candidates. 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 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 SEC. In addition, such statements could be affected by risks and uncertainties related to, among other things: impacts of and uncertainty related to COVID-19; fluctuations in our financial results, particularly given market conditions and the potential economic impact of COVID-19; our need to raise additional money to fund our operations for at least the next 12 months as a going concern; the potential impacts of COVID-19 on our supply chain; risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could continue to be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the timing and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our estimates regarding the potential market opportunity for our product candidates; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; our ability to timely develop and implement anticipated manufacturing, commercialization and marketing

capabilities and strategies for existing product candidates; our ability to attract and retain key personnel; 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, we do not undertake any obligation to update any forward-looking statements.

Company Contact:
Eyenovia, Inc.
John Gandolfo
Chief Financial Officer
jgandolfo@eyenoviabio.com

Investor Contact:
The Ruth Group
Tram Bui / Alexander Lobo
Phone: 646-536-7035/7037
tbui@theruthgroup.com / alobo@theruthgroup.com

Media Contact:
The Ruth Group
Kirsten Thomas
Phone: 508-280-6592
kthomas@theruthgroup.com

(Financial Statements to Follow)

EYENOVIA, INC.

Condensed Balance Sheets

	March 31, 2020 (unaudited)	December 31, 2019
Current Assets:		
Cash	$ 13,656,091	$ 14,152,601
Prepaid expenses and other current assets	860,917	196,680
Total Current Assets	14,517,008	14,349,281
Property and equipment, net	273,739	230,538
Security deposit	117,800	117,800
Total Assets	$ 14,908,547	$ 14,697,619
Liabilities and Stockholders' Equity		
Current Liabilities:		

Accounts payable	$ 1,252,758	$ 1,541,358
Accrued compensation	348,009	916,873
Accrued expenses and other current liabilities	513,963	453,430
Short term note payable	423,165	-
Total Current Liabilities	2,537,895	2,911,661
Deferred rent	45,348	45,351
Total Liabilities	2,583,243	2,957,012
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2020 and as of December 31, 2019	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 19,776,019 and 17,100,726 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	1,977	1,710
Additional paid-in capital	75,445,289	69,409,949
Accumulated deficit	(63,121,962)	(57,671,052)
Total Stockholders' Equity	12,325,304	11,740,607
Total Liabilities and Stockholders' Equity	$ 14,908,547	$ 14,697,619

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended March 31,	
	2020	**2019**
Operating Expenses:		
Research and development	$ 3,634,287	$ 4,008,896
General and administrative	1,836,782	1,942,763
Total Operating Expenses	5,471,069	5,951,659
Loss From Operations	(5,471,069)	(5,951,659)
Other Income:		
Interest expense	(3,681)	-
Interest income	23,840	19,275
Net Loss	$ (5,450,910)	$ (5,932,384)

Net Loss Per Share - Basic and Diluted	$ (0.31)	$ (0.50)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	17,308,804	11,919,973

Source: Eyenovia, Inc.