Eyenovia Reports First Quarter 2019 Financial Results

May 14, 2019

NEW YORK, May 14, 2019 (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, 2019.

Q1 2019 and Recent Business Highlights

- Presented positive results from the MicroStat Phase III MIST-1 and MIST-2 registration studies for pharmacologic mydriasis at the joint American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Administrators (ASOA) annual meeting;
- Received U.S Food and Drug Administration (FDA) acceptance of our investigational new drug (IND) application to initiate the MicroPine Phase III CHAPERONE registration study aimed at reducing the progression of myopia in children; and
- Expanded the MicroProst Phase III program to include chronic angle closure glaucoma (CACG), open angle glaucoma (OAG), and ocular hypertension (OHT) patients in a single registration study.

"We kicked-off 2019 with a number of successes that further validate our novel approach in ophthalmology that we believe will help us advance multiple programs towards Phase III initiations this year," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "The positive MicroStat Phase III results which we presented at the ASCRS annual meeting confirmed that we can deliver drugs to the eye with high precision and efficacy using our microdosing technology. These results also help validate our delivery platform as we work diligently towards the initiation of our MicroPine and MicroProst Phase III programs, in which we expect to begin enrolling patients towards the middle and end of 2019, respectively. We are committed to advancing our clinical initiatives, including the preparation of the necessary registration and stability manufacturing materials for the submission of our first New Drug Application for MicroStat in 2020. We look forward to making 2019 another successful year as we seek to transform the treatment paradigm of front and back-of-the-eye diseases."

First Quarter 2019 Financial Review

For the first quarter of 2019, net loss was approximately $5.9 million, or $(0.50) per share, compared to a net loss of approximately $3.4 million, or $(0.45) per share for the first quarter of 2018.

Research and development expenses totaled approximately $4.0 million for the first quarter of 2019, compared to approximately $2.1 million for the same period in 2018, an increase of approximately 91%.

For the first quarter of 2019, general and administrative expenses were approximately $1.9 million compared to approximately $1.3 million for the first quarter of 2018, an increase of approximately 45%.

Total operating expenses for the first quarter of 2019 were approximately $6.0 million, compared to total operating expenses of approximately $3.4 million for the same period in 2018, an increase of approximately 73%.

As of March 31, 2019, the Company's cash and cash equivalents balance was approximately $14.3 million.

Conference Call and Webcast

The conference call is scheduled to begin at 8:30 am ET on Tuesday, May 14, 2019. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 1468679. 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 21, 2019. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 1468679.

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 mydriasis, myopia progression, glaucoma, and other eye diseases. For more Information please visit www.eyenovia.com.

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 address the growing needs 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. We are developing MicroStat to improve the efficacy and tolerability of pharmacologic mydriasis.

Upcoming Milestone: NDA Filing 2020

About MicroPine for Progressive Myopia
MicroPine is Eyenovia's first-in-class topical treatment for progressive myopia, a back-of-the-eye disease. Progressive myopia is estimated to affect close to 5 million patients 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. Early dose finding studies by collaborative academic groups have demonstrated high therapeutic potential with low dose atropine which can reduce myopia progression by 60 – 70% with a sustained effect through three years. 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)
Upcoming Milestone: MicroPine Phase III Trial Start Mid-2019

About MicroProst for Glaucoma and Ocular Hypertension
MicroProst is Eyenovia's proprietary latanoprost formulation product candidate, which is being developed as a first-line treatment for the reduction of IOP in patients with Chronic Angle Closure Glaucoma (CACG), as well as Primary Open Angle Glaucoma (POAG) and Ocular Hypertension. Currently, there are no FDA-approved therapies specifically indicated for CACG, which accounts for an estimated 10% and 50% of all glaucoma diagnoses in the United States and China, respectively. We believe there are approximately 500,000 patients with CACG in the United States and approximately 3.0 million with POAG for whom chronic, often life-long medication therapy is required.

Feasibility Dose-Finding Studies: MicroProst Phase II EYN PG21
Upcoming Milestone: MicroProst Phase III Trial Start End of 2019

About MicroTears OTC for Hyperemia, Pruritis and Dry Eye
MicroTears is a micro-droplet ocular hyperemia (red eye), pruritis (itch) and ocular lubrication product candidate for the approximately $850 million annual OTC artificial tear market in the United States.

Upcoming Milestone: OTC Monograph Registration 2019

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 with minimal training in 85% of topical medication administrations 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. 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: fluctuations in our financial results; our ability to raise money; risks involved in clinical trials, including, but not limited to, the design, initiation, timing, progress and results of such trials; the timing and our ability to submit applications for, and obtain and maintain regulatory approvals for, our product candidates; our ability to develop and implement commercialization, marketing and manufacturing capabilities and strategies for existing product candidates and our ability to identify new product candidates; the potential advantages of our product candidates; 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; 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.

Caution: New Drug—Limited by Federal (United States) law to investigational use.

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(Financial Statements to Follow)

EYENOVIA, INC.

Condensed Balance Sheets

	March 31, 2019 (unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 14,315,348	$ 19,728,200
Prepaid expenses and other current assets	560,329	132,756
Total Current Assets	14,875,677	19,860,956
Property and equipment, net	34,185	36,738
Security deposit	117,800	117,800
Total Assets	$ 15,027,662	$ 20,015,494
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,061,043	$ 1,509,524
Accrued compensation	417,061	912,104
Accrued expenses and other current liabilities	46,825	677,213
Total Current Liabilities	2,524,929	3,098,841
Deferred rent	43,200	41,584
Total Liabilities	2,568,129	3,140,425
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, 2019 and as of December 31, 2018	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 12,019,148 and 11,468,996 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	1,202	1,147
Additional paid-in capital	54,905,009	53,388,216
Accumulated deficit	(42,446,678)	(36,514,294)
Total Stockholders' Equity	12,459,533	16,875,069
Total Liabilities and Stockholders' Equity	$ 15,027,662	$ 20,015,494

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended March 31,	
	2019	**2018**

Operating Expenses:		
Research and development	$ 4,008,896	$ 2,094,095
General and administrative	1,942,763	1,337,649
Total Operating Expenses	5,951,659	3,431,744
Loss From Operations	(5,951,659)	(3,431,744)
Other Income:		
Interest income	19,275	2,137
Net Loss	$ (5,932,384)	$ (3,429,607)
Net Loss Per Share - Basic and Diluted	$ (0.50)	$ (0.45)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	11,919,973	7,561,915

Source: Eyenovia, Inc.