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Eyenovia Reports First Quarter 2018 Financial Results and Completion of EYN PG21 Study

NEW YORK, May 09, 2018 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ:EYEN), a clinical stage biopharmaceutical company developing a pipeline of ophthalmology products utilizing its patented piezo-print technology to deliver micro-therapeutics topically to the eye, today announced financial results for the first quarter ended March 31, 2018.

1Q 2018 Business Highlights

- Raised $24.5 million in net proceeds from initial public offering in January 2018;
- Completed EYN PG21 study demonstrating a robust intraocular pressure (IOP) lowering effect of the company's micro-therapeutic Latanoprost. Full results will be submitted for presentation at an upcoming medical conference;
- Received positive feedback from FDA to advance MicroProst for Chronic Angle Closure Glaucoma (CACG) into Phase III development;
- Received positive feedback from FDA to advance MicroPine for progressive pediatric Myopia into Phase III development with possibility of only one trial required for registration;
- Expanded executive management, Board of Directors and Scientific Advisory Board.

Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer commented, "We started 2018 with the successful completion of our initial public offering in January, which will help support our late stage clinical pipeline as we steadily advance 3 programs into Phase III development over the next 12 months. We also recently completed an ancillary clinical trial demonstrating the robust IOP lowering effect of our high-precision, piezo-print micro-dosing platform in 30 subjects (60 eyes). This clinical trial builds upon previously reported clinical data from our two Phase II studies in mydriasis and we intend to submit it for presentation to a major medical conference. We are preparing to submit two INDs by the end of 2018 as we move towards the initiation of the MicroStat Mydriasis Phase III program later this year and the MicroProst CACG Phase III program in the first half of 2019. Furthermore, we are encouraged by the FDA feedback to advance MicroPine for pediatric myopia into Phase III development, with the possibility of only one Phase III trial. With our robust pipeline and highly differentiated technology platform, we believe that our accomplished team is well positioned to execute on our outlined programs which have the potential to transform the field of ophthalmology and the way in which we treat front-of-the-eye conditions."

First Quarter 2018 Financial Review

For the first quarter of 2018, net loss was approximately $(3.4) million, or $(0.45) per share, compared to a net loss of approximately $(1.1) million, or $(0.49) per share for the first quarter of 2017.

Research and development expenses totaled approximately $2.1 million for the first quarter of 2018, compared to approximately $0.9 million for the same period in 2017, an increase of 130%.

For the first quarter of 2018, general and administrative expenses were approximately $1.3 million, compared with approximately $0.2 million for the first quarter of 2017, an increase of 583%.

Total operating expenses for the first quarter of 2018 were approximately $3.4 million, compared to total operating expenses of approximately $1.1 million for the same period in 2017, an increase of 210%.

As of March 31, 2018, the Company's cash balance was approximately $27.6 million compared to $5.2 million at December 31, 2017.

Completed initial public offering of 2,730,000 shares of common stock in January 2018. Eyenovia received $24.5 million in net proceeds after underwriting discounts and commissions and other estimated offering expenses.

The Company reiterated its anticipated 12-month key milestones:

- H2 2018: Initiate MicroStat Phase III trial
- H1 2019: Report MicroStat Phase III trial results
- H1 2019: Initiate MicroProst Phase III trial
- H1 2019: Initiate MicroPine Phase III trial
- H1 2019: MicroTears OTC registration

Conference Call and Webcast

The conference call is scheduled to begin at 8:30 am ET on Wednesday, May 9, 2018. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 3097559. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.eyenoviabio.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 16, 2018. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404- 537-3406 (International) with confirmation code 3097559.

About Eyenovia

Eyenovia, Inc. (NASDAQ:EYEN) is a specialty biopharmaceutical company building a portfolio of next generation topical eye treatments based on its proprietary delivery and formulation platform for micro-therapeutics. Eyenovia's pipeline is currently focused on the late-stage development of micro-therapeutics for glaucoma and other eye diseases.

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: risks involved in clinical trials, including, but not limited to, the initiation, 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; our ability to implement our business plan to commercialize 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 estimates regarding the potential market opportunity for our product candidates; intellectual property risks; our current lack of commercialization, marketing and manufacturing capabilities and strategy; our ability to attract and retain key personnel; our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives; our expectations regarding our ability to fund our operating expenses and capital expenditure requirements; the impact of government laws and regulations; our competitive position; and general economic conditions. 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.

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(Financial Statements to Follow)

EYENOVIA, INC.

Condensed Balance Sheets

	March 31, 2018 (unaudited)	December 31, 2017
Assets		

Current Assets:		
Cash	$ 27,602,069	$ 5,249,511
Prepaid expenses and other current assets	358,138	37,149
Total Current Assets	27,960,207	5,286,660
Property and equipment, net	22,635	27,960
Deferred offering costs	-	328,700
Total Assets	$ 27,982,842	$ 5,643,320
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 549,138	$ 246,384
Accrued expenses and other current liabilities	574,259	306,263
Total Current Liabilities	1,123,397	552,647
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized;		
Series A Convertible Preferred Stock, 0 and 20,000,000 shares designated as of March 31, 2018 and December 31, 2017, respectively,		
0 and 2,932,431 shares issued and outstanding		
as of March 31, 2018 and December 31, 2017, respectively	-	293
Series A-2 Convertible Preferred Stock, 0 and 5,714,286 shares designated as of March 31, 2018 and December 31, 2017, respectively,		
0 and 788,827 shares issued and outstanding		
as of March 31, 2018 and December 31, 2017, respectively	-	79
Series B Convertible Preferred Stock, 0 and 10,000,000 shares designated as of March 31, 2018 and December 31, 2017, respectively,		
0 and 918,983 shares issued and outstanding		
as of March 31, 2018 and December 31, 2017, respectively	-	92
Common stock, $0.0001 par value, 90,000,000 shares authorized;		

9,936,771 and 2,566,530 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	994	257
Additional paid-in capital	49,549,244	24,351,138
Accumulated deficit	(22,690,793)	(19,261,186)
Total Stockholders' Equity	26,859,445	5,090,673
Total Liabilities and Stockholders' Equity	$ 27,982,842	$ 5,643,320

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended March 31,	
	2018	**2017**
Operating Expenses:		
Research and development	$ 2,094,095	$ 910,841
General and administrative	1,337,649	195,951
Total Operating Expenses	3,431,744	1,106,792
Loss From Operations	(3,431,744)	(1,106,792)
Other Income:		
Interest income	2,137	443
Net Loss	$ (3,429,607)	$ (1,106,349)
Net Loss Per Share - Basic and Diluted	$ (0.45)	$ (0.49)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	7,561,915	2,266,667

Source: Eyenovia, Inc.