Eyenovia Reports Second Quarter 2024 Financial Results and Provides Corporate Update

August 12, 2024 at 4:05 PM EDT

Following FDA consultation, announced plans for validation of the Gen-2 Optejet® device and 2025 regulatory submission with Mydcombi™ as lead product

Advanced Phase 3 CHAPERONE study of MicroPine as a treatment of pediatric progressive myopia with preparations for analysis in Q4

Commenced sales activities with focus on Mydcombi in 260+ offices and preparations for launch of clobetasol propionate ophthalmic suspension 0.05%, the first new ophthalmic steroid to enter the market in 15 years

Announced development collaborations with Formosa, Senju and SGN to leverage the Optejet for the $5 billion global dry eye disease market

Company to host conference call and webcast today, August 12th, at 4:30 pm ET

NEW YORK, Aug. 12, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company with two FDA-approved products and a late-stage asset in pediatric progressive myopia, today announced its financial and operating results for the second quarter ended June 30, 2024.

Second Quarter 2024 and Recent Business Developments

- Following an FDA meeting in July, announced plans for validation of the advanced Gen-2 Optejet device with production anticipated to begin in Q4 and submission in 2025 for Mydcombi as the lead product. The Gen-2 device was developed to be easier to use and manufacture, bringing the cost of goods for the monthly cartridge towards the company's goal of $20.
- Advanced the Phase 3 CHAPERONE study of MicroPine for pediatric progressive myopia. External sources have valued the pediatric progressive myopia market at over $3.0 billion annually in the U.S. and China.
- Announced collaboration agreements with Formosa Pharmaceuticals, Senju Pharmaceutical Co., Ltd. and SGN Nanopharma to develop novel therapeutics for use with Eyenovia's Optejet® dispenser as potential treatments for dry eye disease, estimated to be a $5 billion global addressable market.
- Reported training and shipping Mydcombi to 63 new offices from April 2024 through June 30, prior to the hiring and onboarding of its sales force; on-track to reach 263 new offices by the end of the third quarter.
- Completed an equity placement with two of the Company's largest shareholders.

Michael Rowe, Chief Executive Officer, commented, "During the second quarter, we made significant progress both advancing our commercial initiatives and furthering co-development agreements that can potentially address new, multi-billion-dollar underserved markets. Our plans to finalize the Gen-2 device are now set following a meeting with the FDA and we look forward to submitting this advanced technology with Mydcombi as the lead product in 2025. Meanwhile, our Mydcombi launch continues to track to plan, with this innovative mydriasis product now available in 63 new ophthalmic offices since launch, with many more coming onboard during the third quarter as momentum accelerates."

"Regarding MicroPine, which we are developing for pediatric progressive myopia, we are preparing for analysis of the Phase 3 CHAPERONE data in the fourth quarter that, if successful, would meaningfully accelerate its remaining development path. We also executed several co-development agreements to evaluate novel therapeutics in our Optejet dispenser as potential treatments for dry eye disease, which is estimated to be a $5 billion addressable market."

"Also, during the second quarter, we completed a registered direct equity offering with two of our largest shareholders at the market price. These additional funds, together with cash on-hand and other currently available capital resources, are expected to fund our operations through the Phase 3 CHAPERONE data, which we view as a significant upcoming milestone for our company."

"We continue to take steps to increase the tangible value of our company, which currently includes two FDA-approved products, a third in late Phase 3 development, and co-development agreements that leverage our novel Optejet technology in large market indications. We believe we are very well positioned to be a leading partner to ophthalmic offices by addressing a broad spectrum of physician and patient needs with a portfolio of highly differentiated products."

Second Quarter 2024 Financial Review

For the second quarter of 2024, net loss was approximately $11.1 million, or $0.21 per share, as compared to a net loss of $6.2 million, or $0.16 per share, for the second quarter of 2023. The second quarter 2024 net loss includes $2.9 million of expense, or $0.05 loss per share, associated with the reacquisition of the license rights for MicroPine from Bausch + Lomb. The Company recorded a cost of revenue write-off of $0.5 million to adjust finished goods commercial inventory to net realizable value in the second quarter of 2024. In addition, other income includes a gain of approximately $1.2 million associated with the change in fair value of equity consideration granted in the Bausch + Lomb and Formosa transactions.

Research and development expenses totaled approximately $4.6 million for the second quarter of 2024, compared to $2.8 million for the second quarter of 2023, an increase of approximately 63.5% due largely to increased clinical expenses from the reacquisition of MicroPine license rights from Bausch + Lomb.

For the second quarter of 2024, general and administrative expenses were approximately $3.8 million, compared to $3.1 million for the second quarter of 2023, an increase of approximately 19.3% reflecting the establishment of the Company's sales force in 2024.

Total operating expenses for the second quarter of 2024 were approximately $11.2 million, including the previously referenced $2.9 million of expenses associated with the Bausch transaction compared to approximately $6.0 million for the second quarter of 2023. This represents an increase of approximately 88.2%. The second quarter 2024 operating expense figure includes approximately $3.8 million of non-cash expenses.

As of June 30, 2024, the Company's unrestricted cash and cash equivalents were approximately $2.3 million. This excludes approximately $5.8 million in gross proceeds from equity offerings completed after June 30, 2024.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, August 12th. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international), and reference conference ID 13747356.

To access the Call me™ feature, which avoids having to wait for an operator, click here.

A live webcast of the conference call will also be available here and 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.

PLEASE GO TO MYDCOMBI.COM FOR IMPORTANT SAFETY INFORMATION for MYDCOMBI™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

PLEASE GO TO CLOBETASOLBID.COM FOR IMPORTANT SAFETY INFORMATION for Clobetasol Proprionate Ophthalmic Suspension 0.05%

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its Optejet platform. Eyenovia is currently focused on the commercialization of Mydcombi (tropicamide+phenylephrine ophthalmic spray) for mydriasis, as well as clobetasol propionate ophthalmic suspension 0.05% to reduce pain and inflammation following ocular surgery, which was approved by the FDA on March 4, 2024.

Eyenovia is also advancing late-stage development of MicroPine for pediatric progressive myopia (partnered with Arctic Vision in China and South Korea).

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 statements regarding the plans, strategies and objectives of management, statements regarding future capital requirements, and estimated market opportunities for our products, 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, 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 any disruptions on our supply chain, including the availability of sufficient components and materials used in our products and product candidates; the potential advantages of our products, product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our products and product candidates; our estimates regarding the potential market opportunity for our products and product candidates; reliance on third parties to develop and commercialize our products and product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our products and product candidates; the risk of defects in, or returns of, our products; 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, 2024 (unaudited)	December 31, 2023
Assets		
Current Assets		
Cash and cash equivalents	$ 2,300,852	$ 14,849,057
Inventories	3,052,142	109,798
Deferred clinical supply costs	412,140	4,256,793
License fee and expense reimbursements receivable	124,173	123,833
Security deposits, current	-	1,506
Prepaid expenses and other current assets	1,394,313	1,365,731
Total Current Assets	7,283,620	20,706,718
Property and equipment, net	3,041,462	3,374,384
Deferred offering costs	170,632	-
Security deposits, non-current	197,168	197,168
Intangible assets	6,122,945	2,122,945
Prepaid expenses, non-current	58,693	-
Operating lease right-of-use asset	1,408,999	1,666,718
Equipment deposits	711,441	711,441
Total Assets	$ 18,994,960	$ 28,779,374
Liabilities and Stockholders' (Deficiency) Equity		
Current Liabilities:		
Accounts payable	$ 1,436,665	$ 1,753,172
Accrued compensation	1,278,178	1,658,613
Accrued expenses and other current liabilities	2,988,128	287,928
Operating lease liabilities - current portion	600,379	501,250
Notes payable - current portion, net of debt discount of $692,567 and $503,914 as of June 30, 2024 and December 31, 2023, respectively	8,730,043	5,329,419
Convertible notes payable - current portion, net of debt discount of $18,117 and $0 as of June 30, 2024 and December 31, 2023, respectively	815,216	-
Total Current Liabilities	15,848,609	9,530,382
Operating lease liabilities - non-current portion	983,839	1,292,667
Notes payable - non-current portion, net of debt discount of $0 and $448,367 as of June 30, 2024 and December 31, 2023, respectively	637,500	4,355,800
Convertible notes payable - net of debt discount of $271,752 and $398,569 as of June 30, 2024 and December 31, 2023, respectively	3,894,915	4,601,431
Total Liabilities	21,364,863	19,780,280

Stockholders' (Deficiency) Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2024 and December 31, 2023 2022	-	-
Common stock, $0.0001 par value, 300,000,000 shares authorized; 55,817,921 and 45,553,026 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	5,582	4,555
Additional paid-in capital	165,091,874	154,486,098
Accumulated deficit	(167,467,359)	(145,491,559)
Total Stockholders' (Deficiency) Equity	(2,369,903)	8,999,094
Total Liabilities and Stockholders' (Deficiency) Equity	$ 18,994,960	$ 28,779,374

EYENOVIA, INC.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating Income				
Revenue	$ 22,625	$ -	$ 27,618	$ -
Cost of revenue	(490,361)	-	(693,388)	-
Gross Loss	(467,736)	-	(665,770)	-
Operating Expenses:				
Research and development	4,597,173	2,811,061	9,028,774	5,333,011
General and administrative	3,758,835	3,149,809	7,396,024	6,086,695
Reacquisition of license rights	2,864,600	-	4,864,600	-
Total Operating Expenses	11,220,608	5,960,870	21,289,398	11,419,706
Loss From Operations	(11,688,344)	(5,960,870)	(21,955,168)	(11,419,706)
Other Income (Expense):				
Other income (expense), net	2,980	119,450	(94,578)	190,443
Change in fair value of equity consideration payable	1,240,800	-	1,240,800	-
Interest expense	(674,001)	(558,003)	(1,352,659)	(1,012,006)
Interest income	64,866	183,563	185,805	286,043
Total Other Income (Expense)	634,645	(254,990)	(20,632)	(535,520)
Net Loss	$ (11,053,699)	$ (6,215,860)	$ (21,975,800)	$ (11,955,226)
Net Loss Per Share - Basic and Diluted	$ (0.21)	$ (0.16)	$ (0.44)	$ (0.32)
Shares Outstanding - Basic and Diluted	53,121,760	38,093,826	49,864,275	37,753,694

Source: Eyenovia, Inc.