November 12, 2024

Eyenovia Reports Third Quarter 2024 Financial Results and Provides Corporate Update

Advanced Phase 3 CHAPERONE study of MicroPine as a treatment of pediatric progressive myopia with preparations for interim analysis this quarter

Commenced the manufacture of registration batches of Mydcombi in its second generation Optejet device

Announced the U.S. launch and commercial availability of clobetasol propionate ophthalmic suspension 0.05% for the treatment of inflammation and pain following ocular surgery

Appointed Andrew Jones as Chief Financial Officer

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

NEW YORK, Nov. 12, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company developing and commercializing advanced products leveraging its proprietary Optejet topical ophthalmic medication dispensing platform, today announced its financial and operating results for the third quarter ended September 30, 2024.

Third Quarter 2024 and Recent Business Developments

- Advanced the Phase 3 CHAPERONE study of MicroPine for pediatric progressive myopia with plans to conduct an interim analysis this quarter. External sources have valued the myopia market at over $3.0 billion annually in the U.S. and China.
- Announced the U.S. launch and commercial availability of clobetasol propionate ophthalmic suspension 0.05%, which is FDA approved for the treatment of post-operative inflammation and pain following ocular surgery.
- 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.
- Commenced the manufacture of registration batches of Mydcombi in its second generation Optejet device, a key step in the FDA approval process for its state-of-the-art Gen-2 Optejet dispensing platform.
- Reported training and shipping Mydcombi to 230 new offices from April through September 30th,2024.
- Appointed Andrew Jones as Chief Financial Officer.
- Raised combined net proceeds of $10.7 million.

Michael Rowe, Chief Executive Officer, commented, “We achieved another significant commercial milestone during the third quarter with the U.S. launch of clobetasol, the first new ocular steroid approved in over 15 years. Clobetasol perfectly complements our mydriasis product, Mydcombi, and allows us to further leverage our sales force while adding significant value to eye doctors and surgeons. We also experienced accelerating sales momentum with Mydcombi, now having reached 230 offices as of September 30th.

“We also took a meaningful step forward in the development of our Gen-2 Optejet device with the commencement of manufacture of registration batches, with Mydcombi as our lead product. We look forward to submitting for FDA approval of this advanced technology with Mydcombi in 2025, and a possible approval in 2026, if successful.

“Regarding MicroPine, which we are developing for pediatric progressive myopia, we are preparing for an interim analysis of the Phase 3 CHAPERONE data this quarter that, if successful, we expect will 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. Together, these indications represent multi-billion-dollar addressable markets in the U.S. alone.”

“With two differentiated commercial products, another in late Phase 3 development, multiple opportunities in dry eye, and the advanced Gen-2 Optejet technology platform, I believe we are creating a foundation from which we can drive significant growth and value creation in the months and years to come,” Mr. Rowe concluded.

Third Quarter 2024 Financial Review

For the third quarter of 2024, net loss was approximately $7.9 million, or $0.11 per share, as compared to a net loss of $7.3 million, or $0.18 per share, for the third quarter of 2023.

Research and development expenses totaled approximately $3.5 million for the third quarter of 2024, which was relatively consistent with $3.6 million reported for the third quarter of 2023.

For the third quarter of 2024, selling, general and administrative expenses were approximately $3.7 million, compared to $2.9 million for the third quarter of 2023, an increase of approximately 27.3% reflecting the establishment of the Company’s sales force in 2024.

Total operating expenses for the third quarter of 2024 were approximately $7.2 million, compared to approximately $6.5 million for the third quarter of 2023. This represents an increase of approximately 10.6%. The third quarter 2024 operating expense figure includes approximately $1.2 million of non-cash expenses.

As of September 30, 2024, the Company’s unrestricted cash and cash equivalents were approximately $7.2 million. Eyenovia continues to evaluate a range of options to secure long-term financing.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, November 12th. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international), and reference conference ID 13748714.

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 an ophthalmic technology company developing and commercializing advanced products leveraging its proprietary Optejet topical ophthalmic medication dispensing platform. The Optejet is especially useful in chronic front-of-the-eye diseases due to its ease of use, enhanced safety and tolerability, and potential for superior compliance versus standard eye drops. Together, these benefits may combine to produce better treatment options and outcomes for patients and providers. The company's pre-NDA candidate, MicroPine, is being developed for pediatric progressive myopia, a global epidemic impacting hundreds of millions of children worldwide and representing a multi-billion-dollar addressable market. The company's current commercial portfolio includes clobetasol propionate ophthalmic suspension, 0.05%, for post-surgical pain and inflammation, and Mydcombi® for mydriasis. Eyenovia has also secured licensing and development agreements for additional multi-billion-dollar indications where the Optejet may be advantageous, including dry eye. 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: the availability of sufficient financial resources to continue clinical development and commercialization of our products; 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.

Eyenovia Contact:
Eyenovia, Inc.
Andrew Jones
Chief Financial Officer
ajones@eyenovia.com

Eyenovia Investor Contact:
Eric Ribner
LifeSci Advisors, LLC
eric@lifesciadvisors.com
(646) 751-4363

Eyenovia Media Contact:
Eyenovia, Inc.
Norbert Lowe
Vice President, Commercial Operations
nlowe@eyenovia.com

EYENOVIA, INC.
Condensed Balance Sheets

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current Assets		
Cash and cash equivalents	$ 7,188,129	$ 14,849,057

Inventories	2,967,256	109,798
Deferred clinical supply costs	408,832	4,256,793
License fee and expense reimbursements receivable	137,594	123,833
Security deposits, current	-	1,506
Prepaid expenses and other current assets	987,754	1,365,731
Total Current Assets	11,689,565	20,706,718
Property and equipment, net	2,752,404	3,374,384
Security deposits, non-current	197,526	197,168
Intangible assets	6,122,945	2,122,945
Prepaid expenses, non-current	46,520	-
Operating lease right-of-use asset	1,275,690	1,666,718
Equipment deposits	711,441	711,441
Total Assets	$ 22,796,091	$ 28,779,374
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,573,940	$ 1,753,172
Accrued compensation	1,656,832	1,658,613
Accrued expenses and other current liabilities	2,518,086	287,928
Operating lease liabilities - current portion	604,647	501,250
Notes payable - current portion, net of debt discount of $562,711 and $503,914 as of September 30, 2024 and December 31, 2023, respectively	6,168,593	5,329,419
Convertible notes payable - current portion, net of debt discount of $72,467 and $0 as of September 30, 2024 and December 31, 2023, respectively	3,260,866	-
Total Current Liabilities	15,782,964	9,530,382
Accrued expenses and other non-current liabilities	316,275	-
Operating lease liabilities - non-current portion	836,434	1,292,667
Notes payable - non-current portion, net of debt discount of $0 and $448,367 as of September 30, 2024 and December 31, 2023, respectively	637,500	4,355,800
Convertible notes payable - non-current portion, net of debt discount of $163,051 and $398,569 as of September 30, 2024 and December 31, 2023, respectively	1,503,615	4,601,431
Total Liabilities	19,076,788	19,780,280

Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized;		
0 shares issued and outstanding as of September 30, 2024 and December 31, 2023	-	-
Common stock, $0.0001 par value, 300,000,000 shares authorized;		
86,375,958 and 45,553,026 shares issued and outstanding		
as of September 30, 2024 and December 31, 2023, respectively	8,638	4,555
Additional paid-in capital	179,065,877	154,486,098
Accumulated deficit	(175,355,212)	(145,491,559)
Total Stockholders' Equity	3,719,303	8,999,094
Total Liabilities and Stockholders' Equity	$ 22,796,091	$ 28,779,374

EYENOVIA, INC.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating Income				
Revenue	$ 1,625	$ 1,198	$ 29,243	$ 1,198
Cost of revenue	(132,522)	(13,416)	(825,910)	(13,416)
Gross Loss	(130,897)	(12,218)	(796,667)	(12,218)
Operating Expenses:				
Research and development	3,471,939	3,578,113	12,500,713	8,911,124
Selling, general and administrative	3,729,091	2,929,855	11,125,115	9,016,550
Reacquisition of license rights	-	-	4,864,600	-
Total Operating Expenses	7,201,030	6,507,968	28,490,428	17,927,674
Loss From Operations	(7,331,927)	(6,520,186)	(29,287,095)	(17,939,892)

Other Income (Expense):				
Other income (expense), net	1,184	(348,226)	(93,394)	(157,783)
Change in fair value of equity consideration payable	-	-	1,240,800	-
Interest expense	(602,109)	(679,222)	(1,954,768)	(1,691,228)
Interest income	44,999	208,901	230,804	494,944
Total Other Expense	(555,926)	(818,547)	(576,558)	(1,354,067)
Net Loss	$ (7,887,853)	$ (7,338,733)	$(29,863,653)	$(19,293,959)
Net Loss Per Share - Basic and Diluted	$ (0.11)	$ (0.18)	$ (0.53)	$ (0.50)
Shares Outstanding - Basic and Diluted	69,558,325	40,139,697	56,476,876	38,563,074

Source: Eyenovia, Inc.