Eyenovia Reports Third Quarter 2023 Financial Results and Provides Business Update

November 13, 2023 at 4:05 PM EST

Acquired U.S. commercial rights to APP13007, currently under FDA review for post-surgical ocular pain and inflammation, from Formosa Pharmaceuticals

Announced FDA approval of Coastline International as contract manufacturer for Mydcombi cartridge subassemblies and preparations for national launch

Company to host conference call and webcast today, November 13th, at 4:30 pm ET

NEW YORK, Nov. 13, 2023 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage, topical ophthalmic company leveraging its Optejet® dispensing technology for both internally developed and acquired programs as well as out-licensing for additional indications, today announced its financial and operating results for the third quarter ended September 30, 2023.

Third Quarter 2023 and Recent Business Developments

- Acquired the U.S. commercial rights to APP13007 for post-surgical ocular pain and inflammation from Formosa Pharmaceuticals. If approved, APP13007 would complement Eyenovia's commercially approved mydriasis product, Mydcombi, and allow for the generation of additional near-term revenue. A New Drug Application (NDA) for APP13007 is currently under review by the FDA, which has assigned a PDUFA action date of March 4, 2024.
- Announced the appointment of senior finance executive Mr. Michael Geltzeiler to Eyenovia's Board as an independent director and Chair of the Audit Committee.
- Announced FDA approval of Coastline International as contract manufacturer for Mydcombi cartridge subassemblies, enabling a national launch in early 2024.
- Initiated training of ophthalmic technicians in the use of Mydcombi through sponsorship of a course at the International Joint Commission on Allied Health Personnel in Ophthalmology (IJCAHPO) 51st Annual Continuing Education (ACE) program.
- Advanced its Gen-2 Optejet device and anticipates shipping to MicroPine partners Bausch and Lomb and Arctic Vision by year-end 2023.
- Continued to validate its manufacturing facilities in Redwood City, CA and Reno, NV, the former having a PDUFA date in February 2024 for use as a commercial facility.
- Presented data from a study of the preservative-free microbial integrity of the Optejet® at the American Academy of Optometry's "Academy 2023 New Orleans" Annual Meeting in October. The study successfully demonstrated the Optejet's ability to maintain product sterility even when exposed to a microbial load that exceeds typical environmental conditions.

Michael Rowe, Chief Executive Officer, commented, "During the third quarter, we expanded our near-term commercial product portfolio with our acquisition of the commercial rights to APP13007 from Formosa Pharmaceuticals. This unique, twice-a-day steroid will compete against products that are typically used four times a day, with a desirable efficacy and safety profile. Together with Mydcombi, we expect the two products to increase the capability of our planned ten-person sales force to generate near-term revenue for our company which in turn will help fund the completion of our internal development programs. APP13007 has the additional benefit of potential use in the Optejet for the treatment of dry eye disease, and after recent positive discussions with the FDA, we are evaluating the timing and value of this potential program.

"We were also pleased to announce recently that Coastline International was approved by the FDA as a contract manufacturer for certain elements of Mydcombi in the Optejet. With Coastline, we expect to initiate manufacturing imminently in preparation for a broader launch in early 2024.

"We have made the strategic decision to prioritize our current Gen-2 Optejet manufacturing capabilities to ensure that our partners, Bausch and Lomb and Arctic Vision, have this advanced product for their pediatric myopia studies by the end of this year. This will shift the manufacture of registration batches of our pre-NDA presbyopia candidate, Apersure, to the first quarter of 2024. We see no downside to this change as the nascent presbyopia market continues to evolve and mature, as evidenced by the disappointing performance of the only available eye drop product for this indication. As new entrants come into the presbyopia market and revitalize it, we look forward to introducing Apersure in the highly differentiated and desirable Optejet dispenser.

"We are also excited to announce today the appointment of Mr. Michael Geltzeiler to our Board as an independent director and Chair of our Audit Committee. Mike has a strong track record of successful value creation for shareholders, including over 17 years of CFO experience at companies including ADT Corporation, Euronext and Readers Digest. We are fortunate to have Mike with his extensive finance background join us at this time,

and I know that he is as excited as I am about the potential that Eyenovia represents.

“With three distinct sources of potential growth – internally developed programs, complementary product acquisitions that can be further developed in the Optejet, and strategic partnerships that license the Optejet for additional indications – I believe we have firmly established ourselves as a leader in topical ophthalmic medication delivery, and I am excited about the many opportunities that are in front of us,” Mr. Rowe concluded.

Third Quarter 2023 Financial Review

For the third quarter of 2023, net loss was approximately $(7.3) million, or $(0.18) per share compared to a net loss of approximately $(7.3) million, or $(0.21) per share, for the third quarter of 2022.

Research and development expenses totaled approximately $3.6 million for the third quarter of 2023 as compared to $3.9 million for the third quarter of 2022.

For the third quarter of 2023, general and administrative expenses were approximately $2.9 million, compared to $3.4 million for the third quarter of 2022.

Total operating expenses for the third quarter of 2023 were approximately $6.5 million compared to $7.2 million for the third quarter of 2022.

As of September 30, 2023, the Company’s cash and cash equivalents were approximately $20.7 million compared to $22.9 million as of December 31, 2022.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, November 13th. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international), and reference conference ID 13741898.

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 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.

IMPORTANT SAFETY INFORMATION for MYDCOMBI ™(tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

INDICATIONS

MYDCOMBI is indicated to induce mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired

CONTRAINDICATIONS: In patients with known hypersensitivity to any component of the formulation

WARNINGS AND PRECAUTIONS

FOR TOPICAL OPHTHALMIC USE. NOT FOR INJECTION
This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of psychotic reaction and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be considered.
Mydriatics may produce a transient elevation of intraocular pressure.
Significant elevations in blood pressure have been reported. Caution in patients with elevated blood pressure.
Rebound miosis has been reported one day after installation.
Remove contact lenses before using.

DRUG INTERACTIONS

Atropine-like Drugs: May exaggerate the adrenergic pressor response
Cholinergic Agonists and Ophthalmic Cholinesterase Inhibitors: May interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors
Potent Inhalation Anesthetic Agents: May potentiate cardiovascular depressant effects of some inhalation anesthetic agents

ADVERSE REACTIONS

- Most common ocular adverse reactions include transient blurred vision, reduced visual acuity, photophobia, superficial punctate keratitis, and mild eye discomfort. Increased intraocular pressure has been reported following the use of mydriatics.
- Systemic adverse reactions including dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity have been reported with the use of tropicamide.

To report SUSPECTED ADVERSE REACTIONS, contact Eyenovia, Inc. At 1-833-393-6684 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch)

Please go to www.mydcombi.com for **FULL PRESCRIBING INFORMATION**

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.

In addition to commercializing Mydcombi, in August 2023, Eyenovia acquired the U.S. commercial rights to APP13007 (clobetasol propionate ophthalmic nanosuspension, 0.05%) from Formosa Pharmaceuticals. APP13007, which is currently under review by the FDA, is a potent steroid being developed to reduce pain and inflammation following ocular surgery. The agency has assigned a Prescription Drug User Fee Act (PDUFA) action date for APP13007 of March 4, 2024.

Eyenovia is also advancing late-stage development of medications in the Optejet device for presbyopia and myopia progression (partnered with Bausch+Lomb in the U.S. and Canada and Arctic Vision in China and South Korea).

For more information, visit www.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 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

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	$ 20,702,212	$ 22,863,520
Inventories	50,296	-
Deferred clinical supply costs	3,622,687	2,284,931
License fee and expense reimbursements receivable	397,014	1,183,786
Security deposits, current	-	119,550
Prepaid expenses and other current assets	1,760,824	1,190,719
Total Current Assets	26,533,033	27,642,506

Property and equipment, net	3,531,365	1,295,115
Security deposits, non-current	198,674	80,874
Intangible assets	2,122,945	-
Operating lease right-of-use asset	1,792,667	1,291,592
Equipment deposits	686,753	726,326
Total Assets	$ 34,865,437	$ 31,036,413
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,426,028	$ 1,428,283
Accrued compensation	1,375,832	1,747,191
Accrued expenses and other current liabilities	295,703	503,076
Operating lease liabilities - current portion	444,616	484,882
Notes payable - current portion, net of debt discount of $327,217 and $33,885 as of September 30, 2023 and December 31, 2022, respectively	3,006,116	174,448
Convertible notes payable - current portion, net of debt discount of $0 and $33,885 as of September 30, 2023 and December 31, 2022, respectively	-	174,448
Total Current Liabilities	6,548,295	4,512,328
Operating lease liabilities - non-current portion	1,441,081	907,644
Notes payable - non-current portion, net of debt discount of $754,919 and $813,229 as of September 30, 2023 and December 31, 2022, respectively	6,549,248	4,190,938
Convertible notes payable - non-current portion, net of debt discount of $452,920 and $813,229 as of September 30, 2023 and December 31, 2022, respectively	4,547,080	4,190,938
Total Liabilities	19,085,704	13,801,848
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 42,898,246 and 36,668,980 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	4,290	3,667
Additional paid-in capital	153,299,865	135,461,361
Accumulated deficit	(137,524,422)	(118,230,463)
Total Stockholders' Equity	15,779,733	17,234,565
Total Liabilities and Stockholders' Equity	$ 34,865,437	$ 31,036,413

EYENOVIA, INC.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating Income				
Revenue	$ 1,198	$ -	$ 1,198	$ -
Cost of revenue	(1,198)	-	(1,198)	-
Gross Profit	-	-	-	-
Operating Expenses:				
Research and development	3,578,113	3,876,876	8,911,124	11,176,326
General and administrative	2,942,073	3,353,352	9,028,768	10,362,907
Total Operating Expenses	6,520,186	7,230,228	17,939,892	21,539,233

Loss From Operations	(6,520,186)	(7,230,228)	(17,939,892)	(21,539,233)
Other Income (Expense):				
Other income (expense), net	(348,226)	70,277	(157,783)	96,580
Interest expense	(679,222)	(177,138)	(1,691,228)	(475,811)
Interest income	208,901	28,093	494,944	30,703
Total Other Income (Expense)	(818,547)	(78,768)	(1,354,067)	(348,528)
Net Loss	$ (7,338,733)	$ (7,308,996)	$ (19,293,959)	$ (21,887,761)
Net Loss Per Share - Basic and Diluted	$ (0.18)	$ (0.21)	$ (0.50)	$ (0.67)
Shares Outstanding - Basic and Diluted	40,139,697	34,631,774	38,563,074	32,778,551

Source: Eyenovia, Inc.