

Eyenovia Reports First Quarter 2023 Financial Results and Provides Business Update

Announced FDA approval of Mydcombi™, a fixed dose combination of tropicamide and phenylephrine for mydriasis, the first FDA approved product to utilize the Optejet®

Received feedback from FDA on its Phase 3 Microline presbyopia candidate that provides a clear and efficient path forward for the program

Entered into co-development agreement with Formosa Pharmaceuticals for the potential development of new topical ophthalmic therapeutics

Company to host conference call and webcast today, May 11, at 4:30 pm ET

NEW YORK, May 11, 2023 (GLOBE NEWSWIRE) -- [Eyenovia, Inc.](#) (NASDAQ: EYEN), an ophthalmic technology company developing the Optejet delivery system for use both in combination with its own drug-device therapeutic programs for mydriasis, presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced its financial and operating results for the first quarter ended March 31, 2023.

First Quarter 2023 and Recent Business Developments

- Announced U.S. Food and Drug Administration (FDA) approval of Mydcombi, the Company's proprietary combination microdose formulation of tropicamide and phenylephrine for inducing mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired. Please see the full prescribing information at www.mydcombi.com.
- Received feedback from FDA on its Phase 3 Microline presbyopia candidate that provides a clear and efficient path forward for the program.
- Entered into a development collaboration agreement with Formosa Pharmaceuticals to combine Eyenovia's Optejet with Formosa's APNT nanoparticle formulation platform for the potential development of new topical ophthalmic therapeutics.
- Announced positive results from a research study, conducted in collaboration with Tufts Medical Center, demonstrating the superiority of the Optejet versus standard eye drops in the administration of the anti-glaucoma medication latanoprost preserved with benzalkonium chloride (BAK). Optejet was found to achieve a therapeutic dose of latanoprost with significantly less exposure to excess drug and harmful preservatives than can be achieved using conventional drops. These results were presented at the Association for Research in Vision and Ophthalmology (ARVO) 2023 annual meeting in April.
- Continued to build out its manufacturing facilities in Redwood City, CA and Reno, NV, which is on track to come online during the third quarter of 2023.

- Licensing partners Bausch+Lomb and Arctic Vision continued to enroll patients in their respective Phase 3 studies of Micropine (US and China) and Microline (China).
- Ended the first quarter of 2023 with approximately \$18.5 million in total cash and cash equivalents. In addition, with the approval of Mydcombi, the Company has the ability to draw down an additional \$5 million on its credit facility with Avenue Capital before July 31, 2023.

Michael Rowe, Chief Executive Officer, commented, "We are proud to be delivering on our commitments in 2023 with the recently announced FDA approval of Mydcombi, our first approved product dispensed using our Optejet technology. We believe the Optejet will transform the way that topical eye drugs are developed and delivered, and this FDA approval marks a significant milestone in its evolution. It is also an important achievement in the context of our current and future partnerships, providing a template for the development of additional ophthalmic therapies administered via the Optejet in high-value ophthalmic indications."

"Regarding our pre-NDA Microline program for presbyopia, we received clear feedback from the FDA that provides an efficient path forward for the program. We are in the process of completing the build-out and validation of our Redwood City manufacturing facility and remain on track to commence the manufacture of launch batches early next year. In the interim, we plan to conduct supportive human factors testing and clinical work demonstrating the usability of the Gen-2 Optejet device, which has been optimized for in-home use."

"With one product approved, and line-of-sight toward a second, we have reached a true inflection point in the evolution of our company. Having an FDA approved product not only provides critical validation of our Optejet technology for our own advanced clinical programs, but also our partnerships as well. To that end, we continue to advance discussions with additional partners that could potentially assess the utility of Optejet in very large indications such as glaucoma and dry eye, among others. I am pleased with our progress to date and look forward to initial commercial sales of Mydcombi this summer together with continued clinical and regulatory progress for us and our partners."

First Quarter 2023 Financial Review

For the first quarter of 2023, net loss was approximately \$(5.7) million, or \$(0.15) per share compared to a net loss of approximately \$(7.3) million, or \$(0.24) per share, for the first quarter of 2022.

Research and development expenses totaled approximately \$2.5 million for the first quarter of 2023 as compared to \$3.7 million for the first quarter of 2022.

For the first quarter of 2023, general and administrative expenses were approximately \$2.9 million, compared to \$3.5 million for the first quarter of 2022.

Total operating expenses for the first quarter of 2023 were approximately \$5.5 million compared to \$7.2 million for the first quarter of 2022.

As of March 31, 2023, the Company's cash and cash equivalents were approximately \$18.5 million compared to \$22.9 million as of December 31, 2022. In addition, with the approval of Mydcombi, the Company has the ability to draw down an additional \$5 million on its credit facility with Avenue Capital before July 31, 2023.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, May 11. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international). 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.

To access the Call me™ feature, which avoids having to wait for an operator, click [here](#).

After the live webcast, the event will be archived on Eyenovia's website for one year.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics. Eyenovia is currently focused on the commercialization of Mydcombi and the late-stage development of microdosed medications for presbyopia and myopia progression. For more information, visit www.eyenovia.com.

The Eyenovia Corporate Information slide deck may be found at ir.eyenovia.com/events-and-presentations.

Eyenovia Contact:

Eyenovia, Inc.
John Gandolfo
Chief Financial Officer
jgandolfo@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

	March 31, 2023	December 31, 2022
	(unaudited)	

Assets

Current Assets:

Cash and cash equivalents	\$ 18,466,322	\$ 22,863,520
Deferred clinical supply costs	3,352,645	2,284,931

License fee and expense reimbursements receivable	973,677	1,183,786
Security deposits, current	119,550	119,550
Prepaid expenses and other current assets	2,011,884	1,190,719
 Total Current Assets	 24,924,078	 27,642,506
Property and equipment, net	2,152,861	1,295,115
Security deposits, non-current	80,874	80,874
Operating lease right-of-use asset	1,508,158	1,291,592
Equipment deposits	643,513	726,326
 Total Assets	 \$ 29,309,484	 \$ 31,036,413

Liabilities and Stockholders' Equity

Current Liabilities:

Accounts payable	\$ 1,402,076	\$ 1,428,283
Accrued compensation	637,189	1,747,191
Accrued expenses and other current liabilities	460,143	503,076
Operating lease liabilities - current portion	472,901	484,882
Notes payable - current portion, net of debt discount of \$123,480		
and \$33,885 as of March 31, 2023 and December 31, 2022, respectively	1,218,963	174,448
Convertible notes payable - current portion, net of debt discount of \$123,480		
and \$33,885 as of March 31, 2023 and December 31, 2022, respectively	709,853	174,448
 Total Current Liabilities	 4,901,125	 4,512,328
Operating lease liabilities - non-current portion	1,133,948	907,644
Notes payable - non-current portion, net of debt discount of \$648,889		
and \$813,229 as of March 31, 2023 and December 31, 2022, respectively	3,730,278	4,190,938
Convertible notes payable - non-current portion, net of debt discount of \$648,889		
and \$813,229 as of March 31, 2023 and December 31, 2022, respectively	3,730,278	4,190,938
 Total Liabilities	 13,495,629	 13,801,848

Stockholders' Equity:

Preferred stock, \$0.0001 par value, 6,000,000 shares
authorized;

0 shares issued and outstanding as of March 31, 2023		
and		
December 31, 2022		
Common stock, \$0.0001 par value, 90,000,000 shares authorized;		
37,991,746 and 36,668,980 shares issued and outstanding		
as of March 31, 2023 and December 31, 2022, respectively	3,799	3,667
Additional paid-in capital	139,779,885	135,461,361
Accumulated deficit	(123,969,829)	(118,230,463)
 Total Stockholders' Equity	 15,813,855	 17,234,565
 Total Liabilities and Stockholders' Equity	 \$ 29,309,484	 \$ 31,036,413

EYENOVIA, INC.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended March 31,	
	2023	2022
Operating Expenses:		
Research and development	\$ 2,521,950	\$ 3,712,584
General and administrative	2,936,886	3,474,965
Total Operating Expenses	<u>5,458,836</u>	<u>7,187,549</u>
 Loss From Operations	 (5,458,836)	 (7,187,549)
Other Income (Expense):		
Other income (expense), net	70,993	(7,073)
Interest expense	(454,003)	(145,237)
Interest income	<u>102,480</u>	<u>194</u>
 Net Loss	 \$ (5,739,366)	 \$ (7,339,665)
Net Loss Per Share - Basic and Diluted	\$ (0.15)	\$ (0.24)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	37,410,587	30,008,194



Source: Eyenovia, Inc.