Eyenovia Announces Updated Strategy and Corporate Priorities to Focus on Shareholder Value Generation and Immediate Commercial Opportunities

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- *Company focusing on multi-billion dollar opportunity in pediatric progressive myopia represented by MicroPine, with interim analysis planned for 4Q 2024 and a potential NDA to the FDA in 2025*
- *Continuing to advance commercialization of Mydcombi for mydriasis and preparing to launch clobetasol propionate ophthalmic suspension 0.05% for post-surgical management of pain and inflammation; both represent large multi-million-dollar opportunities*
- *Company exploring wide range of strategic alternatives*

NEW YORK, April 08, 2024 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company, today announced its plans for accelerating development of its potential multi-billion dollar product for pediatric progressive myopia (MicroPine) and initiated a process to explore strategic alternatives to maximize shareholder value. As part of this process, the Company plans to consider a wide range of options, including potential sale of assets of the Company, a sale of the Company, a merger, or other strategic action. In conjunction with the strategic process and focus on its late stage MicroPine asset, Eyenovia reiterated its immediate commercialization opportunities and corporate savings intended to reduce operating expenses while continuing to support meaningful value generation from the company's two FDA-approved products.

“The pediatric progressive myopia market represents a significant opportunity for Eyenovia both in the United States and China. This disease, for which there are no FDA-approved pharmaceutical treatments, has been called an epidemic by several medical and optometric organizations. The sheer number of children at high risk of developing significant, permanent vision loss due to progressive myopia is estimated to be five million in the U.S., and the value of this indication has been estimated to be $1.8 billion by third-party experts in the field. We are excited by the prospect of an interim analysis of our CHAPERONE data later this year, when we can evaluate whether or not this placebo-controlled study should continue as-is or potentially move rapidly towards an NDA filing in 2025,” stated Michael Rowe, Eyenovia’s Chief Executive Officer.

“In the meantime, we will be evaluating strategic opportunities for MicroPine with organizations that have existing capabilities and infrastructure necessary to fully capitalize on this large opportunity. Additionally, we continue to make significant progress advancing our commercialization strategy, with Mydcombi and Avenova currently being sold through our targeted sales force, and clobetasol to be commercially launched as soon as this summer.”

“We are also preparing to meet with the FDA over the summer to propose a fast path forward for approval of our next generation Optejet device, which, given its optimization for home use and significant manufacturing advantages relative to our current version, not only better positions us to support our current programs and partnerships, but new potential collaborations as well.”

“However, we believe this progress, and the broader potential of MicroPine, which will be back in our hands in a matter of weeks, has been underrecognized and underappreciated by the financial markets. As a result, while we remain intently focused on laying a foundation for accelerating sales growth in 2025, we are in parallel reducing costs in areas that do not impact our ability to deliver on our core strategy and exploring a possible transaction or transactions that could generate capital or otherwise enhance value for our shareholders, who remain very supportive. I look forward to evaluating a comprehensive variety of alternatives with my fellow Board members in the coming weeks.”

Eyenovia is making this announcement to inform shareholders and the public that in addition to the active execution of the company’s ophthalmic programs outlined in its corporate presentation and regulatory filings, the company also plans to engage in discussions for strategic alternatives with the goal of maximizing value for shareholders.

Eyenovia is in the process of engaging with investment banks to assist with the evaluation. There can be no assurance that this process will result in the company entering or completing any transaction. Eyenovia does not intend to make any further disclosures regarding the strategic review process unless and until a specific course of action is approved.

PLEASE GO TO CLOBETASOLBID.COM FOR IMPORTANT SAFETY INFORMATION for CLOBETASOL PROPRIONATE OPHTHALMIC SUSPENSION 0.05%

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

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a commercial stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics. Eyenovia is currently focused on the commercialization of Mydcombi for mydriasis, as well as the ongoing late-stage development of medications in the Optejet device for presbyopia and myopia progression. 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 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 product candidates and platform technology, the timing for sales growth of our approved products, and the outcome of the process to explore strategic alternatives to maximize shareholder value. 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 due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission.

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 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; intellectual property risks; changes in legal, regulatory, legislative and geopolitical environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products and product candidates; and our competitive position.

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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