UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended: December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 001-38365

EYENOVIA, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE	**47-1178401**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
23461 South Point Drive, Suite 390 Laguna Hills, CA	**92653**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (833) 393-6684
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 Par Value	**EYEN**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: none

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any news or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

Auditor PCAOB ID Number: 688	Auditor Name: Marcum LLP	Auditor Location: New York, NY

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2024 (based on the closing price of $47.52 on June 30, 2024, the last trading day of the registrant's most recently completed second fiscal quarter, as adjusted for the 1-for-80 reverse stock split of the registrant's common stock effected on January 31, 2025), was approximately $32.5 million. Common stock held by each officer and director and by each person known to the registrant who owned 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock was 2,830,546 as of April 11, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Information required by Part III hereof will be filed either as part of the registrant's proxy statement for its 2025 Annual Meeting of Stockholders or an amendment to this Form 10-K, and such information is incorporated by reference herein.

Eyenovia, Inc.
Form 10-K
For Year Ended December 31, 2024

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PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Annual Report on Form 10-K that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. Such forward-looking statements include our need to raise additional money to fund our operations for the next twelve months as a going concern; our estimates regarding expenses, future revenue, capital requirements and our need for additional financing and other financial items; the outcome of the process to explore strategic alternatives to maximize shareholder value; any statements of the plans, strategies and objectives of management for future operations; any statements about the advantages of our products and platform technology; estimates regarding the potential market opportunity for our products and platform technology; factors that may affect our operating results; statements about our ability to establish and maintain intellectual property rights; statements about our ability to retain key personnel; statements related to future capital expenditures; statements related to future economic conditions or performance; and other matters that do not relate strictly to historical facts or statements of assumptions underlying any of the foregoing. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "might," "will," "plan," "project," "seek," "should," "target," "would," and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Summary Risk Factors" described below and "Risk Factors" included in Item 1A of Part I of this Annual Report on Form 10-K, and the risks discussed in our other U.S. Securities and Exchange Commission, or SEC, filings. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

As used in this report, the terms "Eyenovia, Inc.," "Eyenovia," "Company," "company," "we," "us," and "our" mean Eyenovia, Inc. and its subsidiaries unless the context indicates otherwise.

Summary Risk Factors

Some of the factors that could materially and adversely affect our financial condition, results of operations, cash flow, the market price of shares of our common stock or our prospects include, but are not limited to, the following. You should read this summary together with the more detailed description of each risk factor contained in Item 1A "Risk Factors" in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

- We will need to raise additional capital to remain a going concern, which may not be available on acceptable terms, or at all.
- Our ongoing exploration of alternative strategic paths may not result in entering into or completing transactions when necessary, and the process of reviewing alternative strategic paths or their conclusion could adversely affect our stock price.
- Delisting of our common stock from Nasdaq could prevent us from maintaining an active, liquid and orderly trading market for our common stock and may materially and adversely impact our ability to consummate certain strategic transactions.
- We have entered into a loan modification agreement with Avenue and, based on our lack of financial liquidity, we cannot guarantee that we will be able to comply with the terms of this agreement, or continue obtaining forbearance if needed.
- We have incurred operating losses since our inception. We expect to continue to incur losses for the foreseeable future and might never achieve or maintain profitability.

Risks Related to the Proposed Combination between Eyenovia and Betaliq

- The proposed business combination may not be consummated on the terms described in the non-binding Letter of Intent (as defined herein) or at all.
- Failure to enter into a definitive business combination agreement or consummate the proposed business combination could negatively affect Eyenovia's business, future business and financial results.
- Eyenovia and Betaliq, Inc. ("Betaliq") will be subject to various uncertainties while the proposed business combination is pending that could adversely affect the anticipated benefits of the business combination.
- Eyenovia expects to incur substantial transaction costs in connection with the proposed business combination.

Risks Related to Regulatory Approval of Our Products and Other Legal Compliance Matters

- We are subject to ongoing regulatory obligations and continued regulatory review of our products, which may result in significant additional expense. Additionally, our products could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

Risks Related to Our Business Operations and Managing Growth

- We are highly dependent on the services of our senior management team, including our Chief Executive Officer, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical, scientific and sales personnel, our business will be harmed.
- We have limited corporate infrastructure.

Risks Related to Our Dependence on Third Parties

- We may encounter delays in the manufacturing of the second generation Optejet device, including as a result of our reliance on third parties for manufacturing activities, and this may cause delays in the commercialization of our products. Any such

delays would increase the risk that we will not have sufficient quantities of our products or such quantities at an acceptable cost, which could delay, prevent or impair our commercialization efforts.

- If we, our service providers or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

Risks Related to Our Intellectual Property and Potential Litigation

- Our success depends on our ability to protect our intellectual property and proprietary technology.
- Our patents covering our proprietary technology may be subject to challenge, narrowing, circumvention and invalidation by third parties.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.
- If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

Risks Related to Ownership of Our Common Stock

- A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.
- The price of our common stock has been, and may continue to be, volatile and may fluctuate substantially, which could result in substantial losses for purchasers of our common stock.
- We have broad discretion in the use of our cash, including the net proceeds from our financings, and might not use them effectively.

Item 1. Business.

Corporate Information

We were organized as a corporation under the laws of the State of Florida on March 12, 2014 under the name "PGP Holdings V, Inc." On May 5, 2014, we changed our name to Eyenovia, Inc. On October 6, 2014, we reincorporated in the State of Delaware by merging into Eyenovia, Inc., a Delaware corporation. Our principal executive office is located at 23461 South Pointe Drive, Suite 390, Laguna Hills, CA 92653, and our phone number is (833) 393-6684. Our website is *www.eyenovia.com*. Information contained on, or that can be accessed through, our website is not incorporated by reference into this report, and you should not consider information on our website to be part of this report.

Overview

We are an ophthalmic technology company developing our proprietary Optejet® topical ophthalmic medication dispensing platform. In November 2024, we received a negative clinical trial result in the development of our development-stage drug-device combination product, MicroPine. As a result, we restructured our company to minimize expenses and engaged an investment bank to explore strategic options in order to maximize shareholder value. We have paused the national sales roll-out of our products clobetasol propionate and Mydcombi® until additional funding is obtained. At the same time, we accelerated our development efforts relating to the Optejet in order to potentially increase the value of that asset in any strategic transaction or capital raising activities.

The ergonomic and functional design of the Optejet allows for horizontal drug delivery and eliminates the need to tilt the head back or the manual dexterity to squeeze a bottle to administer medications. Drug is delivered in a microscopic array of droplets that is both comfortable and matches the amount of fluid that the front of the eye can hold. The precise delivery of a low-volume columnar spray by the Optejet device helps ensure instillation success while minimizing contamination risk with a non-protruding nozzle and self-closing shutter. In clinical trials, the Optejet has demonstrated that its targeted delivery achieves a high rate of successful administration, with 98% of sprays being accurately delivered upon first attempt compared to the established rate reported with traditional eye drops of approximately 50%.

A more physiologically appropriate volume of medication in the range of seven to ten microliters is delivered by the Optejet, which is approximately one-fifth of the 35 to 50 microliter dose typically delivered in a single eye drop. Lower volume of medication exposes the ocular surface to less active ingredients and preservatives, potentially reducing ocular stress and surface damage and improving tolerability. The lower volume also minimizes the potential for drug to enter systemic circulation, with the goal of avoiding some common side effects that are related to overdosing of the eye.

We are developing versions of the Optejet with on-board digital technology that records the date and time of each use. These data may be used to provide reminders via Bluetooth to smart devices and to allow healthcare practitioners to monitor usage. This information can then be used by practitioners and health care systems to measure treatment compliance and improve medical decision making. In this way, the Optejet could serve as an extension of the physician's office by providing information that is not currently possible to collect except through the use of diaries.

MicroLine is our investigational pharmacologic treatment for presbyopia, a non-preventable, age-related hardening of the lens, which causes the gradual loss of the eye's ability to focus on near objects and impairs near visual acuity. We have completed two Phase III studies using our Optejet device. In these studies, patients reported high satisfaction with using the device, and a strong preference over using an eye dropper bottle. Since completing these studies, the market opportunity has markedly deteriorated, and we have chosen to put this program on hold and reallocate our resources towards larger opportunities. When and if the market improves, we have kept open the option to continue development of MicroLine, which would include a meeting with the U.S. Food and Drug Administration (the "FDA") to review our clinical data to date.

Our first product using the Optejet technology, Mydcombi®, is the only FDA-approved fixed combination of the two leading mydriatic agents, tropicamide and phenylephrine, in the United States. As an ophthalmic spray delivered with Optejet technology, Mydcombi may present a number of benefits for ophthalmic surgical centers, optometric and ophthalmic offices and patients. Those benefits may include improved cost-effectiveness in centers that employ single-use bottles for mydriasis, more efficient use of office time and resources, and an overall improved doctor-patient experience.

The first commercial sale of Mydcombi occurred on August 3, 2023 as part of a targeted launch, and we expanded our launch with the hiring and onboarding of ten sales representatives through December 31, 2024. On July 24, 2024, we received written comments

from the FDA providing direction for the design of a clinical bridging study to transition Mydcombi into our new Gen-2 Optejet device, which has a significantly lower cost to manufacture than the currently approved product.

On August 10, 2020, we entered into a license agreement with Arctic Vision (as amended on September 14, 2021, the "Arctic Vision License Agreement") pursuant to which Arctic Vision may develop and commercialize MicroPine (Eyenovia's proprietary drug-device combination of low-dose atropine and the Optejet platform), MicroLine and Mydcombi in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea. Under the terms of the Arctic Vision License Agreement, as amended, we received an upfront payment of $4.25 million before any payments to Senju Pharmaceutical Co., Ltd. ("Senju").

On October 9, 2020, we entered into a license agreement (the "Bausch License Agreement") with Bausch + Lomb ("B+L"), pursuant to which B+L had the rights to develop and commercialize MicroPine in the United States and Canada. Under the terms of the Bausch License Agreement, we received an upfront payment of $10.0 million and we were eligible to receive up to a total of $35.0 million in additional payments, based on the achievement of certain regulatory and launch-based milestones. B+L also agreed to pay royalties to Eyenovia on a tiered basis (ranging from mid-single digit to mid-teen percentages) on gross profits from sales of MicroPine in the United States and Canada, subject to certain adjustments. Under the terms of the Bausch License Agreement, B+L assumed sponsorship of the IND as well as ownership and the costs related to the ongoing CHAPERONE study, which was a Phase III efficacy and safety trial of MicroPine.

On January 12, 2024, we entered into a subsequent agreement with B+L to repatriate our rights to MicroPine and take control of the CHAPERONE study. In this agreement, we agreed to pay B+L $2 million in cash and an additional $3 million in common stock upon successful transfer of the regulatory documents and study elements to Eyenovia. We also agreed to pay B+L a 2% royalty on net sales once MicroPine is commercialized in the United States, assuming receipt of regulatory approvals. We believed that this revised arrangement was in our and our shareholders' best interests, as it could have substantially increased the value of the asset through potential improvements in the conduct of the study, including a planned interim analysis of the data in late 2024.

On September 26, 2024, we announced the U.S. launch and commercial availability of clobetasol propionate ophthalmic suspension 0.05%.

On November 15, 2024, we announced the outcome of an independent review of the clinical results of the three-year efficacy and safety data from the MicroPine Phase III CHAPERONE study conducted by a Data Monitoring Committee ("DMC"). The DMC, made up of independent ophthalmologists and optometrists who specialize in pediatric myopia as well as a statistician, reviewed the safety and efficacy data from all evaluable patients. After the completion of three-year therapy for myopia with MicroPine, statistical superiority was not observed and was deemed unlikely to occur in at least one of the active dose arms compared with placebo, which was the primary efficacy endpoint of the trial. There were no safety issues or serious adverse events identified. As a result of this finding, we closed out the CHAPERONE study and put the project on hold in December 2024.

In light of the results from the CHAPERONE study, the Company is considering a variety of steps to maximize value to all stakeholders, to reduce expenses and to evaluate its strategic options, which may include a business combination, reverse merger, asset sales or a combination of those alternatives. Further information will be made available once the evaluation of strategic options has been completed. The Company implemented a reduction in force affecting approximately 75% of its workforce. The estimated total cost of severance-related expenses relating to this reduction in force is $0.3 million. The remaining staff will be focused on Optejet® Gen-2 development, our dry eye collaborations and clobetasol propionate commercialization.

We successfully expanded our manufacturing capabilities through a partnership with Coastline International, Inc. located in Tijuana, Mexico, as well as the construction of our new manufacturing facility in Reno, Nevada and the construction of our own fill and finish facility in Redwood City, California. The FDA approved the use of both Coastline International and our Redwood City facility for the production of Mydcombi cartridges, and the use of our Reno facility for the production of technical elements such as the base unit for the Optejet device. As part of the Company's steps to maximize value to all stakeholders, to reduce expenses and to evaluate its strategic options, we made the decision to phase out the production and sale of Mydcombi in the GEN-1 device. As a result, we have phased out the manufacturing line at Coastline International, Inc. located in Tijuana, Mexico, and are also modifying the use of our manufacturing facility in Reno, Nevada and our fill and finish facility in Redwood City, California to focus on Optejet® Gen-2 development, our dry eye collaborations and clobetasol propionate commercialization.

In addition to our own development programs, on August 15, 2023, we entered into a license agreement with Formosa Pharmaceuticals, Inc. ("Formosa"), whereby we acquired the exclusive U.S. rights to commercialize any product related to a novel formulation of clobetasol propionate ophthalmic suspension 0.05% (the "Formosa Licensed Product"), which was approved by the FDA, for post-operative inflammation and pain after ocular surgery, on March 4, 2024. The Formosa License will remain in effect for ten years from the date of the first commercial sale of a Formosa Licensed Product, unless earlier terminated.

We paid Formosa an upfront payment in an aggregate amount of $2.0 million which consisted of (a) cash in the amount of $1.0 million and (b) 487,805 shares of common stock valued pursuant to the Formosa License Agreement at $1.0 million. We also capitalized $122,945 of transaction costs in connection with the Formosa License. In addition, we agreed to pay Formosa up to $4.0 million upon the achievement of certain development milestones and up to $80 million upon the achievement of certain sales milestones. The trigger for the initial $2.0 million development milestone payment was FDA approval of the Formosa Licensed Product and the effective date of the acceptance by the Company of the transfer and assignment of the FDA approval, which occurred on March 14, 2024. Based on the achievement of this milestone, we paid Formosa (a) cash in the amount of $1.0 million on April 26, 2024 and (b) 613,496 shares of common stock (calculated pursuant to the Formosa License Agreement at $1.0 million using a five-day volume-weighted average price on March 14, 2024, but valued at $0.4 million on the April 29, 2024 settlement date). The remaining $2.0 million development milestone (to be fully paid in cash) was earned and accrued upon FDA approval, but payment will be triggered on the earlier of twelve months after FDA approval of the Formosa Licensed Product or six months following the first commercial sale of the Formosa Licensed Product.

On August 7, 2024, we entered into a non-binding collaboration agreement with Formosa under which the companies intend to work to develop EYEN-530, a combination of Formosa's clobetasol propionate ophthalmic solution with our Optejet dispensing technology, as a potential treatment for acute dry eye flare-ups.

On November 22, 2024, we entered into the First Amendment (the "First Amendment") to the Supplement to that certain Loan and Security Agreement, dated November 22, 2022 (the "Loan and Security Agreement") with Avenue Capital Management II, L.P., as administrative agent and collateral agent, Avenue Venture Opportunities Fund, L.P., as a lender and Avenue Venture Opportunities Fund II, L.P., as a lender (together, "Avenue"). Pursuant to the First Amendment, Avenue agreed to defer principal and interest payments on amounts outstanding under the Loan and Security Agreement until the end of February 2025. On February 21, 2025, we entered into the Second Amendment (the "Second Amendment") to the Supplement to the Loan and Security Agreement with Avenue. Pursuant to the Second Amendment, Avenue agreed to defer principal and interest payments on amounts outstanding until the end of September 2025. Deferred interest will accrue on the outstanding principal amount at the interest rate (as defined in the Second Amendment).

On December 12, 2024, we announced the engagement of Chardan Capital Markets, LLC ("Chardan"), an investment bank, as the Company's financial advisor in connection with its evaluation of strategic alternatives. With assistance from Chardan, the Company will continue to assess a full range of strategic alternatives, including but not limited to, a business combination, sale of the Company, reverse merger, asset sale, or a combination of alternatives, while also carefully managing its expenses. As part of restructuring to minimize expenses during this process, the Company temporarily halted sales and promotion activities and focused its development efforts on completing the verification and validation studies required for regulatory approval of the Optejet UFD. This device is designed for users to fill with preserved artificial tears or contact lens rewetting solutions at home, providing greater flexibility while leveraging Optejet's advanced delivery system. As of March 2025, Eyenovia is progressing with its development of the Optejet UFD, aiming for a 510K submission in the United States in the fourth quarter of 2025.

On July 26, 2024, we received notice from the staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") providing notification that the Company had regained compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Listing Rule 5550(a)(2). Previously, Nasdaq had notified us on July 2, 2024 that, for the preceding 30 consecutive business days, the closing bid price of our common stock had been below the minimum requirement of $1.00 per share. The notification letter stated that we would be provided 180 calendar days to regain compliance. In order to regain compliance, the closing bid price of our common stock had to be at least $1.00 for a minimum of 10 consecutive business days at any time before December 30, 2024. Subsequently, the Staff determined that, from July 12 to July 25, 2024, the closing bid price of our common stock had been at $1.00 per share or greater. Accordingly, the Company had regained compliance with Listing Rule 5550(a)(2).

On February 25, 2025, we received notice from the Staff of Nasdaq providing notification that the Company had regained compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Listing Rule 5550(a)(2). Previously, Nasdaq had notified us on September 18, 2024 that, for the preceding 30 consecutive business days, the closing bid price of our common stock had been below the minimum requirement of $1.00 per share. The notification letter stated that we would be provided 180 calendar days to regain compliance. In order to regain compliance, the closing bid price of our common stock had to be at least $1.00 for a minimum of 10 consecutive business days at any time before March 17, 2025. On January 31, 2025, the Company effected a reverse stock split of its common stock at a ratio of 1-for-80 (the "Reverse Split"). Upon the effectiveness of the Reverse Split, every 80 issued shares of common stock were reclassified and combined into one share of common stock and the corresponding price per share increased by a multiple of 80. Subsequently, the Staff determined that, from February 3 to February 14, 2025, the closing bid price of our common stock had been at $1.00 per share or greater. Accordingly, the Company had regained compliance with Listing Rule 5550(a)(2).

Recent Development

On March 18, 2025 we entered into a non-binding letter of intent (the "Letter of Intent") with Betaliq, a Delaware corporation, relating to a proposed business combination between Eyenovia and Betaliq. Betaliq is a clinical stage pharmaceutical company with a therapeutic focus on Glaucoma, founded in 2018 through a collaboration with Novaliq GmbH.The parties currently contemplate a reverse merger structure, pursuant to which (i) a newly-formed, wholly-owned subsidiary of Eyenovia would merge with and into Betaliq, with Betaliq as the surviving corporation and a wholly-owned subsidiary of Eyenovia, and (ii) Betaliq would then immediately merge with and into a second newly-formed wholly-owned subsidiary of Eyenovia (the "Second Merger Sub"), with the Second Merger Sub as the surviving corporation. In connection with the closing of the transaction, Eyenovia expects to change its name to "Betaliq, Inc." or such other name as determined by Betaliq and change its trading symbol as determined by Betaliq.

As contemplated by the Letter of Intent, Betaliq stockholders would receive (a) shares of Eyenovia common stock ("Eyenovia Common Stock") and (b) securities convertible into Eyenovia Common Stock in exchange for their shares of Betaliq capital stock ("Betaliq Capital Stock") based on the Exchange Ratio (defined below). Outstanding equity awards, convertible notes, warrants, and any other equity interests or instruments convertible into Betaliq Capital Stock ("Betaliq Stock Rights") would be assumed by Eyenovia and become the equity awards, convertible notes, warrants, and any other equity interests or instruments convertible into equity interests of Eyenovia, as applicable, based on the Exchange Ratio in a manner mutually agreeable to Betaliq and Eyenovia.

As contemplated by the Letter of Intent, the conversion of the Betaliq Capital Stock and Betaliq Stock Rights would be effected pursuant to an exchange ratio (the "Exchange Ratio") intended to result in the following approximate aggregate post-closing percentage ownership: (i) the equity holders of Betaliq immediately prior to the closing (including all Betaliq Stock Rights) would own approximately 83.7% of the equity of the combined company on a fully diluted basis, and (ii) the equity holders of Eyenovia immediately prior to the closing (including outstanding equity awards, convertible notes, warrants, and any other securities or instruments convertible into or exercisable for equity interests of Eyenovia) would own approximately 16.3% of the equity of the combined company on a fully diluted basis. These ownership percentages assume a valuation of approximately $77 million for Betaliq and approximately $15 million for Eyenovia, Eyenovia "net cash" (which will include, among other things, unrestricted current assets in the form of cash and cash equivalents as of the closing minus current liabilities and all expenses related to the proposed transaction as of the closing) of zero at closing, and the inclusion of Optejet and related Eyenovia assets, and are subject to adjustment as described in the Letter of Intent.

Following the closing of the business combination, the combined company's board of directors will be comprised of members to be mutually agreed upon by the parties. Assuming signing and closing of the definitive agreement occurs, stockholder approval of the issuance of Eyenovia securities in excess of limits imposed by Nasdaq listing rules to the former Betaliq stockholders will be sought at a meeting to take place following the closing.

The parties intend to negotiate a definitive business combination agreement consistent with the provisions of the Letter of Intent as well as other terms and conditions typical for transactions of this nature. During the binding exclusivity period set forth in the Letter of Intent, which ends on May 16, 2025 but is subject to extension, the parties have agreed not to solicit or encourage submission of, or participate in discussions or enter into any agreement regarding any other acquisition proposal.

Our Strategy

We are currently exploring strategic business options intended to maximize shareholder value including, if possible, continued commercialization of Mydcombi and clobetasol propionate and completing the development of our Optejet device. Our goal is to become a leading developer and licensor of the Optejet in multiple formats; beginning with the UFD, then adding device-drug combinations and a digital health platform for improved patient care outcomes. These unique products would be commercialized internally and/or with licensees and development partners globally. The key elements of our strategy to achieve this goal are:

Obtain clearance from the U.S. FDA on the Optejet® UFD through the 510K pathway. We are focused on submitting the Optejet for use with artificial tears and contact lens rewetting solutions as a device to the FDA. Successful clearance from the FDA would then establish the existing device for later drug-device submissions through the 505(b)(2) registration pathway, which may reduce development risk compared to new molecular entity programs by working with known compounds with well-established safety and efficacy profiles.

Through partnerships and licensings agreements, establish a portfolio of first-in-class piezo-print micro-therapeutic products for multiple eye treatments through the 505(b)(2) pathway with the FDA. We are focused on integrating our next-generation technology with therapeutic compounds already well established in the topical treatment of ophthalmic indications. We believe that the 505(b)(2) registration pathway, which may reduce development risk compared to new molecular entity programs by working with

known compounds with well-established safety and efficacy profiles, will be available for our development pipeline. We believe a pipeline of patented micro-therapeutic product candidates would be highly differentiated by our improved tolerability and enhanced compliance profile and that our late-stage development programs could lead to additional NDA submissions in novel indications where the products can have unique dosing and therapeutic profiles. We believe that this could lead to favorable pricing and a reduced risk of generic competition.

Improve clinical outcomes and patient experiences while providing an improved tolerability profile with our microdose therapeutics. We believe the Optejet will allow for high precision targeted microdosing for multiple eye treatments, while eliminating ophthalmic over-dosing and reducing ocular exposure to toxic preservatives and pharmacologic ingredients compared to conventional eye drop delivery mechanisms. Our clinical trials have demonstrated similar efficacy to eye drops, as well as improved side effect profile and enhanced patient experience with the Optejet as compared to conventional eye drops.

Leverage our Optecare ™ technology to introduce and develop patient-specific compliance and treatment adherence enhancement programs. The Optejet's mobile e-health technology, Optecare, is designed to track when a patient administers treatments, allowing physicians to monitor patient compliance more accurately. We believe this could enhance patient compliance and improve compliance monitoring by empowering patients and physicians with access to dynamic, real-time monitoring and compliance data for a more intelligent, informed and personalized therapeutic paradigm.

Develop next-generation targeted microdose treatments for other ophthalmic diseases in collaboration with third parties. The Optejet also may be suitable for new molecular entities and applications. Leveraging our existing platform technology, we plan to continue developing, either independently or through strategic relationships with third parties, other product candidates for various eye diseases that can be administered using the Optejet and additional applications for the Optejet.

Limitations of Conventional Eye Therapies

Our microdosing platform technology aims to address the following issues associated with conventional eye drop-based therapies:

Dosing and ease of administration

Multiple third-party studies have confirmed challenges with administering conventional eye drops, which include overdosing, poor compliance, imprecise dosing, variability in drop size, and difficulty with self-administration. One study in patients who were experienced in using eye drops and undergoing treatment for glaucoma for at least six months documented that nine out of ten patients were unable to administer treatment correctly at the end of the six-month study. Patients on average administered almost twice the necessary number of drops with a mean number of drops instilled at 1.8 (+/- 1.2) and one patient administered up to eight drops at one time. In addition, approximately 75% of patients risked bottle contamination or potential ocular trauma by having the eye drop container touch their eyes. Another larger study in 139 patients demonstrated that the proportion of patients able to correctly administer their eye drops was only 22%–30%. Similarly, other studies have demonstrated that the vast majority of patients either overdose or do not administer the required therapy to the eye correctly, which may lead to additional side effects or lack of efficacy.

Side effects associated with conventional eye drop therapies

Topical eye therapies are administered using traditional eye drop pipette approaches. While average tear volume of the eye is 6–8 µL, current eye drop therapies can involve administration of 30–50 µL of liquid containing preservatives and pharmaceutical ingredients. Thus, traditional drops can severely overdose the eye, which, depending on the ingredients, can be associated with ocular side effects including hyperemia, or increased blood flow to the eye, redness, discomfort, stinging, blurred vision, burning, itching, excessive tearing, eye pain, iris pigment changes, foreign body sensation, pigment discoloration, periorbital dermatitis and sunken eye. For some topical medications, there also can be cardiovascular side effects such as changes in heart rate and arrhythmia that are caused when medications are absorbed into the circulation system from overdosing both through conjunctiva absorption and when drugs flow into the nose through the naso-lacrimal duct and are absorbed into the systemic circulation or swallowed. For example, phenylephrine can cause cardiovascular adverse reactions including an increase in blood pressure, syncope, myocardial infarction, tachycardia, arrhythmia and subarachnoid hemorrhage. Severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and rarely death in association with cardiac failure, have been reported following systemic or ophthalmic administration of timolol maleate.

Our Solution: The Optejet

Optejet Base and Cartridge

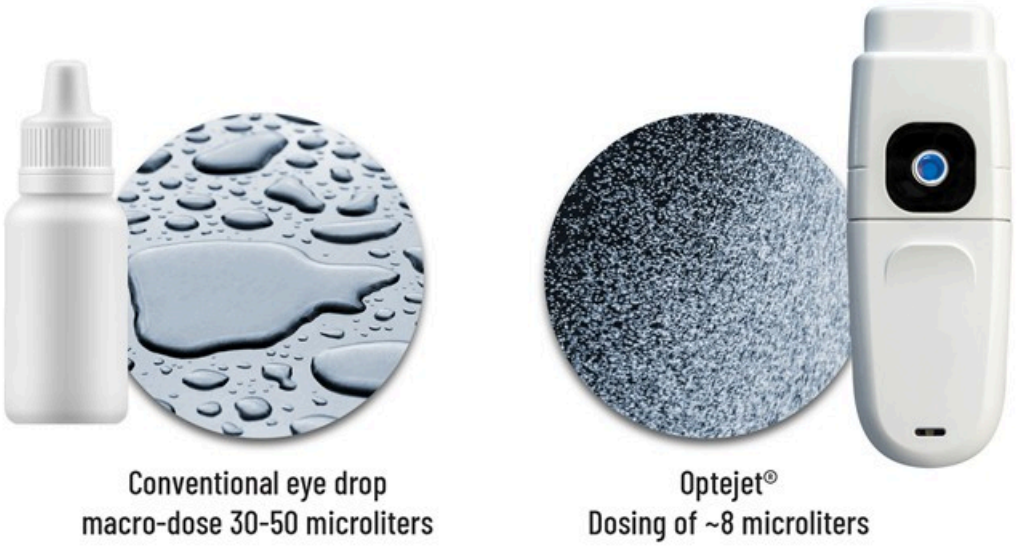
In Use

The Optejet dispenser delivers doses of approximately 7-9 μL, directly coating the corneal surface where 80% of intraocular drug penetration occurs. We believe that microdosing may reduce drug and toxic preservative exposure by more than 75%, thus reducing ocular irritation, and resulting in potentially gentler treatments without compromising the desired clinical effect.

We believe that we are the only company with an FDA-approved product that uses a targeted, metered microdosed spray of ophthalmic topical therapy. The Optejet is based on microdose array print, or MAP, technology, which is also used for pixel-sharp high-precision inkjet printing. The technology is optimized for and applied in ophthalmic delivery to achieve microdosing that can be many times more precise than conventional eye droppers. In addition, our smart, electronic system provides the capability to track when patients administer their medications and deliver this information to patients and physicians via Bluetooth connectivity. Thus, physicians can make decisions regarding therapeutic regimens with knowledge of patient compliance.

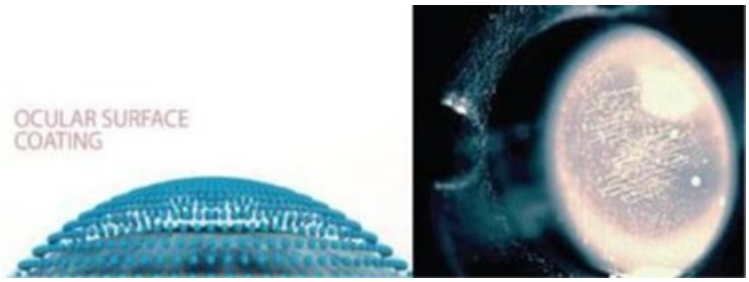
Microdose administration of topical ophthalmic drugs with the Optejet has been tested in preclinical models and clinical trials and shown to provide many advantages over administrations of eye drops. Key advantages of the Optejet include:

Dose reduction: Our microdose delivery technology is designed to achieve precise volumetric control at the microliter level to deliver approximately 8 µL, which is the physiologic capacity of the tear film. This compares favorably to the volume of an eye drop (30–50 µL), which can result in overdosing, ocular toxicity and systemic leaching into the plasma.



Targeted dose instillation: The Optejet allows for targeted delivery to the ocular surface and cornea, avoiding the conjunctival cul-de-sac. The micro-jet spray created by the piezo-electric vibrations is columnated and focused to provide accurate delivery to the corneal surface where the majority of ocular penetration occurs. Additionally, the Optejet is designed with an LED targeting mechanism to facilitate proper positioning and objective alignment, thus increasing the likelihood of successful dose delivery.

Speed of delivery: Our piezo-print technology is similar to high-precision ink-jet printing. Unlike a simple aerosolized mechanism, the Optejet is designed with ejection control that creates a fast and targeted micro-jet delivery. Solution is dispensed to the ocular surface in less time than the average involuntary blink reflex from the time the first droplet hits the corneal surface to the completion of dose delivery.



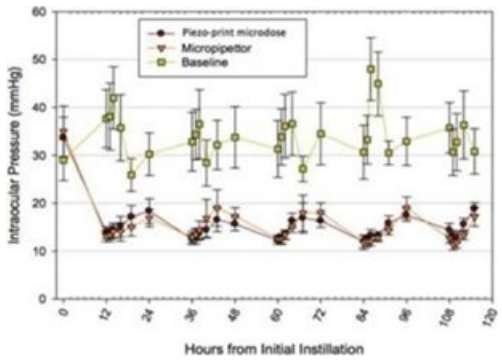
Smart electronics: A key feature of the Optejet is the embedded electronic, Bluetooth enabled Optecare system, which we believe is the first intelligent electronic delivery system for ophthalmic therapies. Our electronic functions are designed to enable patients and physicians to track when doses are administered. We believe this technology will improve compliance and chronic disease management by empowering patients and physicians with access to dynamic, real time monitoring and compliance data for a more intelligent and personalized therapeutic paradigm. Recent changes in payment codes may now provide a way for healthcare providers to bill for this important service.

Clinical Trial Results

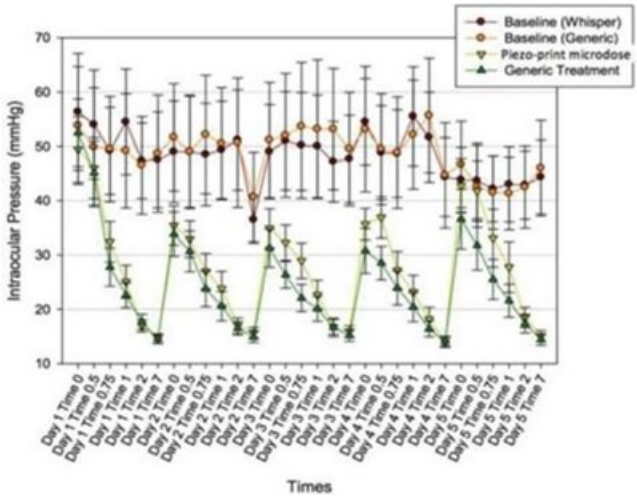
We have an established platform for microdose administration of ophthalmic solutions. Our preclinical and clinical studies suggest that a microdose of approximately 8 µL of medication results in clinical efficacy comparable to that of traditional eye drops, with the advantages of fewer ocular side effects and less systemic exposure. We can use our platform technology with either new or existing molecular entities. We have chosen the latter path for our initial pipeline product candidates.

Prior to initiation of our Phase III clinical studies, we conducted multiple preclinical and early phase studies to validate our piezo-print microdose delivery platform. Data from a canine model of glaucoma demonstrated more than 40% IOP lowering effect at microdose of 8–9 µL latanoprost. Another independent microdose study published in the Journal of Investigative Ophthalmology and Visual Science in 2014 further demonstrated that 3 µL microdose with timolol 0.5% can reduce systemic plasma levels of the drug by a factor of 17.

Diurnal IOP Lowering Effect of a Microdose of Latanoprost Delivered by Pipette vs. Piezo-Print Dispenser in a Canine Model



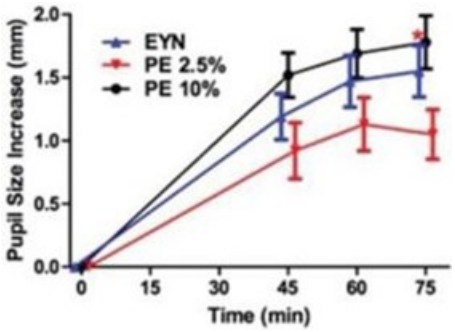
IOP Lowering Effect of Micro-Therapeutic Dose of Latanoprost in Canine Model



The Phase II EYN-1601 clinical trial compared the mydriatic effect of phenylephrine 10% microdosed (~7 µL in volume) with the Optejet (EYN) to phenylephrine 10% (PE 10%) and phenylephrine 2.5% (PE 2.5%) eye drops (each ~32 µL in volume) in 24 eyes. At 75-minute peak dilation, our microdose provided similar mydriatic results (at approximately 1/4 of the dose exposure) to the 10% phenylephrine drops, and superior activity compared to 2.5% phenylephrine drops.

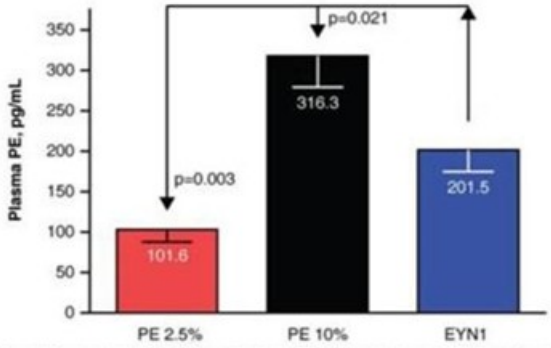
Shown below is mean pupil diameter change from baseline for the 24 eyes studied. The asterisk at t=75 min indicates EYN was observed to be statistically better than PE 2.5% (p=0.009).

PUPIL DIAMETER, INCREASE FROM BASELINE, MM



This study was also informative with regard to systemic drug exposure of these topical treatments. As shown below, microdosed phenylephrine 10% (EYN1) demonstrated 35–40% lower plasma levels as compared with phenylephrine 10% eye drops (PE 10%).

PLASMA PE LEVELS AT 20 MINUTES



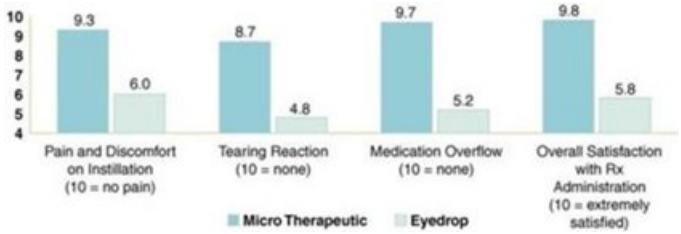
Plasma free PE concentration in venous blood drawn 20 minutes after ocular topical drug administration. Circulating PE was highest in PE 10% subjects (316.3±36.8 pg/mL), and was significantly 36.3% lower in EYN subjects (201.5±27.1 pg/mL; p=.021). Plasma PE was significantly lower in PE 2.5% subjects (101.2±12.9 pg/mL) than in EYN subjects (p=.003).

As shown in the table below, there were also fewer ocular adverse events in the microdosed group (EYN) suggesting an improvement in tolerability as compared to 10% phenylephrine eye drops (PE 10%).

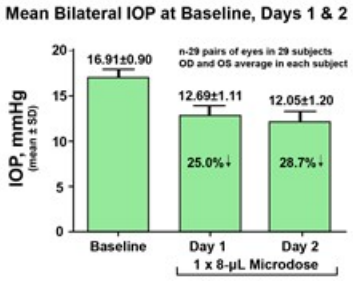
OCULAR ADVERSE EVENTS BY TREATMENT

Adverse Event Description	PE 10% (Eyedrops)	EYN (PE 10% microdose)
Ocular blurriness	1	0
Ocular burning/stinging/irritation	4	1
Ocular dryness	2	0
Subtotal by Treatment Group	7	1

The EYE-103 study investigated a combination of phenylephrine and tropicamide microdose treatment administered using the Optejet compared to conventional eye drops in 102 subjects (204 eyes). In this study, microdosing produced equivalent pupil dilation to eye drops and 91% of participants preferred medication administration with the Optejet versus eye drops (6% preferred eye drops, while 3% expressed no preference [$p < 0.0001$]). On a scale of 1 to 10, with 10 being most favorable, general satisfaction scores were higher with Optejet administration versus eye drops (9.8 ± 0.6 for Optejet vs 5.8 ± 3.0 for eye drops). Ocular comfort scores were nearly two times better with the Optejet than with eye drops.

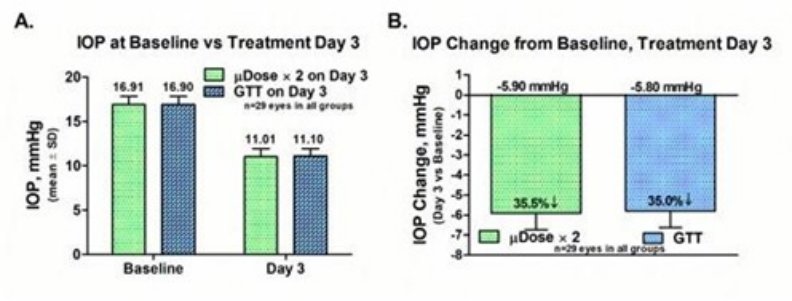


In 2018, Eyenovia completed a third early phase trial (EYN-POC-PG-21) to extend the findings of the two previous trials evaluating Optejet administration of mydriatic agents. This study was a single-center, open-label, prospective, crossover design evaluating the usability, patient tolerability, and proof-of-concept of microdose administration of commercial latanoprost 0.005% using the Optejet. Thirty healthy volunteer subjects (60 eyes) were evaluated for eligibility and consented to study participation. Subsequently, at each of three treatment visits, IOP was measured in the morning. Afterwards, on Treatment Days 1 and 2, a single 8-µL microdose of latanoprost 0.005% ophthalmic solution was administered to each eye using the Optejet. On the morning of Treatment Day 3, each subject received 2 × 8-µL Optejet microdoses (administered approximately 5 minutes apart) in one eye and the other eye received a single eye drop of latanoprost 0.005% ophthalmic solution. For each treatment day, IOP was measured 1, 7, 12, and 24 hours after receiving medication and a mean diurnal IOP was calculated from the four readings. As shown below, mean IOP after medication administration on Days 1 and 2 was lowered by 25.0% and 28.7%, respectively.



Mean bilateral IOP and percent change in IOP in eyes dosed using the Optejet through Treatment Day 2 (N = 29 pairs of eyes from 29 evaluable subjects)

As shown below, on Day 3, mean IOP was 35.5% lower than baseline for eyes receiving microdose latanoprost 0.005% using the Optejet, and 35.0% lower than baseline for eyes receiving a single drop of latanoprost 0.005%.



IOP AT DAY 3 (N=29 EYES OF 29 SUBJECTS PER TREATMENT)

No clinically significant changes were noted in slit lamp observations (including hyperemia) for any subjects who received study treatment and no adverse events were reported. Subjects reported no-to-negligible ocular discomfort after medication administration using the Optejet.

Investigator-administered medication using the Optejet was evaluated in 60 eyes (1 spray/eye) on Days 1 and 2, and in 30 eyes (2 sprays/eye) on Day 3. Optejet administration was successful on the first attempt in 172 of the 180 cases (96%). Subject head movement and/or blinking and investigator proficiency with Optejet use resulted in the need for additional administration in the remaining 4% of cases, the majority of which (6/8) occurred on Day 1. Administration success was achieved on the first attempt on all Day 3 cases. There were no reports of unintentional overdosing, tear fluid overflow, or the dispenser nozzle touching the eye.

In a separate evaluation, subjects were trained on Optejet self-administration with sterile water and then asked to demonstrate Optejet use in each eye during the afternoon of each treatment day. By the afternoon of Day 3, qualified Eyenovia representatives judged that almost 90% of subjects were able to demonstrate accurate self-administration using the Optejet.

This study demonstrated Optejet medication administration to be easy to perform, safe, and comfortable to study subjects. Additionally, Optejet microdose administration of 0.005% latanoprost resulted in mean IOP reduction similar to reported literature for use of latanoprost 0.005% ophthalmic solution administered as traditional eye drops.

Based on the results of these studies further validating microdose delivery of ophthalmic medication, we initiated Phase III programs in mydriasis in late 2018, progressive myopia in 2019, and presbyopia in 2020.

On May 5, 2023, we received notification from the FDA of the approval of Mydcombi (tropicamide and phenylephrine metered ophthalmic spray) for diagnostic pupil dilation. The approved label for the product was advantageous compared with eye drop formulations, with adverse events being infrequent and mild and the incidence of stinging at less than 1% in clinical studies.

Our Products and Product Candidate

Eyenovia currently owns or licenses two FDA-approved products, Mydcombi and clobetasol propionate.

Mydcombi

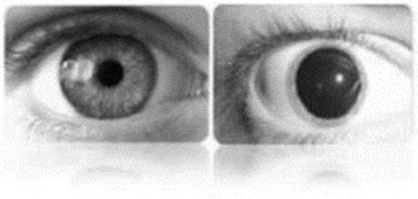
Mydcombi is the only FDA-approved fixed combination of the two leading pupil dilation drugs, tropicamide and phenylephrine, delivered with our Optejet technology. The product is indicted to induce mydriasis (pupil dilation) for routine diagnostic procedures and in conditions where short term pupil dilation is desired. There are approximately 106 million estimated office-based comprehensive and diabetic eye exams and seven million ophthalmic surgical dilations performed every year in the United States. The benefits of Mydcombi include effective, reliable dilation with low risk of cross-contamination as compared with eye dropper bottles, ease of use for technicians and doctors, and good tolerability for patients.

Background of Mydriasis and Market Opportunity

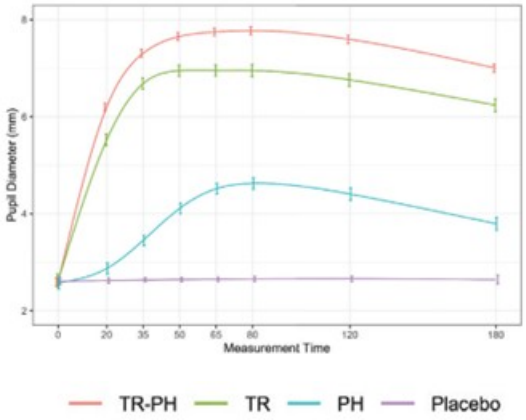
There are an estimated 106 million topical mydriatic applications performed every year as a required part of the comprehensive dilated eye exam and standard retina fundoscopy for diabetic retinopathy screening, macular degeneration evaluation, glaucoma optic disc evaluation and many other back-of-the-eye conditions. There are an additional estimated four million applications for ocular surgery. Most optometrist and ophthalmologist offices maintain bottles of both phenylephrine and tropicamide eyedrops and use the drops in combination. Each bottle is used on multiple patients, which carries a risk of contamination and ocular infection. The bottles are purchased directly from suppliers and are not subject to insurance reimbursement. Our combination therapy allows the purchase of one product for eye dilation. Additionally, the Optejet does not come in direct contact with the eye, thus minimizing the risk of infection.

Most dilated eye exams require the sequential administration of two separate topical pharmacologic agents/drops (tropicamide, followed by phenylephrine). All current mydriatic formulations use conventional macrodose drop delivery (30–50 µL), which can significantly overdose the ocular surface whose physiologic capacity is only 6–8 µL. Studies demonstrate that standard macrodosed pharmacologic dilation is associated with significant ocular discomfort and mild-moderate eye pain. On the standard visual analogue scale for pain, such discomfort can exceed the levels of pain associated with a flu vaccine subcutaneous injection. Additionally, there are systemic safety concerns with mydriatic macrodosing for retinopathy of prematurity retinal screening and pediatric dilated eye exams. Studies comparing microdosed phenylephrine and cyclopentolate to traditional eye drops (30–50 µL drop size) in premature babies and in full-term infants have shown equivalent pupil dilation with drop sizes ranging from 5–8 µL while reducing systemic levels by more than 50%.

Pharmacologic mydriasis: dilated pupil after application



Efficacy and Safety



The above diagram represents the pooled data (MIST-1 and MIST-2) from the approved labeling for Mydcombi. The graph summarizes pupil diameter over time. Vertical bars show 95% confidence interval for the mean at each point. Smooth curves are based on 8 degrees of freedom (df) generalized additive model (GAM) smooth through time, adjusting for baseline pupil diameter. Confidence intervals are not adjusted for correlation.

Mydcombi (TR-PH) was statistically and clinically superior to its components (TR – tropicamide, PH – phenylephrine) as well as placebo at all timepoints post-dosing. By 20 minutes post-dosing, the mean pupil dilation was above 6mm, more than sufficient for a thorough clinical examination.

All adverse events were transient and mild and occurred in fewer than 2% of patients.

Clobetasol Propionate

We have licensed this topical ocular steroid from Formosa and will have commercial rights to this product within the United States. The product was approved by the FDA on March 4, 2024. This unique post-ocular surgery steroid is the first product developed using Formosa's proprietary APNT nanoparticle formulation platform, which reduces an active pharmaceutical ingredient's particle size with high uniformity and purity, thereby allowing penetration to relevant compartments in the eye, and ultimately enhancing bioavailability.

Clobetasol propionate will be the first new steroid in this market in over 15 years, and one of the few that is dosed twice-daily (instead of up to 4 times daily) without the need to taper dosing over a 14 day course of therapy. With 7 million ocular surgeries conducted annually in the United States, we estimate the market opportunity for this product to be over $200 million.

In clinical studies, clobetasol propionate was very effective, with approximately 90% of patients experiencing zero pain towards the end of therapy. Adverse events were few and mild, including 1% of patients experiencing elevated intraocular pressure, which may have been related to the surgery itself.

MicroLine

MicroLine is our investigational proprietary microdosed version of pilocarpine, a well-understood ophthalmic medication that can dose-dependently induce miosis, or a contraction of the pupil. It is a direct acting cholinergic parasympathomimetic agent that stimulates muscarinic acetylcholine receptors present on smooth muscles, including those in the iris and ciliary body. As a result, pilocarpine causes contraction of the iris sphincter muscle, which causes miosis.

Reducing pupil size with pilocarpine has been shown to improve near visual acuity in individuals who have presbyopia. In one clinical study, subjects aged 45−50 years who bilaterally self-administered both pilocarpine 1% and diclofenac 0.1% eyedrops every six hours during the day for up to five years reported good improvement in near vision without compromising distance vision. Thus, pilocarpine's miotic effect may be useful in treating the increasingly compromised near vision that parallels the development of presbyopia.

Background of Presbyopia and Market Opportunity

Presbyopia is the gradual decrease in the ability of the eye's natural lens to accommodate in near vision, resulting in a loss of focus on near objects. In general, onset is around age 40 and is almost universal in adults over the age of 60. In the United States, there are approximately 113 million people with presbyopia; 53 million of them are between the ages of 40 and 55.

For many people, presbyopia is among the first overt signs of aging. There are psychological factors accompanying the use of spectacles and bifocals for the first time, as well as situational inconvenience for either not being able to see well or having to use a vision aiding device. We believe MicroLine may have the potential to be a pharmaceutical option for improving near vision that can work as a companion to spectacles, for when patients wish not to use their reading glasses. Our market research indicates the highest interest in the product concept among people aged 40 to 55 years who otherwise have normal vision and household income in the top half of the country, representing a potential market of approximately 18 million people.

Phase III Clinical Development Programs

We have completed two Phase III studies using our Optejet device. Our initial Phase III study, VISION-1, showed that pilocarpine 2% provided a statistically superior improvement in functional near vision and an acceptable safety profile in presbyopic

subjects with baseline distance-corrected near visual acuity better than 20/80. Our second Phase III study, VISION-2 evaluated the safety, tolerability, and efficacy of Optejet-administered microdosing of pilocarpine 2% as an ophthalmic spray versus placebo.

Since completing these studies, the market opportunity has markedly deteriorated, and we have chosen to put this program on hold and reallocate our resources towards larger opportunities. When and if the market improves, we have kept open the option to continue development of MicroLine, which would include a meeting with the FDA to review our clinical data to date.

Our Technology

The Optejet dispenser comes in two parts:

- the base contains the electronic components which enable generation of control signals designed to ensure consistent, accurate columnated arrays of micro-droplets, as well as dose tracking via Bluetooth connectivity; and

- the disposable cartridge which contains the drug formulation in a primary drug container, targeted dosing system and piezo-driven ejector nozzle, and may contain up to 90 binocular doses.

For administration of our product candidates, the office or patient receives both the base and the disposable cartridge. For refills, the office or patient receives only the disposable cartridge. Doses are delivered by attaching the cartridge to the base, pressing an activation button which loads a single drug dose, then, holding it between one and two inches from the eye while looking directly into an illuminated circle, pressing a second button to emit the micro-droplet delivered medication. The micro-droplets are emitted in a quickly repeating array, that in aggregate form a directed mist. Solution is dispensed to the ocular surface in less than 100 milliseconds between the time the first droplet hits the corneal surface to the completion of dose delivery, which is faster than the average involuntary blink response time. The patient feels a mild, wet sensation on the eye. Several acute clinical trials have been performed to date that demonstrate the Optejet's usability. As a precise and quick-delivered microdose, it does not drip down the face or drain down the naso-lacrimal duct, thereby minimizing delivery of extra product or preservatives to the eye. The rechargeable base has intelligent power management and precision designed circuitry that maximizes battery life allowing for infrequent recharging, while providing consistent dose delivery over the life of each cartridge.

Our system is based on piezo-driven printer technology, which is also used for high-precision ink jet printing. In ink jet printing, piezo technology enables ink to be sprayed with precision to form letters and numbers on paper. Our patented system takes aspects of piezo-driven printer technology, and applies it to the delivery of therapeutics to the eye.

Manufacturing

For clinical supply, Eyenovia relies on internal manufacturing capabilities along with third-party contract manufacturing organizations (CMOs) to produce the Optejet® cartridges and bases. In order to streamline our manufacturing process and reduce costs, Eyenovia has invested in two of its own facilities, one in Redwood City, CA that is FDA-approved for Mydcombi cartridge production, and one in Reno, NV that is FDA-approved for ejector and base unit manufacturing. We also use a CMO, Coastline International in Mexico, for production of certain subassemblies as well as a CMO for the production of our drug substances. We are currently developing and manufacturing the second generation of our device, and on July 24, 2024, we received written comments from the FDA broadly outlining the design of a clinical bridging study to transition Mydcombi into our new Gen-2 Optejet device. Assuming we come to an agreement with the FDA to demonstrate comparability between the two devices, this should provide a two-year path for Eyenovia to introduce the second generation platform.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources. Any product candidates that we successfully develop and commercialize may also compete with existing therapies and new therapies that may become available in the future.

Our potential competitors include large pharmaceutical and biotechnology companies, and specialty pharmaceutical and generic or biosimilar drug companies. Many of our competitors have significantly greater financial and human resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller and other early stage companies may also prove to be significant competitors, particularly

through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring products, product candidates or other technologies that we may target to in-license or acquire in pursuit of our updated business plan.

For Mydcombi, we are not aware of any micro-therapeutics nor of any existing FDA-approved tropicamide-phenylephrine topical fixed combination products even in standard macrodose. There are competitive macrodose drop formulations of individual therapeutics for mydriasis such as tropicamide and phenylephrine marketed by companies such as Akorn, Alcon and others, as well as pharmacies that compound the combination on an individual basis for physicians.

For clobetasol propionate, there are several steroid options in this field, but we are not aware of any product with the combination of dosing, efficacy and safety attributes that our product will have. Additionally, we believe our "value pricing" approach, where patients can expect to pay a fixed amount regardless of their insurance coverage or status, will further differentiate us in this market.

Intellectual Property

Our success may depend on our ability to obtain, maintain and enforce our proprietary rights related to our products and other technologies. We must also operate without infringing the valid, proprietary rights of others while preventing others from infringing our proprietary rights. We will seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications. We may also rely on trade secrets and know-how for some proprietary methods, methods of manufacture, and systems and devices. We continue innovating our technologies, and will file appropriate U.S. and foreign patent applications for our future innovations.

Patents

As of December 31, 2024, we owned twenty-two U.S. issued and allowed utility patents or design patents, and nine pending U.S. patent applications, as well as 101 issued foreign patents, and 23 pending foreign patent applications.

Patent coverage within the portfolio includes issued and pending patent applications related to the following devices and methods:

- A piezoelectric device configured to generate an ejected stream of droplets is the subject of one patent family. The device ejects droplets having an average ejected droplet diameter greater than 20 microns and an average initial droplet ejecting velocity between 0.5 m/s and 10 m/s. Furthermore, the stream of droplets is generated with low entrained airflow so that at least 75% of the mass is deposited on the eye. U.S. patents for these devices are expected to expire in 2031.

- A method of delivering a medicament or solution to an eye with a piezo-ejector device is the subject of another patent family. The method involves delivering an average droplet size of 20 microns to 100 microns in diameter with an average initial droplet ejecting velocity between 1 m/s and 10 m/s to the eye. About 85% to 100% of the ejected mass of droplets is deposited on the eye. U.S. patents for these methods are expected to expire in 2031.

- A device having a piezo-ejector that generates a directed stream of droplets through specially shaped openings in the piezo-ejector is the subject of still another patent family. The openings provide laminar flow through the openings. Laminar flow is provided by shaping the openings with a gradual slope change so that an external entry radius has a circular shape which reduces airflow while providing laminar flow through the openings. U.S. patents related to these devices are expected to expire in 2033.

- A piezo-electric ejector device having a microcontroller which auto-tunes the ejector mechanism is the subject of another patent family. The device generates at least one cycle in a range of drive signal frequencies and obtains time-energy product feedback from a decay signal emitted by the actuator. U.S. patents related to these devices are expected to expire in 2033.

- A method of monitoring the treatment of ophthalmic subjects by capturing images of the eye is the subject of another patent family. Images of the eye are taken which are sufficient to obtain information about the diagnosis or health of the eye. The data is stored and analyzed to monitor treatment. U.S. patents related to this method are expected to expire in 2031.

- A fluid ejector having a fluid loading plate in parallel arrangement with an ejector mechanism is the subject of patent family patented in Europe. The fluid loading plate forms a capillary separation with the ejector mechanism to generate capillary fluid flow. The fluid loading plate is also attached to the reservoir (at a fluid reservoir interface) and to the ejector mechanism (at an ejector mechanism interface) and may have one or more fluid channels from the fluid reservoir interface to the ejector mechanism interface. The ejector produces a stream of droplets having a droplet diameter greater than 15 microns with the stream having low entrained airflow so that the pressure of the stream will be substantially imperceptible.

The expiry of any patent depends upon the legal term for patents in that particular country. In the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment which compensates a patentee for administrative delays by the United States Patent and Trademark Office, or the USPTO, in examining and granting a patent. A patent term may also be shortened if a patent is terminally disclaimed over another patent or application.

The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force.

A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We cannot provide any assurance that any patent term extension with respect to any U.S. patent will be obtained and, if obtained, the duration of such extension. Similar patent term extension/reduction provisions are available in the European Union and other jurisdictions. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we will apply for patent term extensions on issued patents covering our products to the extent available under the applicable law, depending upon the length of any such clinical trials for any product and other factors. The expiration dates referred to above are without regard to potential patent term extension or other market exclusivity that may be available to us. However, we cannot provide any assurances that any such patent term extension of a foreign patent will be obtained and, if obtained, the duration of such extension.

In Asia, we have been granted a patent in each of China and South Korea and two patents in Japan that describe a piezoelectric device configured to generate an ejected stream of droplets with a particular droplet diameter and ejection velocity. We also have seven additional patents granted in China, five additional patents granted in Japan, and four patents granted in Singapore, all related to aspects of the piezoelectric device and methods of using the device.

Trademarks

Our product candidates are marketed under trademarks and service marks that are owned by us. The following words are trademarks in our Company's trademark portfolio and are the subject of either registration, or application for registration, in the United States: APERSURE™, EYENOVIA®, OPTEJET®, EYELATOVA™, EYETANO™ and MYDCOMBI™.

In addition to the trademarks noted above, we will file trademark applications for new trademarks registrations to protect our market positions in the United States and other jurisdictions on an ongoing basis.

Proprietary Technology

In addition to patents, we may rely on trade secrets and proprietary know-how to protect our technology. We endeavor to protect our proprietary technology and processes in the appropriate manner to maintain their secrecy including confidentiality agreements when dealing with third parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. We also require invention assignment agreements with our employees, consultants, and contractors.

Government Regulation and Product Approvals

Government authorities in the United States, at federal, state and local levels, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and

in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

U.S. Government Regulation

In the United States, the FDA regulates drug, biological, device and combination products under the Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. The failure to comply with applicable requirements under the FDCA and other applicable laws at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, voluntary product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

FDA Regulation of Prescription Drugs

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of nonclinical studies, which may include laboratory testing, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND which must take effect before human clinical trials may begin;
- approval by an institutional review board, or IRB, an independent committee charged with protecting the rights and welfare of human research subjects participating in clinical trials, before each clinical trial site may initiate clinical trial enrollment;
- performance of adequate and well-controlled human clinical trial(s) in accordance with good clinical practice, or GCP, regulations to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of an NDA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of selected clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data;
- payment of user fees, with few exceptions, and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical Testing

Preclinical, or nonclinical, testing include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, and generally include *in vitro* and animal studies to assess the toxicity, safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA and the Public Health Service Act to specify that nonclinical testing for drugs and biologics may, but is not required to, include *in vivo* animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or

microphysiological systems), *in silico* studies (i.e., computer modeling), other human or nonhuman biology-based tests (e.g., bioprinting), or *in vivo* animal tests.

The results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after receiving an IND before the corresponding clinical trial may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects may be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the clinical trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that clinical trial at any time. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with FDA certain regulatory requirements in order to use the study as support for an IND or application for marketing approval. In particular, such studies must be conducted in accordance with GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects, and must meet other clinical trial requirements, such as sufficient patient population size and statistical powering. The FDA must be able to validate the data through an onsite inspection, if deemed necessary by the FDA.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a clinical trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by the clinical trial sponsor based on evolving business objectives and/or competitive climate.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give

rise to civil monetary penalties and may prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against non-compliant clinical trial sponsors.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted in accordance with written study protocols detailing, among other things, study objectives, participant inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each phase of a clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase I. The product candidate is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

- Phase II. The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase III. The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow up. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of an NDA.

In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require sponsors of a Phase III clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. A sponsor must submit a diversity action plan to FDA by the time the sponsor submits the trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase III trial planning and timing or what specific information FDA will expect in such plans, but if FDA objects to a sponsor's diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase I, Phase II and Phase III clinical trials might not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Traditional and Section 505(b)(2) NDAs

NDAs for most new drug products are based on two adequate and well-controlled, or pivotal, clinical trials that must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a drug product previously approved under an NDA, published literature, or a combination of both. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on studies conducted for a previously-approved product or FDA's previous findings regarding safety or effectiveness is appropriate, the applicant may eliminate the need to conduct certain pre-clinical studies or clinical trials of the new product. Thus, Section 505(b)(2) often provides an alternate and potentially more expeditious pathway to FDA approval via NDA for new or improved formulations or new uses of previously approved products.

Unlike the abbreviated new drug, or ANDA, pathway used by developers of generic versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) NDA pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, a 505(b)(2) applicant may be seeking approval to market a new dosage form of a previously approved drug or for the treatment of a different patient population, which would require new clinical data to demonstrate safety or effectiveness. The FDA will generally require companies to perform additional studies to support any differences from the previously approved product, called a listed drug. The FDA may then approve the new drug candidate for all or some of the label indications for which the listed drug has been approved, or for any new indication sought by the 505(b)(2) applicant, as applicable. Accordingly, a 505(b)(2) NDA is subject to the same patent certification requirements as an ANDA with respect to the previously-approved drug being referenced, and it may be eligible for the three-year period of marketing exclusivity based on the submission of new clinical data that are essential to the approval of the new 505(b)(2) drug product. For more information, see section below entitled Hatch-Waxman Act and Marketing Exclusivity.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is subject to a substantial user fee. The sponsor of an approved NDA is also subject to an annual prescription drug program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for drugs with orphan designation and a waiver for certain small businesses submitting their first human drug applications for review. Eyenovia is currently eligible for a waiver of the application fees under the small business provisions.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has agreed to certain performance goals in the review process of NDAs. For most applications involving new molecular entities, the FDA has 10 months from the date of filing in which to complete its initial review of a standard application and respond to the applicant, and six months from the date of filing for an application with "priority review." Even if the NDA is filed by the FDA, however, companies cannot be sure that any approval will be granted on a timely basis, if at all. Moreover, the FDA does not always meet its PDUFA goal dates, and the review process for both standard and priority new drug applications may be extended by the FDA for various reasons, including for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA may refer an application for a novel drug product to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation

as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. For fast track products, sponsors may have more frequent interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The FDA may grant breakthrough therapy designation to a drug or biologic meeting certain statutory criteria upon a request made by the IND sponsor. A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner. In addition, breakthrough therapies are eligible for accelerated approval of their respective marketing applications.

The FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case- by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to six months for an new molecular entity NDA from the date of filing.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation, and priority review do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination from well-controlled clinical trials that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis

is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. As part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under the act's amendments to the FDCA, FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The approval process is lengthy and often difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase IV clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. The FDA may also require an applicant to develop a REMS as a condition of approval to ensure that the benefits of the product outweigh its risks and to assure its safe use. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. If the FDA concludes a REMS is needed as a condition of approval, the sponsor must submit a proposed REMS during the application review process; the FDA will not approve the NDA without an approved REMS, if required. The requirement for a REMS can materially affect the potential market and profitability of a product. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements for Prescription Drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic announced or unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any

deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market, and we must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet, as well as the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"). Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Furthermore, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. For example, FDA released proposed regulations in February 2022 to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a State program, each of which is mandated by the DSCSA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, that established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs based on an innovator or "reference" product, Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid pathway combining features of a traditional NDA and a generic drug application. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication Approved Drug Products with Therapeutic Equivalence Evaluations, also referred to as the Orange Book. Clinicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing clinicians or patient.

In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate.

In addition, under the Hatch-Waxman Amendments, the FDA might not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity for an ANDA, 505(b)(2) NDA or supplement thereto if one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. The three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) NDA applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

I. the required patent information has not been filed by the original applicant;

II. the listed patent has expired;

III. the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or

IV. the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the ANDA or 505(b)(2) application.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification.

If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the follow-on application in question has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act, or PREA, amendments to the FDCA, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, PREA was made permanent and sponsors are required to submit pediatric study plans to the FDA prior to the assessment data. In particular, a sponsor that is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase II meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase III or Phase II/III study. The initial PSP must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. The law now requires the FDA to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. It further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor's response. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although FDA has recently taken steps to limit what it considers abuse of this statutory exemption in PREA by announcing that it does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease.

In addition, pediatric exclusivity is another type of non-patent marketing exclusivity in the United States that, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, or listed patents. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a Written Request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months, including orphan drug exclusivity. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The FDA's issuance of a Written Request does not require the sponsor to undertake the described studies.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent restoration of up to five years for patent term lost during product development and the FDA

regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA. We cannot provide any assurance that any patent term extension with respect to any U.S. patent will be obtained and, if obtained, the duration of such extension, in connection with any of our product candidates.

FDA Regulation of Medical Devices

Medical devices are strictly regulated by the FDA in the United States. Under the FDCA a medical device is defined as "an instrument, apparatus, implement, machine, contrivance, implant, -*in vitro*- reagent, or other similar or related article, including a component, part or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of a medical product is achieved through chemical action or by being metabolized by the body, the product is a drug or biologic. If not, it is generally a medical device.

Unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through the premarket notification, or 510(k) process or approved by the FDA pursuant to a premarket approval application, or PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness.

Class I devices are those low risk devices for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR; facility registration and product listing; reporting of adverse medical events and malfunctions; and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Most Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) process.

Class II devices are moderate risk devices and are subject to the FDA's general controls, and any other special controls, such as performance standards, post-market surveillance, and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for most Class II devices is accomplished through the 510(k) process, although some Class II devices are exempt from the 510(k) requirements. To obtain 510(k) clearance, a sponsor must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent to a device that is already legally marketed in the United States and for which a PMA is not required (i.e., a Class II device), including any device that was reclassified from Class III to Class I or II.The device to which the sponsor's device is compared for the purpose of determining substantial equivalence is called a "predicate device." The FDA's goal is to make a substantial equivalence determination within 90 days of FDA's receipt of the 510(k) application, but it often takes longer if the FDA requests additional information. Most 510(k)s do not require supporting data from clinical trials, but the FDA may request such data for certain devices. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new clearance or possibly a pre-market approval. Premarket notifications are subject to user fees unless a specific exemption applies.

Class III devices are deemed by the FDA to pose the greatest risk to patients, such as those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above, and especially devices that are life-sustaining, life-supporting or implanted. All Class III devices must be reviewed and approved by the FDA through the PMA process. A PMA must be supported by extensive data including, but not limited to, technical, nonclinical testing, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA is sufficiently complete, the FDA will accept the application for filing and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although review of the application generally can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, it considers such recommendations when making final decisions on approval. In addition, the FDA will conduct

a preapproval inspection of the manufacturing facility to ensure compliance with the QSR. New PMA applications or PMA application supplements are also required for product modifications that affect the safety and efficacy of the device. PMA (and supplemental PMAs) are subject to significantly higher user fees than are 510(k) premarket notifications.

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they ultimately pose to patients and/or users. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the De Novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request that the FDA determine that the initial classification of its medical device is actually Class I or Class II based on a benefit-risk analysis demonstrating the device actually presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Under the most recent FDA premarket review goals, FDA will attempt to issue a decision on most De Novo classification requests within 150 days of receipt. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. De Novo reclassification requests are also subject to user fees, unless a specific exemption applies.

Post-Marketing Restrictions and Enforcement

After a device is placed on the market, numerous regulatory requirements apply. These include, but are not limited to:

- submitting and updating establishment registration and device listings with the FDA;
- compliance with the QSR, which requires manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- announced or unannounced routine or for-cause device facility inspections by the FDA, which may include our suppliers' facilities; and
- labeling regulations, which prohibit the promotion of products for uncleared or unapproved (or "off-label") uses and impose other restrictions relating to promotional activities;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a risk to health; and
- post-market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to recur. The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer's determination, the FDA can take enforcement action.

The MDR requirements also extend to healthcare facilities that use medical devices in providing care to patients, or "device user facilities," which include hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities, but not physician offices. A device user facility must report any device-related death to both the FDA and the device manufacturer, or any device-related serious injury to the manufacturer (or, if the manufacturer is unknown, to the FDA) within 10 days of the event. Device user facilities are not required to report device malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur but may voluntarily report such malfunctions through MedWatch, the FDA's Safety Information and Adverse Event Reporting Program.

Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability

that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any distributed devices fail to meet established specifications, are otherwise misbranded or adulterated, or if any other material deficiency is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated.

The failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA approvals of new products;
- withdrawals of 510(k) clearance or PMA approvals; or
- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors.

FDA Regulation of Combination Products

A combination product is a product composed of a combination of two or more FDA-regulated product constituent parts or products, e.g., drug-device or biologic-device. Such products often raise regulatory, policy and review management challenges because they integrate constituent parts that are regulated under different types of regulatory requirements and by different FDA Centers, namely, the Center for Drug Evaluation and Research, or CDER, the Center for Devices and Radiological Health, or CDRH, or the Center for Biologics Evaluation and Research, or CBER. Differences in regulatory pathways for each constituent part can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated constituent parts that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug or device where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug or device packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

The FDA's Office of Combination Products, or OCP, was established to provide prompt determination of the FDA Center with primary jurisdiction over the review and regulation of a combination product; ensure timely and effective premarket review by

overseeing the timeliness of and coordinating reviews involving more than one center; ensure consistent and appropriate post-market regulation; resolve disputes regarding review timeliness; and review/revise agreements, guidance and practices specific to the assignment of combination products.

OCP determines which Center will have primary jurisdiction for the combination product, referred to as the Lead Center, based on the combination product's "primary mode of action," or PMOA. A mode of action is the means by which a product achieves an intended therapeutic effect or action. The PMOA is the mode of action that provides the most important therapeutic action of the combination product, or the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product. The Lead Center has primary responsibility for the review and regulation of a combination product; however a second Center is often involved in the review process, especially to provide input regarding the "secondary" component(s). In most instances, the Lead Center applies its usual regulatory pathway. For example, a drug-device combination product assigned to CDER will typically be reviewed through an NDA, while a drug-device combination product assigned to CDRH is typically reviewed through a 510(k), PMA, or De Novo classification request.

Often it is difficult for OCP to determine with reasonable certainty the most important therapeutic action of the combination product. In those difficult cases, OCP will consider consistency with other combination products raising similar types of safety and effectiveness questions, or which Center has the most expertise to evaluate the most significant safety and effectiveness questions raised by the combination product. A sponsor may use a voluntary formal process, known as a Request for Designation, when the product classification is unclear or in dispute, to obtain a binding decision as to which Center will regulate the combination product. If the sponsor objects to that decision, the sponsor may request that OCP reconsider its decision.

Combination products are subject to FDA user fees based on the type of application submitted for the product's premarket approval or clearance. For example, a combination product for which an NDA is submitted is subject to the NDA fee under PDUFA. Likewise, a combination product for which a PMA is submitted is subject to the PMA fee under the Medical Device User Fee and Modernization Act.

Since a combination product incorporates two or more constituent parts that have different regulatory requirements, a combination product manufacturer must comply with all cGMP and QSR requirements that apply to each constituent part. The FDA has issued a combination product cGMP regulation, along with final guidance, describing two approaches a combination product manufacturer may follow to demonstrate compliance. Under these two options, the manufacturer demonstrates compliance with: (1) All cGMP regulations applicable to each separate regulated constituent part included in the combination product; or (2) either the drug cGMP or the QSR, as well as with specified provisions from the other of these two sets of requirements (also called the "streamlined approach").

FDA has stated that our Mydcombi product candidate is a drug-device combination product with a drug PMOA, and thus will be reviewed through an NDA by CDER as the Lead Center with consulting review on the device component provided by CDRH. The QSR will apply to all manufacturing of our device components and we may be subject to additional QSR requirements applicable to medical devices, such as management responsibility, design controls, purchasing controls, and corrective and preventive action.

Review and Approval of Drug Products in China and South Korea (Arctic Vision)

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Procedures Governing Approval of Drug Products in China

The National Medical Products Administration (NMPA) is the main regulatory authority responsible for drug registration, review, and approval in China. NMPA's Drug Evaluation Center (CDE) is responsible for the review of drug clinical trial applications and drug marketing authorization applications for overseas manufactured drugs. After completing the pre-clinical studies and clinical trials supporting the drug registration, the applicant submits the drug marketing authorization application according to the applicable

requirements. After the formal examination of the application materials, acceptance will be given if they meet the requirements. Pharmaceutical, medical, and other technical personnel of the CDE review the accepted drug marketing authorization applications. After a comprehensive review they issue a registration certificate of approval for the subject drug. The validity period of the drug registration certificate is five years. During the validity period the marketing authorization holder is responsible for the safety, effectiveness, and quality control of the approved drug and applies for drug re-registration six months prior to the expiration of the validity period.

Procedures Governing Approval of Drug Products in Korea

The Ministry of Food and Drug Safety (MFDS) is the main regulatory authority responsible for drug registration, review, and approval in South Korea. Under the MFDS, the Pharmaceutical Safety Bureau, and the National Institute of Food and Drug Safety Evaluation (NIFDS) are responsible for the review, approval, and regulation of pharmaceutical products. Pharmaceuticals that require data submission must submit safety and efficacy data for evaluation before receiving approval. This includes drug products that have new effectiveness, composition, or route of administration. The applicant will prepare the application dossier for drug approval. Submit the application to MFDS Management Division for Drug Approval & Review. The MFDS then conducts an initial assessment of the application, generates a report outlining the application dossier, and submits it to the MFDS Drug & Evaluation Department. The Drug & Evaluation department conducts a review of, among other things, the results of the initial assessment, technology, safety & efficacy data, product standards, clinical trial data, good manufacturing practice (GMP) data, Drug Master File (DMF) data, impacts on intrinsic (genetic) factors, and extrinsic (factors). If no further documentation or supplementary data is required, the MFDS issues the applicant a Certificate of Approval.

Pharmaceutical Coverage, Pricing and Reimbursement

Our Mydcombi, MicroLine and clobetasol propionate product candidates are intended as "cash pay" and therefore are not likely subject to the significant uncertainty that exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. The sales of MicroPine, however, would likely depend in part on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients and healthcare providers are unlikely to use our products unless third-party payor coverage is provided and reimbursement by such payor is adequate to cover a significant portion of the cost of our products. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other comparable government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for the product.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Moreover, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that

coverage and adequate reimbursement will be obtained. Nonetheless, product candidates might not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Third-party reimbursement might not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In addition, prices for drugs may be reduced by mandatory discounts or rebates required by federal healthcare programs or discounts and rebates requested by private payors. Any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States may also impact the pricing of drugs. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to products for which the company receives marketing approval in the future and coverage and reimbursement under different federal healthcare programs is not always consistent. Further, private payors often follow the coverage and reimbursement policies established under Medicare. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products for which we receive marketing approval.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for our product candidates will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with healthcare providers, pharmacists, consultants, third-party payors and customers are subject to broadly applicable healthcare laws and regulations that may constrain our business and/or financial arrangements. Applicable federal and state healthcare laws and regulations include without limitation the following:

- the federal Anti-Kickback Statute, or AKS, which prohibits persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, if one purpose of the remuneration is to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties statute;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;

- the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians, certain advanced non-physician healthcare practitioners, and teaching hospitals or to entities or individuals at the request of, or designated on behalf of, the physicians, advanced healthcare practitioners and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

The majority of states also have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures. Some states and local jurisdictions require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

Changes in the Healthcare Marketplace

The United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we

may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, the containment of healthcare costs has become a priority of federal and state governments and the prices of therapeutics have been a focus in this effort. The U.S. government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs, respectively. In recent years, the U.S. Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. The Centers for Medicare and Medicaid Services, CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products we may market in the future. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, included changes to the coverage and payment for products under government health-care programs. The Affordable Care Act included provisions of importance to our potential product candidate that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs products, apportioned among these entities according to their market share in certain government healthcare programs;

- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and

- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the Affordable Care Act when it dismissed a legal challenge to the Affordable Care Act's constitutionality. Further legislative and regulatory changes under the Affordable Care Act remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical and medical device industries as a whole or our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States.The Biden Administration has indicated that lowering prescription drug prices is a priority. For example, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and healthcare insurance industries,and called on HHS to release a comprehensive plan to combat high prescription drug prices. The drug pricing plan released by HHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing HHS to negotiate the cost of Medicare Part B and D drugs. It is unclear how other healthcare reform measures of the Biden administration will impact healthcare laws and regulations or our business.

Other legislative changes have been proposed and adopted since passage of the ACA that affect healthcare expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and was extended by the Consolidated Appropriations Act for 2023, and will remain in effect through 2032 unless additional Congressional action is taken.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. In addition to the sweeping reforms contained in the ACA, other legislative changes have been proposed and adopted in the United States that may affect healthcare expenditures. For example, the 2020 Consolidated Appropriations Act (P.L. 116-94) included a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act, or the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS program for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown.

More recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single-source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. Further, in December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical developers like us. We expect that federal, state and local governments in the United States, as well as foreign governments, will continue to consider legislation directed at lowering the total cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product that is ultimately approved, if approved. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

Human Capital Resources

As of March 15, 2025, we had 14 total employees. Thirteen are full-time employees and one is part-time. We also engage various consultants and contractors.

We consider our relations with our employees to be good. To successfully develop our product candidates, we must be able to attract and retain highly skilled personnel. We continually evaluate the business need and opportunity and balance in-house expertise and capacity with outsourced expertise and capacity.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. Biotechnology and pharmaceutical companies both large and small compete for a limited number of qualified applicants to fill specialized positions. To attract qualified applicants, we offer a total rewards package potentially consisting of base salary and cash target bonus, a comprehensive benefit package and equity compensation. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on performance.

Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values.

Information About Our Directors and Executive Officers

Name	Position
Charles Mather IV	Chairman and Director of Eyenovia
Tsontcho Ianchulev, M.D., M.P.H.	Director of Eyenovia
Michael Geltzeiler	Director of Eyenovia
Rachel Jacobson	Director of Eyenovia
Ram Palanki, Pharm.D.	Director of Eyenovia and Executive Vice President of Commercial Strategy & Operations at REGENXBIO Inc.
Ellen Strahlman, M.D., MHSc	Director of Eyenovia
Michael Rowe	Chief Executive Officer, Principal Financial Officer and Director of Eyenovia
Bren Kern	Chief Operating Officer

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website at www.eyenovia.com as soon as reasonably practicable after electronically filing or furnishing such material to the SEC. The SEC maintains a website (www.sec.gov) that includes our reports, proxy statements and other information.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you might lose all or part of your investment.

RISKS RELATED TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We will need to raise additional capital to remain a going concern, which may not be available on acceptable terms, or at all.

We require significant capital resources in order to continue to operate our business and conduct our exploration of strategic alternatives, and our limited liquidity could materially and adversely affect our business operations. As of December 31, 2024, we had cash and cash equivalents of $2.1 million. As of March 15, 2025, we owed $10.2 million in principal and accrued interest under the Loan and Security Agreement. As of December 31, 2024, we had an accumulated deficit of approximately $195.3 million. We expect to continue to incur cash outflows from operations for the near future. These circumstances raise substantial doubt about our ability to continue as a going concern for at least one year from the date this Form 10-K was filed, and our independent registered public accounting firm included a "going concern" explanatory paragraph in its report on our financial statements for the year ended December 31, 2024, indicating that, without additional sources of funding, our cash at December 31, 2024 is not sufficient for us to operate as a going concern for a period of at least one year from the date that the financial statements included in this Annual Report on Form 10-K are issued. Management's plans concerning these matters, including our need to raise additional capital, are described in Note 2 - Summary of

Significant Accounting Policies - Liquidity and Going Concern of our financial statements included within this Annual Report on Form 10-K.

Implementation of our plans and our ability to continue as a going concern will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies. Also, it is very difficult to project our current monthly cash burn rate given the transitional status of the Company and this estimate may prove inaccurate and we may expend our limited resources sooner. The additional capital we require in order to remain a going concern may not be available on reasonable terms, if at all, due to a variety of factors, including uncertainty about the future direction of the Company, as well as broader conditions in the economy and capital markets, including recent volatility caused by inflation, questions about bank stability and other factors. If we are unsuccessful in our operations to secure additional financing, or if any such incremental financing is not sufficient to fund our operations, we may be required to take additional measures to reduce costs in order to conserve our cash, pursue strategic transactions or file for bankruptcy. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

Our ongoing exploration of alternative strategic paths may not result in entering into or completing transactions when necessary, and the process of reviewing alternative strategic paths or their conclusion could adversely affect our stock price.

We continue to evaluate strategic paths to provide the resources necessary to commercialize Mydcombi and maximize stockholder value. Potential strategic paths may include partnerships, joint ventures, mergers, acquisitions or licensing transactions, a combination of these, or other strategic transactions. There can be no assurance, however, that our evaluation will result in transactions or other alternatives, even when deemed necessary. There is no set timetable for our strategic process and we do not intend to provide updates unless or until the Board of Directors approves a specific action or otherwise determines that disclosure is appropriate or necessary.

Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval, where necessary, and the availability of financing to third parties in a potential transaction with us on reasonable terms. The process of reviewing alternative strategic paths may be time consuming and may involve the dedication of significant resources and may require us to incur significant costs and expenses. It could negatively impact our ability to attract, retain and motivate employees, and expose us to potential litigation in connection with this process or any resulting transaction. If we are unable to effectively manage the process, our financial condition and results of operations could be adversely affected. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of our Company could cause our stock price to fluctuate significantly. Further, any alternative strategic paths that may be pursued and completed ultimately may not deliver the anticipated benefits or enhance stockholder value. There can be no guarantee that the process of evaluating alternative strategic paths will result in our Company entering into or completing potential transactions within the anticipated timing or at all.

Delisting could prevent us from maintaining an active, liquid and orderly trading market for our common stock and may materially and adversely impact our ability to consummate certain strategic transactions.

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq Capital Market or if we are unable to transfer our listing to another stock market. On September 18, 2024, we were notified by The Nasdaq Stock Market LLC, or Nasdaq, that we were in breach of Listing Rule 5550(a)(2), or the ("Minimum Bid Price Rule"), for continued listing on the Nasdaq Capital Market because the minimum bid price of our listed securities for 30 consecutive business days had been less than $1 per share.

On December 12, 2024, we received a letter from Nasdaq notifying us that, because the closing bid price for our common stock was below $0.10 per share for 10 consecutive trading days, we were in breach of Listing Rule 5810(c)(3)(A)(iii). On January 31, 2025, we executed an 80-for-1 reverse stock split, following which we were notified by Nasdaq that we had regained compliance with the Minimum Bid Price Rule.

Nasdaq Listing Rule 5810(c)(3)(A)(iv) states that any listed company that fails to meet the Minimum Bid Price Rule and has effected a reverse stock split over the prior one-year period, or has effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one, will not be eligible for an automatic 180-day grace compliance period and the Nasdaq Listing Qualifications Department is obligated to immediately issue a delisting determination. Therefore, if we were to fall out of compliance with the Minimum Bid Price requirement prior to January 31, 2026, we would not be able to effect a reverse stock split and would immediately be issued a delisting determination.

If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, deterring broker-dealers from making a market in or otherwise seeking or generating interest in our

common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, the price of our common stock may decline, and although our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. If our common stock is delisted from Nasdaq, trading in our securities may be subject to the SEC's "penny stock" rules. These "penny stock" rules will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities. Furthermore, if our common stock is delisted, we would expect it to have an adverse impact on our ability to consummate certain strategic alternatives.

Further, if our common stock is delisted, we would incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our investors' ownership interest will be diluted. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail or delay manufacturing and commercialization plans, which would adversely impact potential revenues, results of operations and our financial condition.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, Mydcombi, Optejet or clobetasol propionate, or grant licenses on terms that might not be favorable to us.

The terms of the Loan and Security Agreement require us to meet certain operating covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On November 22, 2022, we entered into the Loan and Security Agreement with Avenue, which is secured by a lien on all of our assets. The Loan and Security Agreement, as supplemented by the Supplement, provides for term loans in an aggregate principal amount of up to $15.0 million to be delivered in multiple tranches. The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to protect and maintain our intellectual property and comply with all applicable laws, deliver certain financial reports and maintain insurance coverage. Negative covenants include, among others, covenants restricting us from transferring any part of our business or intellectual property, incurring additional indebtedness, engaging in mergers or acquisitions, repurchasing shares, paying dividends or making other distributions, making investments, and creating other liens on our assets, including our intellectual property, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on the incurrence of additional debt and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Loan and Security Agreement or any future debt facility, Avenue may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we were to be liquidated, Avenue's right to repayment would be senior to the rights of the holders of our common stock. Avenue could declare an event of default upon the occurrence of any event that could reasonably be expected to result in what they interpret as a material adverse effect as defined under the Loan and Security Agreement. Any declaration by Avenue of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

We have entered into a loan modification agreement with Avenue and, based on our lack of financial liquidity, we cannot guarantee that we will be able to comply with the terms of this agreement, or continue obtaining forbearance if needed.

As of March 15, 2025, the Company owed $10.2 million in principal and accrued interest under the facility. Amounts outstanding under the facility bear interest at an annual rate equal to the greater of (a) 7.0% and (b) the prime rate as reported in The

Wall Street Journal plus 4.45% (the "Interest Rate"). The maturity date is November 1, 2025. On November 22, 2024, the Company entered into the First Amendment, pursuant to which Avenue agreed to defer principal and interest payments on amounts outstanding until February 28, 2025.

On February 21, 2025, the Company entered into the Second Amendment, pursuant to which Avenue agreed to defer principal and interest payments on amounts outstanding until the end of September 2025. Deferred interest will accrue on the outstanding principal amount at the interest rate as defined in the Second Amendment.

Under the Second Amendment, the Company has agreed to use a portion of the proceeds (net of fees and commissions payable to Chardan) received from sales under its Amended and Restated Sales Agreement (the "ATM Agreement") with Chardan Capital Markets, LLC for its at-the-market offering program (the "ATM Proceeds") to pay down the outstanding principal amount under the Loan and Security Agreement as follows: a) until the Company raises $3 million of aggregate ATM Proceeds, 65% of the ATM Proceeds shall be remitted to Avenue as a payment in respect of the outstanding principal amount, and b) after the Company raises $3 million of aggregate ATM Proceeds, 75% of the ATM Proceeds shall be remitted to Avenue as a payment in respect of the outstanding principal amount.

Under the Second Amendment, at any time on or after April 1, 2025, Avenue will also have the right, in their discretion, but not the obligation, to convert an aggregate amount of up to $10 million of the aggregate principal amount under the Loan and Security Agreement into shares of the Company's common stock, at a price equal to $1.68 per share.

It is possible that the Company may be unable to make payments against the loan when the forbearance period ends on September 30, 2025. If the Company fails to obtain the requisite waivers or further extends the forbearance period, Avenue could declare the Company in default and require repayment of the outstanding balances on the relevant loans. If that were to occur, the Company may not have sufficient funds to pay the applicable debt. We currently do not have sufficient liquidity to repay all the outstanding debt to Avenue.

We have incurred operating losses since our inception. We expect to continue to incur losses for the foreseeable future and might never achieve or maintain profitability.

We have incurred net losses of approximately $195.3 million since inception, have not generated any significant product sales revenue and have not achieved profitable operations. Our net losses were approximately $49.8 million and $27.3 million for the years ended December 31, 2024 and 2023, respectively. We expect to continue to incur substantial losses in future periods while we continue to test and prepare our product candidates for the market. We may never achieve profitability. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- continue to develop the Optejet® User Filled Device;
- develop, maintain, expand and protect our intellectual property portfolio; and
- implement additional operational, financial and management systems

Even if we are able to generate substantial revenues from the sale of our product, we might not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we might not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital or continue our operations.

If we are unable to use carryforward tax losses or benefit from favorable tax legislation to reduce our taxes, our business, results of operations and financial condition may be adversely affected.

We have incurred significant net operating losses since our inception in July 2014. As of December 31, 2024, we had federal net operating loss carry-forwards of approximately $133.7 million, of which approximately $10.8 million will expire at various dates from 2034 to 2037 for federal purposes. If we are unable to use carryforward tax losses to reduce our future taxable basis for corporate tax purposes, our business, results of operations and financial condition may be adversely affected.

Net operating loss and tax credit carry-forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal

Revenue Code of 1986, as amended, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

The federal and state income tax returns are generally subject to tax examinations. To the extent we have tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period. Any unfavorable tax adjustment could have a significant impact on our results of operations and future cash flows. Furthermore, if the United States government decides to eliminate, or reduce the scope or the rate of any tax benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

RISKS RELATED TO THE PROPOSED BUSINESS COMBINATION BETWEEN EYENOVIA AND BETALIQ

The proposed business combination may not be consummated on the terms described in the non-binding Letter of Intent or at all.

On March 18, 2025, Eyenovia entered into the non-binding Letter of Intent with Betaliq, a privately-held company, relating to a proposed business combination between Eyenovia and Betaliq. Although Eyenovia anticipates entering into and closing a definitive business combination agreement in the second quarter of 2025, no assurance can be given that Eyenovia will be able to do so within that timeframe or at all. Execution of a definitive business combination agreement with Betaliq is subject to a number of conditions in the Letter of Intent, including satisfactory completion of due diligence by each party, which due diligence has not been completed as of the date of this report, as well as successful negotiation of the terms and conditions of the business combination agreement. In addition, even if Eyenovia were to negotiate and enter into the definitive business combination agreement, there is no assurance that the proposed business combination would be consummated on the terms described in the Letter of Intent, or at all.

Failure to enter into a definitive business combination agreement or consummate the proposed business combination could negatively affect Eyenovia's business, future business and financial results.

The terms of a definitive business combination agreement are subject to negotiation, and Eyenovia cannot guarantee that the parties will be able to reach acceptable terms. Execution of the definitive business combination agreement is subject to various conditions in the Letter of Intent, including satisfactory completion of due diligence by each party. In the event the parties are unable to negotiate a definitive business combination agreement or consummate the proposed business combination, it will have a material adverse effect on Eyenovia's business, financial condition, and results of operations, including the following:

- Incurring costs related to the negotiation of the business combination agreement, such as legal, accounting, and financial advisory fees;
- Declines in the market price of Eyenovia Common Stock to the extent that such market price reflects an assumption that the business combination would be consummated;
- The diversion of management's attention from day-to-day business operations and the potential disruption to each company's employees and other personnel and business relationships during the period the definitive business combination agreement is being negotiated and stockholder approval is being solicited; and
- The potential for litigation related to the proposed business combination.

Even if the parties are able to enter into a definitive business combination agreement, Eyenovia cannot guarantee that the terms will be as described in the Letter of Intent or that the closing conditions set forth in such business combination agreement, including obtaining the requisite stockholder approval and listing the combined company's shares on Nasdaq, will be satisfied. If Eyenovia is unable to satisfy its closing conditions, or if other mutual closing conditions are not satisfied, Betaliq will not be obligated to complete the business combination.

If the business combination is not completed, Eyenovia's board of directors would need to evaluate other available strategic alternatives, which alternatives may not be as favorable to Eyenovia stockholders as the business combination or available at all and could include winding down its operations, which may result in a total loss of stockholders' investment.

Eyenovia and Betaliq will be subject to various uncertainties while the proposed business combination is pending that could adversely affect the anticipated benefits of the business combination.

Uncertainty about the effect of the proposed business combination on counterparties to contracts, employees, consultants, and other parties may have an adverse effect on Eyenovia and Betaliq. These uncertainties could cause contract counterparties and others who deal with Eyenovia or Betaliq to seek to change existing business relationships and may impair the ability of Eyenovia and Betaliq to attract, retain, and motivate key personnel until the business combination is completed and for a period of time thereafter. Retention and recruitment of employees and consultants may be particularly challenging prior to the completion of the business combination. Eyenovia employees and consultants, and the employees and consultants and prospective employees and consultants of Betaliq, may experience uncertainty about their future roles following the business combination.

The negotiations to enter into a definitive business combination agreement, pursuit of the business combination, and the preparation for the combination of the two companies may place a significant burden on management and internal resources. Any significant diversion of management attention away from ongoing business and any difficulties encountered in the negotiations, transition, and integration process could affect each party's business and limit them from pursuing attractive business opportunities and making other changes to their business prior to the entry into a definitive business combination agreement and/or completion of the business combination.

Eyenovia expects to incur substantial transaction costs in connection with the proposed business combination.

Eyenovia expects to incur a significant amount of non-recurring expenses in connection with the proposed business combination, including legal, accounting, financial advisory, consulting, printing, mailing, and other expenses. In general, these expenses are payable by Eyenovia whether or not the business combination is completed. Additional unanticipated costs may be incurred following consummation of the business combination.

RISKS RELATED TO COMMERCIALIZATION OF OUR PRODUCTS

Our ability to achieve profitability is highly dependent on the commercial success of Mydcombi and clobetasol propionate, and to the extent Mydcombi and clobetasol propionate are not successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

Mydcombi and clobetasol propionate are currently our only products that have been approved by FDA for commercial sale in the United States, and our prospects are substantially dependent on our and our licensees' abilities to successfully commercialize Mydcombi. For the year ended December 31, 2024, we recorded net sales of $57,336. Revenues from sales of Mydcombi, clobetasol propionate and other products through our distribution and co-promotion agreements, have not been sufficient to fund our operations fully in prior periods and we cannot provide assurance that revenues from product sales will be sufficient to fund our operations fully in the future. We will need to generate substantially more product revenue to achieve and sustain profitability. We may be unable to sustain or increase revenues generated from product sales for a number of reasons, including:

- pricing, coverage and reimbursement policies of government and private payers such as Medicare, Medicaid, the U.S. Department of Veterans Affairs, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- a lack of acceptance by physicians, patients and other members of the healthcare community;
- interruptions in supply of Mydcombi from our contract manufacturing partners;
- the availability, relative price and efficacy of Mydcombi as compared to alternative treatment options or branded, compounded or generic competing products;
- an unknown safety risk;
- the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of Mydcombi outside of the United States; and
- changed or increased regulatory restrictions in the United States, European Union and/or other foreign territories.

In addition, we require substantial additional funding to advance manufacturing and commercialization of Mydcombi and development of the Gen-2 Optejet. If additional capital is not available when needed, including because of general market conditions, we may need to significantly scale back or reprioritize our manufacturing and commercialization plans, and potentially even cease our operations.

If we are unable to develop, obtain marketing approval for or successfully commercialize our MicroPine and MicroLine product candidates, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed.

Our products may cause undesirable side effects, which could result in significant negative consequences.

If undesirable side effects of our products are identified, a number of potentially significant negative consequences could result, including:

- marketing of such product may be suspended;
- a product recall or product withdrawal;
- regulatory authorities may withdraw or limit their approvals of such product or may require additional warnings on the label;
- the requirement to develop a REMS for each product or, if a strategy is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable foreign regulatory authority;
- the requirement to conduct additional post-market studies; and
- being sued and held liable for harm caused to patients.

Consequently, our reputation and business operations may suffer.

In addition, adverse side effects caused by any therapeutics that may be similar in nature to our products could result in significant negative consequences for our products.

Any of these events could prevent the achievement or maintaining of market acceptance of the particular product and could significantly harm our business, results of operations and prospects.

If the market opportunities for Mydcombi and clobetasol propionate are smaller than we believe they are, our product revenues may be adversely affected and our business may suffer.

We are currently focusing efforts on commercializing our Mydcombi and clobetasol propionate products, and we have licensed commercialization rights to Mydcombi in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea to Arctic Vision (with Senju retaining such licensed rights in the rest of Asia). Our understanding of both the number of people who have needs for our products, as well as the subset of people who have the potential to benefit from our product in varying countries, are based on estimates in published literature. While we believe these estimates are reasonable, they may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of mydriasis. The number of patients in the United States and elsewhere may turn out to be lower than expected or these patients might not be otherwise amenable to our products or may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

The commercial success of Mydcombi and clobetasol propionate will depend in large part on the degree of market acceptance among ophthalmologists and optometrists, patients, patient advocacy groups, third-party payors and the medical community.

There can be no assurance that Mydcombi and clobetasol propionate will achieve commercial success or market acceptance, which could prevent us from becoming profitable.

We may have difficulties convincing the medical community, third-party payors and consumers to accept and use Mydcombi or clobetasol propionate. Other factors that we believe will affect market acceptance of Mydcombi or clobetasol propionate include:

- the timing of our receipt of any marketing approvals, the terms of any approvals and the countries in which approvals are obtained;
- safety, efficacy and ease of administration of Mydcombi or clobetasol propionate;
- the success of physician education programs;
- the availability of any government and third-party payor reimbursement;
- the pricing of Mydcombi or clobetasol propionate, particularly as compared to alternative treatment methods and medications;
- the extent to which alternative treatment methods and medications are more readily available as compared to the availability of Mydcombi or clobetasol propionate future; and
- the prevalence and severity of any adverse effects.

We face competition in an environment of rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, may adversely affect our financial condition and our, or our licensees', ability to successfully market or commercialize our products.

The specialty pharma market is highly competitive. If we or our licensees are unable to compete effectively with any existing products, new treatment methods and new technologies, we may be unable to commercialize our products.

The specialty pharma market is subject to rapid technological change and is significantly affected by existing rival products and medical procedures, new product introductions and the market activities of other participants. Pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations may pursue the research and development of technologies, drugs or other therapeutic products for the treatment of some or all of the diseases or conditions we are targeting. We may also face competition from products which have already been approved and accepted by the medical community for the treatment of these same indications.

As a result of any of the foregoing factors, our competitors may develop or commercialize products with significant advantages over our products. If our competitors are more successful in commercializing their products than we are, their success could adversely affect our competitive position and harm our business prospects.

If we fail to establish and maintain effective manufacturing and distribution processes our business may be adversely affected.

We have limited resources for the manufacturing, sales, marketing and distribution of drug products. To achieve commercial success for Mydcombi and clobetasol propionate, we will need to establish and maintain an adequate sales force additional manufacturing, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. We may encounter delays in the manufacturing process for Mydcombi that could delay the process of commercialization of the product, which could have a material negative effect on our revenues.

In addition, failure to secure contracts with manufacturers, wholesalers, retailers, or specialty pharmacies could negatively impact the production and distribution of our products, and failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively establish and manage the manufacturing and distribution process, the commercial sales of our products may be severely compromised and our results of operations may be harmed.

We are exposed to the risk of claims seeking monetary damages by individuals and the risk of investigations by regulatory authorities, which could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

We are exposed to the risk of claims seeking monetary damages being filed against us for loss or harm suffered by participants of our prior clinical trials or for loss or harm suffered by users of Mydcombi or clobetasol propionate. In either event, the FDA or the regulatory authorities of other countries or regions may commence investigations of the safety and effectiveness of any such commercialized drug, the manufacturing processes and facilities or marketing programs utilized in respect of any such drug. Such investigations may result in mandatory or voluntary recalls of any such commercialized drug or other significant enforcement action such as limiting the indications for which any such drug may be used, or suspension or withdrawal of approval for any such drug.

Product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

We face an inherent risk of product liability exposure related to the use of Mydcombi or clobetasol propionate. If we cannot successfully defend ourselves against claims that our products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Mydcombi or clobetasol propionate;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue; and
- reduced time and attention of our management to pursue our business strategy.

Our insurance policies might not fully cover the risk of loss associated with our operations. We may need to increase our insurance coverage as we commercialize Mydcombi and clobetasol propionate. Insurance coverage is increasingly expensive. We might not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. In the event that we are required to pay damages for any such claim, we may be forced to seek bankruptcy or to liquidate because our asset and revenue base may be insufficient to satisfy the payment of damages and any insurance that we have obtained or may obtain for product or clinical trial liability might not provide sufficient coverage against potential liabilities.

We may not be able to successfully commercialize Mydcombi or clobetasol propionate due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell Mydcombi or clobetasol propionate profitably.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for products, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or other comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and

- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for Mydcombi or clobetasol propionate and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for our products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, our products. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement are critical to a product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

For products administered by or under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services, or CMS, the federal agency responsible for administering the Medicare program, revises the reimbursement amounts paid to health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments.

We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for our products.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we, or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our products may lose any regulatory approval that has been obtained and we may not achieve or sustain profitability.

If the regulatory authorities in such jurisdictions set prices or make reimbursement criteria that are not commercially attractive for us or our collaborators, our revenues and the potential profitability of our products in those countries would be negatively affected.

RISKS RELATED TO REGULATORY APPROVAL OF OUR PRODUCTS AND OTHER LEGAL COMPLIANCE MATTERS

We are subject to ongoing regulatory obligations and continued regulatory review of our products, which may result in significant additional expense. Additionally, our products could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

The manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting of our products is subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- suspension, limitation, or withdrawal of marketing approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize our products and our value and operating results would be adversely affected.

In addition, the FDA's and other comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay commercialization of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Although we have obtained FDA approval for Mydcombi in the United States, we may never obtain approval for or commercialize Mydcombi or any of our current or future product candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. For example, approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. Drug product approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. In many jurisdictions, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Other than Mydcombi and clobetasol propionate in the United States, we do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required

approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for Mydcombi and clobetasol propionate. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA or comparable foreign regulatory and governmental authorities, Department of Justice, Office of Inspector General for the U.S. Department of Health and Human Services, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities grant regulatory approval for a product, the regulatory approval is limited to those specific uses and indications for which the product is approved. If we are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our products, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, which may require additional nonclinical studies or clinical trials, and must abide by the FDA or a comparable foreign regulatory or governmental authority's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we and any third parties engaged on our behalf are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA or comparable foreign regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by pharmaceutical companies concerning off-label use.

If we are found to have impermissibly promoted Mydcombi or clobetasol propionate, we may become subject to significant liability and government sanctions or enforcement actions. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, engaging in the impermissible promotion of Mydcombi or clobetasol propionate for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements pertaining to certain sales practices and promoting products for off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of pharmaceutical products are subject to additional FDA requirements and restrictions on promotional statements. If the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject

to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Furthermore, the use of our products for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

Our relationships with customers, health care providers, physicians, prescribers, purchasers, third-party payors, charitable organizations and patients are subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which expose us to potential criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

We are subject to certain health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Health care providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third-party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other health care laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

The health care laws that may affect us include: the federal fraud and abuse laws, including the federal Anti-Kickback Statute; false claims and civil monetary penalties laws, including the False Claims Act and Civil Monetary Penalties Law; federal data privacy and security laws, including HIPAA, as amended by HITECH; and the federal Physician Payments Sunshine Act which requires us to report to CMS annually any transfers of value made to physicians (defined broadly to include doctors, dentists, optometrists, podiatrists, chiropractors, and other advanced practice health care professionals), certain non-physician health care practitioners and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable health care laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from other aspects of its business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded health care programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other health care providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded health care programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may

be impaired. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Healthcare legislative reform measures may have a material adverse effect on our financial condition or results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act (the "ACA"), was passed. The ACA was a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. As another example, the 2021 Consolidated Appropriations Act, which was signed into law on December 27, 2020, incorporated extensive health care provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's average sales price to the Department of Health and Human Services, or HHS, as of January 1, 2022, as well as several changes to the statutes governing FDA's drug and biologic programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result, certain sections of the ACA have not been fully implemented or have been effectively repealed through Executive Orders and/or executive agency actions. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA's constitutionality. Further legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, such as changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

Further, over the past several years there has been heightened governmental scrutiny over the manner in which biopharmaceutical manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The probability of success of these newly announced policies, many of which have been subjected to legal challenge in the federal court system, and their potential impact on the U.S. prescription drug marketplace is unknown. There are likely to be continued political and legal challenges associated with implementing these reforms as they are currently envisioned. For example, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries, and called on HHS to release a comprehensive plan to combat high prescription drug prices. The drug pricing plan released by HHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing HHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time-consuming administrative actions. Accordingly, there remains a large amount of uncertainty regarding the federal government's approach to making pharmaceutical treatment costs more affordable for patients.

In August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 (the "IRA"). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. The effect of the Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known. There remains a large amount of uncertainty regarding the federal government's approach to making pharmaceutical treatment costs more affordable for patients.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, California requires pharmaceutical manufacturers to notify certain purchasers, including health insurers and government health plans at least 60 days before any scheduled increase in the wholesale acquisition cost ("WAC"), of their product if the increase exceeds 16%, and further requires pharmaceutical manufacturers to explain whether a change or improvement in the product necessitates such an increase. Similarly, Vermont requires pharmaceutical manufacturers to disclose

price information on certain prescription drugs, and to provide notification to the state if introducing a new drug with a WAC in excess of the Medicare Part D specialty drug threshold. In December 2020, the U.S. Supreme Court also held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs"), and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action. We expect that additional federal and state health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

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Our operations are subject to anti-corruption laws, including the United States Foreign Corrupt Practices Act ("FCPA"), and the United Kingdom Bribery Act 2010 ("Bribery Act"), which apply wherever we do business around the world. We may also become subject to local anti-corruption laws in countries where we may do business in the future, such as Canada's Corruption of Foreign Public Officials Act, the Criminal Law and Anti-unfair Competition Law of the People's Republic of China, the Hong Kong Prevention of Bribery Ordinance, and the Act on Preventing Bribery of Foreign Public Officials in International Business Transactions, or OECD Anti-Bribery Convention, enacted by the Organisation for Economic Co-operation and Development, and adopted by South Korea along with more than 40 other countries, and which is designed to criminalize bribery of public officials in connection with international business transactions. The Bribery Act, FCPA, the OECD Anti-Bribery Convention, and similar international treaties and various countries' local anti-corruption laws, referred to as Anti-Corruption Laws, generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, for example, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential violations of Anti-Corruption Laws, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under Anti-Corruption Laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. As we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our potential international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-United States nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside

of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

We might not be completely effective in ensuring our compliance with all applicable Anti-Corruption Laws or other legal requirements, including Trade Control laws. If we are not in compliance with Anti-Corruption Laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of Anti-Corruption Laws or Trade Control laws by U.K., United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. The coronavirus pandemic has also adversely affected the operations of necessary government agencies. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. In addition, competing demands from other companies or issues can affect the timeliness for which the FDA can review and process our regulatory submissions.

RISKS RELATED TO OUR BUSINESS OPERATIONS AND MANAGING GROWTH

We are highly dependent on the services of our senior management team, including our Chief Executive Officer, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical, scientific and sales personnel, our business will be harmed.

We are highly dependent on our senior management team, including our Chief Executive Officer. The employment agreements we have with our executive officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

In addition, we are dependent on our continued ability to retain and motivate highly qualified additional personnel. If we are not able to retain our management and to retain personnel necessary for the commercialization of our products, we might not be able to sustain our operations or grow.

We might not be able to retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other medical technology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to retain and motivate high-quality personnel and consultants to accomplish our business objectives, our business will be limited.

We have limited corporate infrastructure.

As of March 15, 2025, we had 14 total employees. Thirteen are full-time employees and one is part-time and we rely on third-party contractors for the provision of professional and other services. Our management may need to divert a disproportionate amount of its attention away from our day-to-day operations and devote a substantial amount of time to managing the exploration of our strategic alternatives. We might not be able to effectively manage our day-to-day operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our financial performance, our ability to successfully commercialize Mydcombi and clobetasol propionate, and our ability to find a suitable strategic transaction will depend, in part, on our ability to effectively utilize our corporate infrastructure.

We rely upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

In the ordinary course of our business, we collect and store sensitive data and intellectual property and proprietary business information owned or controlled by ourselves or our customers. This data encompasses a wide variety of business-critical information including research and development information, operational information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information: loss of access; inappropriate disclosure; inappropriate modification; and inadequate monitoring of our controls over the first three risks.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses, breaches, interruptions due to employee error, malfeasance, faulty password management, lapses in compliance with privacy and security mandates, or other disruptions. The risk of a security breach or disruption, particularly through cyber-attack or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Our IT networks and related systems are essential to the operation of our business and our ability to perform day-to-day operations. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur substantial liability. Although we make efforts to maintain the security and integrity of these types of IT networks and related systems, and we have implemented various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging. Our information technology systems may have vulnerabilities, and we may not have the resources or technical sophistication to anticipate or prevent rapidly evolving types of cyberattacks, such as ransomware attacks. A significant cyber incident, including system failure, security breach, disruption by malware or other damage, could interrupt or delay our operations, result in a violation of applicable cybersecurity and privacy and other laws, damage our reputation, cause a loss of customers or expose sensitive customer data, or give rise to monetary fines and other penalties, which could be significant.

Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Third parties may attempt to fraudulently induce employees or other persons into disclosing usernames, passwords or other sensitive information, which may in turn be used to access our information systems, commit identity theft or carry out other unauthorized or illegal activities. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. We engage third-party vendors and service providers to store and otherwise process some of our data, including sensitive and personal information. Our vendors and service providers may also be the targets of the risks described above, including cyberattacks, malicious software, phishing schemes, and fraud. Our ability to monitor our vendors and service providers' data security is limited, and, in any event, third parties may be able to circumvent those security measures, resulting in the unauthorized access to, misuse, disclosure, loss or destruction of our data, including sensitive and personal information, and disruption of our or third-party service providers' systems. We and our third-party service providers may face difficulties in identifying, or promptly responding to, potential security breaches and other instances of unauthorized access to, or disclosure or other loss of, information. Any hacking or other attack on our or our third-party service providers' or vendors' systems, and any unauthorized access to, or disclosure or other loss of, information suffered by us or our third-party service providers or vendors, or the perception that any of these have occurred, could result in legal claims or proceedings, loss of intellectual property, liability under laws that protect the privacy of personal information, negative publicity, disruption of our operations and damage to our reputation, which could divert our management's attention from the operation of our business and materially and adversely affect our business, revenues and competitive position. Moreover, we may need to increase our efforts to train our personnel to detect and defend against cyber- or phishing-attacks, which are becoming more sophisticated and frequent, and we may need to implement additional protective measures to reduce the risk of potential security breaches, which could cause us to incur significant additional expenses.

Any such security breach or interruption, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U.S. states, the U.S. federal government or foreign governments, liability or sanctions under data privacy laws that protect personally identifiable information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful.

In addition, our insurance may be insufficient to cover our losses resulting from cyber-attacks, breaches, or other interruptions, and any incidents may result in loss of, or increased costs of, such insurance. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation.

Our employees, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and other comparable foreign regulatory authorities, provide accurate information to the FDA and other comparable foreign regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and in other jurisdictions, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

We may encounter delays in the manufacturing of the second generation Optejet device, including as a result of our reliance on third parties for manufacturing activities, and this may cause delays in the commercialization of our products. Any such delays would increase the risk that we will not have sufficient quantities of our products or such quantities at an acceptable cost, which could delay, prevent or impair our commercialization efforts.

We do not currently operate and might not be able to timely implement adequate internal manufacturing facilities for all of the components necessary for commercial production of Mydcombi. If we are unable to establish adequate manufacturing processes internally or to reach and maintain agreements with third parties to help us with manufacturing, our commercialization activities would be delayed. Reliance on third-party providers may expose us to more risk than if we were to manufacture our products ourselves. We do not control the manufacturing processes of the third-party suppliers we contract with and are dependent on those third parties for the production of components of our products in accordance with relevant applicable regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. If either we or our third-party suppliers fail to comply with these requirements, we may be subject to regulatory enforcement action, including the seizure of products and shutting down of production.

We do not currently have any agreements with third-party suppliers for the long-term commercial supply of components for Mydcombi. We may be unable to conclude agreements for commercial supply with a sufficient number of suppliers or may be unable

to do so on acceptable terms. If we are unable to reach acceptable agreements with a sufficient number of suppliers of materials, our commercialization activities will be delayed and our ability to implement our business plan will be compromised.

Our manufacturing process is complicated and expensive and it requires months of advance planning. We rely on a limited number of manufacturers for our current supply of Mydcombi for commercialization. If we were unable to acquire the necessary amount of deliverables to meet market demand, our ability to commercialize could be delayed substantially.

Even if we are able to establish and maintain agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory, compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We or our third-party suppliers may encounter shortages in the raw materials or active pharmaceutical ingredients necessary to produce Mydcombi in sufficient quantities for commercialization as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. The failure by us or our third-party suppliers to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of Mydcombi may have a material adverse effect on our business.

Our third-party suppliers may be subject to inspection and approval by regulatory authorities. Our third-party suppliers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third-party suppliers, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of Mydcombi, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize Mydcombi could suffer significant interruptions.

Any disruption, such as a fire, natural hazards or vandalism at our third-party suppliers could significantly interrupt our manufacturing capability. We currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative component supply sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as we build facilities or locate alternative suppliers and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. If changes to third-party suppliers occur, then there also may be changes to manufacturing processes inherent in the setup of new operations for our products. Any such changes could require the conduct of bridging studies before we can use any materials produced at new facilities in our commercial supply. Further, business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption, such as loss of potential sales of Mydcombi. For these reasons, a significant disruptive event of any third-party suppliers could have drastic consequences, including placing our financial stability at risk.

Mydcombi and clobetasol propionate may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and other applicable regulatory requirements and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future suppliers could delay clinical development or marketing approval.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our clinical or commercial demand for Mydcombi or clobetasol propionate, we could experience delays in commercialization. We could be unable to find alternative suppliers of acceptable quality and experience that can produce and supply appropriate volumes at an acceptable cost or on favorable terms. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, would significantly delay commercialization of Mydcombi and clobetasol propionate, which would materially adversely affect our business, financial condition and results of operation.

If we, our service providers or our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

If we, our service providers, or any third-party manufacturers fail to comply with laws regulating the protection of the environment and health and human safety, we could be subject to enforcement actions and our business prospects could be adversely affected.

Our commercialization activities may involve the use of hazardous materials and chemicals or the maintenance of various flammable and toxic chemicals. Failure to adequately handle and dispose of these materials could lead to liabilities for resulting damages, which could be substantial. We also may be subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-home pathogens and the handling of bio-hazardous materials.

If we, our service providers, or any third-party manufacturers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could adversely affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products. These enforcement actions may include:

- restrictions on, or prohibitions against, marketing our products;
- restrictions on importation of our products;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY AND POTENTIAL LITIGATION

Our success depends on our ability to protect our intellectual property and proprietary technology.

Our success depends in large part on our ability to obtain and maintain patent, trade secret and other intellectual property protection in the United States and other countries with respect to our proprietary products. If we do not adequately protect our intellectual property rights, competitors may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patent application and approval process is expensive and time-consuming and we might not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

If the scope of the patent protection we obtain is not sufficiently broad, we might not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and might not adequately protect our rights or permit us to gain or keep any competitive advantage. Although we enter into non-disclosure and confidentiality agreements with parties who have or have had access to confidential or patentable aspects of our research and development output, such as our employees, contractors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. Our pending and future patent applications might not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our patent applications issue as patents, they might not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition,

the laws of foreign countries might not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does.

Some of our future patents and patent applications may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we would need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation might not be provided to us. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our patents covering our proprietary technology may be subject to challenge, narrowing, circumvention and invalidation by third parties.

Any of our patents may be challenged, narrowed, circumvented, or invalidated by third parties. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us.

In addition, our competitors and other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to our products but that uses a technology that falls outside the scope of our patent protection. Our competitors may also seek approval to market generic versions of any approved products and in connection with seeking such approval may claim that our patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still might not provide protection against competing products or processes sufficient to achieve our business objectives. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our products could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We cannot be sure that we were the first to make the technologies claimed in our patents or patent applications or that we were the first to file for patent protection.

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we may license or purchase patent rights were the first to make relevant claimed inventions or were the first to file for patent protection for them. If third parties have filed patent applications on inventions claimed in our patents or applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

The patent application process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance;

- patent applications might not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, narrowed, found to be unenforceable or otherwise might not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our products;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we might not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the composition, use and structure of our products, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and might not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;

- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will be insufficient to protect our technology, provide us with a basis for commercially viable products or provide us with any competitive advantages;

- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under United States or foreign laws; or

- if issued, the patents under which we hold rights might not be valid or enforceable.

Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Obtaining and maintaining patent protection of our technologies depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non- U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Under the terms of some of our licenses or future licenses, we may not have the ability to maintain or prosecute patents in the portfolio, and must therefore rely on third parties to comply with these requirements. Failure by us or our licensors to maintain protection of our patent portfolio could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, it is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any of our present or future partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering our products, our business may be materially harmed.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, however, the life of a patent, and the protection it affords, is limited. As a result, our patent portfolio might not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our products.

Changes to the patent law in the United States or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. The Leahy-Smith America Invents Act, or the America Invents Act, reformed U.S. patent law in part by changing the U.S.

patent system from a "first to invent" system to a "first inventor to file" system, expanding the definition of prior art, and developing a post-grant review system. This legislation changed U.S. patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, and use a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we, our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

In addition, court rulings in cases such as *Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation, Promega Corp. v. Life Technologies Corp. and Abbvie Deutschland GmbH v. Janssen Biotech, Inc.* have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any changes to patent law in the United States or other jurisdictions that impairs our ability to protect our products could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We might not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some foreign countries can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we might not be able to prevent third parties from practicing our inventions in certain foreign countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights might not be effective or sufficient to prevent them from competing.

Agreements through which we license patent rights might not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We might not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, might not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our

products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from commercializing our products.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our products without infringing, misappropriating, or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications that may cover our products. If any third-party patents or patent applications are found to cover our products or their methods of use or manufacture, or our approach to complement inhibition, we might not be free to manufacture or market our products as planned without obtaining a license, which might not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products, including interference and post-grant proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our products. We cannot guarantee that any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our products in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it might not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we might not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we might not have sufficient resources to bring these actions to a successful conclusion. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease manufacturing or commercializing the infringing product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue manufacturing or marketing the infringing product. However, we might not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property and proprietary technology.

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property,

including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license might not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate, or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which might not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any such litigation could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We may be reliant upon licenses to certain patent rights and proprietary technology form third parties that are important or necessary to the commercialization of our product candidates. These and other licenses might not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to commercialize our technology and products in the future. As a result, we might not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. Our licensors may have relied on third party consultants or collaborators or funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, the agreements under which we license patent rights might not give us control over patent prosecution or maintenance, so that we might not be able to control which claims or arguments are presented and might not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We cannot be certain that patent prosecution and maintenance activities by our licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in any licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Further, the agreements under which we currently license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully commercialize the affected products, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under current and any future collaborative relationships;
- our diligence obligations under any license agreement and what activities satisfy such obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our license counterparties and us and our partners; and
- the priority of invention of patented technology.

In spite of our efforts, our license counterparties might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, which may remove our ability to and commercialize the products and technology covered by these license agreements. If any in-licenses are terminated, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. It is possible that we may be unable to obtain any additional licenses that we require at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our product candidates, technology, or the methods for manufacturing them or to develop or license replacement technology, all of which might not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to commercialize the affected products, which could harm our business, financial condition, results of operations, and prospects significantly. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted and our business would be harmed.

In addition to the protection afforded by patents, we also rely on trade secret protection for certain aspects of our intellectual property. However, trade secrets are difficult to protect. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we might not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. Further, if any of our trade secrets were to be

lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If our trademarks and trade names are not adequately protected, then we might not be able to build name recognition in our marks of interest and our business may be adversely affected.

Our trademarks or trade names, including Optejet®, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We might not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks might not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we might not be able to compete effectively and our business may be adversely affected.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 31, 2025, we had 300,000,000 shares of common stock authorized and 2,830,546 shares of common stock outstanding, 1,363,135 shares of common stock issuable upon exercise of warrants, 56,318 shares of our common stock issuable upon exercise of options, 5,952,380 of shares issuable upon the conversion of convertible debt and 247,623 shares of common stock issuable upon the vesting and/or delivery of restricted stock units.

The price of our common stock has been, and may continue to be, volatile and may fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The stock market historically has experienced extreme price and volume fluctuations, such as those seen in 2024. As a result of this volatility, you might not be able to sell your common stock at or above the price at which you purchase it. From January 1, 2020 through March 15, 2025 the per share trading price of our common stock has been as high as $617.60 and as low as $1.43. The per share trading price of our common stock might continue to fluctuate significantly in response to various factors, some of which are beyond our control. These factors include:

- general economic, industry and market conditions, including as a result of the coronavirus pandemic and geopolitical events such as the ongoing war between Russia and Ukraine or between Israel and Hamas;
- our ability to successfully manufacture and commercialize Mydcombi and clobetasol propionate;
- the success of competitive products or technologies;
- commencing, maintaining, or terminating of licensing agreements and other collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- amount of our debt servicing;
- the progress and outcome of our search for strategic alternatives; and
- the other factors described in this "Risk Factors" section.

We have broad discretion in the use of our cash, including the net proceeds from our financings, and might not use them effectively.

Our management will have broad discretion in the application of our cash, including the net proceeds from our financing transactions, and could spend our cash in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash, including the net proceeds from our financings, in a manner that does not produce income or that loses value.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates and other similar effects. Recently, inflation has increased throughout the U.S. economy. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

As a public company, we need to have effective internal controls and disclosure controls, which is costly and time consuming. Failure to develop and maintain adequate financial controls could cause us to have material weaknesses, which could adversely affect our operations and financial position.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Act, and the rules and regulations of our stock exchange. The requirements of these rules and regulations will increase our legal, accounting, and financial compliance costs, will make some activities more difficult, time-consuming, and costly, and may also place undue strain on our personnel, systems, and resources.

We are required to disclose changes made to our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer a "smaller reporting company" as defined in the rules of the SEC. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which would require additional financial and management resources.

An internal control system, no matter how well-designed, cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we might not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline

and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities.

Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations. Any failure to implement and maintain effective internal controls also could adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting that we are required to include in our periodic reports filed with the SEC under Section 404 of the Sarbanes-Oxley Act. Ineffective disclosure controls and procedures or internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors, officers, and employees, entail substantial costs in order to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not be effective, however, in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. In the event that we are not able to demonstrate compliance with Section 404 of the Sarbanes-Oxley Act in a timely manner, that our internal controls are perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and our stock price could decline.

We are an "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million as of the last business day of our most recently completed second quarter if our annual revenues are $100 million or more as of our most recently completed fiscal year, or until our public float exceeds $700 million as of the last business day of our most recently completed second quarter if our annual revenues are less than $100 million as of our most recently completed fiscal year.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation, and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution adopted by a majority of our Board;
- limit the manner in which stockholders can remove directors from the Board, as may be permitted by law;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board;
- limit who may call stockholder meetings;
- authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and

- require all stockholder action to take place at duly called stockholder meetings and disallow the ability of our stockholders to act by majority written consent.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is, to the fullest extent permitted by law, the sole and exclusive forum for substantially all disputes between us and our stockholders. These choice of forum provisions could limit the ability of stockholders to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Unless we consent to the selection of an alternative forum, our certificate of incorporation provides that the Court of Chancery of the State of Delaware, or the Court of Chancery, will be, to the fullest extent permitted by law, the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees or agent to the Company or our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or DGCL, or our certificate of incorporation or bylaws; any action to enforce or determine the validity of our certificate of incorporation or bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Since the choice of forum provisions are only applicable to "the fullest extent permitted by law," as provided in our certificate of incorporation, the provisions do not designate the Court of Chancery as the exclusive forum for any derivative action or other claim for which the applicable statute creates exclusive jurisdiction in another forum. As such, the choice of forum provisions do not apply to any actions arising under the Securities Act of 1933, as amended, or the Exchange Act.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

If securities analysts do not continue to publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If securities analysts do not continue coverage of us, the trading price of our stock could decrease. Additionally, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. We have identified material weaknesses in our internal control over financial reporting, which may raise questions regarding the accuracy and reliability of our financial statements and our ability to report accurately in the future.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. During the process of preparing the financial statements as of and for the year ended December 31, 2024, we determined that we had material weaknesses related to the incorrect valuation of the Company's accounting for shares of common stock that were issued for licensing agreements and debt modification and the impairment of a right-of-use asset. Due to the existence of these material weaknesses, our management has concluded that as of December 31, 2024, our internal control over financial reporting was not effective.

We are taking steps to remediate these material weaknesses. However, we cannot provide any assurance that the measures we have taken to date and that we intend to implement will be sufficient to remediate the material weaknesses that we have identified, or to avoid additional material weaknesses from occurring in the future. These material weaknesses, or those that may occur in the future, could have an adverse effect on our ability to meet our reporting obligations, which could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, harm our reputation, business and financial results, and expose us to litigation or investigations by the SEC or other regulatory authorities.

Item 1B. Unresolved Staff Comments.

Smaller reporting companies such as us are not required to provide the information required by this Item.

Item 1C. Cybersecurity.

Information technology is important to our business operations, and we are committed to protecting the privacy, security and integrity of the data we use in our business, as well as our employee and clinical data. The Company has a comprehensive cybersecurity program in place for assessing, identifying and managing cybersecurity risks that is designed to protect its systems and data from unauthorized access, use or other security impact. This program is integrated into the Company's overall Enterprise Risk Management and Resiliency process.

We continuously monitor and update our information technology networks and infrastructure to prevent, detect, address and mitigate risks associated with unauthorized access, misuse, computer viruses and other events that could have a security impact. We invest in industry standard security technology to protect the Company's data and business processes against risk of cybersecurity incidents. Our data security management program includes identity, trust, vulnerability and threat management business processes, as well as adoption of standard data protection policies.

In terms of governance and oversight, the following is in place to enhance transparency and accountability in cybersecurity management:

Responsibility Assignment:

- The Company's Chief Operating Officer (COO) assumes a pivotal role in overseeing the cybersecurity risk management program. The COO collaborates with business leaders on the matters of cybersecurity across the Company.

Board Oversight:

- Cybersecurity risks fall within the purview of the Audit Committee and, ultimately, the Board of Directors. Regular oversight and reviews occur at established intervals. The Audit Committee engages in discussions with the COO and Company management at least once a year, covering various aspects of cybersecurity risk management, including recent developments, evolving standards, vulnerability assessments, and the threat environment.

We measure our data security effectiveness by benchmarking against industry-accepted methods and we work to remediate any significant findings. We maintain and routinely test backup systems and disaster recovery and also have processes in place to prevent disruptions resulting from our implementation of new software and systems.

We have a comprehensive incident response plan to address cybersecurity incidents. Our incident response plan includes procedures for identifying, containing and responding to cybersecurity incidents and is subject to regular review and assessment to ensure that it is effective in protecting our information technology. To date, we believe that our cybersecurity program has been effective in protecting the confidentiality, integrity, and availability of its information; however, the Company cannot guarantee that its cybersecurity program will be successful in preventing all cybersecurity incidents. Further, we currently maintain a cyber insurance policy that provides coverage for security breaches; however, such insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

We engage external parties, including consultants, computer security firms and risk management and governance experts, to enhance our cybersecurity oversight. In order to oversee and identify risks from cybersecurity threats associated with our use of third-party service providers, we also have a third-party risk management program designed to help protect against the misuse of information

technology by third parties and business partners, which includes certification of our major technology suppliers and any outsourced services through accepted security certification standards.

While we are regularly subject to cybersecurity attacks, ransomware and other security breaches, we have not experienced any material cybersecurity incidents or a series of related unauthorized occurrences for the year ended December 31, 2024. We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

Item 2. Properties.

Our principal executive offices are located in approximately 4,600 square feet of office space in Laguna Hills, California and co-located with our R&D and commercial teams. In addition, we lease approximately 12,000 square feet of office space in Reno, Nevada where we perform certain of our manufacturing development and warehousing activities. We also lease approximately 3,800 square feet of office space in New York City, New York for our finance team. Our lease of approximately 6,700 square feet in Redwood City, California for distribution is set to expire in the third quarter of 2025 and those activities will then transfer to Reno, Nevada.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market for Common Equity

Our common stock trades on the Nasdaq Capital Market under the symbol "EYEN."

Based upon information furnished by our transfer agent, at March 15, 2025, we had approximately 32 holders of record of our common stock.

Dividend Policy

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of this report for disclosure regarding securities authorized for issuance under equity compensation plans required by Item 201(d) of Regulation S-K.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

The following discussion and analysis is based on, and should be read in conjunction with our financial statements for the years ended December 31, 2024 and 2023, which are included elsewhere in this Annual Report on Form 10-K. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. These statements are based on current expectations and assumptions that are subject to risk, uncertainties and other factors. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Actual results could differ materially because of the factors discussed in "Risk Factors" elsewhere in this Annual Report on Form 10-K, and other factors that we have not identified.

Overview

We are an ophthalmic technology company developing our proprietary Optejet® topical ophthalmic medication dispensing platform. In November 2024, we received a negative clinical trial result in the development of our development-stage drug-device combination product, MicroPine. As a result, we restructured our company to minimize expenses and engaged an investment bank to explore strategic options in order to maximize shareholder value. We have paused the national sales roll-out of our products clobetasol propionate and Mydcombi® until additional funding is obtained. At the same time, we accelerated our development efforts relating to the Optejet in order to potentially increase the value of that asset in any strategic transaction or capital raising activities.

The ergonomic and functional design of the Optejet allows for horizontal drug delivery and eliminates the need to tilt the head back or the manual dexterity to squeeze a bottle to administer medications. Drug is delivered in a microscopic array of droplets that is both comfortable and matches the amount of fluid that the front of the eye can hold. The precise delivery of a low-volume columnar spray by the Optejet device helps ensure instillation success while minimizing contamination risk with a non-protruding nozzle and self-closing shutter. In clinical trials, the Optejet has demonstrated that its targeted delivery achieves a high rate of successful administration, with 98% of sprays being accurately delivered upon first attempt compared to the established rate reported with traditional eye drops of approximately 50%.

A more physiologically appropriate volume of medication in the range of seven to ten microliters is delivered by the Optejet, which is approximately one-fifth of the 35 to 50 microliter dose typically delivered in a single eye drop. Lower volume of medication exposes the ocular surface to less active ingredient and preservatives, potentially reducing ocular stress and surface damage and improving tolerability. The lower volume also minimizes the potential for drug to enter systemic circulation, with the goal of avoiding some common side effects that are related to overdosing of the eye.

We are developing versions of the Optejet with on-board digital technology that records the date and time of each use. These data may be used to provide reminders via Bluetooth to smart devices and to allow healthcare practitioners to monitor usage. This information can then be used by practitioners and health care systems to measure treatment compliance and improve medical decision making. In this way, the Optejet could serve as an extension of the physician's office by providing information that is not currently possible to collect except through the use of diaries.

MicroLine is our investigational pharmacologic treatment for presbyopia, a non-preventable, age-related hardening of the lens, which causes the gradual loss of the eye's ability to focus on near objects and impairs near visual acuity. We have completed two Phase III studies using our Optejet device. In these studies, patients reported high satisfaction with using the device, and a strong preference over using an eye dropper bottle. Since completing these studies, the market opportunity has markedly deteriorated, and we have chosen to put this program on hold and reallocate our resources towards larger opportunities. When and if the market improves, we have kept open the option to continue development of MicroLine, which would include a meeting with the U.S. Food and Drug Administration (the "FDA") to review our clinical data to date.

Our first product using the Optejet technology, Mydcombi®, is the only FDA-approved fixed combination of the two leading mydriatic agents, tropicamide and phenylephrine, in the United States. As an ophthalmic spray delivered with Optejet technology, Mydcombi may present a number of benefits for ophthalmic surgical centers, optometric and ophthalmic offices and patients. Those benefits may include improved cost-effectiveness in centers that employ single-use bottles for mydriasis, more efficient use of office time and resources, and an overall improved doctor-patient experience.

The first commercial sale of Mydcombi occurred on August 3, 2023 as part of a targeted launch. On July 24, 2024, we received written comments from the FDA providing direction for the design of a clinical bridging study to transition Mydcombi into our new Gen-2 Optejet device, which has a significantly lower cost to manufacture than the currently approved product.

On August 10, 2020, we entered into a license agreement with Arctic Vision (as amended on September 14, 2021, the "Arctic Vision License Agreement") pursuant to which Arctic Vision may develop and commercialize MicroPine (Eyenovia's proprietary drug-device combination of low-dose atropine and the Optejet platform), MicroLine and Mydcombi in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea. Under the terms of the Arctic Vision License Agreement, as amended, we received an upfront payment of $4.25 million before any payments to Senju Pharmaceutical Co., Ltd. ("Senju").

On October 9, 2020, we entered into a license agreement (the "Bausch License Agreement") with Bausch + Lomb ("B+L"), pursuant to which B+L had the rights to develop and commercialize MicroPine in the United States and Canada. Under the terms of the Bausch License Agreement, we received an upfront payment of $10.0 million and we were eligible to receive up to a total of $35.0 million in additional payments, based on the achievement of certain regulatory and launch-based milestones. B+L also agreed to pay royalties to Eyenovia on a tiered basis (ranging from mid-single digit to mid-teen percentages) on gross profits from sales of MicroPine in the United States and Canada, subject to certain adjustments. Under the terms of the Bausch License Agreement, B+L assumed sponsorship of the IND as well as ownership and the costs related to the ongoing CHAPERONE study, which was a Phase III efficacy and safety trial of MicroPine.

On January 12, 2024, we entered into a subsequent agreement with B+L to repatriate our rights to MicroPine and take control of the CHAPERONE study. In this agreement, we agreed to pay B+L $2 million in cash and an additional $3 million in common stock upon successful transfer of the regulatory documents and study elements to Eyenovia. We also agreed to pay B+L a 2% royalty on net sales once MicroPine is commercialized in the United States, assuming receipt of regulatory approvals. We believed that this revised arrangement was in our and our shareholders' best interests, as it could have substantially increased the value of the asset through potential improvements in the conduct of the study, including a planned interim analysis of the data in late 2024.

On September 26, 2024, we announced the U.S. launch and commercial availability of clobetasol propionate ophthalmic suspension 0.05%.

On November 15, 2024, we announced the outcome of an independent review of the clinical results of the three-year efficacy and safety data from the MicroPine Phase III CHAPERONE study conducted by a Data Monitoring Committee ("DMC"). The DMC, made up of independent ophthalmologists and optometrists who specialize in pediatric myopia as well as a statistician, reviewed the safety and efficacy data from all evaluable patients. After the completion of three-year therapy for myopia with MicroPine, statistical superiority was not observed and was deemed unlikely to occur in at least one of the active dose arms compared with placebo, which was the primary efficacy endpoint of the trial. There were no safety issues or serious adverse events identified. As a result of this finding, we closed out the CHAPERONE study and put the project on hold in December 2024.

In light of the results from the CHAPERONE study, the Company is considering a variety of steps to maximize value to all stakeholders, to reduce expenses and to evaluate its strategic options, which may include a business combination, reverse merger, asset sales or a combination of those alternatives. Further information will be made available once the evaluation of strategic options has been completed. The Company implemented a reduction in force affecting approximately 75% of its workforce. The estimated total cost of severance-related expenses relating to this reduction in force is $0.3 million. The remaining staff will be focused on Optejet® Gen-2 development, our dry eye collaborations and clobetasol propionate commercialization.

We successfully expanded our manufacturing capabilities through a partnership with Coastline International, Inc. located in Tijuana, Mexico, as well as the construction of our new manufacturing facility in Reno, Nevada and the construction of our own fill and finish facility in Redwood City, California. The FDA approved the use of both Coastline International and our Redwood City facility for the production of Mydcombi cartridges, and the use of our Reno facility for the production of technical elements such as the base unit for the Optejet device. As part of the Company's steps to maximize value to all stakeholders, to reduce expenses and to evaluate its strategic options, we made the decision to phase out the production and sale of Mydcombi in the GEN-1 device. As a result, we have phased out the manufacturing line at Coastline International, Inc. located in Tijuana, Mexico, and are also modifying the use of our manufacturing facility in Reno, Nevada and our fill and finish facility in Redwood City, California to focus on Optejet® Gen-2 development, our dry eye collaborations and clobetasol propionate commercialization.

In addition to our own development programs, on August 15, 2023, we entered into a license agreement with Formosa Pharmaceuticals, Inc. ("Formosa"), whereby we acquired the exclusive U.S. rights to commercialize any product related to a novel formulation of clobetasol propionate ophthalmic suspension 0.05% (the "Formosa Licensed Product"), which was approved by the FDA, for post-operative inflammation and pain after ocular surgery, on March 4, 2024. The Formosa License will remain in effect for ten years from the date of the first commercial sale of a Formosa Licensed Product, unless earlier terminated.

We paid Formosa an upfront payment in an aggregate amount of $2.0 million which consisted of (a) cash in the amount of $1.0 million and (b) 487,805 shares of common stock valued pursuant to the Formosa License Agreement at $1.0 million. We also capitalized $122,945 of transaction costs in connection with the Formosa License. In addition, we agreed to pay Formosa up to $4.0 million upon the achievement of certain development milestones and up to $80 million upon the achievement of certain sales milestones. The trigger for the initial $2.0 million development milestone payment was FDA approval of the Formosa Licensed Product and the effective date of the acceptance by the Company of the transfer and assignment of the FDA approval, which occurred on March 14, 2024. Based on the achievement of this milestone, we paid Formosa (a) cash in the amount of $1.0 million on April 26, 2024 and (b) 613,496 shares of common stock (calculated pursuant to the Formosa License Agreement at $1.0 million using a five-day volume-weighted average price on March 14, 2024, but valued at $0.4 million on the April 29, 2024 settlement date). The remaining $2.0 million development milestone (to be fully paid in cash) was earned and accrued upon FDA approval, but payment will be triggered on the earlier of twelve months after FDA approval of the Formosa Licensed Product or six months following the first commercial sale of the Formosa Licensed Product.

On August 7, 2024, we entered into a non-binding collaboration agreement with Formosa under which the companies intend to work to develop EYEN-530, a combination of Formosa's clobetasol propionate ophthalmic solution with our Optejet dispensing technology, as a potential treatment for acute dry eye flare-ups.

On November 22, 2024, we entered into the First Amendment (the "First Amendment") to the Supplement to that certain Loan and Security Agreement, dated November 22, 2022 (the "Loan and Security Agreement") with Avenue Capital Management II, L.P., as administrative agent and collateral agent, Avenue Venture Opportunities Fund, L.P., as a lender and Avenue Venture Opportunities Fund II, L.P., as a lender (together, "Avenue"). Pursuant to the First Amendment, Avenue agreed to defer principal and interest payments on amounts outstanding under the Loan and Security Agreement until the end of February 2025. On February 21, 2025, we entered into the Second Amendment (the "Second Amendment") to the Supplement to the Loan and Security Agreement with Avenue. Pursuant to the Second Amendment, Avenue agreed to defer principal and interest payments on amounts outstanding until the end of September 2025. Deferred interest will accrue on the outstanding principal amount.

On December 12, 2024, we announced the engagement of Chardan, an investment bank, as the Company's financial advisor in connection with its evaluation of strategic alternatives. With assistance from Chardan, the Company will continue to assess a full range of strategic alternatives, including but not limited to, a business combination, sale of the Company, reverse merger, asset sale, or a combination of alternatives, while also carefully managing its expenses. As part of restructuring to minimize expenses during this process, the Company temporarily halted sales and promotion activities and focused its development efforts on completing the verification and validation studies required for regulatory approval of the Optejet UFD. This device is designed for users to fill with preserved artificial tears or contact lens rewetting solutions at home, providing greater flexibility while leveraging Optejet's advanced delivery system. As of March 2025, Eyenovia is progressing with its development of the Optejet UFD, aiming for a 510K submission in the United States in the fourth quarter of 2025.

On July 26, 2024, we received notice from the staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") providing notification that the Company had regained compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Listing Rule 5550(a)(2). Previously, Nasdaq had notified us on July 2, 2024 that, for the preceding 30 consecutive business days, the closing bid price of our common stock had been below the minimum requirement of $1.00 per share. The notification letter stated that we would be provided 180 calendar days to regain compliance. In order to regain compliance, the closing bid price of our common stock had to be at least $1.00 for a minimum of 10 consecutive business days at any time before December 30, 2024. Subsequently, the Staff determined that, from July 12 to July 25, 2024, the closing bid price of our common stock had been at $1.00 per share or greater. Accordingly, the Company had regained compliance with Listing Rule 5550(a)(2).

On February 25, 2025, we received notice from the Staff of Nasdaq providing notification that the Company had regained compliance with the $1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Listing Rule 5550(a)(2). Previously, Nasdaq had notified us on September 18, 2024 that, for the preceding 30 consecutive business days, the closing bid price of our common stock had been below the minimum requirement of $1.00 per share. The notification letter stated that we would

be provided 180 calendar days to regain compliance. In order to regain compliance, the closing bid price of our common stock had to be at least $1.00 for a minimum of 10 consecutive business days at any time before March 17, 2025. On January 31, 2025, the Company effected a reverse stock split of its common stock at a ratio of 1-for-80 (the "Reverse Split"). Upon the effectiveness of the Reverse Split, every 80 issued shares of common stock were reclassified and combined into one share of common stock and the corresponding price per share increased by a multiple of 80. Subsequently, the Staff determined that, from February 3 to February 14, 2025, the closing bid price of our common stock had been at $1.00 per share or greater. Accordingly, the Company had regained compliance with Listing Rule 5550(a)(2).

Historically, we have financed our operations principally through equity offerings. We have also generated cash through licensing arrangements and our credit facility with Avenue. However, based upon our current operating plan, there is substantial doubt about our ability to continue as a going concern for at least one year from the date that our financial statements were issued. Our ability to continue as a going concern depends on our ability to complete additional licensing or business development transactions, raise additional capital through the sale of equity or debt securities to support our future operations or the completion of a transaction consistent with the strategic alternatives that we are exploring. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives, take additional measures to reduce costs or file for bankruptcy.

Our net losses were $49.8 million and $27.3 million for the years ended December 31, 2024 and 2023. As of December 31, 2024, we had working capital deficit and an accumulated deficit of approximately $13.3 million and $195.3 million, respectively.

Financial Overview

Revenue and Cost of Revenue

Revenue is mostly earned from the sale of our products, Mydcombi and clobetasol propionate. The first commercial sale of Mydcombi occurred on August 3, 2023 and the first sale of clobetasol propionate occurred on October 4, 2024, both as part of a targeted launch.

Cost of sales consisted mostly of the cost of the production of the products that were sold, but also write downs of our inventory to their net realizable value.

Research and Development Expenses

Research and development expenses are incurred in connection with the research and development of our microdose therapeutics and consist primarily of contract service expenses. Given where we are in our life cycle, we do not separately track research and development expenses by project. Our research and development expenses consist of:

- direct clinical and non-clinical expenses, which include expenses incurred under agreements with contract research organizations, contract manufacturing organizations, and costs associated with preclinical activities, development activities and regulatory activities;

- personnel- related expenses, which include expenses related to consulting agreements with individuals that have since entered into employment agreements with us as well as salaries, non-cash stock-based compensation and other compensation of employees that is attributable to research and development activities; and

- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, marketing, insurance and other supplies used in research and development activities.

We expense research and development costs as incurred. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or other information our vendors provide to us.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of payroll and related expenses, legal and other professional services, insurance expense, marketing expense, and non-cash stock-based compensation expense.

Results of Operations

Year Ended December 31, 2024 Compared with Year Ended December 31, 2023

Revenue and Cost of Revenue

Revenue for the year ended December 31, 2024 totaled $57,336, which was offset by cost of revenues of $3,927,228. Write-down of inventories to net realizable value for the year ended December 31, 2024 totaled approximately $3.9 million, compared to $12,218 for the year ended December 31, 2023. The $3.9 million was comprised of $0.4 million of adjustments to bring the inventory to list price or net realizable value, a $0.4 million additional write-down of short-dated inventory to net realizable value, and $3.1 million of write-downs of commercial inventory due to the uncertainty associated with the Company's clobetasol propionate and Mydcombi products and its exploration of strategic alternatives.

Revenue for the year ended December 31, 2023 totaled $3,787, which was offset by cost of revenues of $16,005.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2024 totaled $14.5 million, an increase of $1.5 million, or 11.5%, as compared to $13.0 million recorded for the year ended December 31, 2023. Research and development expenses consisted of the following:

	For the Year Ended December 31,	
	2024	2023
Salaries and benefits	$ 6,215,323	$ 6,869,585
Direct clinical and non-clinical expenses	3,072,416	714,995
Supplies and materials	2,195,608	1,762,676
Depreciation expense	1,112,463	776,479
Facilities expenses	834,406	1,442,001
Non-cash stock based compensation expenses	623,049	839,038
Other expenses	409,457	571,058
Total research and development expenses	$ 14,462,722	$ 12,975,832

The increase in direct clinical and non - clinical expenses was primarily due to increased clinical studies costs in connection with the reacquisition of the CHAPERONE license, a reduction in reimbursements from Arctic Vision for GEN - 2 development costs due to GEN - 2 development nearing completion, and R&D work on GEN - 2 formulations for Mydcombi. The increase in supplies and materials was primarily due to the reduction of engineering cost reimbursements from B+L in connection with the reacquisition of the CHAPERONE license from B+L. The increase in depreciation expense was primarily due to a new manufacturing line placed in service during fiscal year 2023. The decrease in personnel - related expenses was primarily due to a decrease in accrued bonuses and amortization period for older equity grants and forfeitures during fiscal year 2024. The decrease in other expenses was primarily due to the decrease in temporary staff compared to 2023 while in the process of hiring permanent employees. terminations in fiscal year 2024. The decrease in facilities expenses was primarily due to lower facilities and manufacturing startup costs incurred in 2024 compared to 2023. The decrease in non - cash stock - based compensation was primarily due to the ending of the amortization period for older equity grants and forfeitures during fiscal year 2024. The decrease in other expenses was primarily due to the decrease in temporary staff compared to 2023 while in the process of hiring permanent employees.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the year ended December 31, 2024 totaled $14.3 million, an increase of $1.9 million, or 15.0%, as compared to $12.4 million recorded for the year ended December 31, 2023. Selling, general and administrative expenses consisted of the following:

	For the Year Ended December 31,	
	2024	2023
Salaries and benefits	$ 5,226,885	$ 3,964,522
Professional fees	2,967,185	2,870,946
Non-cash stock based compensation	1,081,224	1,658,852
Insurance expense	853,434	933,284
Other	801,676	175,515
Sales and marketing	747,349	1,097,402
Investor relations	662,126	398,273
FDA PDUFA fees	564,311	104,183
Travel, lodging and meals	535,115	305,270
Facilities expense	485,059	494,823
Director fees and expense	408,750	415,326
Total selling, general and administrative expenses	$ 14,333,114	$ 12,418,396

The increase in personnel-related expenses was primarily due to new staff additions related to commercialization efforts into fiscal year 2024. The increase in professional fees was primarily due to the short-term need for temporary staff while in the process of hiring permanent employees and increased costs due to additional SEC filings in 2024. The increase in regulatory expenses was primarily due to the FDA Prescription Drug User Fee Act ("PDUFA") fees for Mydcombi and clobetasol propionate in 2024. The increase in investor relations costs during 2024 was primarily due to increased filings and shareholder communications related to our January 2025 special meeting of shareholders. The increase in travel, lodging and meals was primarily due to increased travel by the sales team to promote Mydcombi and clobetasol propionate. The decrease in non-cash stock-based compensation was primarily due to the ending of the amortization period for older equity grants and forfeitures during fiscal year 2024. The decrease in sales and marketing was primarily due to the decrease in expenditure on conferences and conference exhibits and meetings in fiscal year 2024. The decrease in insurance expense was primarily due to a reduction in D&O insurance premiums from 2023. The increase in other expenses was primarily due to foreign tax and development of our pharmacy network in fiscal year 2024.

Reacquisition of License Rights

Reacquisition of license rights for the year ended December 31, 2024 totaled $4.9 million, compared to no expense for the year ended December 31, 2023. The $4.9 million is comprised of the aggregate $5.0 million of payments ($2.0 million of cash and $3.0 million settled in common stock) to B+L in connection with the reacquisition of the Bausch Licensed Product (which we are recording as an operating expense), partially offset by $0.1 million allocated to the repurchase of equipment.

Asset Impairments

Asset impairments expense for the year ended December 31, 2024 was $11.2 million, compared to no expense for the year ended December 31, 2023. Uncertainty associated with our business and our exploration of our strategic options has led us to record impairments of our intangible assets of $6.1 million, property and equipment of $2.5 million, equipment deposits of $0.7 million, prepaid expenses of $0.7 million, operating lease right-of-use asset of $0.4 million, deferred clinical supply costs of $0.4 million and other assets of $0.4 million.

Other Income (Expense)

Total other expense for the year ended December 31, 2024 was approximately $1.1 million, a decrease of $0.8 million, compared to approximately $1.9 million for the year ended December 31, 2023. Total other expense for the year ended December 31, 2024 primarily consisted of approximately $2.5 million of interest expense related to the Avenue loan, partially offset by $1.2 million of changes in fair value of equity consideration (the equity payable for the B+L and Formosa transactions) and $0.2 million of interest income, primarily from Treasury bills. Total other expense for the year ended December 31, 2023, primarily consisted of approximately $2.4 million of interest expense related to the Avenue loan and $0.4 million for the potential replacement cost for returned products,

primarily offset by $0.2 million of income from the sale of clinical supplies and $0.7 million of interest income, mainly from Treasury bills.

Liquidity and Going Concern

We measure our liquidity in a number of ways, including the following:

	December 31,	
	2024	2023
Cash and Cash Equivalents	$ 2,121,463	$ 14,849,057
Working Capital	$ (13,279,008)	$ 11,176,336
Notes Payable (Gross)	$ 10,740,402	$ 15,637,500

Cash Flow

Since inception, we have experienced negative cash flows from operations and our operations have primarily been funded by proceeds received in equity and debt financings. At December 31, 2024, our accumulated deficit since inception was $195.3 million. As of December 31, 2024, we had a cash and cash equivalents balance of $2.1 million, a working capital deficit of approximately $13.1 million and stockholders' deficiency of $12.7 million. As of December 31, 2024 and December 31, 2023, we had $10.7 million and $15.6 million, respectively, of gross debt outstanding.

During the years ended December 31, 2024 and 2023, our sources and uses of cash were as follows:

Net cash used in operating activities for the year ended December 31, 2024 was approximately $30.1 million, which includes cash used to fund a net loss of $49.8 million, increased by $0.3 million of net cash used by changes in the levels of operating assets and liabilities, partially offset by $20.0 million of non-cash expenses. Net cash used in operating activities for the year ended December 31, 2023 was approximately $23.8 million, which includes cash used to fund a net loss of $27.3 million, increased by $1.5 million of net cash used by changes in the levels of operating assets and liabilities, partially offset by $4.9 million of non-cash expenses.

Net cash used in investing activities for the year ended December 31, 2024 was approximately $0.2 million, which was primarily related to the purchase of property and equipment. Net cash used in investing activities for the year ended December 31, 2023 was approximately $4.0 million, which includes $2.9 million attributable to purchases of property and equipment and $1.1 million attributable to the license agreement with Formosa.

Net cash provided by financing activities for the year ended December 31, 2024 totaled approximately $17.6 million, which was primarily attributable to $17.0 million of net proceeds from the sale of common stock and warrants in equity offerings and, $6.1 million of net proceeds from the sale of common stock in our "at-the-market" offering, partially offset by $5.5 million from the repayment of notes payable. Net cash provided by financing activities for the year ended December 31, 2023 totaled approximately $19.8 million, which was primarily attributable to $10.9 million of net proceeds from the sale of common stock and warrants from an equity offering, $4.6 million of net proceeds from the sale of common stock in our at-the-market offering and $4.9 million of net proceeds from the credit facility with Avenue, partially offset by $0.6 million from the repayment of notes payable.

Contractual Obligations and Commitments

During the next twelve months we have commitments to pay (a) $5.5 million to settle our December 31, 2024 accounts payable, accrued expenses and other current liabilities, (b) $0.6 million relating to our non-cancelable operating lease commitments, and (c) $10.7 million of gross payments due under our notes payable and convertible notes payable (if not previously converted).

After the next twelve months we have commitments to pay (a) $0.7 million relating to our non-cancelable operating lease commitments.

Avenue Loan and Security Agreement

As discussed in Note 8 – Notes Payable and Convertible Notes Payable, on November 22, 2022, we entered into the Loan and Security Agreement with Avenue, for an aggregate principal amount of up to $15,000,000. The initial tranche of the Loan and Security

Agreement was $10,000,000. On May 22, 2023, pursuant to the Loan and Security Agreement, we received an additional tranche of debt funding in the amount of $5,000,000. The Avenue Loan bears interest at an annual rate equal to the greater of (A) 7.0% and (B) the prime rate as reported in The Wall Street Journal plus 4.45%. The Avenue Loan maturity date is November 1, 2025. The additional funding triggered the extension of the interest-only period from the original 12 months to 18 months (through May 2024) for the entire outstanding balance due under the Loan and Security Agreement (initial and additional tranches).

Following the interest-only period, we will make equal monthly payments of principal until the maturity date, plus interest. We must also make a final payment equal to 4.25% of the initial and additional tranches, amounting to a premium of $637,500 on the aggregate borrowing. If we prepay the Avenue Loan, we will be required to pay a prepayment fee of 2% if the Avenue Loan is prepaid during the second year and 1% if the Avenue Loan is repaid during the third year.

On November 22, 2024, we entered into an amendment of the Avenue Loan whereby the Lender agreed to defer principal and interest payments on the amounts outstanding until March 2025.

On February 21, 2025, we entered into a second amendment of the Avenue Loan whereby the Lender agreed to defer principal and interest payments on amounts outstanding until the end of September 2025. Deferred interest will accrue on the outstanding principal amount at the interest rate stated in the original Avenue Loan. Pursuant to the amendment, up to $10,000,000 of the principal amount outstanding may be converted at the option of the Lender into shares of our common stock at a conversion price of $1.68 per share, subject to typical anti - dilution adjustments

The Avenue Loan requires us to make and maintain representations and warranties and other agreements that are customary in Loan agreements of this type. The Avenue Loan is secured by all of our assets globally, including intellectual property. The Avenue Loan also contains customary events of default, including non-payment of principal or interest, violations of covenants, bankruptcy and material judgments. Upon the occurrence of an event of default, all interest and principal will be accelerated and immediately become due and payable. In addition, Avenue will have the right to exercise any other right or remedy provided by applicable law.

Going Concern

As of December 31, 2024, we had cash and cash equivalents of approximately $2.1 million and an accumulated deficit of approximately $195.3 million. For the years ended December 31, 2024 and 2023, we incurred net losses of approximately $49.8 million and $27.3 million, respectively, and used cash in operations of approximately $30.1 million and $23.8 million, respectively. We do not have recurring revenue and have not yet achieved profitability. We expect to continue to incur cash outflows from operations. These circumstances raise substantial doubt about our ability to continue as a going concern for at least one year from the date that these financial statements are issued. Implementation of our plans and our ability to continue as a going concern will depend upon our ability to generate sufficient recurring revenues, ability to raise further capital, through the sale of additional equity or debt securities or the completion of a transaction consistent with the strategic alternatives that we are exploring or otherwise, to support our future operations.

Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings. If we are unable to generate sufficient recurring revenues, secure additional capital, or the completion of a transaction consistent with the strategic alternatives that we are exploring. we may be required to curtail our research and development initiatives, take additional measures to reduce costs in order to conserve our cash or file for bankruptcy.

Risks and Uncertainties

The continuing worldwide implications of the war between Russia and Ukraine and the conflict in the Middle East remain difficult to predict at this time. The imposition of sanctions on Russia by the United States and other countries and counter sanctions by Russia, and the resulting economic impacts on oil prices and other materials and goods, could affect the price of materials used in the manufacture of our product candidates. If the price of materials used in the manufacturing of our product candidates increase, that would adversely affect our business and the results of our operations.

Critical Accounting Estimates

We prepare our financial statements in accordance with U.S. generally accepted accounting principles, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined above.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data.

See the financial statements included at the end of this report beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on his evaluation, our principal executive officer and principal financial and accounting officer concluded that, as of December 31, 2024, our disclosure controls and procedures were designed to, and were effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosures as of December 31, 2024.

Management's Report on Internal Control over Financial Reporting

Our management, including our principal executive officer and principal financial and accounting officer, is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and

expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013 Framework). Based on this evaluation under the 2013 Framework, our principal executive officer and principal financial and accounting officer has concluded that our internal control over financial reporting was ineffective as of December 31, 2024.

Specifically, management's conclusion was based on the following material weaknesses which existed as of December 31, 2024:

- We failed to properly design and implement effective controls over the accounting for certain significant and complex, non-routine transactions and events. Specifically, the Company failed to properly account for the fair value of common equity shares issued in relation to the consideration for licensing agreements and debt modification.

- We failed to properly design and implement effective controls over identifying and recording impairments of Right-of-Use (ROU) assets. Specifically, we determined that the controls designed to review and approve the impairment analysis for ROU assets were not adequately designed or operating effectively. This deficiency resulted from a lack of sufficient precision in our control activities to properly account for the impairment of ROU assets and to appropriately measure the impairment loss.

A material weakness is a control deficiency or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Notwithstanding the existence of the material weaknesses as described above, we believe that the financial statements in this Annual Report fairly present, in all material respects, our financial position, results of operations and cash flows as of the dates, and for the periods presented, in conformity with GAAP.

Remediation Plan

Our management is committed to taking further action and implementing necessary enhancements or improvements, including those necessary to address the material weaknesses cited above. However, the material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption for non-accelerated filers.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Information required by this Item concerning our directors is incorporated by reference from the sections captioned "Election of Directors" and "Corporate Governance Matters" contained either in our proxy statement related to the 2025 Annual Meeting of Stockholders (the "2025 Proxy Statement") or an amendment to this Form 10-K, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

The information required by this Item concerning our Audit Committee is incorporated by reference from the section captioned "Corporate Governance Matters —Board Committees—Audit Committee" contained in our 2025 Proxy Statement or an amendment to this Form 10-K.

We have adopted a code of business conduct and ethics relating to the conduct of our business by all of our employees, executive officers, and directors. The policy is posted on our website, www.eyenovia.com.

The information required by this Item concerning our executive officers is incorporated by reference from the section captioned "Executive Officers" contained in our 2025 Proxy Statement or an amendment to this Form 10-K.

The information required by this Item concerning compliance with Section 16(a) of the Exchange Act is incorporated by reference from the section captioned "Delinquent Section 16(a) Reports" contained in our 2025 Proxy Statement or an amendment to this Form 10-K.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference to the information under the sections captioned "Executive Compensation," and "Director Compensation" contained in our 2025 Proxy Statement or an amendment to this Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table provides information as of December 31, 2024 about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing equity compensation plans (including individual arrangements):

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders			
2014 Equity Incentive Plan, as amended	8,889	$ 280.41	—
Amended and Restated 2018 Omnibus Stock Incentive Plan	66,886	209.50	14,227
Equity compensation plans not approved by security holders	—	—	—
Total	75,775	$ 217.82	14,227

The other information required by this Item is incorporated by reference to the information under the section captioned "Security Ownership of Certain Beneficial Owners and Management" contained in our 2025 Proxy Statement or an amendment to this Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference to the information under the section captioned "Certain Relationships and Related-Party Transactions" and "Corporate Governance Matters" contained in our 2025 Proxy Statement or an amendment to this Form 10-K.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated by reference to the information under the section captioned "Audit Committee Report" contained in our 2025 Proxy Statement or an amendment to this Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List of documents filed as part of this report:

1. Financial Statements:

   The financial statements of the Company and the related reports of the Company's independent registered public accounting firm thereon have been filed under Item 8 hereof.

2. Financial Statement Schedules:

   None.

3. Exhibits Index

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

		Incorporated by Reference from Filings as Noted Below (Unless Otherwise Indicated)			
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**
3.1	Third Amended and Restated Certificate of Incorporation	8-K	001-38365	3.1	January 29, 2018
3.1.1	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation	8-K	001-38365	3.1.1	June 14, 2018
3.1.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation	8-K	001-38365	3.1	June 14, 2024
3.1.3	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation	8-K	001-38365	3.1	January 31, 2025
3.2	Second Amended and Restated Bylaws	8-K	001-38365	3.1	February 7, 2022
4.1	Description of Securities		-		Filed herewith
4.2	Form of Class B Warrant Issued on March 24, 2020	8-K	001-38365	4.2	March 25, 2020
4.3	Warrant Amendment Agreement, dated June 28, 2024	8-K	001-38365	10.3	July 1, 2024
4.4	Form of Warrant Issued on May 7, 2021	8-K	001-38365	4.1	May 10, 2021
4.5	Form of Warrant Issued on July 1, 2024	8-K	001-38365	4.1	July 1, 2024
4.6	Form of Warrant Issued on September 30, 2024	8-K	001-38365	4.1	September 30, 2024

4.7	Amendment No. 1 to Warrant Issued on September 30, 2024, dated December 9, 2024		--		Filed herewith
4.8	Form of Warrant Issued on November 26, 2024	8-K	001-38365	4.1	November 26, 2024
4.9	Amendment No. 1 to Warrant Issued on November 26, 2024, dated December 9, 2024		-		Filed herewith
4.10	Form of Warrant Issued on December 9, 2024	8-K	001-38365	4.1	December 9, 2024
4.11	Form of Series A Warrant Issued on January 17, 2025	8-K	001-38365	4.1	January 16, 2025
4.12	Form of Series B Warrant Issued on January 17, 2025	8-K	001-38365	4.2	January 16, 2025
10.1	Exclusive License Agreement, dated March 18, 2015, between Eyenovia, Inc. and Senju Pharmaceutical Co., Ltd.	S-1	333-222162	10.1	December 19, 2017
10.1.1#	Amendment to the Exclusive License Agreement by and between Eyenovia, Inc. and Senju Pharmaceutical Co., Ltd., dated April 8, 2020	10-Q	001-38365	10.24	August 14, 2020
10.1.2#	Letter Agreement by and between Eyenovia, Inc. and Senju Pharmaceutical Co., Ltd., dated August 10, 2020	10-Q	001-38365	10.27	August 14, 2020
10.1.3#	Amendment No. 2 to the Exclusive License Agreement by and between Eyenovia, Inc. and Senju Pharmaceutical Co., Ltd., dated September 14, 2021	10-Q	001-38365	10.2	November 12, 2021
10.4#	License Agreement by and between Eyenovia, Inc. and Arctic Vision (Hong Kong) Limited, dated August 10, 2020	10-Q	001-38365	10.28	August 14, 2020
10.5#	Amendment No. 1 to License Agreement by and between Eyenovia, Inc. and Arctic Vision (Hong Kong) Limited, dated September 14, 2021	10-Q	001-38365	10.1	November 12, 2021
10.6#	Mutual Termination and Reassignment, dated January 12, 2024, by and between Eyenovia, Inc and Bausch + Lomb Ireland Limited	10-K	001-38365	10.38	March 18, 2024
10.8#	License Agreement, dated August 15, 2023, by and between Eyenovia, Inc. and Formosa Pharmaceuticals, Inc.	10-Q	001-38365	10.1	November 13, 2023

10.9	Loan and Security Agreement, dated November 22, 2022, by among Eyenovia, Inc., Avenue Capital Management II, L.P., Avenue Venture Opportunities Fund, L.P. and Avenue Venture Opportunities Fund II, L.P.	10-K	001-38365	10.30	March 31, 2023
10.10	Supplement to the Loan and Security Agreement, dated November 22, 2022, by among Eyenovia, Inc., Avenue Capital Management II, L.P., Avenue Venture Opportunities Fund, L.P. and Avenue Venture Opportunities Fund II, L.P.	10-K	001-38365	10.31	March 31, 2023
10.11	Subscription Agreement, dated November 22, 2022, by and among Eyenovia, Inc., Avenue Venture Opportunities Fund, L.P. and Avenue Venture Opportunities Fund II, L.P.	10-K	001-38365	10.32	March 31, 2023
10.15*#	Employment Agreement, dated July 26, 2022, by and between Eyenovia, Inc, and Michael Rowe	10-Q	001-38365	10.2	August 11, 2022
10.17*	Employment Agreement, dated December 19, 2022, by and between Eyenovia, Inc. and Bren Kern	10-K	001-38365	10.33	March 31, 2023
10.18*	Non-Employee Director Compensation Policy, as amended	10-Q	001-38365	10.1	November 14, 2022
10.19*	Eyenovia, Inc. 2014 Equity Incentive Plan, as amended	S-8	333-233278	10.14	August 14, 2019
10.20*	Form of Nonqualified Stock Option Agreement	S-8	333-233278	10.15	August 14, 2019
10.21*	Eyenovia, Inc. Amended and Restated 2018 Omnibus Stock Incentive Plan, as Amended	8-K	001-38365	10.1	June 27, 2023
10.22*	Form of Restricted Stock Unit Agreement	10-K/A	001-38365	10.34	May 1, 2023
10.23*	Form of Notice of Inducement Stock Option Grant	10-Q	001-38365	10.7	November 12, 2024
10.24*	Form of Indemnification and Advancement Agreement	10-Q	001-38365	10.8	November 12, 2024
10.25#	Amended and Restated Sales Agreement, dated December 30, 2024, by and between Eyenovia, Inc. and Chardan Capital Markets, LLC	8-K	001-38365	1.1	December 30, 2024
10.26	Inducement Letter, dated January 16, 2025	8-K	001-38365	10.1	January 16, 2025

19.1	Insider Trading Policy		--	Filed herewith
23.1	Consent of Marcum LLP		--	Filed herewith
31.1	Certification of the Principal Executive Officer and Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002		--	Filed herewith
32.1	Certification of the Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		--	Filed herewith
32.2	Certification of the Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		--	Filed herewith
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation	10-K	001-38365	March 18, 2024
101	Inline interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets as of December 31, 2024 and 2023; (ii) Statements of Operations for the Years Ended December 31, 2024 and 2023; (iii) Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2024 and 2023; (iv) Statements of Cash Flows for the Years Ended December 31, 2024 and 2023; and (v) Notes to Financial Statements		--	Filed herewith
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document contained in Exhibit 101		--	Filed herewith

* Management contract or other compensatory plan.

\# Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) are the type of information that the Company treats as private or confidential.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Sections 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

EYENOVIA, INC.

Date: April 15, 2025

By: /s/ Michael Rowe
Michael Rowe
Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael Rowe Michael Rowe	Chief Executive Officer (Principal Executive and Financial and Accounting Officer) and Director	April 15, 2025
/s/ Tsontcho Ianchulev Tsontcho Ianchulev	Director	April 15, 2025
/s/ Rachel Jacobson Rachel Jacobson	Director	April 15, 2025
/s/ Charles E. Mather IV Charles E. Mather IV	Director	April 15, 2025
/s/ Ram Palanki Ram Palanki	Director	April 15, 2025
/s/ Ellen Strahlman Ellen Strahlman	Director	April 15, 2025
/s/ Michael Geltzeiler Michael Geltzeiler	Director	April 15, 2025

EYENOVIA, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Eyenovia, Inc**.**

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Eyenovia, Inc. (the "Company") as of December 31, 2024 and 2023, the related statements of operations, changes in stockholders' (deficiency) equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit**s**. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum llp

Marcum llp

We have served as the Company's auditor since 2017.

New York, NY
April 15, 2025

EYENOVIA, INC.

Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current Assets		
Cash and cash equivalents	$ 2,121,463	$ 14,849,057
Inventories	—	109,798
Deferred clinical supply costs	—	4,256,793
License fee and expense reimbursements receivable	24,827	123,833
Security deposits, current	14,968	1,506
Prepaid expenses and other current assets	605,941	1,365,731
Total Current Assets	2,767,199	20,706,718
Property and equipment, net	—	3,374,384
Security deposits, non-current	182,200	197,168
Intangible assets	—	2,122,945
Operating lease right-of-use asset	718,360	1,666,718
Equipment deposits	—	711,441
Total Assets	$ 3,667,759	$ 28,779,374
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,199,768	$ 1,753,172
Accrued compensation	144,161	1,658,613
Accrued expenses and other current liabilities	3,178,513	287,928
Operating lease liabilities - current portion	575,163	501,250
Notes payable - current portion, net of debt discount of $527,870 and $503,914 as of December 31, 2024 and 2023, respectively	5,212,532	5,329,419
Convertible notes payable - current portion, net of debt discount of $263,930 and $0 as of December 31, 2024 and 2023, respectively	4,736,070	—
Total Current Liabilities	16,046,207	9,530,382
Operating lease liabilities - non-current portion	717,504	1,292,667
Notes payable - non-current portion, net of debt discount of $0 and $448,367 as of December 31, 2024 and 2023, respectively	—	4,355,800
Convertible notes payable - non-current portion, net of debt discount of $0 and $398,569 as of December 31, 2024 and 2023, respectively	—	4,601,431
Total Liabilities	16,763,711	19,780,280
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; none issued and outstanding as of December 31, 2024 and 2023		
Common stock, $0.0001 par value, 300,000,000 shares authorized; 1,506,369 and 569,409 shares issued and outstanding as of December 31, 2024 and 2023, respectively	151	57
Additional paid-in capital	182,213,889	154,490,596
Accumulated deficit	(195,309,992)	(145,491,559)
Total Stockholders' Equity	(13,095,952)	8,999,094
Total Liabilities and Stockholders' Equity	$ 3,667,759	$ 28,779,374

The accompanying notes are an integral part of these financial statements.

EYENOVIA, INC.

Statements of Operations

	For the Years Ended December 31,	
	2024	**2023**
Operating Income		
Revenue	$ 57,336	$ 3,787
Cost of revenue	(3,927,228)	(16,005)
Gross Profit	(3,869,892)	(12,218)
Operating Expenses:		
Research and development	14,462,722	12,975,832
Selling, general and administrative	14,333,114	12,418,396
Reacquisition of license rights	4,864,600	—
Asset impairments	11,207,897	—
Total Operating Expenses	44,868,333	25,394,228
Loss From Operations	(48,738,225)	(25,406,446)
Other (Expense) Income:		
Other expense	(90,601)	(176,411)
Change in fair value of equity consideration payable	1,240,800	—
Interest expense	(2,484,431)	(2,371,851)
Interest income	254,024	693,612
Total Other Expense	(1,080,208)	(1,854,650)
Net Loss	$ (49,818,433)	$ (27,261,096)
Net Loss Per Share - Basic and Diluted	$ (59.81)	$ (53.15)
Shares Outstanding - Basic and Diluted	832,997	512,912

The accompanying notes are an integral part of these financial statements.

EYENOVIA, INC.

Statements of Changes in Stockholders' (Deficiency) Equity

	For the Years Ended December 31, 2024 and 2023				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	(Deficiency) Equity
Balance - January 1, 2023	458,362	$ 46	$ 135,464,982	$ (118,230,463)	$ 17,234,565
Issuance of common stock and warrants in registered direct offering [1][5]	52,482	5	10,886,109	—	10,886,114
Issuance of common stock as consideration for licensing agreement [2]	6,097	1	999,999	—	1,000,000
Exercise of pre-funded stock warrants	28,162	3	22,526	—	22,529
Issuance of common stock in At the Market Program [3]	23,326	2	4,591,890	—	4,591,892
Cashless exercise of stock options	259	—	—	—	—
Exercise of stock options	125	—	27,200	—	27,200
Stock-based compensation	—	—	2,497,890	—	2,497,890
Issuance of common stock related to vested restricted stock units	596	—	—	—	—
Warrant modification - incremental value [4]	—	—	1,738,700	—	1,738,700
Warrant modification - in issuance costs for registered direct offering [5]	—	—	(1,738,700)	—	(1,738,700)
Net loss	—	—	—	(27,261,096)	(27,261,096)
Balance - December 31, 2023	569,409	57	154,490,596	(145,491,559)	8,999,094
Issuance of common stock in At the Market Program [6]	70,381	7	6,047,362	—	6,047,369
Issuance of common stock as consideration for licensing agreement [7]	7,668	1	436,808	—	436,809
Issuance of common stock as consideration for reacquisition of licensing agreement [8]	28,742	3	2,322,388	—	2,322,391
Issuance of common stock and warrants in offerings [9]	653,493	66	17,011,256	—	17,011,322
Exercise of pre-funded stock warrants	152,905	15	1,208	—	1,223
Warrant modification and additional warrants - incremental value [10]	—	—	2,868,000	—	2,868,000
Warrant modification and additional warrants - in issuance costs for offering [11]	—	—	(2,868,000)	—	(2,868,000)
Issuance of common stock as consideration for modification of loan agreement	23,771	2	199,998	—	200,000
Stock-based compensation	—	—	1,704,273	—	1,704,273
Net loss	—	—	—	(49,818,433)	(49,818,433)
Balance - December 31, 2024	1,506,369	$ 151	$ 182,213,889	$ (195,309,992)	$ (13,095,952)

[1] Includes gross proceeds of $11,977,468 less total cash issuance costs of $1,091,354.
[2] Shares issued as partial consideration for License Agreement with Formosa Pharmaceuticals Inc.
[3] Includes gross proceeds of $4,733,909 less total issuance costs of $142,017.
[4] Warrant originally granted in the March 2022 offering was modified in connection with the registered direct offering
[5] Warrant modification in connection with registered direct offering accounted for as a non-cash issuance cost of the registered direct offering, but is presented on a separate line item for clarity.
[6] Includes gross proceeds of $6,234,402 less total issuance costs of $187,033.
[7] Shares issued as partial consideration for License Agreement with Formosa Pharmaceuticals Inc.
[8] Shares issued as partial consideration for reversion of License Agreement with Bausch & Lomb Ireland Limited.
[9] Includes gross proceeds of $19,385,015, less total cash issuance costs of $2,373,693.
[10] Offering includes modification of warrants and additional warrants in the July 2024 offering.
[11] Non-cash warrant modification and additional warrants issuance costs related to one of the offerings are shown on a separate line item for clarity.

The accompanying notes are an integral part of these financial statements.

EYENOVIA, INC.

Statements of Cash Flows

	For the Years Ended December 31,	
	2024	**2023**
Cash Flows From Operating Activities		
Net loss	$ (49,818,433)	$ (27,261,096)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,704,273	2,497,890
Change in fair value of equity consideration payable	(1,240,800)	—
Depreciation of property and equipment	1,128,449	783,208
Amortization of debt discount	759,049	681,860
Asset impairments	11,207,897	—
Write-down of inventories to net realizable value	3,085,450	12,218
Provision for returned clinical supplies	—	400,000
Reacquisition of license rights	2,864,600	—
Non-cash rent expense	528,359	529,311
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	554,020	434,128
License fee and expense reimbursement receivables	99,006	1,059,953
Deferred clinical supply costs	868,328	(2,271,862)
Inventories	—	(122,016)
Security and equipment deposits	1,506	1,750
Accounts payable	446,596	324,889
Accrued compensation	(1,514,452)	(88,578)
Accrued expenses and other current liabilities	(293,579)	(315,148)
Lease liabilities	(501,250)	(503,046)
Net Cash Used In Operating Activities	(30,120,981)	(23,836,539)
Cash Flows From Investing Activities		
Purchases of property and equipment	(161,477)	(2,847,592)
Investment in intangible asset	—	(1,122,945)
Net Cash Used In Investing Activities	(161,477)	(3,970,537)
Cash Flows From Financing Activities		
Proceeds from sale of common stock and warrants in offerings [1] [2]	19,385,015	11,977,468
Payment of offerings issuance costs	(2,373,693)	(1,091,354)
Proceeds from sale of common stock in At the Market Program	6,234,402	4,733,909
Payment of issuance costs for At the Market Program	(187,033)	(142,017)
Proceeds from exercise of stock options	—	27,200
Proceeds from exercise of stock warrants	1,223	22,529
Proceeds from note payable and equity issued to Avenue	—	5,000,000
Payment of issuance costs for notes issued to Avenue	—	(125,982)
Repayments of notes payable	(5,505,050)	(609,140)
Net Cash Provided By Financing Activities	17,554,864	19,792,613
Net Decrease in Cash and Cash Equivalents	(12,727,594)	(8,014,463)
Cash and Cash Equivalents - Beginning of Period	14,849,057	22,863,520
Cash and Cash Equivalents - End of Period	$ 2,121,463	$ 14,849,057

The accompanying notes are an integral part of these financial statements.

EYENOVIA, INC.

Statements of Cash Flows, continued

	For the Years Ended December 31,	
	2024	**2023**
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ 1,622,479	$ 1,690,548
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Purchase of insurance policy financed by note payable	$ 505,050	$ 609,140
Accrual for intangible asset milestone obligation	$ 2,000,000	$ —
Reclassification of deferred clinical supply costs to inventories	$ 2,975,652	$ —
Right-of-use assets and lease liabilities recognized upon lease renewal	$ —	$ 904,437
Vendor deposits applied to purchases of property and equipment	$ —	$ 14,885
Original issue discount on notes payable	$ —	$ 212,500
Warrant modification and additional warrants - incremental value	$ 2,868,000	$ 1,738,700
Issuance of common stock as consideration for licensing agreement	$ —	$ 1,000,000
Cashless exercise of stock options	$ —	$ 2
Common stock issued as consideration for licensing agreement	$ 436,809	$ —
Common stock issued as consideration for reacquisition of licensing agreement	$ 2,322,391	$ —
Common stock issued in consideration for equipment received in conjunction with licensing agreement	$ (135,400)	$ —
Common stock issued as consideration for modification of loan agreement	$ 200,000	$ —
Interest expense added to note principal	$ 102,902	$ —
Issuance of common stock related to vested restricted stock units	$ —	$ 4

[1] For 2023, includes gross proceeds of $11,977,468, of which $4,168,011 is pre-funded warrants.
[2] For 2024, includes gross proceeds of $19,385,015, of which $1,240,926 is pre-funded warrants.

The accompanying notes are an integral part of these financial statements.

Note 1 – Business Organization, Nature of Operations and Basis of Presentation

Organization and Operations

Eyenovia, Inc., ("Eyenovia" or the "Company") is an ophthalmic technology company developing a proprietary Optejet® topical ophthalmic medication dispensing platform. In November 2024, the Company received a negative clinical trial result in their development-stage drug-device combination product, MicroPine. As a result, the Company restructured, minimized expenses and engaged with an investment bank to explore strategic options in order to maximize shareholder value. The Company has paused the national sales roll-out of its products clobetasol propionate and Mydcombi® until additional funding can be obtained. At the same time, the Company accelerated development efforts relating to the Optejet.

Basis of Presentation

On January 31, 2025, the Company effected a reverse stock split of its common stock at a ratio of 1–for-80 (the "Reverse Split"). Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the Reverse Split and adjustment of the conversion price or exercise price of each outstanding equity award, convertible security and warrant as if the transaction had occurred as of the beginning of the earliest period presented (see Note 15 – Subsequent Events - Reverse Stock Split)

Note 2 – Summary of Significant Accounting Policies And Going Concern

Going Concern

As of December 31, 2024, the Company had unrestricted cash and cash equivalents of approximately $2.1 million and an accumulated deficit of approximately $195.3 million. For the years ended December 31, 2024 and 2023, the Company incurred net losses of approximately $49.8 million and $27.3 million, respectively, and used cash in operations of approximately $30.1 million and $23.8 million, respectively. The Company does not have recurring revenue and has not yet achieved profitability. The Company expects to continue to incur cash outflows from operations for the near future. These circumstances raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the date that these financial statements are issued. Implementation of the Company's plans and its ability to continue as a going concern will depend upon the Company's ability to generate sufficient recurring revenues, the Company's ability to raise further capital, through the sale of additional equity or debt securities or the completion of a transaction consistent with the strategic alternatives that we are exploring or otherwise, to support its future operations.

The Company's operating needs include the planned costs to operate its business, including amounts required to fund working capital and capital expenditures. The Company's future capital requirements and adequacy of its available funds will depend on many factors, including the Company's ability to execute a strategic partnership or merger, ability to successfully commercialize its products and services, competing technological and market developments, and the need to enter into collaborations with other companies, or acquire other companies or technologies to enhance or complement its product and service offerings. If the Company is unable to generate sufficient recurring revenues or secure additional capital, it may be required to curtail its research and development initiatives, take additional measures to reduce costs in order to conserve its cash or file for bankruptcy.

Use of Estimates

Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP, requires management to make estimates, judgments and assumptions that affect the amounts reported in the financial statements and the amounts disclosed in the related notes to the financial statements. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, fair value calculations for equity securities, establishment of valuation allowances for deferred tax assets, revenue recognition, the recoverability and useful lives of long-lived assets, the realization of inventories and deferred clinical supply costs, the recovery of deferred costs and the deferral of revenues. Certain of the Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that actual results could differ from those estimates.

See Note 2 - Summary of Significant Accounting Policies — Stock-Based Compensation for additional discussion of the use of estimates in estimating the fair value of the Company's common stock.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents in the financial statements. As of December 31, 2024 and 2023, the Company had Treasury bills with original maturity dates of three months or less in the amount of $0 and $5,450,118 respectively.

The Company has cash deposits in financial institutions that, at times, may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits. The Company has not experienced losses in such accounts and periodically evaluates the creditworthiness of its financial institutions. As of December 31, 2024 and 2023, the Company had cash and cash equivalent balances in excess of FDIC insurance limits of $1,658,188 and $14,243,870, respectively.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation, amortization and impairments, which is recorded commencing at the in-service date using the straight-line method at rates sufficient to charge the cost of depreciable assets to operations over their estimated useful lives, which range from 1 to 10 years. Leasehold improvements are amortized over the lesser of (a) the useful life of the asset; or (b) the remaining lease term. Maintenance and repairs are charged to operations as incurred. The Company capitalizes costs attributable to the betterment of property and equipment when such betterment extends the useful life of the assets. Vendor deposits toward the purchase of property and equipment are reflected as equipment deposits on the accompanying balance sheets. The Company commences depreciation of assets when they are placed in service.

Impairment of Long-lived Assets

The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. An impairment would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The Company recorded $11,207,897 in impairment losses during the year ended December 31, 2024, of which $9,797,198 was for the Company's long-lived assets consisting of $6,122,945 of intangible assets, $3,254,254 of property and equipment, which includes $711,441 of equipment deposits, and $420,000 of operating lease right-of-use assets. The Company did not record any impairment losses during the year ended December 31, 2023.

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on Accounting Standards Codification, or ASC Topic 820 "Fair Value Measurements and Disclosures", or ASC 820, which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities;

Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable; and

Level 3 — inputs that are unobservable (for example, cash flow modeling inputs based on assumptions).

The carrying amounts of the Company's financial instruments, such as cash and cash equivalents, restricted cash, accounts payable, and notes payable approximate fair values due to the short-term nature or effective interest rates of these instruments.

Income Taxes

The Company is subject to Federal, New York State and City, and State of California income taxes and files tax returns in those jurisdictions.

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in the financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts, or temporary differences, at enacted tax rates in effect for the years in which such temporary differences are expected to reverse.

The Company utilizes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

The Company's policy is to classify assessments, if any, for tax-related interest as interest expense and penalties as selling, general and administrative expenses in the statements of operations.

Revenue Recognition

The Company's revenues are generated primarily through product sales or research, development and commercialization agreements. The terms of such agreements may contain multiple promised goods and services, which may include (i) licenses to its intellectual property, and (ii) in certain cases, payment in connection with the manufacturing and delivery of clinical supply materials. Payments to the Company under these arrangements typically include one or more of the following: non-refundable, upfront license fees; milestone payments; payments for clinical product supply, and royalties on future product sales.

The Company analyzes its arrangements to assess whether such arrangements involve joint operating activities. For collaboration arrangements that are deemed to be within the scope of ASC Topic 808, "Collaborative Arrangements", or ASC 808, the Company allocates the contract consideration between such joint operating activities and elements that are reflective of a vendor-customer relationship and, therefore, within the scope of ASC Topic 606, "Revenue from Contracts with Customers", or ASC 606. The Company's policy is to recognize amounts allocated to joint operating activities as a reduction in research and development expense.

Under ASC 606, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps:

- Step 1: Identify the contract with the customer;
- Step 2: Identify the performance obligations in the contract;
- Step 3: Determine the transaction price;
- Step 4: Allocate the transaction price to the performance obligations in the contract; and
- Step 5: Recognize revenue when the company satisfies a performance obligation.

During the years ended December 31, 2024 and 2023, the Company recognized revenue primarily from the following type of contract:

Product sales – Revenue is recognized at the point in time the customer obtains control of the goods and the Company satisfies its performance obligation, which is generally at the time it ships the product to the customer.

The Company must make significant judgments in its revenue recognition process, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation. Milestone payments represent variable consideration that will be recognized when the performance obligation is achieved. Sales-based royalty payments derived from usage of intellectual property are recognized when those sales occur.

Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered discretionary purchase options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

During 2020, the Company entered into a license agreement, or the Arctic Vision License Agreement, with Arctic Vision (Hong Kong) Limited, or Arctic Vision, and a license agreement, or the Bausch License Agreement, with Bausch Health Companies, Inc., or Bausch + Lomb. Each license has three revenue components:

1) an upfront license fee;
2) milestone payments and
3) royalty payments.

Arctic Vision License Agreement

On August 10, 2020, the Company entered into the Arctic Vision License Agreement pursuant to which Arctic Vision may develop and commercialize MicroPine for the treatment of progressive myopia and MicroLine for the treatment of presbyopia in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea. On September 14, 2021, the Company and Arctic Vision executed Amendment 1 to the Arctic Vision License Agreement pursuant to which Arctic Vision may develop and commercialize MicroStat for the treatment of mydriasis in Greater China and South Korea.

Milestone Payments

The Company may receive up to $37.7 million in milestone payments in connection with the Arctic Vision License Agreement, as amended, based on various development and regulatory milestones, including the initiation of clinical research and regulatory approvals in Greater China and South Korea, related to the filing of marketing authorization applications of approximately $13.2 million and the receipt of regulatory approvals of approximately $24.5 million. It is currently unknown when the remaining milestones related to the performance obligations will be achieved.

Royalty Payments

Arctic Vision also will purchase its supply of MicroPine, MicroLine and MicroStat from the Company or, for such products not supplied by the Company, pay the Company a mid-single digit percentage royalty on net sales of such products, subject to certain adjustments. No royalty payments were earned through December 31, 2024. The Company will pay a percentage in the range from 30% to 40% of such payments, royalties, or net proceeds of such supply to Senju pursuant to the Senju License Agreement. See Note 10—Related Party Transactions—Senju License Agreement for additional details.

Bausch License Agreements

On October 9, 2020, the Company entered into a license agreement (the Bausch License Agreement"), pursuant to which Bausch + Lomb was permitted to develop and commercialize the Bausch Licensed Product (as defined in the Bausch License Agreement) in the United States and Canada (the "Licensed Territory"). Bausch + Lomb could terminate the Bausch License Agreement, with respect to the Bausch Licensed Product to either country in the Licensed Territory, at any time for convenience upon 90 days' written notice.

On January 12, 2024, the Company and Bausch + Lomb entered into a mutual termination and reassignment agreement (the "Letter Agreement"), pursuant to which Eyenovia reacquired the rights to the Bausch Licensed Product. The terms of the agreement include the immediate transfer of the rights and the subsequent transfer of certain assets relating to the Bausch Licensed Product from Bausch + Lomb to the Company in exchange for cash and common stock consideration. In addition, under the terms of the Letter Agreement, the Company agreed to pay Bausch + Lomb a low single-digit royalty on its net sales of the Bausch Licensed Product in the United States and Canada for a period of ten years from the date of the first commercial sale by the Company (or its affiliates or licensees) of the Bausch Licensed Product in the United States. Under the Letter Agreement, (i) the Company will re-acquire any and all licenses and other rights granted by the Company to Bausch + Lomb under the original Bausch License Agreement, (ii) any and all licenses and other rights granted by Bausch + Lomb to the Company under the License Agreement are terminated, other than as set forth in the Letter Agreement, and (iii) other than as set forth in the Letter Agreement, Bausch + Lomb is released from all of their ongoing obligations under the License Agreement, including development and commercialization obligations.

Pursuant to the Letter Agreement, the Company paid Bausch + Lomb an upfront payment of $ 2.0 million in cash on January 22, 2024. The Company recorded this amount as an operating expense. In connection with the entry into the Letter Agreement, the Company also agreed to issue Bausch + Lomb $ 3.0 million in shares of the Company's common stock, following the Regulatory Transfer Date (the "Transfer Date"). On April 11, 2024, the Transfer Date, the transfer of the rights and certain assets relating to the CHAPERONE trial from Bausch + Lomb to the Company, was completed. On May 3, 2024, the Company issued Bausch + Lomb 28,742 shares of the Company's common stock (calculated pursuant to the Letter Agreement at $3.0 million using a thirty-day volume-weighted average price on April 11, 2024, but valued at $2.3 million on the May 3, 2024 settlement date, resulting in a $0.7 million change in fair value of the equity consideration payable), in satisfaction of its obligations pursuant to the Letter Agreement.

Pursuant to the Side Letter (see Note 10 – Commitments and Contingencies - Defective Clinical Supply), the Company agreed to pay approximately $0.5 million to Bausch + Lomb related to the defective clinical supply. It was also agreed that the Company will receive approximately $0.25 million from Bausch + Lomb to fund the vendor hold back liability that will be due upon completion of the CHAPERONE study. In addition, the Company purchased $0.5 million of clinical supplies from Bausch + Lomb in April 2024.

Clinical Supply Arrangements

Bausch + Lomb and Arctic Vision had contracted with the Company to manufacture and supply them with the appropriate drug-device combination products to conduct their clinical trials on a cost plus 10% mark-up basis. Based on the Letter Agreement with Bausch + Lomb referenced above, the arrangement with Bausch + Lomb is terminated. The arrangement with Arctic Vision is still in place. The Company's licensing agreement with Arctic Vision represent collaborative arrangements and they are not a customer with respect to the clinical supply arrangements. The Company's policy is to (a) defer the materials and manufacturing costs in order to properly match them up against the income from the clinical supply arrangements; and (b) report the net income from the clinical supply arrangements as other income. Deferred clinical supply costs were $0.0 million and $4.3 million at December 31, 2024 and 2023, respectively. Net income from the sale of clinical supplies was included in other income and amounted to $0.0 million and $0.2 million for the years ended December 31, 2024 and 2023, but a $0.4 million provision for possible product returns was also charged against the results for the year ended December 31, 2023. This provision was for the cost to replace or rework the defective clinical supply product. See Note 10 – Commitments and Contingencies – Defective Clinical Supply.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. The cost of inventory that is sold to third parties is included within cost of sales. The Company will periodically review for slow-moving, excess or obsolete inventories.

Inventory is primarily comprised of drug-device combination products, which are available for commercial sale, as follows:

	December 31,	
	2024	2023
Finished goods	$ —	$ 30,683
Work-in-process	—	—
Raw materials	—	79,115
Total inventory	$ —	$ 109,798

During the year ended December 31, 2024, the Company recorded a charge of approximately $3.1 million of inventories to cost of revenue in order to write down inventories to their net realizable value.

Intangible Assets

Intangible assets are stated at fair value as of the date acquired, less accumulated amortization. Amortization is calculated based on the estimated useful lives of the assets, using the straight-line method or another method that more fairly represents the utilization of the assets.

The Company periodically evaluates the remaining useful lives of our intangible assets to determine whether events or circumstances warrant a revision to the remaining periods of amortization. In the event that the estimate of an intangible asset's remaining useful life

has changed, the remaining carrying amount of the intangible asset is amortized prospectively over that revised remaining useful life. If it is determined that an intangible asset has an indefinite useful life, that intangible asset would be subject to impairment testing annually or whenever events or circumstances indicate that its carrying value may not, based on future undiscounted cash flows or market factors, be recoverable.

Operating Leases

The Company leases its facilities under non-cancellable operating leases. The Company evaluates the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease and recognizes the right-of-use asset and lease liabilities based on the present value of future minimum lease payments over the expected lease term. The Company recognizes a liability to make lease payments, the "lease liability", and an asset representing the right to use the underlying asset during the lease term, the "right-of-use asset". The lease liability is measured at the present value of the remaining lease payments, discounted at the Company's incremental borrowing rate. The Company's leases do not generally contain an implicit interest rate and therefore the Company uses the incremental borrowing rate it would expect to pay to borrow on a similar collateralized basis over a similar term in order to determine the present value of its lease payments. The right-of-use asset is measured at the amount of the lease liability adjusted for the remaining balance of any lease incentives received, any cumulative prepaid or accrued rent if the lease payments are uneven throughout the lease term, any unamortized initial direct costs, and any impairment of the right-of-use-asset. Operating lease expense consists of a single lease cost calculated so that the remaining cost of the lease is allocated over the remaining lease term on a straight-line basis, variable lease payments not included in the lease liability, and any impairment of the right-of-use asset.

Research and Development

Research and development expenses are charged to operations as incurred. The Company records prepaid expenses on its balance sheet for the payment of research and development expenses in advance of services being provided.

The Company's license agreements were determined to represent collaborative arrangements. Pursuant to these collaborative arrangements, the licensee is required to reimburse the Company for certain research and development expenses. Providing research and development activities in the context of a collaboration agreement is not an ordinary activity for the Company. Accordingly, the licensee is not a customer with respect to the reimbursements and such payments are not subject to ASC 606 – Revenue Recognition. The Company's policy is to recognize the reimbursements as contra – research and development expense. The receivable for such payments, plus other license payments, is included in "license fee and expense reimbursements receivable" on the accompanying balance sheets.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and the fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. Upon the exercise of an option, the Company issues new shares of common stock out of the shares reserved for issuance under its equity plans. See Note 12 – Stockholders' Equity – Stock Options for additional information related to estimating the fair value of stock options.

Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period, plus fully vested shares that are subject to issuance for little or no monetary consideration. Diluted loss per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock. The following table presents the computation of basic and diluted net loss per common share:

	For the Years Ended December 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (49,818,433)	$ (27,261,096)
Denominator (weighted average quantities):		
Common shares issued	830,569	498,848
Add: Prefunded warrants	—	13,025
Add: Undelivered vested restricted shares	2,428	1,038
Denominator for basic and diluted net loss per share	832,997	512,912
Basic and diluted net loss per common share	$ (59.81)	$ (53.15)

The following securities are excluded from the calculation of weighted average dilutive shares of common stock because their inclusion would have been anti-dilutive:

	December 31,	
	2024	2023
Warrants	1,166,017	136,581
Options	68,183	66,329
Convertible notes	29,096	29,096
Restricted stock units	4,611	1,325
Total potentially dilutive shares	1,267,907	233,331

Subsequent Events

The Company has evaluated subsequent events through the date which the financial statements were issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed.

Recently Issued Accounting Standards

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The amendments in this update address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This update also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this standard but does not expect it to have a material impact on its financial statements.

In November 2024, The FASB issued ASU 2024-03, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220 – 04). This update requires an entity to disclose more detailed information regarding expenses for the entity. The amendments require that at each interim and the annual reporting period, the entity must disclose amounts related to purchases of inventory, employee compensation, depreciation, intangible asset amortization and depreciation, depletion, and amortization recognized as part of oil and gas- producing activities. Including the amounts, the entity is required to disclose and qualitative description of the amounts remaining in relevant expense captions, and to disclose the total amount of selling expenses and the definition of selling

expenses. The amendments in this update should be applied prospectively to financial statements issued for reporting periods, and retrospectively to any prior periods presented in the financials. Although early adoption is permitted, the new guidance becomes effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Since this new ASU addresses only disclosures, the Company does not expect the adoption of this ASU to have any material effects on its financial condition, results of operations or cash flows.

Recently Adopted Accounting Standards

In November 2023, the FASB issued ASU 2023-07 "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures." These amendments require a public entity to disclose significant segment expenses and other segment items on an annual and interim basis and to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. Public entities with a single reporting segment are required to provide both the new disclosures and all of the existing disclosures required under ASC 280. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted this ASU for the year ended December 31, 2024. Since this new ASU addresses only disclosures, the adoption of this ASU did not have a material effect on the Company's financial condition, results of operations or cash flows.

Note 3 – Prepaid Expenses and Other Current Assets

As of December 31, 2024 and 2023, prepaid expenses and other current assets consisted of the following:

	December 31,	
	2024	2023
Payroll tax receivable	$ 288,705	$ 500,684
Prepaid insurance expenses	148,117	167,338
Prepaid general and administrative expenses	61,610	85,938
Prepaid patent expenses	49,967	48,409
Prepaid research and development expenses	26,996	421,056
Prepaid rent and security deposit	18,750	18,750
Other	10,688	—
Prepaid conference expenses	1,108	123,556
Total prepaid expenses and other current assets	$ 605,941	$ 1,365,731

As of December 31, 2024, the Company wrote off $710,820 of prepaid regulatory expenses, due to the uncertainty associated with the Company's clobetasol propionate and Mydcombi products and its exploration of strategic alternatives.

Note 4 - Property and Equipment, Net

As of December 31, 2024 and 2023, property and equipment consisted of the following:

	December 31,	
	2024	2023
Equipment	$ 4,013,211	$ 3,038,651
Leasehold improvements	1,788,537	1,754,779
	5,801,748	4,793,430
Less: impairment	(3,254,254)	—
Less: accumulated depreciation	(2,547,494)	(1,419,046)
Property and equipment, net	$ —	$ 3,374,384
Equipment not yet placed in service	$ —	$ 711,441

Depreciation expense was $1,128,449 and $783,208 for the years ended December 31, 2024 and 2023, respectively, of which $1,112,464 and $776,479, respectively, was included within research and development expenses and $15,985 and $6,729, respectively, was included in selling, general and administrative expenses in the accompanying statements of operations.

As of December 31, 2023, the Company had $711,441 of outstanding deposits for equipment purchases, which are presented as non-current assets on the balance sheet. As of December 31, 2024, the Company impaired the $711,441 outstanding deposits due to the uncertainty associated with idling its manufacturing operations for Mydcombi.

Additionally, the Company impaired $3,254,254 of its remaining fixed assets due to the uncertainty associated with its operations and its exploration of strategic alternatives.

Note 5 – Intangible Assets

On August 15, 2023, the Company entered into a license agreement (the "Formosa License") with Formosa Pharmaceuticals Inc. ("Formosa"), whereby the Company acquired the exclusive U.S. rights to commercialize any product related to a novel formulation of clobetasol propionate ophthalmic suspension, 0.05% (the "Formosa Licensed Product"), which was approved by the FDA for ophthalmic use for inflammation and pain after ocular surgery and supplemental disease indications, if any, associated with the New Drug Application for the Formosa Licensed Product. The Formosa License will remain in effect for ten years from the date of the first commercial sale of a Formosa Licensed Product, unless earlier terminated. The Company paid Formosa the aggregate amount of $2.0 million (the "Upfront Payment"), consisting of (a) cash in the amount of $1.0 million and (b) 6,097 shares of common stock, which is included in Intangible Assets on the accompanying balance sheet. The Company also capitalized $122,945 of transaction costs, which were primarily legal expenses. In addition to the Upfront Payment, the Company must pay Formosa up to $4.0 million upon the achievement of certain development milestones and up to $80.0 million upon the achievement of certain sales milestones. The trigger for the initial $2.0 million development milestone payments was FDA approval of the Formosa Licensed Product and the effective date of the acceptance by the Company of the transfer and assignment of the FDA approval. This occurred on March 14, 2024. Under the provisions of the Formosa License, the Company had 45 days from the effective date of acceptance of the transfer and assignment of FDA approval to make the payment half in cash and half in common stock, otherwise the payment due would revert to be fully in cash. The Company paid Formosa the aggregate amount of $2.0 million, consisting of (a) cash in the amount of $1.0 million on April 26, 2024 and (b) 7,668 shares of common stock on April 29, 2024 (calculated pursuant to the Formosa License using a five-day volume-weighted average price on March 14, 2024, but valued at $0.4 million on the April 29, 2024 settlement date, resulting in a $0.6 million change in fair value of the equity consideration payable), which was included in our impairment of Intangible Assets at December 31, 2024. The second $2.0 million development milestone (to be fully paid in cash) was earned upon FDA approval of the Formosa Licensed Product and payment was triggered on the earlier of twelve months after FDA approval or six months following the first commercial sale of the Formosa Licensed Product. As of the Form 10-K filing date, this payment remains unpaid and under negotiation. Because the payment became probable and estimable, the Company recorded an additional $2.0 million increase in the intangible asset which was included in accrued expenses at December 31, 2024.

It was determined that the transaction represented an asset acquisition, rather than a business combination, because substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset. Consequently, the accounting is pursuant to the cost accumulation model. The Upfront Payment has been capitalized as an intangible asset by the Company.

In October 2024, the Company had its first commercial sale of the Licensed Product, however, due to the uncertainty associated with its clobetasol propionate product, the Company impaired the full $6,122,945 carrying value of the Formosa License at December 31, 2024.

Note 6 – Accrued Compensation

As of December 31, 2024 and 2023, accrued compensation consisted of the following:

	December 31,	
	2024	2023
Accrued bonus expenses	$ —	$ 1,302,997
Accrued payroll expenses	144,161	355,616
Total accrued compensation	$ 144,161	$ 1,658,613

Note 7 – Accrued Expenses and Other Current Liabilities

As of December 31, 2024 and 2023, accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2024	2023
Accrued intangible milestone obligation	$ 2,000,000	$ —
Other	302,880	7,835
Accrued licensee reimbursement	295,711	—
Accrued rework of clinical supply returns	250,000	100,000
Accrued fixed asset disposal costs	125,000	—
Accrued professional services	111,750	63,028
Accrued clinical studies costs	85,409	—
Credit card payable	7,763	27,193
Accrued research and development expenses	—	89,872
Total accrued expenses and other current liabilities	$ 3,178,513	$ 287,928

Note 8 – Notes Payable and Convertible Notes Payable

As of December 31, 2024 and 2023, notes payable and convertible notes payable consisted of the following:

	December 31, 2024			December 31, 2023		
	Notes Payable	Debt Discount	Net	Notes Payable	Debt Discount	Net
Current portion:						
Avenue - Note payable	$ 5,740,402	$ (527,870)	$ 5,212,532	$ 5,833,333	$ (503,914)	$ 5,329,419
Avenue - Convertible note payable	5,000,000	(263,930)	4,736,070	—	—	—
Total current portion	$ 10,740,402	$ (791,800)	$ 9,948,602	$ 5,833,333	$ (503,914)	$ 5,329,419
Non-Current portion:						
Avenue - Note payable	$ —	$ —	$ —	$ 4,804,167	$ (448,367)	$ 4,355,800
Avenue - Convertible note payable	—	—	—	5,000,000	(398,569)	4,601,431
Total non-current portion	$ —	$ —	$ —	$ 9,804,167	$ (846,936)	$ 8,957,231

BankDirect Capital Finance Loan

On February 24, 2023, the Company issued a note payable in the amount of $609,140 for the purchase of a directors and officers' liability insurance policy (the "2023 D&O Loan"). The note accrued interest at a rate of 7.11% per year and matured on August 24, 2023. The 2023 D&O Loan was payable in six monthly payments of $103,639 consisting of principal and interest. The note payable was repaid in full during the year ended December 31, 2023. Interest expense was $12,694 for the year ended December 31, 2023.

On February 24, 2024, the Company issued a note payable in the amount of $505,050 for the purchase of a directors and officers' liability insurance policy (the "2024 D&O Loan"). The note accrued interest at a rate of 8.15% per year and matured on October 24, 2024. The 2024 D&O Loan was payable in eight monthly payments of $65,076 consisting of principal and interest. The note payable was repaid in full during the year ended December 31, 2024. Interest expense was $15,558 for the year ended December 31, 2024.

Avenue Ventures Loan

On November 22, 2022, the Company entered into a Loan and Security Agreement (the "Avenue Loan Agreement") with Avenue Venture Opportunities Fund, L.P., ("Avenue 1"), and Avenue Venture Opportunities Fund, L.P. II, ("Avenue 2"), and together with Avenue, (the "Lender"), for an aggregate principal amount of up to $15,000,000 (the "Avenue Loan"). The initial tranche of the Avenue Loan was $10,000,000, consisting of $4,000,000 from Avenue and $6,000,000 from Avenue 2. Up to $5,000,000 of the principal amount outstanding may be converted at the option of the Lender into shares of the Company's common stock at a conversion price of $171.84

per share, subject to typical anti-dilution adjustments. The Avenue Loan bears interest at an annual rate equal to the greater of (a) 7.0% and (b) the prime rate as reported in The Wall Street Journal plus 4.45%. The Avenue Loan maturity date is November 1, 2025. The Company was able to request an additional $5,000,000 of gross funding between April 1, 2023 and July 31, 2023, subject to agreed-upon conditions. The Company must also make an incremental final payment equal to 4.25% of the aggregate funding, amounting to a premium of $425,000 on the initial tranche. The Company will make monthly interest-only payments during the first twelve months of the Avenue Loan, which could be increased to up to eighteen months upon the achievement of specified performance milestones. Following the interest-only period, the Company will make equal monthly payments of principal and interest until the maturity date, plus interest. If the Company prepays the Avenue Loan, it will be required to pay a prepayment fee of 3% if the Avenue Loan is prepaid during the first year, 2% if the Avenue Loan is prepaid during the second year and 1% if the Avenue Loan is repaid during the third year.

On May 22, 2023, pursuant to the Loan and Security Agreement, the Company received an additional tranche of non-convertible debt funding in the amount of $5,000,000. The Company paid approximately $126,000 of origination and legal fees connected to this debt funding. The additional funding is subject to the same interest and maturity date as the initial tranche. The additional funding triggered the extension of the interest-only payment period from the original 12 months to 18 months (through May 2024) for the entire outstanding balance due under the Avenue Loan Agreement (initial and additional tranches). Following the interest-only period, the Company will make equal monthly payments of principal until the maturity date, plus interest. The Company must also make a final payment equal to 4.25% of the additional tranche, amounting to a premium of $212,500 on the additional tranche. The total final payment on the aggregate borrowing is $637,500. If the Company prepays the Avenue Loan, it will be required to pay a prepayment fee of 2% if the Avenue Loan is prepaid during the second year and 1% if the Avenue Loan is repaid during the third year.

In June 2024, the Company began making principal payments related to that certain loan and security agreement (the "Loan and Security Agreement") with Avenue Capital Management II, L.P. and related entities (together, "Avenue") in the amount of $833,333 per month plus interest.

On November 22, 2024, the Company entered into an amendment of the Avenue Loan (the "First Amendment"), whereby the Lender agreed to defer principal and interest payments on the amounts outstanding until March 2025. In connection with the First Amendment, the Company granted an aggregate of 23,771 shares of its common stock to the Lender. The price per share was based on the Company's five trading-day volume-weighted average price (VWAP) preceding the date of the First Amendment of approximately $8.42 per share. The shares have a gross value of approximately $200,000. This is accounted for as a component of debt discount.

The Avenue Loan requires the Company to make and maintain representations and warranties and other agreements that are customary in loan agreements of this type. The Avenue Loan is secured by all of the Company's assets, including intellectual property. The Avenue Loan also contains customary events of default, including non-payment of principal or interest, violations of covenants, bankruptcy and material judgments. Upon the occurrence of an event of default, all interest and principal immediately become due and payable. In addition, Avenue will have the right to exercise any other right or remedy provided by applicable law.

The following is a summary of the Avenue loan at December 31, 2024:

	December 31, 2024		
	Non-Convertible	Convertible	Total
Aggregate Loan Funding	$ 10,000,000	$ 5,000,000	$ 15,000,000
Capitalized Interest Added To Loan Balance	102,902	—	102,902
Final Payment	637,500	—	637,500
	10,740,402	5,000,000	15,740,402
Less: Payments	(5,000,000)	—	(5,000,000)
Less: Unamortized Debt Discount	(527,870)	(263,930)	(791,800)
	5,212,532	4,736,070	9,948,602
Less: Current Portion	(5,212,532)	(4,736,070)	(9,948,602)
Notes Payable, Non-Current	$ —	$ —	$ —

During the years ended December 31, 2024 and 2023, the Company recorded interest expense relating to the Avenue Loan of $2,468,863 (which includes $759,049 of amortization of debt discount) and $2,359,157 (which includes $681,860 of amortization of debt discount), respectively.

See Note 15 – Subsequent Events - Avenue Ventures Loan Second Amendment.

Note 9 – Income Taxes

The provision for income taxes consists of the following (expenses) benefits:

	For The Years Ended December 31,	
	2024	2023
Deferred tax (provision) benefit:		
Federal	$ 12,749,587	$ 5,381,793
State and local	9,773,203	(849,201)
	22,522,790	4,532,592
Change in valuation allowance	(22,522,790)	(4,532,592)
Provision for income taxes	$ —	$ —

The provision for income taxes differs from the United States Federal statutory rate as follows:

	For The Years Ended December 31,	
	2024	2023
Federal statutory rate	(21.0)%	(21.0)%
State tax rate, net of federal benefit	(13.2)%	0.0 %
Permanent differences	1.0 %	1.2 %
Research & development tax credits	(0.8)%	0.0 %
Prior period adjustments and other	(3.6)%	1.3 %
Rate and apportionment changes	(7.6)%	1.9 %
Change in valuation allowance	45.2 %	16.6 %
Effective income tax rate	0.0 %	0.0 %

Deferred tax assets consist of the following:

	For The Years Ended December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 35,921,285	$ 23,804,461
Research and development tax credits	1,995,653	528,894
Capitalized research and development costs	8,177,548	3,581,962
Stock-based compensation	3,026,311	2,080,864
Intangible assets	3,322,919	688,745
Lease liability	441,895	376,883
Property and equipment	246,074	—
Total gross deferred tax assets	53,131,685	31,061,809
Valuation allowance	(52,886,116)	(30,363,326)
Deferred tax assets, net of valuation allowance	245,569	698,483
Deferred tax liabilities		
Property and equipment	—	(348,323)
Right of use asset	(245,569)	(350,160)
Deferred tax liabilities, net	$ —	$ —
Changes in valuation allowance	$ (22,522,790)	$ (4,532,592)

As of December 31, 2024, the Company had approximately $133,700,000 of domestic federal net operating loss carryforwards, or NOLs, that may be available to offset future federal taxable income. Approximately $10,800,000 of those NOLs will expire during the years ranging from 2034 to 2037. The remaining NOLs of approximately $122,900,000 have no expiration dates. Internal Revenue Code Section 382 limits the utilization of approximately $35,000,000 of those NOLs to approximately $918,000 on an annual basis as a result of ownership changes that occurred through July 15, 2019. As of December 31, 2024, the Company had approximately $66,400,000 of state NOLs, of which approximately $66,200,000 will expire during the years ranging from 2040 to 2044, and approximately $200,000 will not expire, and had approximately $52,200,000 of local NOLs which do not expire.

The Company has assessed the likelihood that deferred tax assets will be realized in accordance with the provisions of ASC 740 “Income Taxes Accounting”, or ASC 740. ASC 740 requires that a valuation allowance be established when it is “more likely than not” that all, or a portion of, deferred tax assets will not be realized. The assessment considers all available positive or negative evidence, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. After the performance of such reviews as of December 31, 2024 and 2023, management believes that uncertainty exists with respect to future realization of its deferred tax assets and has, therefore, established a full valuation allowance as of those dates.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company’s financial statements as of December 31, 2024 and 2023. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

No tax audits were commenced or were in process during the years ended December 31, 2024 and 2023. No tax related interest or penalties were incurred during the years ended December 31, 2024 and 2023. The Company’s federal, state and local income tax returns beginning with the year ended December 31, 2021 remain subject to examination.

Note 10 – Commitments and Contingencies

Employment Agreements

As of December 31, 2024, the aggregate potential severance pay for the executive officers of the Company is approximately $1,029,000.

Defective Clinical Supply

During the third quarter of 2023, a certain portion of clinical supply product sold by the Company to Bausch + Lomb was determined to be defective. On April 23, 2024, the Company and Bausch + Lomb executed a letter agreement (the "Side Letter") pursuant to which the Company and Bausch + Lomb agreed that the Company would pay approximately $0.4 million to Bausch + Lomb related to the defective clinical supply which charge was included within other income (expense) during the year ended December 31, 2023, because the original sales to the licensee were recorded on that line item. See Note 2 – Summary of Significant Accounting Policies - Bausch License Agreements.

Operating Leases

In April 2022, the Company entered into a new lease agreement for 3,916 square feet in Laguna Hills, California. The new lease term is five years and two months, commencing on June 1, 2022 and expiring on July 31, 2027. The monthly base rent ranges from $9,203 to $10,358 per month over the term of the lease. The security deposit is $11,400. The Company's rent expense for all Laguna Hills space is recorded in selling, general and administrative expense and amounted to $117,890 and $118,746 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company recorded an impairment of the right-of-use asset of $116,000 associated with this lease in the Company's financial statements due to the uncertainty associated with its operations and its exploration of strategic alternatives.

In May 2022, the Company entered into a lease agreement to lease 10,880 square feet of office space in Reno, Nevada. The lease term is five years and four months, commencing on May 23, 2022 and expiring on September 23, 2027. The monthly base rent ranges from $13,056 to $16,663 per month over the term of the lease. The security deposit is $53,000. The Company's rent expense for this space is recorded in research and development expense and amounted to $169,303 and $164,950 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company recorded an impairment of the right-of-use asset of $80,000 associated with this lease in the Company's financial statements due to the uncertainty associated with its operations and its exploration of strategic alternatives.

In February 2023, the Company exercised its options to renew its three leases in Redwood City, California, for a total of approximately 6,700 square feet. The leases were due to expire on August 31, 2023. The leases were extended from September 1, 2023 to August 31, 2025. The aggregate monthly base rent ranges from $15,742 to $16,700 per month over the term of the lease. The security deposit is $14,968. The Company's rent expense for this space is recorded in research and development expense and amounted to $193,591 and $192,710 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company recorded an impairment of the right-of-use asset of $125,000 associated with this lease in the Company's financial statements due to the uncertainty associated with its operations and its exploration of strategic alternatives.

In June 2023, the Company entered into an extension agreement to renew its lease for approximately 3,800 square feet of office space in New York, NY. The lease was due to expire on September 30, 2023. The lease was extended from November 1, 2023 to December 31, 2026. The monthly base rent ranges from $19,633 to $21,298 per month over the term of the lease. The security deposit is $117,800. The Company's rent expense for this space is recorded in selling, general and administrative expense and amounted to $220,394 and $233,534 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company recorded an impairment of the right-of-use asset of $99,000 associated with this lease in the Company's financial statements due to the uncertainty associated with its operations and its exploration of strategic alternatives.

A summary of the Company's right-of-use assets and liabilities is as follows:

	For the Years Ended December 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating activities	$ 501,250	$ 503,046
Right-of-use assets obtained in exchange for lease obligations		
Operating leases	$ —	$ 904,437
Weighted Average Remaining Lease Term (Years)		
Operating leases	2.16	3.04
Weighted Average Discount Rate		
Operating leases	10.0 %	10.0 %

Future minimum payments under the Company's operating lease agreements are as follows:

For the Years Ending December 31,	Minimum Lease Payments
2025	$ 675,400
2026	560,996
2027	214,618
Total future minimum lease payments	1,451,014
Less: Imputed interest	(158,347)
Present value of lease liabilities	1,292,667
Less: current portion	(575,163)
Lease liabilities, non-current portion	$ 717,504

Litigations, Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

Senju License Agreement

See Note 11 – Related Party Transactions - Senju License Agreement for a related party agreement entered into with Senju.

Note 11 – Related Party Transactions

Senju License Agreement

During 2015, the Company entered into an exclusive license agreement with Senju, or the Senju License Agreement, whereby the Company agreed to grant to Senju an exclusive, royalty-bearing license for its microdose product candidates for Asia to sublicense, develop, make, have made, manufacture, use, import, market, sell, and otherwise distribute the microdose product candidates. In consideration for the license, Senju agreed to pay to Eyenovia five percent (5%) royalties on sales (net of certain manufacturing costs) for the term of the Senju License Agreement, subject to certain adjustments upon the loss of patent coverage for the term of the license agreement. The agreement will continue in full force and effect, on a country-by-country basis, until the latest to occur of: (i) the tenth (10th) anniversary of the first commercial sale of such a product candidate in a country; or (ii) the expiration of the licensed patents in a country. As of the date of this filing, there have been no commercial sales of such a product in Asia; therefore, no royalties have been earned. Senju is owned by the family of a former member of the Company's Board of Directors.

On April 8, 2020, Eyenovia entered into an amendment, (the "Senju License Amendment"), to the Senju License Agreement. Pursuant to the Senju License Amendment, the Company can license to any third party the right to research, develop, commercialize, manufacture or use certain products, or the Senju Licensed Products previously licensed to Senju in China (including the People's Republic of China, Hong Kong, Macao, and Taiwan) and South Korea, or the Territory.

Pursuant to the Senju License Amendment, the Company must pay Senju (a) a percentage in the range of 30% to 40% of revenue on (i) any lump-sum payments the Company receives from the third party, (ii) revenue (net of costs) obtained by the Company from contract research and/or development of the Senju Licensed Product in the Territory, and (iii) revenue (net of costs) obtained by the Company from contract manufacture for the device of the Senju Licensed Product in the Territory, the aggregate of which must be at least a $9 million minimum payment to Senju; and (b) a percentage in the range of 30% to 40% of any sales royalty revenue the Company receives from the third party. Since the Company executed a third-party license prior to the April 8, 2021 expiration of the Senju License, the Senju License Amendment will remain in effect for the duration of the license, subject to early termination.

The Senju License Agreement was further amended in a Letter Agreement by and between the Company and Senju on August 10, 2020, or the Letter Agreement. Pursuant to the Letter Agreement, the Company will pay to Senju a percentage in the range of 30% to 40% of certain payments, royalties, or net proceeds received from Arctic Vision in connection with the Arctic Vision License Agreement. The Senju License Agreement was amended further by the License Amendment 2, effective September 14, 2021, ("Amendment 2"). The Amendment 2 excludes Greater China and South Korea from the territory in which Senju was granted an exclusive royalty-bearing license from the Company. In consideration for this exclusion, and upon and after the execution of Amendment 1 with Arctic Vision, the Company must make payments to Senju based on non-royalty license revenue and sales revenue, including the following:

1. a one-time upfront payment of $250,000, paid on September 17, 2021, which represented an inducement to Senju to approve Amendment 1 of the Arctic Vision License Agreement related to the MicroStat product.
2. a percentage in the range from 30% to 40% of any upfront or milestone lump sum payments, or net revenues received by the Company in connection with any licensed product using piezo-print technology in a microdose dispenser containing: (a) the chemical substance atropine sulfate as its sole active ingredient and that is used for the treatment of myopia in humans; (b) the chemical substance pilocarpine as its sole active ingredient and that is used for the treatment of presbyopia in humans; or (c) the chemical substances phenylephrine and tropicamide in combination as active ingredients that are used for pharmaceutical mydriasis in humans (the "LA2 Licensed Product") from certain third parties, and
3. a percentage in the range from thirty to forty percent of the amounts received by the Company in connection with sales of the LA2 Licensed Product in China and South Korea by certain third parties.

Advisory Agreement

In August 2022, the Company entered into an agreement with Dr. Ianchulev, or the Executive Chairman Agreement, pursuant to which Dr. Ianchulev agreed to provide medical expertise and consultation related to the Company's research and development programs, and such other matters as reasonably requested by the Company for an initial period of one year. The terms allowed for the agreement to be extended by mutual agreement of the parties. In consideration for Dr. Ianchulev's services, the Company agreed to provide Dr. Ianchulev with a $5,000 monthly retainer throughout the term of the agreement, in addition to the compensation payable to all non-employee members of the Board. As of December 31, 2024, the agreement was still in effect.

Note 12 – Stockholders' (Deficiency) Equity

Authorized Capital

The Company is authorized to issue 300,000,000 shares of common stock, par value of $0.0001 per share, and 6,000,000 shares of preferred stock, par value of $0.0001 per share. The holders of the Company's common stock are entitled to one vote per share. The Board of Directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, redemption, voting or other rights. On June 12, 2024, at the Annual Shareholders' Meeting, the Company proposed and the shareholders approved an increase in the authorized number of shares of the Company's common stock from 90,000,000 to 300,000,000 at the same par value of $0.0001 per share.

Equity Incentive Plans

On April 7, 2020, the Company's Board of Directors approved the Company's Amended and Restated 2018 Omnibus Stock Incentive Plan (the "Restated Plan"), which stockholders approved on June 30, 2020. Under the Restated Plan, as amended on June 16, 2022 and June 27, 2023, 83,750 shares of the Company's common stock are reserved for issuance. The Restated Plan requires that all equity awards issued under the Restated Plan vest at least twelve months from the applicable grant date, subject to accelerated vesting, and provides that no dividend or dividend equivalent will be paid on any unvested equity award, although dividends with respect to unvested portions of equity may accrue and be paid when, and if, the awards later vest and the shares are actually issued to the grantee. In addition, the Restated Plan sets an annual limit on the grant date fair value of awards to any non-employee director, together with any cash fees paid during the year, of $150,000, subject to certain exceptions for a non-executive chair of the Board. As of December 31, 2024, the number of securities remaining available for future issuance under equity compensation plans was 14,227. On January 21, 2025, the stockholders approved an amendment to the Company's Amended and Restated 2018 Omnibus Stock Incentive Plan to reserve an additional 350,000 shares of the Company's common stock for issuance (see Note 15 – Subsequent Events, Increase of 2018 Omnibus Stock Incentive Plan Shares).

Common Stock Issuances

Pursuant to the License and certain milestone achievements, the Company issued 7,668 shares of common stock valued at $0.4 million on April 29, 2024 to Formosa (see Note 5 – Intangible Assets).

On May 3, 2024, the Company issued Bausch + Lomb 28,742 shares of the Company's common stock, valued at $2.3 million, in satisfaction of its obligations pursuant to the Letter Agreement (see Note 2 – Summary of Significant Accounting Policies - Bausch License Agreements).

At-The-Market Program

December 2021 Sales Agreement

On December 14, 2021, the Company entered into a Sales Agreement, (the "December 2021 Sales Agreement"), with SVB Securities under which the Company may offer and sell, from time to time at its sole discretion, shares of common stock for gross proceeds of up to $50.0 million through SVB Securities as its sales agent, or the 2021 Offering. The issuance and sale of shares, if any, of common stock by the Company under the December 2021 Sales Agreement will be pursuant to the Company's Registration Statement on Form S-3 (File No. 333-261638) filed with the SEC on December 14, 2021, or the Registration Statement, and the prospectus relating to the 2021 Offering filed therewith that forms a part of the Registration Statement.

Subject to the terms and conditions of the December 2021 Sales Agreement, SVB Securities may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended. SVB Securities will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay SVB Securities a commission equal to three percent (3.0)% of the gross sales proceeds of any common stock sold through SVB Securities under the December 2021 Sales Agreement, and also has provided SVB Securities with certain indemnification rights.

During the year ended December 31, 2023, the Company received approximately $4.7 million in gross proceeds and $4.6 million in net proceeds from the sale of 23,327 shares of its common stock under the December 2021 Sales Agreement with Leerink Partners, LLC, formerly known as SVB Securities ("Leerink Partners").

During the year ended December 31, 2024, the Company received approximately $6.2 million in gross proceeds and $6.0 million in net proceeds from the sale of 70,382 shares of its common stock under the December 2021 Sales Agreement with Leerink Partners.

On December 30, 2024, the Company entered into an Amended and Restated Sales Agreement (the "A&R Sales Agreement") with Chardan Capital Markets, LLC ("Chardan") with respect to the Company's existing at-the-market offering program. The A&R Sales Agreement amends and restates the December 2021 Sales Agreement by and between the Company and Leerink Partners to, among other things, replace Leerink Partners with Chardan as sales agent. The Company will pay Chardan a commission equal to three percent (3.0)% of the gross sales proceeds of any common stock sold through Chardan under the December 2021 Sales Agreement, and also has provided Chardan with certain indemnification rights.

At December 31, 2024, no shares had settled under the A&R Sales Agreement with Chardan.

Offerings

August 2023 Offering and Warrant Modification

On August 24, 2023, the Company entered into a securities purchase agreement with a certain institutional and accredited investor (the "Purchaser"), pursuant to which the Company agreed to sell, in a registered direct offering by the Company directly to the Purchaser (the "August 2023 Offering"), 52,483 shares of common stock, pre-funded warrants to purchase up to 28,162 shares of common stock and warrants to purchase up to 60,484 shares of common stock (the "Common Warrants" and, together with the Pre-Funded Warrants, the "Warrants"). The combined offering price for each share of common stock and accompanying Common Warrant was $148.80, and the combined offering price for each Pre-Funded Warrant and accompanying Common Warrant was $148.00.

The Common Warrants will be exercisable beginning six months following the date of issuance and may be exercised for a period of five years from the initial exercisability date at an exercise price of $178.40 per share. The Pre-Funded Warrants were immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full at an exercise price of $0.80 per share. The exercise prices and numbers of shares of common stock issuable upon exercise of the Common Warrants and the Pre-Funded Warrants are subject to typical anti-dilution provisions. A holder may not exercise any portion of such holder's Common Warrants or Pre-Funded Warrants to the extent that the holder would own more than 4.99% of the Company's outstanding common stock immediately after exercise (unless the holder otherwise elects a limitation of 9.99%). The Company determined that the Warrants met the criteria to be classified as equity.

The net cash proceeds of the August 2023 Offering were approximately $10.9 million after deducting cash issuance costs in the aggregate amount of approximately $1.1 million. The August 2023 Offering closed on August 29, 2023.

In connection with the August 2023 Offering, the Company entered into a warrant amendment agreement (the "Amendment") with the Purchaser, whereby the Company agreed to amend the March 2022 Investor Warrants to (i) reduce the exercise price from $283.20 per share of common stock to $178.40 per share of common stock, (ii) extend the term of the March 2022 Investor Warrants until March 1, 2029, (iii) include a stockholder approval requirement in connection with a modification of the beneficial ownership limitation and (iv) prohibit exercise of the March 2022 Investor Warrants for the six-month period following the effective date of the Amendment.

The Company accounted for the modification of the March 2022 Investor Warrants as an exchange of the old warrants for new warrants. The incremental value of the new warrant (resulting from the decrease in exercise price from $283.20 to $178.40 per share and the extension of the warrant expiration date to March 1, 2029) was measured as the excess of the fair value of the modified warrants over the fair value of the original warrants immediately before modification. The increase in the incremental value of $1,738,700 was credited to additional paid-in-capital ("APIC") and debited to APIC as an issuance cost of the August 2023 Offering.

2024 Offerings and Warrant Modification

A summary of the 2024 offerings is presented below:

	Common Stock		Additional Paid-In Capital	Total Stockholders' Equity
	Shares	Amount		
April Offering	40,297	$ 4	$ 1,888,825	$ 1,888,829
July Offering	94,697	10	4,299,391	4,299,401
August Offering	160,624	16	4,451,091	4,451,107
September Offering	107,875	11	3,597,659	3,597,670
November Offering	112,500	11	1,058,792	1,058,803
December Offering	137,500	14	1,715,498	1,715,512
	653,493	$ 66	$ 17,011,256	$ 17,011,322

April Offering

On April 8, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") with a single fundamentals-based healthcare investor (the "Purchaser"), pursuant to which the Company agreed to sell, in a registered direct offering by the Company directly to the Purchaser (the "April 2024 Offering"), 40,297 shares of common stock. The price per share in the April 2024 Offering was $49.63. The aggregate gross proceeds to the Company from the 2024 April Offering were $2.0 million, and net proceeds after offering costs were approximately $1.9 million.

July Offering and Warrant Amendment

On July 1, 2024, the Company closed on a registered direct offering (the "July 2024 Offering") with certain institutional and accredited investors (the "July 2024 Investors"), pursuant to which the Company sold 94,697 shares of common stock and warrants to purchase up to 94,697 shares of common stock. The combined offering price for each share of common stock and accompanying warrant was $52.80. The Company also agreed to issue warrants to purchase an additional 21,872 shares of common stock (the "Additional Warrants") to one of the July 2024 Investors. All of the new warrants become exercisable six months following their issuance, at an exercise price of $55.20 per share, and may be exercised until January 2, 2030.

In connection with the July 2024 Offering, the Company entered into warrant amendment agreements (the "Amendments") with the holders of previously issued warrants (the "Prior Warrants") to purchase up to an aggregate of 129,828 shares of common stock, whereby the Company agreed to amend the Prior Warrants to reduce the exercise price of the Prior Warrants from $178.40 and $197.60 per share of common stock to $55.20 per share of common stock, extend the term of the Prior Warrants until January 2, 2030 and prohibit exercise of the Prior Warrants for the six-month period following the effective date of the Amendments.

The aggregate gross proceeds to the Company from the July 2024 Offering were approximately $5.0 million, and net proceeds after cash offering costs were approximately $4.3 million. Offering costs include placement agent fees of $0.4 million and Company legal fees of $0.3 million. In addition, there were $2.9 million of non-cash issuance costs which represents the value of the Additional Warrants, plus the modification date incremental value of the modified Prior Warrants as compared to the original Prior Warrants, as an issuance cost of the warrant exercise.

August Offering

On August 21, 2024, the Company agreed to sell 160,624 shares of common stock to certain institutional and accredited investors (the "August Investors"), in some cases pursuant to a securities purchase agreement (the "August 2024 Offering"). The price per share in the August 2024 Offering was $32.00. The aggregate gross proceeds to the Company from the August 2024 Offering were approximately $5.1 million, and net proceeds after offering costs were approximately $4.5 million.

September Offering and Warrant Amendment

On September 30, 2024, the Company closed on a registered direct offering (the "September 2024 Offering") with a certain purchaser, pursuant to which the Company sold to the purchaser 107,875 shares of common stock; pre-funded warrants to purchase up to 821

shares of common stock; and warrants to purchase up to 108,696 shares of common stock at an exercise price of $40.00 per share. The combined offering price for each share and accompanying warrant was $36.80. The combined offering price for each pre-funded warrant and accompanying Warrant was $36.79, which is equal to the purchase price per share in the September 2024 Offering, minus $0.008, the exercise price per share of the pre-funded warrants. The warrants will be exercisable beginning six months following the date of issuance and may be exercised until March 31, 2030. The aggregate gross proceeds to the Company from the September 2024 Offering were approximately $4.0 million, and net proceeds after offering costs were approximately $3.6 million. On October 1, 2024, the holder of the 821 pre-funded warrants issued in the September Offering, exercised the pre-funded warrants at a price of $0.008 per share of common stock.

In connection with the December Offering, the Company entered into an amendment of the September Offering warrants to require stockholder approval to be exercisable and the termination date to be five years after stockholder approval.

Subsequently, on January 21, 2025, the stockholders voted to approve the exercise of the September Offering warrants (see Note 15 – Subsequent Events - Stockholder Approval of Warrants).

November Offering and Warrant Amendment

On November 24, 2024, the Company closed on a registered direct offering (the "November 2024 Offering") with an institutional investor, pursuant to which the Company sold to the purchaser 112,500 shares of common stock; pre-funded warrants to purchase up to 38,522 shares of common stock; and warrants to purchase up to 302,045 shares of common stock at an exercise price of $8.608 per share. The combined offering price for each share and accompanying warrant was $8.608 The combined offering price for each pre-funded warrant and accompanying Warrant was $8.60, which is equal to the purchase price per share in the November 2024 Offering, minus $0.008, the exercise price per share of the pre-funded warrants. The warrants will be exercisable beginning six months following the date of issuance and may be exercised until November 24, 2029. The aggregate gross proceeds to the Company from the November 2024 Offering were approximately $1.3 million, and net proceeds after offering costs were approximately $1.1 million. On November 25, 2024, the holder of the 38,522 pre-funded warrants issued in the November Offering, exercised the pre-funded warrants at a price of $0.008 per share of common stock.

In connection with the December Offering, the Company entered into an amendment of the November Offering warrants to require stockholder approval to be exercisable and the termination date to be five years after stockholder approval.

Subsequently, on January 21, 2025, the stockholders voted to approve the exercise of the November Offering warrants (see Note 15 – Subsequent Events - Stockholder Approval of Warrants).

December Offering

On December 5, 2024, the Company closed on a registered direct offering (the "December 2024 Offering") with an institutional investor, pursuant to which the Company sold to the purchaser 137,500 shares of common stock; pre-funded warrants to purchase up to 113,563 shares of common stock; and warrants to purchase up to 502,126 shares of common stock at an exercise price of $7.752 per share. The combined offering price for each share and accompanying warrant was $7.752. The combined offering price for each pre-funded warrant and accompanying Warrant was $7.744, which is equal to the purchase price per share in the December 2024 Offering, minus $0.008, the exercise price per share of the pre-funded warrants. The warrants required stockholder approval to be exercisable and the termination date to be five years after stockholder approval. The aggregate gross proceeds to the Company from the December 2024 Offering were approximately $1.9 million, and net proceeds after offering costs were approximately $1.7 million. On December 11, 2024, the holder of the 113,563 pre-funded warrants issued in the December Offering, exercised the pre-funded warrants at a price of $0.008 per share of common stock.

Subsequently, on January 21, 2025, the stockholders voted to approve the exercise of the December Offering warrants (see Note 15 – Subsequent Events - Stockholder Approval of Warrants).

Warrants

The issuance date or modification date fair value of stock warrants issued or modified during the years ended December 31, 2024 and 2023 was determined using the Black Scholes method, with the following assumptions used:

	For the Years Ended December 31,	
	2024	2023
Risk free interest rate	4.39% - 5.22%	4.48%
Expected term	0.7 - 5.5 years	4.0 - 5.5 years
Expected volatility	86% - 118%	81%
Expected dividends	n/a	n/a

A summary of the warrant activity during the year ended December 31, 2024 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years
Outstanding January 1, 2024	136,582	$ 182.40	—
Granted (1)	1,029,435	17.22	—
Repriced - (Old) (2)	(129,828)	179.65	—
Repriced - (New) (2)	129,828	55.20	—
Exercised (1)	—	—	—
Outstanding December 31, 2024	1,166,017	$ 22.33	5.0
Exercisable December 31, 2024	6,754	$ 236.88	1.2

(1) Warrants granted and exercised exclude 152,916 Pre-Funded Warrants with an exercise price of $0.0001.
(2) Repriced warrants represent the reset of the exercise price of certain warrants to purchase 129,828 shares of common stock to a price of $55.20 per share.

The following table presents information related to warrants as of December 31, 2024:

Warrants Outstanding		Warants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$7.7520	502,126 (1)	—	—
$8.6080	302,045 (1)	—	—
$40.0000	108,696 (1)	—	—
$55.2000	246,398 (2)	—	—
$197.5680	2,900	0.2	2,900
$217.9200	2,705	0.2	2,705
$380.8000	1,149	6.3	1,149
	1,166,017	1.2	6,754

(1) These warrants become exercisable on January 21, 2025.
(2) These warrants become exercisable on January 1, 2025.

During the year ended December 31, 2024, Pre-Funded Warrants for the purchase of 152,905 shares of the Company's common stock with an exercise price of $0.008 per share were exercised for aggregate proceeds of $1,223.

During the year ended December 31, 2023, warrants for the purchase of 28,162 shares of the Company's common stock with an exercise price of $0.80 per share were exercised for aggregate proceeds of $22,529.

Stock-Based Compensation Expense

The Company records stock-based compensation expense related to stock options and restricted stock units, or RSUs. For the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation expense of $1,704,273 ($623,049 of which was included within research and development expenses and $1,081,224 was included within selling, general and administrative expenses on the statements of operations) and $2,497,890 ($839,038 of which was included within research and development expenses and $1,658,852 was included within selling, general and administrative expenses on the statements of operations), respectively.

Restricted Stock Units

A summary of the restricted stock units activity during the year ended December 31, 2024 is presented below:

	Number of RSUs	Weighted Average Exercise Price
RSUs non-vested January 1, 2024	1,322	$ 169.60
Granted	4,608	52.00
Vested	(1,322)	169.60
Forfeited	—	—
RSUs non-vested December 31, 2024	4,608	$ 52.00
Vested RSUs undelivered December 31, 2024	3,015	$ 173.90

To date, the RSUs have only been granted to directors in accordance with the Company's Amended and Restated 2018 Omnibus Stock Incentive Plan. The Company's policy is not to deliver shares underlying the RSUs until the termination of service.

On June 12, 2024, the Company granted members of its Board of Directors an aggregate of 4,608 RSUs under the Restated Plan. Each RSU is subject to settlement into one share of the Company's common stock. The RSUs vest on the earlier of (i) the one-year anniversary of the date of grant and (ii) the date of the 2025 annual stockholders meeting, subject to the grantee remaining on the Board until then. The RSUs had a grant date fair value of $239,772, which will be recognized over the vesting period. In 2024, there were no shares of common stock issued related to vested RSUs.

Between June 27, 2023 and November 14, 2023, the Company granted members of its Board of Directors an aggregate of 1,322 RSUs under the Restated Plan. Each RSU is subject to settlement into one share of the Company's common stock. The RSUs vest on the earlier of (i) the one-year anniversary of the date of grant and (ii) the date of the 2024 annual stockholders meeting, subject to the grantee remaining on the Board until then. The RSUs had a grant date fair value of $224,800, which will be recognized over the vesting period. In 2023, there were 597 of common shares issued related to vested RSUs.

As of December 31, 2024, there was $109,897 of unrecognized stock-based compensation expense related to RSUs which will be recognized over a weighted average period of 0.45 years.

Stock Options

A summary of the option activity during the year ended December 31, 2024 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2024	66,329	$ 264.85	—	—
Granted	27,351	87.86	—	—
Exercised	—	—	—	—
Forfeited	(25,497)	183.18	—	—
Outstanding, December 31, 2024	68,183	$ 231.06	4.3	$ —
Exercisable, December 31, 2024	51,494	$ 273.72	5.6	$ —

The following table presents information related to stock options as of December 31, 2024:

Options Outstanding			Options Exercisable	
Exercise Price	Number of Options	Weighted Average Remaining Life In Years	Number of Options	
$0.01 - $79.99	9,164	—	—	
$80 - $159.99	21,253	5.4	15,026	
$160 - $239.99	14,117	6.5	13,220	
$240 - $319.99	9,321	5.7	9,068	
$320 - $399.99	3,480	6.5	3,332	
$400 - $479.99	332	1.8	332	
$480 - $559.9	8,636	5.0	8,636	
$560+	1,880	3.2	1,880	
	68,183	5.6	51,494	

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following approximate assumptions:

	For the Year Ended December 31,	
	2024	2023
Expected term (years)	5.50 - 10.00	5.50 - 10.00
Risk free interest rate	3.47% - 4.72%	3.44% - 4.72%
Expected volatility	80% - 87%	80% - 95%
Expected dividends	0.00%	0.00%

The Company has computed the fair value of stock options granted using the Black-Scholes option pricing model. Option forfeitures are accounted for at the time of occurrence. The expected term used for options issued is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the “simplified” method to develop an estimate of the expected term of “plain vanilla” option grants. The Company uses its historical volatility for the period from its initial public offering through the valuation date in computing the expected volatility. Accordingly, the Company is utilizing an expected volatility figure based on a review of its historical volatility over a period of time equivalent to the expected life of the instrument being valued. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of

the instrument being valued. The Company has not declared dividends, is currently in the development stage and has no plan to declare future dividends at this time.

The weighted average estimated grant date fair value of the stock options granted for the years ended December 31, 2024 and 2023 was approximately $63 and $132 per share, respectively.

As of December 31, 2024, there was $949,697 of unrecognized stock-based compensation expense related to stock options which will be recognized over a weighted average period of 1.3 years.

Note 13 – Employee Benefit Plans

401(k) Plan

In April 2019, the Company adopted the Eyenovia 401(k) Plan, or the Plan, which went into effect in May 2019. All Company employees are able to participate in the Plan, subject to eligibility requirements as outlined in the Plan documents. Under the terms of the Plan, eligible employees are able to defer a percentage of their pay every pay period up to annual limitations set by Congress and the Internal Revenue Service under Section 401(k) of the Internal Revenue Code. The Company's Board of Directors approved a matching contribution equal to 100% of elective deferrals up to 4% of eligible earnings with the matching contribution subject to certain vesting requirements as outlined in the Plan documents. For the years ended December 31, 2024 and 2023, the Company recorded expense of $264,104 and $218,170 associated with its matching contributions, respectively.

Note 14 – Segment Reporting

The Company has one operating and reporting segment (ophthalmic technology), namely, the development and commercialization of ophthalmic solutions. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The chief operating decision maker ("CODM"), who is the Company's chief executive officer, utilizes the Company's financial information on an aggregate basis for purposes of making operating decisions, allocating resources and assessing financial performance, as well as for making strategic operations decisions and managing the organization. The measure of segment assets is reported on the balance sheet as total assets.

The Company's significant expenses reviewed by the CODM for the years ended December 31, 2024 and 2023 are as follows:

	For the Years Ended December 31,	
	2024	2023
Revenue:		
Revenue	$ 57,336	$ 3,787
Less:		
Cost of revenue	(3,927,228)	(16,005)
Gross Loss	(3,869,892)	(12,218)
Less:		
Research and Development:		
Salaries and benefits	6,215,323	6,869,585
Direct clinical and non-clinical expenses	3,072,416	714,995
Supplies and materials	2,195,608	1,762,676
Depreciation expense	1,112,463	776,479
Facilities expenses	834,406	1,442,001
Non-cash stock based compensation expenses	623,049	839,038
Other Expenses [1]	409,457	571,058
Selling General and Administrative:		
Salaries and benefits	5,226,885	3,964,522
Professional fees	2,967,185	2,870,946
Non-cash stock based compensation	1,081,224	1,658,852
FDA PDUFA fees	853,434	933,284
Insurance expense	801,676	175,515
Sales and marketing	747,349	1,097,402
Investor relations	662,126	398,273
Travel, lodging and meals	564,311	104,183
Other Expenses [2]	535,115	305,270
Facilities expense	485,059	494,823
Director fees and expense	408,750	415,326
Reacquisition of license rights	4,864,600	—
Asset impairments	11,207,897	—
Total Expense:	44,868,333	25,394,227
Loss from Operations	(48,738,225)	(25,406,445)
Other (expense) income, net [3]	(1,080,208)	(1,854,650)
Net Loss	**$ (49,818,433)**	**$ (27,261,095)**

(1) Other research and development expenses include outsourced engineering and IT systems used for research and development.
(2) Other selling, general, and administrative expenses include, distribution for specialty pharmacy networks, Nasdaq / SEC fees, software services, corporate tax, and depreication expense.
(3) All other items include gains and losses in the change in fair value of equity consideration payable, interest expense, net of interest income, and other non operating expenses.

Note 15 – Subsequent Events

January 2025 Offering

On January 16, 2025, the Company entered into an Inducement Offer (the "Inducement Offer") with an Investor (the "Investor"), by which the Company agreed to reduce the exercise price of 197,118 existing warrants ("the Existing Warrants") from $55.20 per share, to $5.272 per share. The Inducement Offer had a limited exercise period, until January 17, 2025, to exercise the Existing Warrants (the "Exercise Period").

In connection with the Inducement Offer, if the Investor exercised the Existing Warrants within the Exercise Period, the Company agreed to issue 197,118 Series A Common Stock Purchase Warrants and 197,118 Series B Common Stock Purchase Warrants to purchase an additional 394,236 shares of common stock at an exercise price of $5.272 per share which may be exercised for five years from the initial exercise date. The warrants become exercisable upon stockholder approval.

On January 17, 2025, the Investor exercised the Existing Warrants within the Exercise Period. The aggregate gross cash proceeds to the Company from the inducement offer were approximately $1.0 million, and net cash proceeds after offering costs were approximately $0.9 million.

Stockholder Approval of 2024 Warrants

On January 21, 2025, in connection with the December Offering, the stockholders approved the exercise of the September Offering warrants, the November Offering warrants and the December Offering warrants (see Note 12 – Stockholders' Equity - Offerings).

Reverse Stock Split

On January 31, 2025, the Company effected the Reverse Split of its common stock at a ratio of 1-for-80. Upon the effectiveness of the Reverse Split, every 80 issued shares of common stock were reclassified and combined into one share of common stock. In addition, the number of shares of common stock issuable upon the exercise of the Company's equity awards, convertible securities and warrants was proportionally decreased, and the corresponding conversion price or exercise price was proportionally increased. No fractional shares were issued as a result of the Reverse Split, stockholders who would otherwise be entitled to receive a fractional share will be entitled to receive a cash payment in lieu of such fractional share. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the Reverse Split and adjustment of the conversion price or exercise price of each outstanding equity award, convertible security and warrant as if the transaction had occurred as of the beginning of the earliest period presented.

Avenue Ventures Loan Second Amendment

On February 21, 2025, the Company entered into a second amendment of the Avenue Loan Agreement (the "Second Amendment") whereby the Lender agreed to defer principal and interest payments on amounts outstanding until the end of September 2025. Deferred interest will accrue on the outstanding principal amount at the interest rate stated in the original Avenue Loan.

Under the Second Amendment, the Company has agreed to use a portion of the proceeds (net of fees and commissions payable to Chardan) received from sales under the A&R Sales Agreement (the "A&R Proceeds") to pay down the outstanding principal amount under the Avenue Loan Agreement as follows: a) until the Company raises $3.0 million of aggregate A&R Proceeds, 65% of the A&R Proceeds shall be remitted to the Lenders as a payment in respect of the outstanding principal amount, and b) after the Company raises $3.0 million of aggregate A&R Proceeds, 75% of the A&R Proceeds shall be remitted to the Lenders as a payment in respect of the outstanding principal amount.

Pursuant to the Second Amendment, at any time on or after April 1, 2025, the Lenders will also have the right, in their discretion, but not the obligation, to convert an aggregate amount of up to $10.0 million of the aggregate principal amount under the Avenue Loan Agreement into shares of the Company's common stock, at a price equal to $1.68 per share.

Increase and Issuance of 2018 Omnibus Stock Incentive Plan Shares

On January 21, 2025, the stockholders approved an amendment to the Company's Amended and Restated 2018 Omnibus Stock Incentive Plan to reserve an additional 350,000 shares of the Company's common stock for issuance thereunder, which number will not be adjusted as a result of the Reverse Split.

On February 5, 2025, the Company granted 240,000 shares of restricted stock units in the aggregate to consultants and employees. The shares vest on the earliest of (i) one year from the date of issuance, (ii) a change in control of the Company, and (iii) with respect to employees, the date on which their employment with the Company is terminated, other than by such employee's voluntary resignation.

At-The-Market Program

Subsequent to December 31, 2024, the Company received approximately $5.9 million in gross proceeds from the sale of 1,127,100 shares of its common stock pursuant to its Sales Agreement with Chardan in its "at-the-market" offering. In connection with the Second Amendment mentioned above, the Company paid Avenue $777,369 in gross proceeds received from the at-the-market offering, which was equivalent to 65% of the proceeds raised from February 21, 2025 to March 31, 2025.

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2024, Eyenovia, Inc. ("we", "our" and "us") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, $0.0001 par value per share. The following summary of our common stock does not purport to be complete and is subject to, and qualified in its entirety by reference to, our Third Amended and Restated Certificate of Incorporation, as amended (our "Charter"), and our Second Amended and Restated Bylaws (our "Bylaws"), which are included as exhibits to this Annual Report on Form 10-K, and to the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL").

Description of Common Stock

Our authorized capital stock consists of 300,000,000 shares of common stock, $0.0001 par value per share, and 6,000,000 shares of preferred stock, $0.001 par value per share. As of March 31, 2025, there were 2,830,546 shares of our common stock outstanding and no shares of preferred stock outstanding. All outstanding shares of our common stock are fully paid and nonassessable.

Holders of our common stock are entitled to the following rights.

- *Voting Rights*. The holders of our common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders. Notwithstanding the previous sentence, unless otherwise provided by law or the Charter, holders of our common stock are not entitled to vote on any amendment to the Charter that relates solely to the terms of one or more outstanding series of preferred stock of the holders of such series are entitled, either separately or together with the holders of one or more other such series, to vote on such amendment. An election of directors by our stockholders is determined by a plurality of the votes cast by the stockholders entitled to vote on the election. On other matters, where a quorum is present at a meeting, a matter shall be decided by the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy and entitled to vote on the subject matter, except where a different vote is required by law, the Charter or the Bylaws. Our stockholders do not have cumulative voting rights.

- *Dividend Rights*. Holders of our common stock are entitled to receive dividends out of funds legally available therefor at the times and in the amounts that our Board of Directors may determine, subject to any rights of any then outstanding preferred stock.

- *No Preemptive or Similar Rights*. Holders of our common stock have no preemptive, redemption, conversion or subscription rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

- *Right to Receive Liquidation Distributions*. In the event of our liquidation, dissolution or winding-up, the holders of our common stock are entitled to receive ratably all the remaining assets available for distribution to our stockholders after the payment of all debts and other liabilities and subject to any rights of then outstanding preferred stock.

- *Listing*. Our common stock is listed on the Nasdaq Capital Market under the symbol "EYEN".

- *Transfer Agent and Registrar*. The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

Warrants

As of March 31, 2025, we had outstanding the following warrants, which will expire on the dates stated unless exercised earlier in full (collectively, the "Warrants"):

i. 8,467.875 warrants to purchase up to 8,467.875 shares of common stock at an exercise price of $55.200 per share which will expire on January 1, 2030;

ii. 1,148.550 warrants to purchase up to 1,148.550 shares of common stock at an exercise price of $380.800 per share which will expire on May 6, 2031;

iii. 40,811.638 warrants to purchase up to 40,811.638 shares of common stock at an exercise price of $55.200 per share which will expire on January 2, 2030

iv. 108,695.663 warrants to purchase up to 108,695.663 shares of common stock at an exercise price of $40.000 per share which will expire on March 31, 2030;

v. 302,044.625 warrants to purchase up to 302,044.625 shares of common stock at an exercise price of $8.608 per share which will expire on May 26, 2030;

vi. 502,125.625 warrants to purchase up to 502,125.625 shares of common stock at an exercise price of $7.752 per share which will expire on January 21, 2030;

vii. 394,236.125 warrants to purchase up to 394,236.125 shares of common stock at an exercise price of $5.272 per share which are expected to be exercisable upon receipt of approval of the Company's stockholders in accordance with the applicable rules and regulations of The Nasdaq Capital Market and will expire on the five-year anniversary of the date of such approval; and

No holder of Warrants will have or exercise any rights held by holders of our common stock solely by virtue thereof as a holder of Warrants, including the right to vote or to receive dividends or other distributions as a holder of our common stock.

The exercise prices of the Warrants, the number of shares of our common stock issuable upon the exercise of each Warrant and the number of Warrants outstanding are subject to adjustment from time to time upon the occurrence of certain events including, but not limited to subdivision of one or more classes of its outstanding shares of common stock into a greater number of shares by any stock split, stock dividend, recapitalization or otherwise.

The foregoing summary of the Warrants does not purport to be complete and is qualified in its entirety by reference to the forms of Warrant, which are filed as exhibits to the Annual Report on Form 10-K to which this exhibit is attached.

Anti-Takeover Effects of Delaware Law and our Charter and Bylaws

Delaware law, our Charter and our Bylaws contain provisions that could have the effect of delaying, deferring or discouraging another person from acquiring control of us by means of a tender offer, proxy contest or otherwise, or to remove our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders otherwise consider to be in our or their best interest, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our Board of Directors.

Delaware Business Combination Statute. We are subject to Section 203 of the DGCL. Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person or entity became an interested stockholder unless:

- prior to such time, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the outstanding voting stock of the corporation, excluding for this purpose shares owned by persons who are directors and also officers of the corporation and by specified employee benefit plans; or

- at or after such time, the business combination is approved by the board of directors of the corporation and by the affirmative vote, and not by written consent, of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

For the purposes of Section 203, a "business combination" is broadly defined to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

An "interested stockholder" is a person who, together with affiliates and associates, owns or within the immediately preceding three years did own 15% or more of the corporation's voting stock.

Charter and Bylaw Provisions. Various provisions of our Charter and Bylaws could deter hostile takeovers or delay or prevent changes in control of our Board of Directors or management team, including the following:

- *Issuance of Undesignated Preferred Stock*. Our Charter provides our Board of Directors the ability, without action by our stockholders, to issue up to 6,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board of Directors. Our Board of Directors may utilize these shares for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of preferred stock would enable our Board of Directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.
- *Board of Director Vacancies*. Subject to the rights of holders of any series of preferred stock, any vacancy on our Board of Directors, including a vacancy resulting from an enlargement of our Board of Directors, may be filled only by the affirmative vote of a majority of directors then in office. The limitation on the filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.
- *Special Meetings of Stockholders*. Under our restated certificate, our stockholders may no longer take action by written consent, and may only take action at annual or special meetings of our stockholders. Our Charter provides that, subject to the rights of holders of any series of preferred stock and except as required by law, special meetings of our stockholders may be called only by the Chairman of the Board of Directors, our Chief Executive Officer, or the Board of Directors pursuant to a resolution adopted by a

majority of the Board of Directors. This provision might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- *Advance Notice Requirements*. Our Bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, including proposed nominations of persons for election to the Board of Directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board of Directors or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Exhibit 4.7

AMENDMENT NO. 1 TO
COMMON STOCK PURCHASE WARRANT

THIS AMENDMENT NO. 1 TO COMMON STOCK PURCHASE WARRANT (this "Amendment") is entered into as of December [ ], 2024, by and between Eyenovia, Inc., a Delaware corporation (the "Company"), and Armistice Capital Master Fund Ltd. (the "Holder").

WHEREAS, the Holder is the holder of that certain common stock purchase warrant issued by the Company on September 30, 2024 (the "Original Warrant") to purchase 8,695,653 shares of common stock, par value $0.0001 per share ("Common Stock"), of the Company;

WHEREAS, pursuant to Section 5(l) of the Original Warrant, the Original Warrant may be modified or amended or the provisions thereof waived with the written consent of the Company and the Holder; and

WHEREAS, the Company and the Holder desire to amend the Original Warrant as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual agreements contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Company and the Holder hereby agree as follows:

1. Amendment to Initial Exercise Date and Termination Date. The first sentence of the introductory paragraph of the Original Warrant is hereby amended and restated in its entirety as follows:

> "THIS COMMON STOCK PURCHASE WARRANT (this "Warrant") certifies that, for value received, Armistice Capital Master Fund Ltd. or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time or times on or after the Stockholder Approval Date (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on the five-year anniversary of the Initial Exercise Date (the "Termination Date") but not thereafter, to subscribe for and purchase from Eyenovia, Inc., a Delaware corporation (the "Company"), up to 8,695,653 shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock."

2. Amendment to Definitions. Section 1 of the Original Warrant is hereby amended by inserting the following new definitions in the appropriate alphabetical order:

> "Stockholder Approval" means such approval required by the applicable rules and regulations of the Nasdaq Capital Market (or any successor entity thereof) from the stockholders of the Company with respect to the issuance of all of the Warrant Shares upon the exercise of this Warrant.
>
> "Stockholder Approval Date" means the date on which Stockholder Approval is received and deemed effective under Delaware law.

3. Addition of Section 2(f). Section 2 of the Original Warrant is hereby amended by inserting at the end of such Section the following new subsection (f):

> f) Stockholder Approval. The Company shall hold a special meeting of stockholders (which may also be at the annual meeting of stockholders) at the

earliest practicable date after the date hereof, but in no event later than January 31, 2025, for the purpose of obtaining Stockholder Approval with the recommendation of the Board that such proposal be approved, and the Company shall solicit proxies from its stockholders in connection therewith in the same manner as all other management proposals in such proxy statement, and all management-appointed proxyholders shall vote their proxies in favor of such proposal. If the Company does not obtain Stockholder Approval at the first meeting, the Company shall call a meeting every sixty (60) days thereafter to seek Stockholder Approval until Stockholder Approval is obtained.

4. No Further Amendment. Except as amended by this Amendment, the Original Warrant remains unaltered and shall remain in full force and effect.

5. Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Amendment shall be determined in accordance with the provisions of that certain Securities Purchase Agreement, dated as of September 26, 2024, as amended, between the Company and the Holder.

6. Counterparts. This Amendment may be executed in any number of counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. Signatures delivered by facsimile, electronic mail (including as a PDF file) or other transmission method shall be deemed to be original signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Amendment.

[*Signature page follows*]

IN WITNESS WHEREOF, each of the Company and the Holder has caused this Amendment to be executed and delivered by its officer thereunto duly authorized as of the date first above indicated.

COMPANY
EYENOVIA, INC.

By: _____
Name:
Title:

HOLDER
ARMISTICE CAPITAL MASTER FUND LTD.
By: Armistice Capital, LLC
its Investment Manager

By: _____
Name:
Title:

Exhibit 4.9

AMENDMENT NO. 1 TO

COMMON STOCK PURCHASE WARRANT

THIS AMENDMENT NO. 1 TO COMMON STOCK PURCHASE WARRANT (this "Amendment") is entered into as of December [ ], 2024, by and between Eyenovia, Inc., a Delaware corporation (the "Company"), and Armistice Capital Master Fund Ltd. (the "Holder").

WHEREAS, the Holder is the holder of that certain common stock purchase warrant issued by the Company on November 26, 2024 (the "Original Warrant") to purchase 24,163,570 shares of common stock, par value $0.0001 per share ("Common Stock"), of the Company;

WHEREAS, pursuant to Section 5(l) of the Original Warrant, the Original Warrant may be modified or amended or the provisions thereof waived with the written consent of the Company and the Holder; and

WHEREAS, the Company and the Holder desire to amend the Original Warrant as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual agreements contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Company and the Holder hereby agree as follows:

1. Amendment to Initial Exercise Date and Termination Date. The first sentence of the introductory paragraph of the Original Warrant is hereby amended and restated in its entirety as follows:

> "THIS COMMON STOCK PURCHASE WARRANT (this "Warrant") certifies that, for value received, Armistice Capital Master Fund Ltd. or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time or times on or after the Stockholder Approval Date (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on the five-year anniversary of the Initial Exercise Date (the "Termination Date") but not thereafter, to subscribe for and purchase from Eyenovia, Inc., a Delaware corporation (the "Company"), up to 24,163,570 shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock."

2. Amendment to Definitions. Section 1 of the Original Warrant is hereby amended by inserting the following new definitions in the appropriate alphabetical order:

> "Stockholder Approval" means such approval required by the applicable rules and regulations of the Nasdaq Capital Market (or any successor entity thereof) from the stockholders of the Company with respect to the issuance of all of the Warrant Shares upon the exercise of this Warrant.
>
> "Stockholder Approval Date" means the date on which Stockholder Approval is received and deemed effective under Delaware law.

3. Addition of Section 2(f). Section 2 of the Original Warrant is hereby amended by inserting at the end of such Section the following new subsection (f):

> f) Stockholder Approval. The Company shall hold a special meeting of stockholders (which may also be at the annual meeting of stockholders) at the

earliest practicable date after the date hereof, but in no event later than January 31, 2025, for the purpose of obtaining Stockholder Approval with the recommendation of the Board that such proposal be approved, and the Company shall solicit proxies from its stockholders in connection therewith in the same manner as all other management proposals in such proxy statement, and all management-appointed proxyholders shall vote their proxies in favor of such proposal. If the Company does not obtain Stockholder Approval at the first meeting, the Company shall call a meeting every sixty (60) days thereafter to seek Stockholder Approval until Stockholder Approval is obtained.

4. No Further Amendment. Except as amended by this Amendment, the Original Warrant remains unaltered and shall remain in full force and effect.

5. Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Amendment shall be determined in accordance with the provisions of that certain Securities Purchase Agreement, dated as of November 24, 2024, as amended, between the Company and the Holder.

6. Counterparts. This Amendment may be executed in any number of counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. Signatures delivered by facsimile, electronic mail (including as a PDF file) or other transmission method shall be deemed to be original signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Amendment.

[*Signature page follows*]

IN WITNESS WHEREOF, each of the Company and the Holder has caused this Amendment to be executed and delivered by its officer thereunto duly authorized as of the date first above indicated.

COMPANY
EYENOVIA, INC.

By: _____
Name:
Title:

HOLDER
ARMISTICE CAPITAL MASTER FUND LTD.

By: Armistice Capital, LLC
its Investment Manager

By: _____
Name:
Title:

Exhibit 19.1

INSIDER TRADING POLICY

and Guidelines with Respect to
Certain Transactions in Company Securities

This Policy provides guidelines to employees, officers, directors and consultants of Eyenovia, Inc. and any subsidiaries (the "*Company*") with respect to transactions in the Company's securities and the disclosure of material nonpublic information regarding the Company.

Applicability of Policy

This Policy applies to all transactions in the Company's securities, including common stock, options to purchase common stock, and any other securities the Company may issue from time to time, such as preferred stock, warrants or convertible debentures, as well as to derivative securities relating to the Company's stock, such as exchange-traded options, whether or not issued by the Company. It applies to all officers of the Company and their assistants, all directors, all employees of the Company, and all consultants to the Company who receive or have access to material, nonpublic information ("*Inside Information*") regarding the Company (collectively, "*Insiders*"). This Policy also applies to (i) members of an Insider's immediate family (including, without limitation, domestic partners and adopted or step-children) or other persons living in the same household as the Insider (other than household employees); (ii) all persons who execute trades on behalf of Insiders; and (iii) investment funds, trusts, retirement plans, partnerships, corporations and other entities over which Insiders have control or have the ability to influence or direct investment decisions concerning securities (the persons and entities covered by clauses (i) through (iii) above are sometimes referred to in this Policy as "*Affiliated Persons*") and to any person who receives Inside Information from any Insider or Affiliated Person (such persons, together with Insiders and Affiliated Persons, "*Covered Persons*").

Any person who possesses Inside Information regarding the Company is subject to this Policy for so long as the information is either material or not publicly known, even after such person's termination of employment by or affiliation with the Company.

Statement of Policy

It is the policy of the Company to oppose the misuse of Inside Information in securities trading and the unauthorized disclosure of any nonpublic information acquired in the workplace. In addition, federal and state laws prohibit "insider trading," the purchase or sale of securities in breach of a fiduciary duty or other relationship of trust and confidence, on the basis of material nonpublic information about the security.

1. **Trading on Inside Information.** No Covered Person shall engage in any transaction involving the Company's securities, including any offer to purchase or offer to sell (other than certain transactions subject to specific exceptions as described below under "Certain Exceptions"), during any period commencing with the date that he or she first possesses Inside Information concerning the Company, and ending at the close of business on the second full Trading Day following the date of public disclosure of such information via press release (or other method of broad public dissemination) or at such time as such information is no longer material, as advised by the Company. As used herein, the term "*Trading Day*" shall mean a day on which the stock exchange or market on which the Company's stock trades is open for trading.

2. **Tipping.** No Covered Person may disclose ("*tip*") Inside Information to any other person (including family members, close friends and financial and personal counselors) where such information may be used by such person to engage in transactions in securities on the basis of that information, nor shall such Covered Person make recommendations or express opinions on the basis of Inside Information as to trading in the Company's securities. This policy does not restrict legitimate business communications to Company personnel who require the information in order to perform their business duties.

3. **Confidentiality of Nonpublic Information.** Nonpublic information relating to the Company is the property of the Company and the unauthorized disclosure of such information is forbidden even after termination of employment by or affiliation with the Company.

Potential Criminal and Civil
Liability and/or Disciplinary Action

The U.S. Securities and Exchange Commission (the "*SEC*"), the stock exchanges and the Financial Industry Regulatory Authority, Inc. use sophisticated electronic surveillance techniques to uncover insider trading. In addition, the SEC and criminal prosecutors vigorously enforce insider trading laws.

1. **Liability for Insider Trading.** Covered Persons may be subject, in addition to disgorgement of profits (or of losses avoided), to criminal penalties of up to $5,000,000 and up to 20 years in jail for violating federal insider trading laws. The Company could also be subject to federal civil fines as a result of such violations by Covered Persons. Violations of applicable state securities laws related to insider trading may also subject Covered Persons and the Company to additional penalties.

2. **Liability for Tipping.** Covered Persons may also be liable for improper transactions by any person (commonly referred to as a "*tippee*") to whom they have disclosed

Inside Information regarding the Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in the Company's securities. Regulatory authorities have imposed large penalties even when the disclosing person did not profit from the trading.

3. **Possible Disciplinary Actions.** Insiders who violate this Policy may also be subject to disciplinary action by the Company, which may include, but is not limited to, ineligibility for future participation in the Company's equity incentive plans, termination and/or referral to appropriate law enforcement and regulatory authorities. The Company may determine that specific conduct violates this Policy, whether or not the conduct also violates the law.

Guidelines

1. **Trading Windows and Blackout Periods.**

To ensure compliance with this Policy and applicable federal and state securities laws, subject to specific exceptions as described below under "Certain Exceptions", directors and officers of the Company, as well as certain employees as designated by the Chief Executive Officer, may not conduct transactions involving the Company's securities other than during the period in any fiscal quarter commencing at the close of business on the second full Trading Day following the Company's disclosure via press release (or other method of broad public dissemination) of the financial results of the Company for the prior fiscal quarter or year and ending at the close of business on the last day of the last month of the fiscal quarter (each, a "*Trading Window*").

The safest period for trading in the Company's securities, assuming the absence of Inside Information, is generally the first few Trading Days of the Trading Window. Periods outside of a Trading Window ("*Blackout Periods*") are particularly sensitive periods of time for transactions in the Company's securities from the perspective of compliance with applicable securities laws. This is due to the fact that officers, directors and certain other persons will, as any quarter progresses, be increasingly likely to possess Inside Information about the Company's expected financial results for the quarter. Therefore, such persons may not transaction in the Company's securities during any Blackout Period.

It should be noted that even during a Trading Window any person possessing Inside Information concerning the Company should not engage in any transactions in the Company's securities until such information has been known publicly for at least two full Trading Days. Each person is individually responsible at all times for compliance with the prohibitions against insider trading. Trading in the Company's securities during the Trading Window should not be considered a "safe harbor", and all Covered Persons should use good judgment at all times.

From time to time, the Company may impose on certain Covered Persons a special Blackout Period during an otherwise open Trading Window because of developments known to the Company and not yet disclosed to the public. In such event, the Company may notify particular individuals that they should not engage in any transaction involving the Company's securities during such period and should not disclose to others the fact that the Trading Window has been closed.

2. **Hedging, Margin Accounts and Pledging.** Hedging, holding securities of the Company in margin accounts, and pledging Company securities as collateral for a loan are strongly discouraged. Hedging (such as use of prepaid variable forwards, equity swaps, collars or otherwise) can have unintended consequences, and margin accounts authorize brokers to sell stock to cover amounts owed to them. A forced sale could occur at a time when the individual has knowledge of Inside Information about the Company. A similar result can occur when Company stock is pledged as collateral for a loan.

3. **Pre-clearance of Trades.** The Company has determined that all officers and directors of the Company should refrain from trading in the Company's securities, even during a Trading Window, without first complying with the Company's mandatory "pre-clearance" procedures, a copy of which is attached hereto as Exhibit A. Officers and directors should contact the Company's Chief Executive Officer prior to initiating any transaction in the Company's securities. The Company may also find it necessary, from time to time, to require compliance with the pre-clearance process from certain employees, consultants and contractors. The existence of the foregoing pre-clearance procedures does not in any way obligate the Company to approve any transaction for which pre-clearance is sought.

If pre-clearance is granted for a particular transaction, the transaction should be completed promptly, and in any event within three Trading Days following receipt of pre-clearance unless an exception is granted (provided that if you become aware of material nonpublic information before executing the transaction, you must cancel the transaction). Approved transactions that are not effected within this period will be subject to receiving pre-clearance again.

4. **Individual Responsibility.** Every Insider of the Company has the individual responsibility to comply with this Policy against insider trading (and to ensure compliance with this Policy by his or her Affiliated Persons). Appropriate judgment should be exercised in connection with any transactions in the Company's securities.

A Covered Person may, from time to time, have to forego a proposed transaction in the Company's securities even if he or she planned to make the transaction before learning of the Inside Information and even though the Covered Person believes he or she may suffer an economic loss or forego anticipated profit by waiting.

Applicability of Policy to Inside Information and Trading Regarding Other Companies

This Policy and the guidelines described herein also apply to Inside Information relating to other companies, including the Company's collaborative partners, customers, vendors and suppliers (collectively, "*business partners*"), as well as companies with which trading in the Company's securities is highly correlated, such as other companies developing products or product candidates targeting indications that are similar to those the Company is pursuing. Civil and criminal penalties, and termination of employment, may result from trading on Inside Information regarding the Company's business partners and companies with which trading in the Company's securities is highly correlated. All Insiders should treat Inside Information about the Company's business partners and companies with which trading in the Company's securities is highly correlated with the same care as is required with respect to information relating directly to

the Company.

Inside Information

As described above, "*Inside Information*", for the purposes of this Policy, is material, nonpublic information.

It is not possible to define all categories of material information. However, information should be regarded as material if there is a reasonable likelihood that it would be considered important to an investor in making an investment decision regarding a transaction in the Company's securities. Either positive or negative information may be material. While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, such information should always be considered carefully to determine whether it is material. Examples of such information may include:

- Clinical and preclinical trial results
- FDA or other regulatory action or communications
- Financial results, including unexpected results
- Projections of future earnings or losses
- News of a pending or proposed merger, acquisition or other strategic transaction
- News of the disposition of a subsidiary
- Impending bankruptcy or financial liquidity problems
- Gain or loss of a substantial collaborative partner, customer or supplier
- Significant product or product candidate developments, including meeting or failing to meet milestones
- Changes in dividend policy
- New product or service announcements of a significant nature
- Significant product defects, modifications or recalls
- Significant product pricing changes
- Stock splits or cash or stock dividends
- New equity or debt offerings
- Significant litigation exposure due to actual or threatened litigation
- Major changes in senior management
- Listing status on an exchange or market
- Material cybersecurity incidents

Nonpublic information is information that has not been widely disseminated to the general public, such as through a press release carried over a major news service, a public filing with the SEC or materials sent to stockholders (e.g., a proxy statement or widely disseminated prospectus). Information is also nonpublic if it has been widely disseminated to the public, but sufficient time has not elapsed to permit the investment community to absorb and evaluate the information. In general, the Company considers one full Trading Day after public release to be sufficient for investor absorption and evaluation.

Federal, state and stock exchange investigators will scrutinize a questionable trade after the fact with the benefit of hindsight, so you should always err on the side of deciding that the information in question is material and not trade. If you have questions regarding specific

information or contemplated transaction, please contact the Company's Chief Executive Officer.

Certain Exceptions

For purposes of this Policy, the following transactions are not subject to Trading Windows:

1. **Transactions under Company Equity Incentive Plans**. The exercise of stock options for cash (or via withholding of shares by the Company to cover the exercise price and/or taxes) under the Company's equity incentive plans, but not the sale of any shares received upon such exercise (whether to pay the exercise price and/or taxes or otherwise), is exempt from this Policy. In addition, this Policy does not apply to the vesting of equity awards and corresponding delivery of shares. However, the Company does not exempt from this Policy the sale of stock received under the Company's stock option or other equity incentive plans (pursuant to stock options, restricted stock awards, stock bonuses or otherwise) or any action taken by a participant pursuant to such plans (or awards thereunder) that results in the participant receiving consideration based on the market price of the Company's stock.

2. **Gifts of Company Securities**. Gifts of Company securities are exempt from this Policy. It is important to note, however, that gifts are not allowed to circumvent the insider trading laws. For instance, an Insider's gift of Company securities to someone during a Blackout Period that applies to such Insider, who then in turn sells Company securities in that same period, is not allowed as the Insider is not allowed to sell that security under the insider trading laws or pursuant to this Policy. Gifts of Company securities by [officers and directors of the Company] are subject to the pre-clearance procedures described above.

3. **Pre-Approved Rule 10b5-1 Plans and Non-Rule 10b5-1 Trading Arrangements**.

In addition, transactions effected pursuant to a pre-approved Rule 10b5-1 Plan or Non-Rule 10b5-1 Trading Arrangement (each, as defined below) will not be subject to this Policy.

Rule 10b5-1 Plans

Rule 10b5-1 promulgated under the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), provides an affirmative defense against insider trading claims if an Insider engages in transactions in Company securities outside of a Trading Window and without pre-clearance of such transactions, even when in possession of Inside Information about the Company, provided that the transactions occur pursuant to a pre-approved plan that complies with Rule 10b5-1 (a "*Rule 10b5-1 Plan*") that came into existence while such Insider was not in possession of any Inside Information.

If an Insider intends to engage in transactions pursuant to a Rule 10b5-1 Plan, such plan must:

(A) consist of a plan, arrangement or instruction that satisfies the requirements of Rule 10b5-1;

(B) be documented in writing;
(C) be established in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1;
(D) if the Insider is an officer or director, include a certification that at the time of the adoption of the Rule 10b5-1 Plan, the Insider (1) is not aware of any material, nonpublic information about the Company or its securities and (2) is adopting the Rule 10b5-1 Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1;
(E) prohibit the first trade under the Rule 10b5-1 Plan from occurring for ("cooling off" periods): (1) if the Insider is an officer or director, the longer of (x) 90 days following the adoption of the Rule 10b5-1 Plan or (y) two business days following the disclosure in certain periodic reports of the Company's financial results for the fiscal quarter in which the plan was adopted (but not to exceed 120 days following adoption of the Rule 10b5-1 Plan); and (2) if the Insider is not an officer or director, at least 30 days after the Insider's entry into the Rule 10b5-1 Plan;
(F) be established during an open Trading Window at a time at which such Insider does not possess any Inside Information about the Company; and
(G) be pre-approved in writing by the Company's Chief Executive Officer.

In addition, an officer or director adopting a new Rule 10b5-1 Plan may not have any other outstanding Rule 10b5-1 Plans, and may not subsequently enter into any additional Rule 10b5-1 Plans, unless otherwise approved by the Chief Executive Officer and only in cases where having multiple Rule 10b5-1 Plans is in accordance with the federal securities laws.

Non-Rule 10b5-1 Trading Arrangements

The SEC has established criteria for trading arrangements that do not satisfy all of the criteria of Rule 10b5-1 but are still intended to operate as a defense to a claim of insider trading ("*Non-Rule 10b5-1 Trading Arrangements*"). These criteria are set forth in Item 408 of Regulation S-K under the Securities Act of 1933, as amended. Non-Rule 10b5-1 Trading Arrangements are subject to similar procedural requirements as Rule 10b5-1 Plans but do not involve "cooling off" periods and are not subject to restrictions on overlapping plans.

Approval

Any proposed transaction in Company securities not in accordance with the specifications of an approved Rule 10b5-1 Plan or Non-Rule 10b5-1 Trading Arrangement (including, without limitation, the amount, price or timing of a purchase or sale) must be reported immediately to the Chief Executive Officer and will be subject to all of the required transaction restrictions and procedures contained in this Policy. Any modification (including termination) of an Insider's approved Rule 10b5-1 Plan or Non-Rule 10b5-1 Trading Arrangement requires pre-approval by the Chief Executive Officer. Such modification must occur during a Trading Window at a time at which such Insider is not in possession of any Inside Information. Note also any modification to the amount, pricing, or timing of purchases or sales of securities under a Rule 10b5-1 Plan will constitute the termination of the plan and adoption of a new plan, which means that any such modification will trigger the need for the new trading plan to satisfy all of the elements of Rule 10b5-1, including a new "cooling off" period, before trading can begin again.

The Chief Executive Officer may refuse to approve a Rule 10b5-1 Plan or Non-Rule 10b5-1 Trading Arrangement as they deem appropriate including, without limitation, if they determine that the applicable plan, arrangement or instruction does not satisfy the requirements of Rule 10b5-1 or Item 408 of Regulation S-K, as applicable. The Chief Executive Officer may consult with the Company's legal counsel before approving a Rule 10b5-1 Plan or Non-Rule 10b5-1 Trading Arrangement. If the Chief Executive Officer does not approve an Insider's Rule 10b5-1 Plan or Non-Rule 10b5-1 Trading Arrangement, such Insider must adhere to all of the required transaction restrictions and procedures until such time as a plan or arrangement is approved.

Additional Information – Directors and Officers

Directors and certain designated officers of the Company must comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Exchange Act ("*Section 16*"). Section 16(b) of the Exchange Act allows the Company to recover any profit realized by any such director or officer resulting from any combination of purchases and sales of the Company's equity securities (and any "derivative" securities) within a six-month period, whether or not they had knowledge of any Inside Information at that time. Neither the receipt of an option under the Company's equity plans, nor the exercise of that option, will be deemed a purchase under Section 16(b); however, the sale of any such shares is a sale under Section 16(b). Directors and officers remain subject to these Section 16 requirements and restrictions for a period of up to six months after terminating their positions with the Company. The Company has provided, or will provide, separate memoranda and other appropriate materials to its officers and directors regarding compliance with Section 16 and its related rules.

Moreover, no officer, director or insider may ever make a short sale of the Company's stock.

Inquiries

Please direct your questions as to any of the matters discussed in this Policy to the Company's Chief Executive Officer, at mmrowe@eyenovia.com.

* * * * *

Adopted by the Board of Directors on April 16, 2018, and revised on June 12, 2023 and March 11, 2025.

EYENOVIA, INC.

PRE-CLEARANCE AND COMPLIANCE PROCEDURES

To ensure compliance with the accelerated reporting requirements for reporting insider transactions in securities of Eyenovia, Inc. (the "*Company*"), to help prevent any inadvertent violations of applicable federal and state securities laws, and to avoid even the appearance of trading on inside information, we are implementing the following:

1. Our Mandatory Pre-clearance Procedure. Directors and officers of the Company and its subsidiaries, and any other persons designated under our Insider Trading Policy or otherwise designated by our Board of Directors as being subject to the Company's pre-clearance procedures, together with their family members, may not engage in any transaction involving Company securities (including market or private purchases or sales, option exercises, pledges, gifts, contributions to a trust, or any other transfers) without first obtaining pre-clearance of the transaction from the Company's Chief Executive Officer. A request for pre-clearance should be submitted to the Company's Chief Executive Officer at least two days in advance of the proposed transaction. The Company's Chief Executive Officer will then determine whether the transaction may proceed and, if so, assist in complying with the new reporting requirements.

If pre-clearance is granted for a particular transaction, the transaction should be completed promptly, and in any event within three trading days following receipt of pre-clearance unless an exception is granted (provided that if you become aware of material nonpublic information before executing the transaction, you must cancel the transaction). Approved transactions that are not effected within this period will be subject to receiving pre-clearance again.

Any person subject to the pre-clearance requirements who wishes to implement a new trading plan under SEC Rule 10b5-1 (a "Rule 10b5-1 Plan") or in compliance with Item 408 of Regulation S-K (a "Non-Rule 10b5-1 Trading Arrangement") must first pre-clear the plan with the Chief Executive Officer. In addition, any officer or director of the Company who wishes to enter into such a trading plan must seek approval of the timing parameters of the trades to be made under such plan from the full Board of Directors prior to entry into the plan.

Transactions effected pursuant to a pre-cleared trading plan will not require further pre-clearance at the time of the transaction if the plan specifies the dates, prices and amounts of the contemplated trades, or establishes a formula for determining the dates, prices and amounts. Those transactions, however, must be reported immediately to the Chief Executive Officer.

2. Designated Broker and New Broker Interface Procedures. The reporting of transactions will require tight interface with brokers handling transactions for our Insiders. A knowledgeable, alert broker can act as a gatekeeper, helping ensure compliance with our pre-clearance procedures and helping prevent inadvertent violations.

We intend to work out a coordinated procedure with a brokerage firm selected by management. Those of you who are not currently using management's designated broker as your broker are encouraged to enter all your transactions in Company securities through such broker. (We will select a broker who can assure us that it will not seek to reinvest the funds from your transactions in Company securities or seek any of your other securities business.)

Whether you choose to use our designated broker or your own broker, we will require that you and your broker sign the enclosed Broker Instruction/Representation which imposes two requirements on the broker handling your transactions in Company securities:

(a) Not to enter any order (except for orders under pre-approved Rule 10b5-1 Plans or Non-Rule 10b5-1 Trading Arrangements) without

- first verifying with the Company that your transaction was pre-cleared, and
- complying with the brokerage firm's compliance procedures (*e.g.,* Rule 144); and

(b) To report **immediately** to the Chief Executive Officer via telephone and in writing (via e-mail or fax) the details of every transaction involving company stock, including gifts, transfers, pledges and all transactions pursuant to Rule 10b5-1 Plans and Non-Rule 10b5-1 Trading Arrangements.

Please sign and have your broker sign the enclosed Broker Instruction/Representation Form and return it to us promptly so that we can work out with your broker a coordinated procedure.

3. Broker-Assisted Cashless Exercises of Options. The Sarbanes-Oxley Act makes it illegal for issuers to extend or maintain credit, or arrange for the extension of credit in the form of a personal loan to any executive officer or director. In most cashless exercises of options, there is typically a delay of a few days from the time of exercise to the date the issuer receives the exercise price. Some attorneys have speculated that these arrangements could be deemed an impermissible extension of credit arranged by issuers for their insiders. Consequently, unless and until this issue gets resolved to our satisfaction, we must insist on receipt of cash simultaneous with any issuance of shares pursuant to exercise of an option by an insider. We believe that most brokers can do cashless exercises for you this way.

Any person who has a question about these procedures or its application to any proposed transaction may obtain additional guidance from the Company's Chief Executive Officer, or from Megan Gates at Covington & Burling LLP, our outside counsel, at (617) 785-4653.

Certification

All directors, officers and employees subject to the procedures set forth in this document must certify their understanding of, and intent to comply with, such procedures. Please return the enclosed Insider Certification immediately.

Broker Instruction/Representation

[Name and Address of Broker]

Re: Eyenovia, Inc.

Ladies and Gentlemen:

As my designated broker for effecting transactions in the securities of Eyenovia, Inc. (the "*Company*"), I hereby instruct you to follow the following procedures in connection with executing any trade or other transaction in Company securities on my behalf:

1. Do not enter any order (except for orders under pre-approved plans intended to comply with Rule 10b5-1 promulgated under the Securities Exchange Act of 1934 ("Rule 10b5-1 Plans") or Item 408 of Regulation S-K promulgated under the Securities Act of 1933 ("Non-Rule 10b5-1 Trading Arrangements")) without

   - first verifying with the Company that the transaction was pre-cleared, and
   - complying with your firm's compliance procedures (*e.g.,* Rule 144); and

2. Report **immediately** to the Company via telephone and in writing (via e-mail or fax) the details of **every** transaction involving Company securities, including gifts, transfers, pledges and all transactions pursuant to Rule 10-1 Plans and Non-Rule 10b5-1 Trading Arrangements.

Company contacts:

Primary Contact:

Phone: (__)

Fax: (__)

Email:

Backup Contact:

Phone: (__)

Fax: (__)

Email:

[Signature Page Follows]

Name of Insider

(Signature of Insider)

The undersigned broker confirms receipt of this instruction letter and agrees to comply with the terms hereof:

Name of Broker

(Signature of Authorized Signatory for Broker)

Insider Certification

The undersigned, an employee, consultant, officer or director of Eyenovia, Inc. (the "*Company*"), hereby certifies to the Company that:

1. he or she has received and understands his or her obligations outlined in the Company's Pre-clearance and Compliance Procedures; and

2. he or she intends to comply with those procedures.

Name of Insider:

Signature of Insider:

Exhibit 23.1

Independent Registered Public Accounting Firm's Consent

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-237790, File No. 333-268832 and 333-282458) and Form S-8 (File No. 333-227049, File No. 333-233278, File No. 333-233280, File No. 333-246288, File No. 333-261035, File No. 333-266823, File No. 333-272962, 333-283184 and 333-285583) of our report dated April 15, 2025, relating to the financial statements of Eyenovia, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2024.

/s/ Marcum LLP

New York, NY
April 15, 2025

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Rowe, certify that:

1. I have reviewed this annual report on Form 10-K of Eyenovia, Inc. for the year ended December 31, 2024;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2025

/s/ Michael Rowe
Name: Michael Rowe
Title: Chief Executive Officer
(Principal Executive Officer)
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Eyenovia, Inc. (the "Company") on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Rowe, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2025

/s/ Michael Rowe
Name: Michael Rowe
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Eyenovia, Inc. (the "Company") on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Rowe, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 15, 2025

/s/ Michael Rowe
Name: Michael Rowe
Title: Principal Financial Officer
(Principal Financial and Accounting Officer)